IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN; ZACHARY MARTELL; BRIAN MCNEMAR, SHAWN ANDERSON a/k/a SHAUNTAE ANDERSON and LEANN JAMES, individually and on behalf of all others similarly situated,

Plaintiffs,

vs.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; CYNTHIA BEANE, in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES; JASON HAUGHT, in his official Capacity as Director of the West Virginia Public Employees Insurance Agency; and THE HEALTH PLAN OF WEST VIRGINIA, INC.,

Defendants.

Civil Action No.

3:20-cv-00740

REMOTE VIDEOTAPED DEPOSITION OF

JOHANNA OLSON-KENNEDY, M.D.

April 25, 2022

Reported By: Amy E. Simmons, CSR, RPR, CRR, CRC

REMOTE VIDEOTAPED DEPOSITION OF
JOHANNA OLSON-KENNEDY, M.D.

BE IT REMEMBERED that the remote videotaped deposition of JOHANNA OLSON-KENNEDY, M.D., was taken via videoconference by the Defendants before Veritext Legal Solutions, Amy E. Simmons, Court Reporter and Notary Public in and for the County of Ada, State of Idaho, on Monday, the 25th day of April, 2022, commencing at the hour of 8:39 a.m. Pacific Daylight Time in the above-entitled matter.

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Also Present: Michele Clanton-Lockhart

So I think what is important is thinking about what people are balancing when they make those decisions.

Q. (BY MR. DAVID) Is there a more significant post-surgical period of recovery for a genital surgery than there is for a chest surgery?

MS. BORELLI: Objection; form.

THE WITNESS: Generally speaking, absolutely.

Q. (BY MR. DAVID) And as a foundational question, I assume that when you are referring a patient for a surgical consultation for gender-affirming surgery, that is to treat gender dysphoria, correct?

MS. BORELLI: Objection; form.

THE WITNESS: That's correct in my practice, yes.

Q. (BY MR. DAVID) And so the goal would be to reduce the distress associated with -- sticking with chest surgery -- the stress associated with that person's chest; is that right?

MS. BORELLI: Objection; form.

THE WITNESS: That's correct.

Q. (BY MR. DAVID) Are there other risks that you are hoping that will be reduced as a

REPORTER'S CERTIFICATE

STATE OF IDAHO)
) ss.
COUNTY OF ADA)

I, AMY E. SIMMONS, Certified Shorthand Reporter and Notary Public in and for the State of Idaho, do hereby certify:

That prior to being examined, the witness named in the foregoing deposition was by me duly sworn remotely to testify to the truth, the whole truth and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named and thereafter reduced to typewriting under my direction, and that the foregoing transcript contains a full, true and verbatim record of said deposition.

I further certify that I have no interest in the event of the action.

WITNESS my hand and seal this 10th day of May, 2022.

AMY E. SIMMONS
CSR, RPR, CRR, CRC and Notary Public in and for the State of Idaho.

My Commission Expires: 06-13-2022

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN, *et al.*, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740

HON. ROBERT C. CHAMBERS, JUDGE

EXPERT REBUTTAL REPORT OF DR. JOHANNA OLSON-KENNEDY, M.D., M.S.

I, Johanna Olson-Kennedy, M.D., M.S., declare as follows:

1. My name is Johanna Olson-Kennedy. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have been asked by Plaintiffs' counsel to provide my expert opinion on gender identity, the treatment and diagnosis of gender dysphoria, particularly as it pertains to children and adolescents, and to respond to, rebut, and provide my expert opinion regarding the report by Dr. Stephen B. Levine in this case ("Levine Report").

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

4. I received my Doctor of Medicine (M.D.) degree from the Chicago Medical School in 1997. In 2000, I completed my residency in pediatrics at the Children's Hospital of

Orange County, California, and from 2000 to 2003, I was a Fellow in adolescent medicine at the Children's Hospital of Los Angeles.

5. I have been a licensed physician in California since 2000 and am Double Board Certified by the American Board of Pediatrics in Pediatrics and in Adolescent Medicine. I specialize in the care of transgender youth and gender diverse children, and am currently the Medical Director of the Center for Transyouth Health and Development, in the Division of Adolescent Medicine at the Children's Hospital in Los Angeles, California. The Center is one of the largest clinics in the United States for transgender youth and provides gender diverse youth with both medical and mental health services, including consultation for families with gender diverse children and routine use of medications to suppress puberty in peri-pubertal youth (i.e., youth at the onset of puberty), gender affirming hormone use for masculinization and feminization as well as surgical referrals. Under my direction, the Center conducts rigorous research aimed at understanding the experience of gender diversity and gender dysphoria from childhood through early adulthood.

6. Over the course of my work with this population during the past 16 years, I have provided services for approximately 1,000 young people and their families, and currently have an active panel of around 650 patients of varying ages, up to 25 years old.

7. I have been awarded research grants to examine the impact of early interventions, including puberty-delaying treatment and gender affirming hormones, on the physiological and psychosocial development of gender diverse and transgender youth. I have lectured extensively on the treatment and care of gender diverse children and transgender adolescents, including topics such as pubertal suppression, gender affirming hormone therapy, transitioning teens and the adolescent experience, age considerations in administering hormones, and the needs, risks,

and outcomes of hormonal treatments. I have published numerous articles and chapters, both peer reviewed and non-peer reviewed, on transgender health-related issues.

8. I am currently the principal investigator on a multisite NIH grant which recently received funding to continue, for an additional 5 years, an ongoing study examining the impact of gender affirming medical care for transgender youth on physiologic and psychological health and well-being. The first five years have already been completed. This is the first study of its kind in the U.S. to determine longitudinal outcomes among this population of vulnerable youth. The study to date has yielded approximately 26 manuscripts.

9. I am an Associate Professor at the Keck School of Medicine at the University of Southern California and attending physician at Children's Hospital of Los Angeles. I have been a member of the World Professional Association for Transgender Health (WPATH) since 2010, and a Board Member of the U.S. Professional Association for Transgender Health (USPATH) since 2017. I am also a member of the Society for Adolescent Health and Medicine and the American Academy of Pediatrics. In addition, I am a member of the LGBT Special Interest Group of the Society for Adolescent Health and Development.

10. I am the 2014 Recognition Awardee for the Southern California Regional Chapter of the Society for Adolescent Health and Medicine.

11. In 2019, I was invited by the University of Bristol as a Benjamin Meaker visiting professor, the purpose of which is to bring distinguished researchers from overseas to Bristol in order to enhance the research activity of the university.

12. In preparing this report, I have relied on my training and years of research and clinical experience, as set out in my curriculum vitae, and on the materials listed therein. A true and accurate copy of my curriculum vitae is attached hereto as Exhibit A. It documents my

education, training, research, and years of experience in this field and includes a list of publications.

13. I have also reviewed the materials listed in the attached bibliography (Exhibit B). The sources cited therein are authoritative, scientific peer-reviewed publications. I generally rely on these materials when I provide expert testimony, and they include the documents specifically cited as supportive examples in particular sections of this declaration.

14. In addition, I have reviewed the First Amended Complaint in this case and the report by Dr. Levine.

15. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

Prior Testimony

16. In the last four years, I have testified as an expert at trial or by deposition in the following cases: *Kadel v. Folwell*, Case No. 1:19-cv-00272-LCB-LPA (M.D.N.C.); *In the interest of JA.D.Y. and JU.D.Y.*, Children, Case No. DF-15-09887 (255th Jud. District Ct., Dallas Cty., Tex.); and *Paul E. v. Courtney F.*, No. FC2010-051045 (Superior Ct., Maricopa Cty., Ariz.).

Compensation

17. I am being compensated for my work on this matter at a rate of $200.00 per hour for preparation of declarations and expert reports, as well as any pre-deposition and/or pre-trial

preparation and any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

II. EXPERT OPINIONS[1]

A. Gender Identity

18. Gender identity, often simply termed "gender," is a distinct characteristic and is defined as one's internal sense of being male, female, both, neither, or some other gender identity. It has a strong biological basis. Every person has a gender identity. The term cisgender refers to a person whose gender identity matches their sex assigned at birth. The term transgender refers to a person whose gender identity does not match their sex assigned at birth.

19. Historically, "gender" was equated with a person's sex assigned at birth, which refers to the sex assigned to a person when they are born, generally based on external genitalia. However, a more contemporary understanding of gender shows that one's gender identity may differ from one's sex assigned at birth.

20. While both gender identity and sex are often assumed and treated as binary and oppositional, they are more accurately experienced as along a spectrum. For example, there are multiple sex characteristics, such as genitalia, chromosomal makeup, hormones, and variations in brain structure and function. For some of these characteristics there is significant variance as reflected by the dozens of intersex mechanisms and varying gender identities. Additionally, not all sex characteristics, including gender identity, are always in alignment. Accordingly, the Endocrine Society Guidelines, state that, "As these may not be in line with each other (*e.g.*, a

[1] Subsections A and B of this report explain several concepts and provide some necessary background information that is necessary to understand the more specific critiques of the report by Dr. Levine that I lay out in subsection C.

person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided."

21. As early as 1966 it has been understood that gender identity cannot be changed. Efforts to do so have been shown to be unsuccessful and harmful.

22. "Conversion" or "reparative" therapy refers to the practice of attempting to change an individual's sexual orientation and attractions from members of the same sex to those of the other sex. A similar model of therapy for individuals with a transgender identity or experience has historically been an approach promoted by some individuals, such as Dr. Levine, notwithstanding its ineffectiveness and harmful effects. Accordingly, 20 states and the District of Columbia have banned reparative therapy for youth, and major medical organizations have issued statements deeming the practice to be unethical.

23. A Williams Institute report published in 2018 estimates that just under 700,000 LGBT individuals in the United States have undergone "conversion therapy" at some point in their lifetime, about half of those during adolescence. Because some psychiatrists and sexologists working in the 1960's and 70's perpetuated the idea that being transgender was likely the result of a pathological early childhood experience, many professionals and lay community members continue to believe that gender is malleable. Tactics have ranged from simple redirection, thought pattern alteration or hypnosis to aversion techniques including induction of vomiting, nausea, paralysis, or electric shocks to change the expression, behavior, and assertion of one's authentic gender. (Mallory, et al., 2019). However, multiple studies show that gender identity has a strong biological basis and cannot be changed. As such, reparative therapy is both ineffective and harmful for transgender and gender diverse youth.

B. Gender Dysphoria and its Treatment

24. Gender Dysphoria (GD) is a serious medical condition characterized by distress due to a mismatch between assigned birth sex and a person's internal sense of their gender. By definition this diagnosis applies to transgender people, not cisgender people. GD was formerly categorized as Gender Identity Disorder (GID) but the condition was renamed in May 2013, with the release by the American Psychiatric Association (APA)'s fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V). In announcing this change, the APA explained that in addition to the name change, the criteria for the diagnosis were revised "to better characterize the experiences of affected children, adolescents, and adults." The APA further stressed that "gender nonconformity is not in itself a mental disorder. The critical element of gender dysphoria is the presence of clinically significant distress associated with the condition."

25. On May 25, 2019, the World Health Assembly approved International Classification of Diseases (ICD) version 11 that had been published by the World Health Organization in 2018. In this newest version of the ICD, all transgender-related diagnostic codes were removed from the chapter "Mental and Behavioral Disorders," and the code "Gender incongruence" was included in a new chapter "Conditions related to sexual health." These codes replaced the outdated "Gender Identity Disorder of childhood" (F64.2), "Gender Identity Disorder not otherwise specified" (F64.9), "transsexualism" (F64.0), and "Dual-role transvestism" (F64.1) codes which perpetuated the idea that patients seeking and undergoing medical interventions for this medical condition are mentally ill. (Suess Schwend, 2020).

26. For a person to be diagnosed with GD, there must be a marked difference between the individual's expressed/experienced gender and their assigned sex at birth , present for at least

six months. In children, the desire to be of the other gender must be present and verbalized.[2] The condition must cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

27. The World Professional Association of Transgender Health (WPATH) has clear recommendations for the health of transgender and gender non-conforming people in what is now the Standards of Care version 7. The SOC are based on the best available science and expert professional consensus. They are currently under revision to create an updated version 8. The WPATH Standards of Care have been endorsed and cited as authoritative by most major medical associations in the United States, including the American Medical Association, the American Psychiatric Association, the American Psychological Association, the Endocrine Society, the Pediatric Endocrine Society, the American College of Physicians, and the American Academy of Family Physicians, among others.

28. The UCSF Center for Excellence in Transgender Care as well as the Endocrine Society have both published comprehensive guidelines for the care of transgender and non-binary individuals that are largely consistent with the WPATH Standards of Care.

29. There are a significant number of *pre-pubertal* children who demonstrate an interest or preference for clothing, toys, and games that are stereotypically of interest to members of the "other" gender. Some of these children are transgender and some are not. It is the study of such *pre-pubertal* children that has created confusion about the persistence of gender dysphoria into adolescence and adulthood. Specifically, the *pre-pubertal* children who were the

[2] Notably, the DSM-IV included a separate diagnosis for GID in children, which required the child to display a number of behaviors stereotypical of the non-natal gender. That diagnosis, and its list of behavioral requirements, have been deleted from the DSM-V and replaced by updated and more precise diagnostic criteria.

subject of research endeavors in the late 20th century included both of these groups of children, those that would have met current criteria for a diagnosis of "Gender Dysphoria in Children" and those who would be considered "sub-threshold" for this diagnosis. At the time of these studies, criteria B had not yet been added to the diagnosis, which is "the presence of clinically significant distress associated with the condition." In addition, the criteria for then-used "gender identity disorder in children" diagnosis did not require a child to have "a strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)," which the current "gender dysphoria in children" diagnosis does. Thus, given the broader criteria used at the time, it is unsurprising that some of the research undertaken toward the end of the 20th century demonstrated that most children who exhibited gender-nonconforming behavior did not go on to have a transgender identity in adolescence. Yet, notwithstanding its inapplicability and faulty underpinnings, this "evidence" has been used to argue against gender affirmation for children and adolescents.

30. In any event, these arguments are wholly irrelevant to the question of coverage and provision of medical care as treatment for GD. That is because the majority of desistance research to date is among gender non-conforming pre-pubescent children, and my clinical experience has been that if gender dysphoria and gender identification with a gender other than that recorded at birth persists into adolescence, then desistance is incredibly rare. No medical or surgical treatments are recommended for *pre-pubertal* children.

31. Additionally, no studies have ever demonstrated that gender affirmation in childhood "leads to" a child being transgender who otherwise might not have been. Studies have demonstrated that the majority of youth whose GD and cross-gender identity continue to be present in adolescence, or those whose GD emerges in adolescence, are highly unlikely to

identify and live as cisgender individuals. Youth with GD, particularly those who are unaffirmed and denied care, are at high risk for depression, anxiety, isolation, self-harm and suicidality at the onset of puberty-related changes that feel wrong to them.

32. In his report, Dr. Levine discusses a number of approaches to care, though he fails to properly describe them and to discuss their limitations.

33. One of the approaches discussed by Dr. Levine is also known as "reparative" or "corrective" therapy. As discussed above, this so-called "therapy" has proven to be ineffective at best, and harmful at worst, and has been deemed to be unethical.

34. **"Redirection"** – Under this approach, advocated by people like Dr. Levine, a mental health therapist would encourage caregivers to use positive reinforcement to try to "redirect" children toward behavior that is more typical of their birth-designated sex or less gender specific. Underlying this approach is the assumption that a child's gender identity is malleable through social interventions. The goal of redirection is thus to eliminate gender-diverse desires and expressions over time, and to try to prevent the transgender child from being transgender. This approach is not recommended because negative reinforcement (e.g., shaming the child for gender diverse expression) has substantial negative mental and social health consequences. (Turban and Ehrensaft, 2018; Ehrensaft, 2017). It also ignores that gender identity is innate and cannot be involuntarily changed.

35. **Wait-and-see** – The wait-and-see approach (also called watchful waiting) involves waiting to see if the child's gender identity will change as the child gets older. This approach typically recommends that caregivers prohibit a prepubertal social transition but may allow cross-gender play and clothing within the home or support both masculine and feminine activities as the child explores their interests in other social settings. The wait-and-see approach

assumes that gender is binary and becomes fixed at a certain age; it pathologizes gender diversity. It is distinguished from following the child's lead, an affirming approach that allows the child to present in the gender role that feels correct and moves at a pace that is largely directed by the child. This watchful waiting approach ignores evidence that young children thrive when given permission to live in the gender that is most authentic to them and are at risk for symptomatic behaviors if prevented from doing so. (Ehrensaft, 2017).

36. **Affirmation –** The affirmative approach considers no gender identity outcome: transgender, cisgender, or otherwise, to be preferable. (Turban and Ehrensaft, 2018). It permits a child to explore gender development and self-definition within a safe setting. A fundamental concept of this approach is that gender diversity is not a mental illness. The gender affirmative model is defined as a method of therapeutic care that includes allowing children to speak for themselves about their self-experienced gender identity and expressions and providing support for them to evolve into their authentic gender selves, no matter at what age. Under this model, a child's self-report is embedded within a collaborative model with the child as subject and the collaborative team including the child, parents, and professionals. Support is not characterized by "encouraging" children or youth to be transgender or not, but rather by allowing children who express a desire to undergo a social transition (which may include changing names, pronouns, clothing, hairstyles, etc.) to do so. **For children who have not yet reached puberty, medical intervention is unnecessary and unwarranted.** After the onset of puberty medical interventions such as puberty blockers, and later hormones and surgery may be appropriate.

37. While some argue that gender affirmation leads a child or adolescent down a path of inevitable transgender identity, no such evidence exists, either in the scientific or the clinical

setting. To the contrary, studies show that gender identification does not meaningfully differ before and after social transition. (Rae, et al., 2019).

38. Under both the "wait and see" and affirmative care models, as understood in the scientific literature, medical care is recommended following the onset of puberty. (Ehrensaft, 2017).

39. The most effective treatment for adolescents and young adults with GD, in terms of both their mental and medical health, contemplates an approach allowing each patient to access care based on their particular need. Medical and surgical treatment interventions are determined by the care team (usually a medical and mental health professional) in collaboration with the patient, and the patient's family. These medical decisions are made by the care team in conjunction with the patient and the patient's family and consider the patient's social situation, the level of gender dysphoria, developmental stage, chronologic age, existing medical conditions, and other relevant factors. Sometimes treatment begins with puberty delaying medications (also referred to as puberty blockers), later followed by gender affirming hormones. Most youth accessing treatment are already well into or have completed puberty. Gender-affirming genital surgeries are generally sought after hormone treatment has commenced.

40. *Puberty blockers:* The beginning signs of puberty in transgender youth (the development of breast buds in birth-assigned females and increased testicular volume in birth-assigned males) is often a painful and sometimes traumatic experience that brings increased body dysphoria and the potential development of a host of comorbidities including depression, anxiety, substance abuse, self-harming behaviors, social isolation, high-risk sexual behaviors, and increased suicidality. Puberty blocking, which involves the administration of gonadotrophin-releasing hormone analogues (GnRH), essentially pauses puberty, thereby

allowing the young person an opportunity to explore gender without having to experience the anxiety and distress associated with developing the undesired secondary sexual characteristics. In addition, for parents/guardians uneducated about gender diversity and/or who have only recently become aware of their child's transgender identity, puberty blockers provide additional time and opportunity to integrate this new information into their own experience and to develop skills to support their child. Puberty suppression also has the benefit of potentially rendering obsolete some gender-affirming surgeries down the line, such as male chest reconstruction, tracheal shave, facial feminization, and vocal cord alteration, which otherwise would be required to correct the initial "incorrect" puberty.

41. Puberty suppression has been used safely for decades in children with other medical conditions and is a reversible intervention. If the medication is discontinued, the young person continues their endogenous puberty several months after puberty suppression is discontinued. The "Dutch protocol," developed from a study conducted in the Netherlands and published in 2006, calls for the commencement of puberty blockers for appropriately diagnosed and assessed gender dysphoric youth as early as 12 years of age. (de Vries, et al., 2014). Both the Endocrine Society and the WPATH's Standards of Care, however, recommend initiation of puberty suppression at the earliest stages of puberty (usually, Tanner 2, assuming someone is engaged in services before or around this time), regardless of chronological age, in order to avoid the stress and trauma associated with developing secondary sex characteristics of the natal sex.

42. A growing body of evidence that demonstrates the positive impact of pubertal suppression in youth with GD on psychological functioning including a decrease in behavioral and emotional problems, a decrease in depressive symptoms, and improvement in general functioning. (Turban, et al., 2020; de Vries, et al., 2014).

43. Puberty-delaying treatment, thus, affords youth the opportunity to undergo a single, correct pubertal process and avoid many of the surgical interventions previously necessary for assimilation into an authentic gender role. It is a simple reversible intervention that has the capacity to improve health outcomes and save lives. Over the course of my work in the past sixteen years with gender diverse and transgender youth, I have prescribed hormone suppression for over 300 patients. All of those patients have benefitted from putting their endogenous puberty process on pause, even the small handful who discontinued GnRH analogues and went through their endogenous puberty. Many of these young people were able to matriculate back into school environments, begin appropriate peer relationships, participate meaningfully in therapy, and family functions. Children who had contemplated or attempted suicide or self-harm (including cutting and burning) associated with monthly menstruation or the anxiety about their voice dropping were offered respite from those dark places of despair. GnRH analogues for puberty suppression are, in my opinion, a sentinel event in the history of transgender medicine, and have changed the landscape almost as much as the development of synthetic hormones.

44. *Gender affirming hormones:* Cross-gender or gender affirming hormone therapy involves administering steroids of the experienced sex (i.e., their gender identity) (estrogen for transfeminine individuals and testosterone for transmasculine individuals). The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person to achieve a gender phenotype that matches as closely as possible to their gender identity. Gender affirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others are irreversible (e.g., deepening of the voice, breast development).

Eligibility and medical necessity should be determined case-by-case, based on an assessment of the youth's unique cognitive and emotional maturation and ability to provide knowing and informed consent. The decision would be made only after a careful review with the youth and parents/guardians of the potential risks and benefits of hormone therapy. The youth's primary care provider, therapist, or another experienced mental health professional can help document and confirm the patient's history of gender dysphoria, the medical necessity of the intervention, and the youth's readiness to transition medically.

45. *Gender-affirming surgeries:* Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include vaginoplasty, tracheal shave, liposuction, breast implants, and orchiectomy for transfeminine individuals and chest reconstruction, hysterectomy, oophorectomy, salpingectomy, construction of neo-scrotum, and metoidioplasty or phalloplasty for transmasculine individuals.

46. The current WPATH Standards of Care recommend that genital surgery – i.e., surgery which may render the individual sterile – not be carried out until the individual reaches the legal age of majority to give consent for medical procedures, while acknowledging that care is individualized. In addition, the Standards recommend that the other surgical interventions (e.g., chest surgery for transgender males and breast augmentation for transgender females) may occur earlier than the legal age of consent, preferably after ample time living in the desired gender role and after one year of hormone therapy. The Standards of Care, however, further recognize that these are individual determinations and that "different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression."

47. Gender affirming medical interventions are considered medically necessary and are recognized as such by many major professional organizations. The denial of this care results in negative health consequences.

48. There are those, like Dr. Levine, who would make the argument that the recent uptick in youth presenting for services related to GD is the result of "social contagion." But if "social contagion" applied to gender and gender identity, there would be zero transgender people because of the consistent exposure to an overwhelming majority of cisgender people. The social contagion argument that is posited by some confuses the relationship between one's recognition of their gender and their exposure to gender related information and community – particularly with regard to internet activity – asserting that youth are declaring themselves to be transgender or gender diverse because they were exposed to this online, or they have multiple friends who are also experiencing GD. But adolescent development includes finding like groups of peers, which extends to finding friend groups who are also gender diverse. Finally, attributing GD to "social contagion" is a simplistic perspective that ignores that the process of seeking care is complex and difficult and involves parental consent for minors.

49. There is no scientific evidence that one develops gender dysphoria from being exposed to people with GD. To the contrary, most evidence shows that gender identity has a biological basis (Korpaisarn, et al., 2019; Saraswat, et al., 2015) and is affixed by early childhood (Slaby, et al., 1975).

C. Specific Critiques

50. Overall, Dr. Levine shows a lack of familiarity and understanding regarding the existing research about gender identity and gender dysphoria, as well as the clinical experience surrounding the treatment of gender dysphoria, particularly regarding transgender youth. This

lack of familiarity and understanding makes sense, as Dr. Levine appears to have very limited experience working with transgender youth and has not been a member of WPATH for decades.

51. Dr. Levine has critiqued and opposed the provision of gender affirming care as treatment for gender dysphoria for decades. Yet, in all of these years, he has not undertaken the research he calls for to answer the questions he raises. Rather it seems his primary goal is opposing affirming care for transgender people, instead of finding answers to questions and providing the best care for transgender people suffering from gender dysphoria.

52. Below I outline additional, more specific critiques regarding Dr. Levine's report.

53. Dr. Levine's claim that treatment for gender dysphoria is experimental and unproven is simply a statement of opinion, and not fact. *See, e.g.*, Levine Report ¶ 23. We have decades of research and clinical experience on gender dysphoria and its care. To be sure, as with all medical care, there is a range of quality in the existing data regarding the treatment of gender dysphoria (see UCSF Guidelines), and there is certainly a need for additional studies of a longitudinal nature. But again, that is true with most medical care.

54. One of the intrinsic elements of rating the quality of evidence is the study design. Randomized controlled studies are considered the highest quality in the grading of evidence. But given the length of time that gender affirming medical interventions have been around and vast amount of clinical knowledge about their efficacy, having untreated control groups of patients with gender dysphoria is unethical. For that reason, the majority of studies investigating the impact of gender affirming medical interventions are observational. This is not uncommon. For example, "Despite GnRH analogue treatment being used in precocious puberty for more than 20 years, there are no randomized controlled trials to evaluate the effect of GnRHa on a final height compared with untreated controls." (Mul, et al., 2008). However, there are several studies

which demonstrate the safety and positive impact of gender affirming medical interventions. Additionally, larger longitudinal studies are currently underway to help substantiate the significant existing data we have. (de Vries, et al, 2021; Weinand, 2015).

55. Additionally, although it is not possible to ethically conduct randomized control trials for gender-affirming care, we have a large de facto group of untreated individuals with gender dysphoria who experience significant psychiatric symptoms because of widespread barriers to access to care. Clinicians who are competent in the care of transgender individuals practice according to a "first do no harm" ethic which understands that doing nothing is not a neutral option for those with gender dysphoria. Multiple studies have demonstrated the safety of gender affirming hormones, and a growing body of evidence does the same with regards to the safety of GnRH analogs. (Kuper, et al., 2020; Chew, et al., 2018; Colton-Meier, et al., 2011). The same is true with regards to surgery. (Marano, et al., 2021; Olson-Kennedy, et al., 2018; Murad, et al., 2010; Smith, et al., 2005; Pfafflin & Junge, 1998).

56. Dr. Levine inaccurately suggests that diagnosis of gender dysphoria is done solely through a patient's self-diagnosis. Levine Report ¶ 148. His critique demonstrates a fundamental misunderstanding of how gender affirming care is provided. While we have continued to attain a greater understanding about the etiology of gender incongruence, patients do not "self-diagnose," as Dr. Levine suggests. However, it is not unusual or extraordinary in medicine for a provider to consider patients' reports of their symptoms as part of the medical assessment. Much like the diagnosis of many clinical conditions, providers rely on self-report to ascertain accurate diagnoses. Consider the diagnosis of chronic fatigue. The diagnostic criteria for this diagnosis include the following: fatigue so severe that it interferes with the ability to engage in pre-illness activities; of new or definite onset (not lifelong); not substantially alleviated

by rest; worsened by physical, mental or emotional exertion. Like gender dysphoria, these diagnostic criteria are a subjective telling of an individual's personal experience. It is incumbent upon providers of gender affirming care to acquire skills that help them ascertain many details about their patient's gender experience including but not limited to the history, developmental trajectory and expectations regarding treatment options.

57. Dr. Levine also discusses the increase in numbers of youth presenting for care related to GD in recent years. Levine Report ¶ 59. For one, varying estimates of prevalence are the result of inconsistent measures of transgender populations. Some studies have assessed the fraction of a population which had received the DSM-IV diagnosis of GID or the ICD 10 diagnosis of transsexualism, both of which were limited to clinical populations who sought a binary transition (male-to-female or female-to-male). For example, the prevalence reported in DSM-5 (0.005–0.014% for birth-assigned males; 0.002–0.003% for birth-assigned females) are based on people who received a diagnosis of GID or transsexualism and were seeking hormone treatment and surgery from gender specialty clinics, and, therefore, do not reflect the prevalence of all individuals with gender dysphoria or who identify as transgender. Other studies have reported on those who self-identified as transgender or gender incongruent and found that measuring self-identity yields much higher numbers. In 2016, data from the Center for Disease Control's Behavioral Risk Factor Surveillance System suggested that 0.6% of U.S. adults identify as transgender, double the estimate utilizing data from the previous decade. (Byne, et al., 2018). Ultimately, there is nothing surprising about the fact that more transgender people have begun identifying themselves to others as societal stigma has started to abate.

58. Dr. Levine further suggests that after "self-diagnosis" transgender patients will receive "rapid approval" for medical interventions. Levine Report ¶ 148. Self-reporting of

symptoms, as discussed above, is considered by the medical community to be an important aspect of history taking to assist professionals in the process of providing a diagnosis, but it is only part of the process. While many patients may have an acute understanding that they are experiencing gender dysphoria, providers in this field rely on their own understanding and clinical experience in working with patients with GD in order to exercise professional judgment while making this diagnosis and providing recommendations for care. Rather than providing hasty approval as Dr. Levine suggests, the process is careful, thoughtful, and considered. If anything, historically , unnecessarily long periods of psychiatric evaluation were required prior to initiating any medical intervention because gender incongruence was considered a psychopathologic condition.

59. Dr. Levine claims that there is a lack of consensus among psychiatrists and psychotherapists about the cause of, and therapeutic response to, gender dysphoria and because of this, the field is experimental. The entire field of medicine is dynamic, growing as more information becomes available. This does not preclude professionals from providing interventions and necessary care. For example, in the field of cancer care a more complete understanding of how cancer is acquired, spread, and contained leads to improvement in chemotherapy, as well as other modalities for intervention. Whether or not individuals consider the field of cancer to be experimental or not is irrelevant and does not preclude practitioners from providing available treatment.

60. In his discussion about "biology," Dr. Levine makes several assertions that bear examination. First, Dr. Levine references that no matter how many endocrinological or surgical procedures an individual undergoes, they can never be made a "complete man" or "complete woman," reserving that label to those who possess the germinal cells of ovaries or testes and can

reproduce. Levine Report ¶ 18. Terms like "complete man" or "complete woman" are not scientific, as even recognized by the work of Magnus Hirschfield over a century ago and ignore the current scientific understanding of sex. Note that, as described above, there are multiple sex characteristics. Indeed, aside from its offensiveness, Dr. Levine's opinion would mean that people born with differences in sex development (DSD) conditions could not also be considered a "complete man" or "complete woman."

61. Dr. Levine also references "rapid-onset gender dysphoria," and critiques WPATH for not discussing it in WPATH's upcoming eighth version of the Standards of Care. Levine Report ¶ 79. This is a fabricated name for a fabricated entity that arose out of a deeply flawed research endeavor that gathered parents of youth with gender dysphoria from distinctly anti-gender affirming websites. (Littman 2021.) Investigators and clinicians who practice in this area of expertise do not utilize this terminology.

62. Dr. Levine asserts that a disproportionate number of children from communities of color are diagnosed with gender dysphoria. Levine Report ¶ 156. This is patently untrue across the United States. In fact, the opposite is true. The youth seeking puberty suppression do not deviate significantly from general demographics; indeed, the preponderance of youth seeking puberty suppression are of European descent. In any event, this is irrelevant. Many medical conditions impact some communities more than others. (Manton, et al., 1997). That is not a reason to deny medically necessary health care. Additionally, nothing in the science supports withholding medically necessary care from patients simply because they are neuro-diverse, and the predominant recommendation is certainly not that individuals with ASD be denied care related to their gender dysphoria simply for being neuro-atypical.

63. Dr. Levine distorts the literature to suggest that gender-affirming care does not lower suicidality, and indeed insinuates that such care may contribute to suicidality. *See, e.g.*, Levine Report ¶ 95. Dr. Levine misuses the data, specifically, the Cecilia Djhene manuscript about suicidality among transgender women who underwent genital surgery compared to the entire population statistics. This research has been consistently misused, much to the dismay of the first author, whom I have communicated with about this very issue. The Dhejne study specifically states that, "For the purpose of evaluating whether sex reassignment is an effective treatment for gender dysphoria, it is reasonable to compare reported gender dysphoria pre and post treatment. Such studies have been conducted either prospectively or retrospectively and suggest that sex reassignment of transsexual persons improves quality of life and gender dysphoria." Dr. Levine's characterization of the Dhejne research is misleading, because the two comparison groups were transgender women who underwent surgery and aged matched individuals from the general population of Sweden. It is well known that transgender individuals have a higher suicide rate than cisgender individuals. That is explained by the fact that transgender people, even after obtaining gender affirming care, suffer from large and disproportionate rates of discrimination, harassment, family rejection, and violence, all of which could contribute to larger suicidality rates when compared to the general population. Additionally, the data in the Dhejne study was gathered from patients seeking surgery between 1973 and 2003. The political and cultural context is vastly different in 2021 and the surgical techniques are improved.

64. Dr. Levine further equates participants who are lost to follow up as a potential indicator of desistance and/or who regretted undergoing medical interventions, Levine Report ¶ 92, but he provides no support for his assertions. A recent study confirms that the majority of

people who detransition do so because of external factors such as pressure from family and societal stigma. (Turban, et al., 2021). In addition, studies show that regret rates for those who have undertaken gender affirming care are extremely low. (Narayan, et al., 2021; Wiepjes, et al., 2018).

65. Dr. Levine and others who espouse similar "concern" about gender affirming medical procedures have had decades to test their own recommendations about how gender dysphoria should be managed. Nothing scientific has come from those efforts, except several accountings of the negative sequelae experienced by many who underwent conversion therapy. Dr. Levine also assumes that gender-affirming care focuses only on moving youth down a transgender pathway, without spending any time or effort addressing the young person's mental health. Both of these claims are false. Mental health practitioners who are practicing an affirming model of care are providing a safe space in which mental health symptoms or issues can be identified and addressed. Conversion therapy is not supported by any scientific evidence or rigorous data.

66. It is concerning that Dr. Levine consistently misrepresents the affirmative model of care, particularly in pre-pubertal children. Affirming approaches promote exploration of gender development and self-definition within a safe setting. A fundamental concept of this approach is that gender diversity is not a mental illness. The gender affirmative model is defined as a method of therapeutic care that includes allowing children to speak for themselves about their gender identity and expressions and providing support for them to evolve into their authentic gender selves. Support is not characterized by "encouraging" children or youth to be transgender or not. Interventions may include social transition, the changing of one's

presentation to more closely align with one's gender, as well as later medical interventions after the onset of puberty, such as puberty blockers, hormones, or surgery.

67. Dr. Levine asserts that there is a growing body of evidence that suggests that affirmation of gender diverse children results in a higher likelihood of persistence of gender incongruence. He cites an article entitled "The myth of persistence: Response to 'A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-conforming children'" by Temple Newhook et al. (2018) written by Ken Zucker. This is not a research article. It simply provides a rebuttal by Dr. Zucker to a previous manuscript. In it Dr. Zucker reviews some of the existing literature about persistence and desistance of gender incongruence among children over time. As previously noted, though, the studies upon which Dr. Zucker relies were based on the now obsolete and overly broad categorizations contained in the diagnosis for "Gender Identity Disorder in Children." None of the studies use the current DSM-5 "Gender Dysphoria in Children" diagnosis. Thus, the desistance rates of which Dr. Levine speaks include children who did not identify as transgender to begin with or would be considered "sub-threshold" for a Gender Dysphoria diagnosis. In addition, research shows that children who identify as transgender into adolescence, which is when any medical treatment begins, persist in their transgender identity. (de Vries, et al., 2011).

68. Dr. Levine attempts to create a causal relationship by asserting that gender affirmation (social transition specifically) in childhood causes children to continue to assert a gender incongruent with the sex they assigned at birth and that they would not have done so had they not undergone social transition. There is a failure to consider the clinical observation that children who end up socially transitioning are often experiencing the greatest distress about their gender incongruence, a discussed predictor of persistence. He presents an argument against

affirmation, social transition in particular, in light of the data that suggests the majority of children with gender non-conforming behaviors in childhood grow out of those behaviors and feelings as they move into adolescence. However, research shows that that gender identification does not meaningfully differ before and after social transition. (Rae, et al., 2019).

69. Even if we fully embrace the idea that most children who are gender non-conforming in childhood do not go on to assert gender incongruence in adolescence, it has no relevance to the medical treatment of adolescents and adults who do have gender incongruence, which is the subject of this case. The question is not "should we provide access to medical interventions for people who had GD in childhood that dissipated in adolescence?" because that population is not the population presenting for treatment and medical care is not indicated for that population of children. Transgender adolescents and adults with gender dysphoria are the patients we are discussing.

70. Dr. Levine goes on to discuss the purported lack of quality evidence regarding the impact of gender affirming interventions. Like all areas of medicine, clinical care often outpaces the science in various respects, as is the case with transgender youth care. But the current evidence base for treatment of transgender youth is commensurate with the evidence base for many other types of treatment for adolescents. Additionally, the increase in younger patients seeking services is being paralleled by the increase in data collection, with the promise of the creation of a rich database to better answer some of the still unanswered questions. Nothing about that is unique to gender dysphoria. Additionally, many existing studies have small numbers of participants because transgender experience is uncommon, there exist multiple barriers to accessing services, and there is a historical mistrust of medical institutions based on

an unimaginable amount of harm that such institutions have perpetuated upon this vulnerable community. (Sharman, 2016).

71. Dr. Levine also "wonder[s]" whether using medications off label (i.e., without formal approval by the U.S. Food and Drug Administration) is supportable. Levine Report ¶ 103. But it is common for medications to be used "off label" across all domains of medicine. In addition to there being fewer studies in children and adolescents, pharmaceutical companies often do not want to spend the money to get an FDA indication for use in a very small population.

72. Dr. Levine critiques the Endocrine Society's guidelines for the treatment of gender dysphoria, Levine Report ¶ 104, observing that the guidelines grade the evidence supporting hormone interventions for adolescents as low quality. Dr. Levine fails to understand that this is typical of clinical guidelines for many widely accepted types of care. In fact, within the Endocrine Society Guidelines for the clinical care of pediatric obesity, 48% of the recommendations are graded as very low-quality evidence. By contrast, within the Endocrine Society Gender Dysphoria/Gender Incongruence guidelines, only 23% of the recommendations are graded as very low-quality evidence. It is unlikely that Dr. Levine would suggest we don't treat pediatric obesity because the recommendations are based on low quality evidence. This is another example of applying a different standard to gender affirming care than to other areas of medicine.

73. Dr. Levine asserts that there is no data to suggest that affirmation will lower suicide deaths more than a psychotherapeutic model or watchful waiting, *see e.g.*, Levine Report ¶ 95, while also admitting that his preferred model of providing psychotherapy and withholding other medical interventions is "lacking in long-term evidence" and "quality evidence." Levine

Report ¶¶ 37, 160. However, there is evidence that youth who have been exposed to both a psychotherapeutic model and/or a watchful waiting approach, which deny affirmation and withhold medical care from adolescents, have died by suicide. It does not seem logical to keep employing a method that has been unsuccessful in preventing such deaths. His criticism of Jack Turban's manuscript includes that there was a high level of suicidality (both ideation and attempts) among both those who wanted and received blockers and those who wanted and did not receive blockers. Levine Report ¶ 114. That was not the thrust of the article. The article was demonstrating a decrease of suicidal ideation among the cohort that got blockers. While it is true that the raw data indicates that a higher percentage of the group that had access to puberty blockers had hospitalizations related to suicide attempts (n=5), this difference was not statistically significant, whereas lifetime suicidal ideation was statistically significantly lower in that cohort.

74. Dr. Levine opines about what he believes are a series of health risks related to gender-affirming care. Levine Report ¶¶ 118-144. As a psychiatrist, Dr. Levine is not qualified to offer opinions on several of these topics, including the intricacies of gender-affirming surgery. Nonetheless, I respond to several of his claims here.

75. **Disease and mortality:** Dr. Levine suggests that a series of health effects are associated with gender-affirming care, Levine Report ¶¶ 119-123, but his claims simply demonstrate a lack of familiarity with how these medical interventions are provided. For example, he cites risks involved with hormonal interventions, Levine Report ¶¶ 119, 122-123, but seems unfamiliar with the fact that newer evidence is demonstrating that the cardiovascular risk from gender affirming hormones is actually much lower than previously thought, as even one of his own sources show. As with every area of medicine, the risks and benefits of treatment

are discussed with the patient, and patients are monitored to ensure that their risk profile remains within the normal range.

76. Dr. Levine also refers briefly to puberty-delaying treatment as affecting height. Levine Report ¶ 134. The use of puberty blockers may impact height, but primarily providing an opportunity for transmasculine youth to grow taller, which is generally a desirable feature. Additionally, Dr. Levine makes the conclusory allegation that "[s]hortened life expectancy has been repeatedly documented." Levine Report ¶ 120. To the extent he suggests that gender-affirming care reduces one's life expectancy, no data support that exclusion—in fact, as discussed above they support the opposite conclusion.

77. **Fertility:** Dr. Levine expresses concerns about fertility from surgery and cross-sex hormone therapy, and claims (inaccurately) that puberty blockers may cause infertility as well. Levine Report ¶¶ 127-128. Aside from this being an overly simplistic perspective about a significantly long and complicated process, it is wholly divorced from the reality of care for transgender people. First, like all health care, gender affirming care for every transgender person is individualized. There simply is no one specific route. Second, there is no evidence that affirmation of pre-pubertal children in their identity or the provision of puberty blockers lead to sterility. Indeed, the effects of puberty blockers are reversible. To the extent a person desires and needs hormone treatment or surgery, such care is not provided until well into maturity and after discussion of the effects of such. In addition, patients who may need a procedure or treatment that will result in the side-effect of sterility are informed of such consequences and are provided with alternative options such as fertility preservation before initiating such care. (Chen, et al., 2017).

78. **Sexual function:** Dr. Levine asserts, without support, that puberty blockers may contribute to lack of sexual function. When data are lacking, we rely on clinical experience gathered from patient care and conversations as well as existing data on extrapolatable cases. There is a body of research on the capacity of minors for sexual arousal and orgasm, and there is no data to support the idea that gender affirmation diminishes sexual capacity. More commonly youth with GD experience dysphoria from the act of masturbation, and often even the possibility or thoughts around sexual intimacy. In fact, there is data that demonstrates improved satisfaction with sexual intimacy after gender affirming interventions.

79. Informed consent is the legal embodiment of the concept that each individual has the right to make decisions affecting their health. Physicians engaged in patient-physician relationships involving medical informed consent have a moral responsibility to identify the best treatments for each patient on the basis of available medical evidence and to discuss with patients the hoped-for benefits and the potential risks. Physicians must allow for patients' questions about the proposed treatments, benefits, and risks and must answer those questions from the available medical literature and their professional experience. This exchange of information and ideas is the foundation of the patient-physician partnership and promotes informed decision making in the most complex medical situations. (Paterick, et al., 2008). As noted above, speaking from my own clinical experience, at our center we strive to ensure that we are obtaining informed consent from every patient (and their parent/guardian) throughout the course of treatment.

80. **Psychosocial effects:** Dr. Levine expresses concern that puberty-delaying medication will "halt" maturation, and cause transgender adolescents to "undergo[] puberty at a substantially older age." Levine Report ¶¶ 134-135. Dr. Levine's assertion that puberty

suppression for a limited time has adverse effects on cognition is not supported by evidence within the realm of transgender youth care. Additionally, puberty suppression does not impact somatic growth, or emotional maturation. Dr. Levine fails to point out that experiencing the changes of a puberty that does not align with one's gender identity creates significant problems for transgender and nonbinary youth, including an exacerbation of anxiety, depression, isolation and sometimes poor coping mechanisms including self-harm and substance abuse. Youth going through an endogenous puberty that does not align with their gender express that it is difficult for them to participate in school, therapy, family and social activities. Most youth who utilize puberty blockers will likely go on to add exogenous hormones so that they do undergo puberty on the somewhat older side of normal range, but still well within normal range.

III. CONCLUSION

81. In conclusion, I do not disagree that, as with every field of medicine, there is more to learn in the field of transgender youth care. That is why I became an investigator. However, there is room to provide gender affirming medical interventions in a thoughtful manner that extrapolates from relevant fields of science and medicine, existing data, and clinical expertise while simultaneously carrying out further investigations. The denial of much needed care only serves to harm transgender people.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 17 day of March, 2022.

Johanna Olson-Kennedy (Mar 17, 2022 10:26 PDT)

Johanna Olson-Kennedy, M.D., M.S.

Subscribed and sworn before me, a Notary Public in and for the County of Norfolk, State of Virginia, this 17 day of March, 2022.

KETSIA MCCLEASE
Electronic Notary Public
Commonwealth of Virginia
Registration No. 327724
My Commission Expires Apr 30, 2023

Ketsia McClease
Signature of Notary

This notarial act was performed online by way of two-way audio/video communication technology.

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Final Audit Report 2022-03-17

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Exhibit A

CURRICULUM VITAE
JOHANNA OLSON-KENNEDY MS, MD
MAY 8, 2021

EDUCATION AND PROFESSIONAL APPOINTMENTS

EDUCATION:

Year	*Degree, Field, Institution, City*
1992	BA, Mammalian Physiology, UC San Diego, San Diego
1993	MS, Animal Physiology, The Chicago Medical School, Chicago
1997	MD, Medical Doctor, The Chicago Medical Shool, Chicago
2015	MS, Clinical and Biomedical Investigations in Translational Science, USC, Los Angeles

POST-GRADUATE TRAINING:

Year-Year	*Training Type, Field, Mentor, Department, Institution, City*
1997-1998	Internship, Pediatrics, Children's Hospital Orange County, Orange
1998-2000	Residency, Pediatrics, Antonio Arrieta, Children's Hosptial Orange County, Orange
2000-2003	Fellowship, Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles
2012-2015	Master's Degree, Clinical and Biomedical Investigations in Translational Science, USC

ACADEMIC APPOINTMENTS:

Year-Year	*Appointment*	*Department, Institution, City, Country*
2012-present	Medical Director	The Center for Transyouth Health and Development, Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA
2008-2012	Fellowship Director	Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA
2006-2016	Assistant Professor of Clinical Pediatrics	Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA
2016 - Present	Associate Professor of Clinical Pediatrics	Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA

LICENSURE, CERTIFICATIONS

LICENSURE:

Year	*License number, State, Status*
2000	A-67352, California, Active

BOARD CERTIFICATION OR ELIGIBILITY:

Year	*Board, State, Status*
2001, 2009, 2015	Pediatrics, California, active

SPECIALTY CERTIFICATION:

Year	*Specialty Certification, Status*
2003, 2013	Adolescent Medicine, California, active

HONORS, AWARDS:

Year	*Description*	*Awarding agency, address, city*
2019	Benjamin Meaker Visiting Professorship	University of Bristol, Bristol UK
2015	The Champion Award	The Division of Adolescent Medicine; CHAMPION FUND 5000 Sunset Blvd. Los Angeles
2014	Recognition Award for Outstandin Compassionate and Innovative Service	SoCal Society for Adolescent Health and Medicine Regional Chapter, Los Angeles
2014	Anne Marie Staas Ally Award	Stonewall Democratic Club; 1049 Havenhurst Drive #325, West Hollywood
2012	Extraordinary Service Award	Equality California, 202 W 1st St., Suite 3-0130 Los Angeles
2010	Clinical Research Academic Caree Development Award	Saban Research Center TSRI Program: Community Health Outcomes and Intervention, Los Angeles
2009	Health Care Advocacy Champion	Democratic Advocates for Disability Issues, Los Angeles

TEACHING

UNDERGRADUATE, GRADUATE AND MEDICAL STUDENT (OR OTHER) MENTORSHIP:

Year-Year	*Trainee Name*	*Trainee Type*	*Dissertation/Thesis/Project Title*
2020-Present	Richard Mateo Mora	MD	Fertility Preservation Among Transgender Women
2019-2021	Laer Streeter	MD	Comparison of Histrelin Implants
2016-Present	Jonathan Warus	MD/KL2	Affecting Pre-Exposure Prophylaxis (PreP) Decision Making to Improve Youth Engagement in HIV Prevention Services
2015-2020	Shannon Dunlap	PhD	Developmental Aspects of Gender Non-Conformong Youth
2015-2016	David Lyons	MD	Transgender Youth Clinical Clerkship
2014-2015	Michael Haymer	MD	Transgender Youth Clinical Clerkship

POSTGRADUATE MENTORSHIP:

Year-Year	*Trainee Name*	*If past trainee, current position and location*
2020-Present	Marianela Gomez-Rincon	Adolescent Medicine Fellow
2015-2018	Jonathan Warus, MD	Faculty, CHLA/USC Keck School of Medicine
2015-2017	Patrick Shepherd, MD	CHLA Endocrinology Fellow
2014	Julie Spencer, MD	Adolescent Medicine Provider Kaiser Hospital
2013	Shelley Aggarwal, MD	Clinical Instructor – StanfordUniversity School of Medicine
2012-2013	Lisa Simons, MD	Clinical Instructor – Lurie Children's Hospital

SERVICE

DEPARTMENT SERVICE:

Year-Year	*Position, Committee*	*Organization/Institution*
2010-2015	Secretary, The CHAMPION Fund Executive Board	The Division of Adolescent Medicine, Children's Hospital Los Angeles

PROFESSIONAL SERVICE:

Year-Year	*Position, Committee*	*Organization/Institution*
2012-present	Member, LGBT Special Interest Group	Society for Adolescent Health and Medicine

CONSULTANTSHIPS AND ADVISORY BOARDS:

Year	*Position, Board*	*Organization/Hospital/School, Institution*
2017 - Present	Board Member	US Professional Association of Transgen Health
2021	Member, Advisory Board	The National LGBTQIA+ Health Education Center
2010-2017	Member, Advisory Board	Transyouth Family Allies
2017-present	Member, National Medical Committee	Planned Parenthood

PROFESSIONAL SOCIETY MEMBERSHIPS:

Year- Year	*Society*
2017 - present	US Professional Association for Transgender Health
2014-present	Society for Pediatric Research
2010-present	World Professional Association for Transgender Health
2006-2011	Los Angeles Pediatric Society (Past president 2010)
2005-2012	American Academy of Pediatrics
2003-present	Society for Adolescent Health and Medicine

MAJOR LEADERSHIP POSITIONS: (E.G., DEAN, CHAIR, INSTITUTE DIRECTOR, HOSPITAL ADMINISTRATION, ETC.)

RESEARCH AND SCHOLARSHIP

EDITORSHIPS AND EDITORIAL BOARDS:

Year-Year	*Position*	*Journal/Board Name*
2015-present	Associate Editor	Journal of Transgender Health

MANUSCRIPT REVIEW:

Year-Year	*Journal*
2018-present	Journal of Transgender Health
2018 - present	Clinical Child Psychology and Psychiatry
2018 - present	Journal of Sexual Medicine
2015-present	Journal of Transgender Health
2014-present	International Journal of Transgenderism
2014-present	LGBT Health
2014-present	Journal of Adolescent Health
2014-present	Pediatrics

MAJOR AREAS OF RESEARCH INTEREST

Research Areas
1. Gender diverse children, transgender youth and young adults
2. HIV medication adherence

GRANT SUPPORT - CURRENT:

Grant No. (PI)2R01HD082554-06A1	*Dates of Award: 2021-2026*
Agency: NICHD	*Percent Effort 25%*
Title: The Impact of Early Medical Treatment in Transgender Youth	
Description: This is the continuations of a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.	
Role: Principle Investigator	
*Total Direct Costs: $*4,918,586	

Grant No. (PI) 1R01HD097122-01	*Dates of Award: 2019-2024*
Agency: NICHD	*Percent Effort 10%*
Title: A Longitudinal Study of Gender Nonconformity in Prepubescent Children	
Description: The purpose of this study is to establish a national cohort of prepubertal transgender/gender nonconforming (TGNC) children (and their parents), and longitudinally observe this cohort to expand the body of empirical knowledge pertaining to gender development and cognition in TGNC children, their mental health symptomology and functioning over time, and how family-initiated social gender transition may predict or alleviate mental health symptoms and/or diagnoses.	
Role:Co-Investigator	
Total Direct Costs: $2,884,950	

GRANT SUPPORT - PAST:

Grant No. (PI) 1RO1HD082554-01A1	*Dates of Award: 2015-2020*
Agency: NICHD	*Percent Effort 45%*
Title: The Impact of Early Medical Treatment in Transgender Youth	
Description: This is a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.	
Role: Principle Investigator	
*Total Direct Costs: $*4,631,970	
Grant No. (COI) R01AI128796-01	Dates of Award: 2/24/17-1/31/18
Agency: NIAID	Percent Effort: 5%
Title: Maturation, Infectibility and Trauma Contributes to HIV Susceptibility in Adolescents	
Description: This proposal explores the overarching hypothesis that fluctuations in sex steroid levels and mucosal trauma (sexual activity) are key determinants of mucosal immune activation and epithelial integrity, and that microbial communities are central to these processes. We will pursue this hypothesis by examining longitudinal changes in the anogenital microbiome as well as protein expression at these mucosal sites during sexual maturation (cisgender youth) and in hormonally-controlled sexual maturation (transgender youth). Associations between sex steroid levels, microbial community composition, mucosal trauma, and vaginal proteins will be determined and modeled.	
Role: Co-Investigator	
Total Direct Costs: $44,816	

Grant No. (PI) U01HD040463	*Dates of Award* 2006 – 2016
Agency: NIH/NICHD	*Percent Effort: 10%*
Title: Adolescent Medicine Trials Network for HIV/AIDS	
Description: Adolescent Medicine Trials Network for HIV/AIDS	
Role: Co-Investigator	
Total Direct Costs: 2,225,674	

Grant No. (PI) SC CTSI 8KL2TR000131	*Dates of Award: 2012-2014*

Agency: KL2 Mentored Career Research Development Program of the Center for Education, Training and Career Development	*Percent Effort: 37.5%*
Title: The Impact of Hormone Blockers on the Physiologic and Psychosocial Development of Gender Non-Conforming Peri-Pubertal Youth	
Description: This study aimed to understand the impact of puberty blocking medications on mental health and physiolgic parameters in peri-pubertal transgender youth.	
Role: Principal Investigator	
Total Direct Costs: 191,525	

Invited Lectures, Symposia, keynote addresses

Year	*Type*	*Title, Location*
2021	Invited Lecture	Approach to the Care of Gender Diverse Children and Transgender Youth, USC Keck Medical School, Virtual Lecture
2021	Invited Lecture	Caring for Gender Diverse and Transgender Youth. SLO Acceptance, Cal Poly, Virtual Presentation
2020	Symposium	Trans Youth Care, Chico Transgender Week, Virtual Presentation
2020	Invited Lecture	Gender Nonconforming and Transgender Youth, Novartis, Virtual Presentation
2020	Invited Lecture	Advanced Hormones; More than Just T and E, CHLA, Virtual Presentation
2020	Invited Lecture	Video Telehealth and Transgender Youth, Telehealth Best Practices for the Trans Community, The Central Texas Transgender Health Coalition, Virtual Presentation
2020	Invited Lecture	Caring for Gender Diverse and Transgender Youth , Center for Juvenile Justice Reform Supporting the Well-Being of LGBTQ Youth Certificate Program, Virtual Presentation
2020	Invited Lecture	Gear Talk, Transforming Families, Virtual Lecture
2020	Invited Lecture	Tips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual Presentation
2020	Invited Lecture	Caring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentation
2020	Invited Lecture	Approach to the Care of Gender Non-conforming Children and Transgender Youth, USC Medical School, Los Angeles, CA
2020	Invited Lecture	Medical Interventions for transgender youth, Cal State Los Angeles, Los Angeles
2020	Plenary Session	Understanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CA
2019	Keynote	Transgender Youth Care, SickKids, Toronto, Canada

2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	Symposium	TransYouth Care; Flagstaff, AZ
2019	Keynote	Future Directions, USPATH, Washington DC
2019	Invited Lecture	Just a Boy, Just a Girl, Gender Odyssey San Diego, San Diego, CA
2019	Invited Lecture	Hormonas que Affirman el Genero pasa Juventud y Adultos Menores Trans, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Infancia Trans y da Genero Diverso, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Gender Dysphoria; A Deeper Dive Beyond the Diagnosis, Keynote address, Inaugaral LGBTQ summit, Santa Clara CA
2019	Invited Lecture	Transgender and Gender Non-conforming Youth, Ascend Residential Treatment, Utah
2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah
2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, UCLA Olive View, CA
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, Good Samaritan, CA
2019	*Invited Lecture*	Gender Dysphoria; A Deeper Dive Beyond the Diagnosis, Advance LA Conference, California
2019	Invited Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, USC Keck School of Medicine Reproductive Health Section. Los Angeles, CA
2019	Invited Lecture	Transgender Youth: Medical and Mental Health Needs, Bristol, United Kingdom
2019	Invited Lecture	Rethinking Gender, University of Bristol, United Kingdom
2019	Invited Lecture	Puberty Suppression in Youth with Gender Dysphoria, Fenway Trans Health Program, Boston
2019	Invited Lecture	Recognizing the Needs of Transgender Youth, California Department of Corrections And Rehabilitation, Ventura, CA
2019	Invited Lecture	Gender Dysphoria; Beyond the Diagnosis, Gender Education Demystification Symposium, GA
2019	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Los Angeles Superior Court/Los Angeles Bar Association Training, CA
2019	Invited Lecture	Supporting Gender Diverse and Transgender Youth; A Deeper Look at Gender Dysphoria, Oakwood School, CA

2018	Invited Lecture	Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults: Comparison of Nonsurgical and Postsurgical Cohorts, Buenos Aires, Argentina
2018	Invited Lecture	Transyouth Care – An NIH Multisite Study About the Impact of Early Medical Treatment in Transgender Youth in the US, Buenos Aires, Argentina
2018	Invited Lecture	Transgender Youth and Gender Affirming Hormones; A 6-8 year follow-up, Buenos Aires, Argentina
2018	Invited Lecture	Supporting Gender Diverse and Transgender Youth: A Deeper Look at Gender Dysphoria, Studio City, CA
2018	Invited Lecture	Gender Dysphoria: Beyond the Diagnosis, Washington DC
2018	Invited Lecture	Uso de Hormonas Reaffirmantes de Genero en Adolescentes Transgenero, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	Invited Lecture	Bloquedores de la Pubertad, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	Invited Lecture	Working with Trans and Gender Non-Conforming Youth, Children's Hospital Orange County, CA
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, Ascend Residential, Encino CA
2018	Invited Lecture	Gender Dysphoria; Beyond the Diagnosis; Midwest LGBTQ Health Symposium, Chicago, IL
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, California State University Northridge, Northridge, CA
2018	Invited Lecture	Puberty Suppression and Gender Affirming Hormones, Gender Fest, Las Vegas, NV
2018	Invited Lecture	Gender Google; Gender Odyssey Family Conference, Seattle WA
2018	Invited Lecture	Gender Dysphoria; Beyond the Diagnosis, Gender Odyssey Family Conference, Seattle WA
2018	Invited Lecture	Puberty Suppression: What, When, and How, Gender Odyssey Family Conference, Seattle WA
2018	Invited Lecture	Gender Dysphoria; School Nurse Organization of Idaho Annual Conference, Idaho
2018	Invited Lecture	Understanding Gender Dysphoria, Gender Spectrum Family Conference, Moraga, CA
2018	Invited Lecture	Puberty Suppression and Gender Affirming Hormones, Gender Odyssey Family, Los Angeles, CA
2018	Invited Lecture	Gender Dysphoria – Beyond the Diagnosis, Gender Odyssey Family, Los Angeles, CA
2018	Invited Lecture	Gender and What You Should Know, Archer School for Girls, Brentwood, CA
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Oceanside, CA

2018	Invited Lecture	Gender Dysphoria: Beyond the Diagnosis, Advance LA, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Andrology Society of America Clinical Symposium, Portland, OR
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Center for Early Education, Los Angeles, CA
2017	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Santa Barbara, CA
2017	Invited Lecture	Gender Dysphoria, Beyond the Diagnosis, Pink Competency, Oslo Norway
2017	Invited Lecture	"Just a Boy, Just a Girl" Gender Infinity, Houston TX
2017	Invited Lecture	Caring for Gender Non-Conforming Children and Transgender Adolescents:
		A United States Perspective, Pink Competency, Oslo Norway
2017	Invited Lecture	Gender Dysphoria; Beyond the Diagnosis, Models of Pride, Los Angeles, CA
2017	Invited Lecture	Puberty Delay and Cross Hormones for Trans* Youth, Models of Pride, Los Angeles, CA
2017	Invited Lecture	Healthcare for TGNC Youth, Expanding Competency for LGBT Youth in the System, Washington DC
2017	Invited Lecture	Gender Non-conforming and Transgender Children and Youth; Center for Early Education, West Hollywood, CA
2017	Invited Lecture	Rethinking Gender, University of Massachusetts
		Annual Convocation Welcome Luncheon, Worcester, MA
2017	Invited Lecture	Puberty Delay and Cross Hormones for Trans* Youth, Gender Odyssey Family Conference, Seattle, WA
2017	Invited Lecture	Puberty Suppression; What, When and How, Gender Odyssey Family Conference, Seattle, WA
2017	Invited Lecture	Just a Boy, Just a Girl, Gender Odyssey, Los Angeles, California
2017	Invited Lecture	Puberty Blockers and Cross Sex Hormones, Gender Odyssey, Los Angeles, California
2017	Invited Lecture	Caring for Gender Non-conforming and Transgender youth and Young Adults, Diverse Families Forum: The Importance of Family Support In The Trans And LGBT Children, Organized by COPRED and The International Association Of Families For Diversity (FDS), Mexico City, Mexico
2017	Invited Lecture	Gender Non-Conforming Children and Transgender Youth, Board of Behavioral Sciences, Orange, CA
2017	Invited Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, Santa Monica Rape Treatment Center, Santa

		Monica, CA
2017	Invited Lecture	Gender Nonconforming and Transgender Youth, CSU Fullerton, Fullerton, CA
2017	Invited Lecture	Rethinking Gender, Chico TransGNC Week, Chico, California
2017	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Chico TransGNC Week, Chico, California
2017	Invited Lecture	Transgender Youth Care in the New Millennium, USC Law and Global Health Initiative, Los Angeles, CA

Invited Grand Rounds, CME Lectures

Year	*Type*	*Title, Location*
2021		
2020	CME Lecture	Histrelin Implants for Suppression of Puberty in Youth with Gender Dysphoria: a Comparison of 50 mcg/day (Vantas) and 65 mcg/day (SupprelinLA), WPATH Conference, Virtual Presentation
2020	CME Lecture	Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults, Comparison of Post-surgical and Non-surgical Cohorts, WPATH Conference, Virtual Presentation
2020	CME Lecture	Gender Affirmation Through a Social Justice Lens, SAHM Conference, Virtual Presentation
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, AAP Conference, Virtual Lecture
2020	CME Lecture	Conversations with LGBTQ youth; the role of the pediatrician, AAP Conference, Virtual Lecture
2020	Grand Rounds	Creating Affirming Environments for Trans and Gender Diverse Patients, USC OB/Gyn Grand Rounds, Virtual Presentation
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Resident Lecture, CHLA
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Facey Medical Group, Los Angeles, CA
2020	Plenary Lecture	Reframing Gender Dysphoria, LEAH Conference, Los Angeles, CA
2020	CME Lecture	Gender Affirming Care for Pre and Peri-pubertal Trans and Gender Diverse Youth, LEAH Conference, Los Angeles, CA
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Division of Endocrinology, USC, Los Angeles , CA
2020	Plenary Session	Understanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CA
2019	Symposium	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Stockton, CA

2019	Keynote	Transgender Youth Care, SickKids, Toronto, Canada
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	CME Lecture	Gender Diverse and Transgender Youth, Harbor UCLA Medical Center Grand Rounds, Torrance, CA
2019	CME Lecture	Gender Dysphoria – Beyond the Diagnosis, Gender Odyssey San Diego, San Diego, CA
2019	CME Lecture	Hormones 201 – Beyond T and E, Gender Odyssey San Diego, San Diego, CA
2019	*Grand Rounds*	Transgender Youth; What's New in 2019?, Children's Hospital Los Angeles, CA
2019	Oral Presentation	Male Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults, European Professional Association of Transgender Health, Rome Italy
2019	Oral Presentation	Transgender Youth and Gender Affirming Hormones; 5-7 Year Follow Up, European Professional Association of Transgender Health, Rome Italy
2019	CME Educational Lecture	Gender Dysphoria; Beyond the Diagnosis, European Professional Association of Transgender Health, Rome Italy
2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Children's Hospital Orange County, CA
2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Stanislaus County Behavioral Health and Recovery Services, CA
2019	CME Eduational Lecture	Rethinking Gender, Olive View Medical Center Grand Rounds, CA
2018	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Glendale Unified School District, CA
2018	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Youth, CME by the Sea, CA
2018	CME Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Austin, TX
2018	CME Educational Lecture	Gender Affirming Hormone Therapy for Transmasculine Adolescents and Young Adults, Gender Infinity, Houston, Texas
2018	CME Educational Lecture	Outside of the Binary; Care for Non-Binary Adolescents and Young Adults, Gender Infinity, Houston, Texas
2018	CME Educational Lecture	Chest Dysphoria and the Impact of Chest Reconstruction, Gender Infinity, Houston, Texas
2018	CME Educational Lecture	Just a Girl, Just a Boy, Gender Infinity, Houston, Texas
2018	CME Educational Lecture	Hormones 201: More than Testosterone and Estrogen, Gender Odyssey Professional Symposium, WA
2018	CME Educational Lecture	Male Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults, Gender Odyssey Professional Symposium,

		WA
2018	CME Educational Lecture	Chest Surgery, Gender Spectrum, Moraga, CA
2018	CME Educational Lecture	Understanding Gender Dysphoria, Gender Spectrum, Moraga, CA
2018	CME Educational Lecture	Puberty Suppression and Gender Affirming Hormones, Gender Odyssey, Los Angeles, CA
2018	CME Educational Lecture	Gender Dysphoria – Beyond the Diagnosis, Gender Odyssey, Los Angeles, CA
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Desert Oasis Healthcare, Palm Desert, CA
2018	CME Educational Lecture	Puberty Blockers and Gender Affirming Hormones for Transgender Youth: What Do We Know, and What Have We Learned, Pediatric Academic Societies, Toronto, Canada
2018	CME Workshop	Mental and Medical Healthcare for Transgender Adolescents, California Association of Marriage and Family Therapists, Garden Grove, CA
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Keck School of Medicine, Los Angeles, CA
2018	Grand Rounds	Caring for Gender Non-Conforming Children and Transgender Adolescents, Primary Children's Hospital, Salt Lake City, UT
2018	CME Educational Lecture	Caring for Transgender Youth, Chico Trans Week, Chico, CA
2018	CME Educational Lecture	Rethinking Gender, UCSD Medical School, San Diego, CA
2018	CME Educational Lecture	Rethinking Gender, UCLA Medical School, Los Angeles, CA
2018	CME Educational Lecture	Transyouth Care – Self-reflection On Personal Biases and Their Impact On Care, Society for Adolescent Health and Medicine, Seattle WA
2018	CME Educational Lecture	Rethinking Gender, Society for Adolescent Health and Medicine, Seattle WA
2018	CME Educational Lecture	Providing 360 degree transgender hormone therapy: beyond the protocols, Medical Directors Council (MeDC) 14th Annual Clinical Update in Reproductive Health and Medical Leadership, Snowbird, Utah
2018	CME Educational Lecture	Gender Dysphoria: Beyond the Diagnosis, Gender Education and deMystification Symposium, Salt Lake City, Utah
2018	CME Educational Lecture - Keynote	Rethinking Gender, SoCal LGBTQIA health conference, Los Angeles, CA
2017	CME Educational Seminar	The Care of Gender Non-Conforming children and Transgender Youth; Orange County Health Care Agency, Orange County, CA
2017	CME Educational Lecture	Rethinking Gender, Adolescent Grand Rounds, Children's Hospital Los Angeles, Los Angeles, CA
2017	CME Educational Lecture	"Just a Boy, Just a Girl" Gender Infinity, Houston TX
2017	CME Educational Lecture	Chest Dysphoria – The Impact of Male Chest Reconstruction, Gender Infinity, Houston TX

2017	CME Educational Lecture	Outside of the Binary; Care for Non-Binary Adolescents and Young Adults, Gender Infinity, Houston TX
2017	CME Educational Lecture	Puberty Blockers; What, When and How, Gender Infinity, Houston TX
2017	CME Educational Lecture	Gender Non-Conforming Children and Transgender Youth, Pasadena CA
2017	CME Educational Lecture	Gender Non-Conforming Children and Transgender Youth; Integrated Care Conference, Los Angeles, CA
2017	CME Educational Lecture	Gender Non-Conforming and Transgender Children and Adolescents; A Multidisciplinary Approach, California Psychiatric Association Annual Conference, Yosemite, CA
2017	CME Educational Lecture	Gender Non-Conforming and Transgender Children and Adolescents, Developmental Pediatrics continuing education lecture, Children's Hospital Los Angeles, CA
2017	CME Educational Lecture	Masculinizing Hormones, Central Texas Transgender Health Conference, Austin, TX
2017	CME Educational Lecture	Children, Youth, Families and Hormone Blockers, Central Texas Transgender Health Conference, Austin, TX
2017	CME Educational Lecture	Chest Dysphoria – The Impact of Male Chest Reconstruction, Gender Odyssey Professional Symposium, Seattle, WA
2017	CME Educational Lecture	Puberty Delay and Cross Hormones for Transyouth, Gender Odyssey Professional Symposium, Seattle, WA
2017	CME Invited Lecture	Just a Girl, Just a Boy, Gender Odyssey Professional Symposium, Seattle, WA
2017	CME Educational Lecture	Gender Dysphoria, Gender Spectrum Family Conference, Moraga, CA
2017	CME Educational Lecture	Care of Gender Non-Conforming Children and Transgender Adolescents, Lopez Family Foundation Educational Lecture, Los Angeles, CA
2017	CME Educational Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, USC Keck School of Medicine Reproductive Health, Los Angeles, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2017	CME Educational Lecture	Puberty Suppression in the United States; practice models, lessons learned, and unanswered questions, US Professional Association of Transgender Health, Los Angeles, CA
2017	CME Educational Lecture	The Impact of Male Chest Reconstruction on Chest Dysphoria in Transmasculine Adolescents and Young Men; A Preliminary Study, US Professional Association of Transgender Health, Los Angeles, CA
2017	CME Educational Lecture	Outside of the Binary; Care for Non-Binary Adolescents and Young Adults, US Professional Association of Transgender Health, Los Angeles, CA

PUBLICATIONS:

*** INDICATES TRAINEES**
**** INDICATE YOURSELF AS CO-FIRST OR CO-CORRESPONDING OR SENIOR AUTHORS**

REFEREED JOURNAL ARTICLES:

Julian J*, Salvetti B, Held J, Lara-Rojas L, **Olson-Kennedy J**, (2020), The Impact of Chest Binding in Transgender and Gender Diverse Youth and Young Adults, Journal of Adolescent Health, DOI://https://doi.org/10.1016/j.jadohealth.2020.09.029

Olson-Kennedy J, Streeter LH*, Garofalo R, Chan YM, Rosenthal SM (2020) Histrelin implants for suppression of puberty in youth with gender dysphoria: a comparison of 50 mcg/day (Vantas) and 65 mcg/day (SupprelinLA), Transgender Health X:X, 1–7, DOI: 10.1089/trgh.2014.0032.

Chen D, Abrams M, Clark L, Ehrensaft D, Tishelman AC, Chan YM, Garofalo R, **Olson-Kennedy J**, Rosenthal SM, Hidalgo MA, Psychosocial Characteristics of Transgender Youth Seeking Gender-Affirming Medical Treatment: Baseline Findings From the Trans Youth Care Study, Journal of Adolescent Health, 2020, ISSN 1054-139X https://doi.org/10.1016/j.jadohealth.2020.07.033.

Millington K, Schulmeister C, Finlayson C, Grabert R, **Olson-Kennedy J**, Garofalo R, Rosenthal SM, Chan YM. Physiological and Metabolic Characteristics of a Cohort of Transgender and Gender-Diverse Youth in the United States. *J Adolesc Health*. 2020 May

Lee JY, Finlayson C, **Olson-Kennedy J,** Garofalo R, Chan Y, Glidden DV, Rosenthal SM, Low bone mineral density in early pubertal transgender/gender diverse youth: Findings from the Trans Youth Care Study, *Journal of the Endocrine Society*, bvaa065. https://doi.org/10.1210/jendso/bvaa065

Olson-Kennedy J, Chan YM, Rosenthal S, et al. Creating the Trans Youth Research Network: A Collaborative Research Endeavor. *Transgend Health*. 2019;4(1):304–312. Published 2019 Nov 1. doi:10.1089/trgh.2019.0024

Rider G, Berg D, Pardo S, **Olson-Kennedy J,** Sharp C, Tran K, Calvetti S, Keo-Meier C, Using the Child Behavior Checklist (CBCL) with transgender/gender nonconforming children and adolescents. Clinical Practice in Pediatric Psychology. 7(3):291–301, 2019 Sep

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Clark B, Virani A, Ehrensaft D, **Olson-Kennedy J**, (2019) Resisting the Post-Truth Era: Maintaining a Commitment to Science and Social Justice in Bioethics, The American Journal of Bioethics, 19:7, W1-W3, DOI: 10.1080/15265161.2019.1618951

Sayegh CS, MacDonell KK, **Olson-Kennedy J**. The Impact of Cell Phone Support on Psychosocial Outcomes for Youth Living with HIV Nonadherent to Antiretroviral Therapy. AIDS Behav. Accepted for publication 2018. Role: Conceptualized the research, Edited manuscript

Olson-Kennedy J**, Warus J*, Okonta V, Belzer M, Clark LF., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. JAMA Pediatrics, 2018 May 1;172(5):431-436. doi: 10.1001/jamapediatrics.2017.5440. Role: Conceptualized the research, wrote and edited manuscript; first author

Olson-Kennedy J**, Okonta V, Clark LF, Belzer M, Physiologic Response to Gender-Affirming Hormones Among Transgender Youth, Journal of Adolescent Health, Volume 0, Issue 0 Published online October 2017; DOI: http://dx.doi.org/10.1016/j.jadohealth.2017.08.005 Role: Conceptualized the research, wrote and edited manuscript; first author.

Olson-Kennedy J,** Cohen-Kettenis P. T., Kreukels B.P.C, Meyer-Bahlburg H.F.L, Garofalo R, Meyer W, Rosenthal S.M., Research Priorities for Gender Nonconforming/Transgender Youth: Gender Identity Development and Biopsychosocial Outcomes, Curr Opin Endocrinol Diabetes Obes. 2016 Jan 27. [Epub ahead of print]: Role: coordinated information from all authors, wrote all drafts, and finalized manuscript; first author

Olson J**, Schrager S, Belzer M, Simons L*, Clark L. Baseline physiologic and psychosocial characteristics of transgender youth seeking care for gender dysphoria. Journal of Adolescent Health, July 2015 doi: 10.1016/j.jadohealth.2015.04.027 Role: Conceptualized the research, wrote and edited manuscript; first author.

Klein DA, Ellzy JA, **Olson J****. Care of a transgender adolescent. Am Fam Physician. 2015;92(2):143-148. Role: Edited manuscript; senior author

Belzer M, Kolmodin MacDonell K, Clark L, Huang J, **Olson J**, Kahana S, Naar S, Sarr M, Thornton S. Acceptability and feasibility of a cell phone support intervention for youth living with hiv with nonadherence to antiretroviral therapy, AIDS Patient Care and STDs, Vol. 29, No. 6, June 2015: 338-345. doi: 10.1089/apc.2014.0282; Role: edited manuscript;

Olson J**, Schrager S M., Clark L F., Dunlap S L., Belzer M. Subcutaneous testosterone: an effective delivery mechanism for masculinizing young transgender men, LGBT Health. September 2014, 1(3): 165-167. doi:10.1089/lgbt.2014.0018. Role: conceptualized research, collected data, first authored manuscript; First author

Schrager SM, **Olson J,** Beharry M*, Belzer M, Goldsich K*, Desai M, Clark LF. Young men and the morning after: a missed opportunity for emergency contraception provision? J Fam Plann Reprod Health Care. 2015 Jan;41(1):33-7. doi: 10.1136/jfprhc-2013-100617. Epub 2014 Jan 24. PubMed PMID: 24465024. Role: conceptualized research project, edited manuscript.

Belzer ME, Naar-King S, **Olson J**, Sarr M, Thornton S, Kahana SY, Gaur AH, Clark LF; Adolescent Medicine Trials Network for HIV/AIDS Interventions. The use of cell phone support for non-adherent HIV-infected youth and young adults: an initial randomized and controlled intervention trial. AIDS Behav. 2014 Apr;18(4):686-96. doi: 10.1007/s10461-013-0661-3. PubMed PMID: 24271347; PubMed Central PMCID: PMC3962719. Role: Edited manuscript

Simons L*, Schrager SM, Clark LF, Belzer M, **Olson J**.** Parental support and mental health among transgender adolescents. J Adolesc Health. 2013 Dec;53(6):791-3. DOI: 10.1016/j.jadohealth.2013.07.019. Epub 2013 Sep 4. PubMed PMID: 24012067; PubMed Central PMCID: PMC3838484. Role: Conceptualized research, collected data, edited manuscript

Olson J,** Forbes C, Belzer M. Management of the transgender adolescent. Arch Pediatr Adolesc Med. 2011 Feb;165(2):171-6. doi: 10.1001/archpediatrics.2010.275. Review. PubMed PMID: 21300658. Role: Drafted and edited manuscript: first author

Puccio JA, Belzer M, **Olson J**, Martinez M, Salata C, Tucker D, Tanaka D. The use of cell phone reminder calls for assisting HIV-infected adolescents and young adults to adhere to highly active antiretroviral therapy: a pilot study. AIDS Patient Care STDS. 2006 Jun;20(6):438-44. PubMed PMID: 16789857. Edited manuscript.

Belzer M, Sanchez K, **Olson J**, Jacobs AM, Tucker D. Advance supply of emergency contraception: a randomized trial in adolescent mothers. J Pediatr Adolesc Gynecol. 2005 Oct;18(5):347-54. PubMed PMID: 16202939. Edited manuscript.

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Forcier M, **Olson J****, Transgender and Gender Nonconforming Youth, AM:STARs Hot Topics in Adolescent Health: Adolescent Medicine State of the Art Reviews, 25(2), August 2014 American Academy of Pediatrics Section on Adolescent Health

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By American Academy of Pediatrics Section on Adolescent Health 2018
ISBN (paper): 978-1-61002-136-4

Olson-Kennedy J**. Mental Health Disparities Among Transgender Youth Rethinking the Role of Professionals. *JAMA Pediatr.* 2016;170(5):423–424. doi:10.1001/jamapediatrics.2016.0155

Olson J**, Garofalo R. The peripubertal gender-dysphoric child: puberty suppression and treatment paradigms. Pediatr Ann. 2014 Jun;43(6):e132-7. doi: 10.3928/00904481-20140522-08. PubMed PMID: 24972421. Role: Drafted and edited manuscrpt: first author

Hildago MA, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, Spack NP, **Olson J****. The gender affirmative model: What we know and what we aim to learn. *Human Development*, 2013, 3: 285-290. Edited manuscript; senior author

Olson J**, Forcier M, Overview of the management of gender nonconformity in children and adolescents, In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA Role: co-first authored manuscript – drafting and editing.

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Olson, J**. Lesbian, gay, bisexual, transgender, queer youth and the internet- a virtual closet or cornucopia? – California Pediatrician, Jan 2011

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MEDIA AND TELEVISION APPEARANCES:

France 24 TV – Transgender Youth, 2015

The DeMita Fletcher Family: What We Learned From Our Transgender Son , People.com

Eisenhower Medical Center Hosts Transgender Symposium, Desert Sun

Transgender 13-year-old Zoey having therapy, BBC

Driven to Suicide, People Magazine

Gay Dads with Gender Non-Conforming Kids, Gays with Kids

Transgender Teen Opens Up about Struggles, Journey, ABC 7

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Bruce Jenner's transgender journey will lead to more understanding, many say, Daily News

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Exhibit B

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Pediatrics

Child Development

Psychological Medicine

Public Health Rev

LGBT health

Pediatrics

Journal of child psychology and psychiatry, and allied disciplines *59*

Journal of Clinical and Translational Endocrinology

The journal of sexual medicine *15*

Exhibit
0001

CHAPTER 100– GENERAL INFORMATION

CHANGE LOG

Replace	Title	Change Date	Effective Date
Sections: 110, 121, 150, 151, 152, 153, 160, 161, 170, 180, 191	Various	12/02/04	01/01/05
Section 140	Manual Updates	12/02/04	01/01/05
Section 153	Other Contact Information	12/02/04	01/01/05
	Medicaid Managed Care	12/02/04	01/01/05
Section 161	General Non-Covered Services	12/02/04	01/01/05

CHAPTER 100– GENERAL INFORMATION

12/2/2004

Sections: 110, 121, 150, 151, 152, 153, 160, 161, 170, 180, 191

Introduction: The terms beneficiary and recipient have been replaced by member throughout the entire manual.

Directions: Replace the pages containing these sections.

Change: Replace current sections with the updated ones.

Section 140

Introduction: The manual update process has undergone some changes. Also the contact phone numbers in this section have changed.

Directions: Replace the page containing this section.

Change: Replace old phone numbers with the new ones.

Section 153

Introduction: Some of the contact phone numbers in this section have changed because of the change in contractors.

Directions: Replace the page containing this section.

Change: Replace old phone numbers with the new ones.

Introduction: Added wording related to PCCM Program.

Directions: Replace the page containing this section.

Change: Add PCCM Program.

Section 161

Introduction: Removed Gastric By-pass from the section since this surgery is now a covered service under certain conditions.

Directions: Replace the page containing this section.

Change: Delete gastric by-pass as a non-covered service.

CHAPTER 100—GENERAL INFORMATION

TABLE OF CONTENTS

DISCLAIMER: This manual does not address all the complexities of Medicaid policies and procedures, and must be supplemented with all State and Federal Laws and Regulations.

- Speech and Hearing Services
- Transportation Services
- Vision Services.

Certain services are covered only for specific categories of eligible members. All covered Medicaid services, both traditional and special services, must be medically necessary, may be limited in scope, i.e., specific number of units of services, and may be subject to prior authorization.

BMS contracts with West Virginia Medical Institute (WVMI) for the review and approval of all hospital inpatient services for Medicaid members. However, physicians, acute care hospitals, rehab hospitals for members under age 21 only, and psychiatric hospitals for members under 21 only, must obtain prior authorization before admission of the patient. For documented emergencies, the patient may be admitted, but the request for prior authorization must be made to WVMI within 24 hours or the first working day after admission.

Refer to appropriate the applicable provider manual for specific provider policy and billing instructions for each of these covered services.

161 GENERAL NON-COVERED SERVICES

The WV Medicaid Program does not cover certain services and items regardless of medical necessity.

Some examples are identified below:

- Acupuncture
- Artificial insemination, in vitro fertilization, infertility services, or sterilization reversal
- Autopsy
- Christian Science services
- Cosmetic surgery services
- Dental services for members 21 years of age and over (except for treatment of fractures of mandible and maxilla and biopsy), removal of cysts and tumors, and emergency extractions
- Drugs for weight gain or loss, hair growth, fertility, cosmetic use, and those considered investigational or unproven
- Duplicate services
- Equipment or supplies which are primarily for patient comfort and/or family or caretaker convenience (Note: One mobility item is covered in a five-year period.)
- Experimental or investigational/research services or drugs
- Inpatient psychiatric services for individuals between 22 and 65 years of age, except acute care admissions
- Optometry services for individuals over age 21, except the first pair of glasses after cataract surgery
- Personal comfort and convenience items or services, whether on an inpatient or outpatient basis, such as television, telephone, barber or beauty service, guest services, and similar incidental services and supplies, even when prescribed by a physician
- Radial Keratotomy; Lasik surgery

- Services rendered outside the scope of a provider's license
- Sterilization for individuals under age 21
- Transsexual surgery
- Fees for missed appointments*
- Fees to copy medical records
- Weight loss programs or drugs for weight loss
- Services rendered by students as part of their clinical or academic training.

* Enrolled providers cannot bill Medicaid members for missed appointments.

The above list is illustrative only. It should not be construed as a complete or exhaustive list of excluded items or services.

Refer to Chapter 400 for additional information on member responsibilities for payment, and appicable provider manuals for specific covered and non-covered services.

The "WV Works" Program covers dental and optometry services for certain eligible adult Medicaid members. Please note: Not all Medicaid-eligible members are eligible for enrollment in the "WV Works" Program. Contact the local DHHR office for questions regarding specific benefits and possible coverage for patients.

170 RELATIONSHIP TO MEDICARE

Medicaid covers medically necessary health services furnished to individuals who meet specific income, resource, and eligibility standards. Medicare is a federal program that offers health insurance coverage to individuals 65 years of age or older, to those who have received social security disability benefits for 24 consecutive months, to those who have end-stage renal disease, to those on advanced life support, and to other eligible individuals, as specified by other provisions of the Social Security Act.

WV Medicaid covers the applicable co-insurance and deductible amounts, not to exceed Medicaid's allowable payment, for services covered by Medicare Parts A and B for all eligible Medicaid members who are also entitled to Medicare benefits. The Medicaid Program may also provide payment for services not covered by Medicare.

A member with both Medicare and Medicaid coverage is identified as "dual eligible." Medicaid reimburses secondary to Medicare. If a Medicare Supplemental policy exists in addition to Medicare and Medicaid coverage, Medicaid is the third-party payer subsequent to Medicare and Medicare Supplemental payments. Medicaid is always the payer of last resort.

Refer to Chapter 300 for more specific provider information on the Medicare program and its relationship to WV Medicaid, including Medicare provider numbers as part of your Medicaid participation responsibilities.

For information related to claim submission procedures for services rendered to a "dual eligible" member, refer to Chapter 300.

180 OUT-OF-STATE SERVICES

Non-emergency, out-of-state services provided to WV Medicaid members routinely require prior authorization from the BMS Out-of-State Unit, Bureau for Medical Services. For HMO members, follow the respective HMO prior-authorization requirements. If applicable, contact BMS at 1-304-558-1700.

Exhibit
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CHAPTER–519 COVERED SERVICES, LIMITATIONS, AND EXCLUSIONS FOR PRACTITIONER SERVICES – INCLUDING PHYSICIANS, PHYSICIAN ASSISTANTS, AND ADVANCED REGISTERED NURSE PRACTITIONERS

CHANGE LOG

Replace	Title	Change Date	Effective Date
Attachment 18	Infant and Child Oral Health Fluoride Varnish Program for Primary Care Practitioners	01/16/12	01/16/12
Section 519.20.1	Prior Authorization for Outpatient Surgeries	01/10/06	02/15/06
Section 519.13.2.1	Immunization for Children	11/21/05	11/30/05
Section 519.19.1	Prior Authorization for Outpatient Surgeries	10/24/05	Postponed
Section 519.12.5	Medicaid Diabetes Disease State Management	10/4/05	10/15/05
Section 519.13.2.2	Immunizations for Adults	10/4/05	10/24/05
Section 519.13.2.1	Immunizations for Children	9/28/05	7/18/05
Section 519.19.1	Prior Authorization for Outpatient Surgeries	9/28/05	11/1/05
Section 519.14.3	Prior Authorization Requirements for Imaging Procedures	9/1/05	10/1/05
Section 519.7.6	Nursing Facility Visits	5/17/05	6/1/05
Section 519.11.3	Psychiatric Services	5/17/05	6/1/05
Section 519.12.1	Caloric Vestibular Testing	5/17/05	6/1/05

CHAPTER 519—COVERED SERVICES, LIMITATIONS AND EXCLUSIONS FOR PRACTITIONERS SERVICES

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TOPIC **PAGE NO.**

519.15 UNLISTED SERVICES, DRUGS, PROCEDURES, OR ITEMS

Unlisted services, drugs, procedures, or items (as defined by HCPCS) are used only when there is no code that describes the service, item, or procedure provided to a Medicaid member. Unlisted codes must always be billed on paper with a description of the service provided, e.g., an operative report or clinical notes.

When billing for other unlisted services, procedures, or items, the claim must be accompanied by all documentation necessary to justify reimbursement (i.e., operative reports, cost invoices, etc).

519.16 NON-COVERED ITEMS – MEDICAL SUPPLIES/DURABLE MEDICAL EQUIPMENT

Payment will not be authorized for non-covered items – medical supplies/durable medical equipment. Details of non-covered items – medical supplies/durable medical equipment are found in the Chapter 506 pertaining to durable medical equipment.

519.17 NON-COVERED SERVICES

Certain services and items are not covered by the Medicaid Program. Non-covered services include, but not limited to, the following:

- Acupressure
- Acupuncture
- Autopsy
- Cardiac rehabilitation programs, pulmonary rehabilitation programs, and other rehabilitation programs
- Chelation therapy
- Claims received more than 12 months after the date of service
- Completion of forms and reports, except for eligibility purposes as specifically requested by the Department of Human Services using ~~E~~SRT" letters of request
- Cosmetic procedures, medical or surgical, the primary purpose of which is to improve the member's appearance. Such procedures include, but not limited to, otoplasty for protruding ears of lop ears, rhinoplasty (except to correct nasal deformity), nasal reconstruction, excision of keloids, fascioplasty, osteoplasty for prognathism or micrognathism or both, dermabrasion, certain skin grafts, malar augmentation, breast implants for other than breast cancer reconstruction, and lipectomy
- Courtesy Calls (visits in which no identifiable medical service was rendered)
- Dietary (food) supplements, except as provided in a hospital or nursing home
- Direct payments to members (payments are made to the provider of service)
- Domestic or housekeeping services, except to the extent they may be provided under a home health service plan
- Drugs and supplies dispensed by the physician which are acquired by the physician at no cost
- Educational services
- Experimental/Research/Investigational medical or surgical procedures
- Genetic testing
- Hypnosis
- Immunizations required for travel outside the Continental United States
- Incidental surgical Procedures (i.e., incidental appendectomy, lysis of adhesions, excision of previous scar, etc.) performed at the same time as a major surgical procedure
- Infertility services (i.e., artificial insemination, in vitro fertilization, etc.)
- Inhalation Therapy (chronic basis)

- Injections and visits solely for the administration of injections unless medically necessary and the member's inability to take appropriate oral medications are documented in the member's medical record and on the claim form
- Inpatient rehabilitation services for members over 18 years of age
- Items/Services not related to medical care that were provided for the convenience of the member, their custodian, or the provider
- Maintenance services if no progress is being made
- Mass screenings for any condition
- Massage therapy
- Meals-on-Wheels (or similar food service arrangements)
- Naturopathy
- Non-legend Drugs (over-the-counter drugs), except for the following:
  - Family planning supplies
  - Insulin
  - Diabetic syringes/Needles/Testing kits
  - End-Stage Renal Disease (ESRD) Vitamin/Vitamin mineral preparations and other medications related to ESRD services.

NON-LEGEND DRUGS FOR MEMBERS RESIDING IN LONG-TERM CARE (LTC) FACILITIES (skilled and intermediate nursing homes) are to be furnished by the LTC and are not to be billed to the member or the Department of Health and Human Resources.

- Nutritional (dietary) counseling
- Operating surgeon may not bill for the administration of anesthesia, except epidural anesthesia
- Pain Clinics (Specific medical procedures ordered by the physician for treatment are covered)
- Payment to a physician for laboratory services as payment is made directly to the facility performing these services. (The physician may have a laboratory specifically approved for Medicaid purposes; the laboratory must have a Medicaid laboratory provider number)
- Personal comfort items (items which do not directly contribute to the treatment of an illness or injury or to the functioning of a malformed body part)
- Physician services denied by Medicare as not medically necessary, ineffective, unsafe, or without proven clinical value
- Physician services included as part of the cost of an inpatient facility or hospital outpatient department
- Pre-operative evaluations for anesthesia are included in the fee for administration of anesthesia and the provider may not bill them
- Procedures prohibited by State or Federal statute or regulations
- Pulmonary rehabilitation programs and other similar rehabilitation programs
- Referrals from one physician to another for treatment of specific member problems are not to be billed as consultations
- Reflexology
- Rehabilitation programs such as cardiac, pulmonary, dietary, weight control, etc.
- Respiratory therapy
- Routine Foot Care, except for those members having a metabolic disease such as diabetes and the metabolic disease must be documented
- Services and items under a Workers Compensation law or other payment services
- Services provided as inpatient hospital services if the service could appropriately and safely be

performed on an outpatient basis in an office or outpatient hospital setting unless the procedure is performed as a secondary necessary procedure
- Services provided by students
- Services provided for the purpose of relieving discomfort
- Services which are not medically justified
- Services which are provided at no charge to patients who are not Medicaid members (i.e., services provided free to the general public cannot be billed to Medicaid)
- Sex change surgery (transsexual surgery)
- Sex determination services
- Spectacle (glasses) cases
- Sterilizations when the member is under 21 years of age, institutionalized, or mentally incompetent
- Tai chi
- Telephone contacts with members or on their behalf
- Tempomandibular Joint Syndrome (TMJ) surgery or treatment
- Visits solely for one or more of the following:
  - Prescription pickup
  - Collection of specimens for laboratory procedures
  - Ascertaining members' weight.
- Weight reduction (obesity) clinics/programs.
- Yoga

519.18 BILLING AND REIMBURSEMENT

Practitioners must bill WV Medicaid directly for covered services provided to Medicaid members. However, payment may be made to a practitioner's employer when the practitioner is required as a condition of employment to turn over his/her fees to the employer or when the facility where a service is rendered has a signed contract with the practitioner that requires the facility to submit the claim. **Chapters 300 and 600** contain additional information.

As is consistent with Federal law prohibiting Medicaid providers from balance billing, (i.e., billing an amount in excess of the Medicaid fee), the practitioner may not bill the member any additional amount regardless of the setting in which a service is rendered.

519.18.1 HCPCS CODES

The Center for Medicare and Medicaid Services (CMS) of the Federal Government has mandated that all States implement the HCPCS codes to identify medical services provided to Medicaid members.

HCPCS is a coding system that uses the AMA's Current Procedural Terminology, fourth edition (CPT-4) as its base (Level I codes) and then nationalizes non-standard codes used by various states so all state and federal payers of medical claims use the same coding system (Level II codes).

In an effort to maintain uniformity with National Correct Coding Policies implemented by CMS, the BMS incorporates the National Correct Coding Initiative methodologies for the analysis of standard medical and surgical practice. These policies were developed based on coding conventions defined in the AMA's CPT-4 Manual, in national and local policies, in edits and in coding guidelines developed by national societies. They are consistent with federally and state mandated program policies. Incorporating these edits into the review process does not represent new policy or monitoring procedures by the BMS and should not be interpreted as such. These edits represent generally accepted standards of medical and surgical practice. Adherence to these policies will be monitored

Welcome

Aetna Better Health® of West Virginia

2021-2022 Member Handbook

Mountain Health Trust – Medicaid

AetnaBetterHealth.com/WestVirginia

86.20.301.1-WV

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Aetna Better Health® of West Virginia

CFAIN0002152

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COURT ORDERED SERVICES

Medically necessary court ordered treatment services are covered by Aetna Better Health. Court ordered services are subject to, BMS review and determination and member appeals.

SECOND MEDICAL OPINIONS

You may need a second opinion for an illness, surgery and/or confirming a treatment of care your practitioner has told you that you need. Contact your practitioner or Member Services for help to get a second opinion. If an appropriate provider or practitioner for the second opinion is not available within the Aetna Better Health network, we will arrange for you to get the second opinion outside the network. There is no cost to you for the second opinion.

SERVICES NOT COVERED

Some services are not available through Aetna Better Health or Medicaid. If you choose to get these services, you may have to pay the entire cost of the service. Aetna Better Health is not responsible for paying for these services:

- All non-medically necessary services
- Sterilization of a mentally incompetent or institutionalized individual
- Except in an emergency, inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner, acting within the scope of practice, who is responsible for the diagnosis or treatment of a particular patient's condition
- Organ transplants, except corneal transplant
- Treatment for infertility and the reversal of sterilization
- Sex transformation procedures and hormone therapy for sex transformation procedures
- All cosmetic services, except in the case of accidents or birth defects
- Christian science nurses and sanitariums
- Duplicate Services
- Service codes determined by Bureau for Medical Services as not covered
- Health services or supplies from nonparticipating practitioners, except in an emergency, for family planning or when otherwise approved by Aetna Better Health
- Health Services prohibited by law or regulation
- For adults, TMJ and other dental problems related to malocclusion unless proven to be life-threatening

This is not a complete list of the services that are not covered by Aetna Better Health. If a service is not covered, not authorized, or is provided by an out-of-

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86.20.301.1-WV

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Aetna Better Health® of West Virginia

CFAIN0002203

The HealthPlan

WEST VIRGINIA MEDICAID MANAGED CARE MEMBER HANDBOOK

SFY 2022

(July 1, 2021 – June 30, 2022)

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Behavioral Health Services Not Covered:

- Services provided to individuals under the age of 21 performed in a children's residential treatment facility
- Any services that are covered by fee-for-service
- School-based services

If there is a mental health or substance abuse emergency, please call 911 right away.

COURT ORDERED SERVICES

Medically necessary court ordered treatment services are covered by The Health Plan. Court ordered services are subject to BMS reviews and determination.

SERVICES NOT COVERED

Some services are not available through The Health Plan or Medicaid. If you choose to get these services, you may have to pay the entire cost of the service. The Health Plan is not responsible for paying for these services and others:

- All non-medically necessary services.
- Except in an emergency, inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner, acting within the scope of practices, who is responsible for the diagnosis or treatment of a particular patient's condition.
- Cosmetic/plastic surgery will be covered only to correct conditions from accidents/injuries like a car accident and birth defects like a cleft lip. Breast implants are covered only for mastectomy due to breast cancer or fibrocystic breast disease. You may have to get a second opinion before getting these services.
- Removal/replacement of breast implants must be proven medically necessary. Implants must have been inserted for reconstructive purposes due to mastectomy for breast cancer or fibrocystic breast disease. You may have to get a second opinion before getting these services.
- These conditions must have happened while you were a member of The Health Plan. If not, The Health Plan must determine an ongoing history of medically necessary cosmetic/plastic surgery to correct these conditions. The Health Plan may do so by looking at your past medical records.

- Removal of breast implants that were inserted for cosmetic reasons only will not be covered.
- Oral surgery for adults will be covered to correct conditions from accidents/injuries, like a car accident. The accident/injury must have happened *while* you were a member of The Health Plan. An oral surgeon *must* be needed to correct these conditions. These services must start within six months of the accident/injury.
- Custodial or home care, rest and respite care, or other services primarily to assist in the activities of daily living and personal comfort items (to include cleansing and luxury items) are not paid for by The Health Plan. This includes personal services and residential services.
- Health care that is for research, investigation, or experimental as determined by The Health Plan, is not paid for by The Health Plan. The Health Plan will look at standards of the AMA, FDA, NIH, Medicare, or reports of consultants to decide if a health care treatment is experimental or investigational.
- Private rooms are not paid for, except when medically needed and approved by The Health Plan. Personal or comfort items and services like guest meals, lodging, radio, television, and telephone are not paid for by The Health Plan.
- Hospital or medical care for problems that state or local law requires treatment in a public facility is not paid for by The Health Plan.
- Any injury or sickness when any benefits, settlements, awards, or damages will be received or paid will not be paid for by The Health Plan. This also includes workers' comp, employer's liability or similar law or act. This applies even if you waived your rights to workers' comp, employer's liability, or similar laws or acts. Be sure to tell The Health Plan if you will get any benefits, settlements, awards, damages, or workers' comp.
- Reversal of voluntary sterilization and associated services and/or expenses will not be paid for by The Health Plan.
- Sterilization for members under age 21 will not be paid for by The Health Plan.
- Sex change, hormone therapy for sex transformation, and gender transition procedures/expenses will not be paid for by The Health Plan. Procedures, services and supplies related to sexual dysfunction will not be paid for by The Health Plan.
- Special services not approved by The Health Plan will not be paid for.

TheHealthPlan

Provider Procedural Manual

Corporate Office

1110 Main Street
Wheeling, WV 26003

P: 1.800.624.6961
F: 1.740.699.6169
TTY: 711

healthplan.org

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Section 1 - Welcome

Section 2 – Physician Availability

Section 3 – Member Benefits

Section 4 – Medicare

Section 5 – Medicaid

Exclusions, continued

- Sex change, hormone therapy for sex transformation, and gender transition procedures/expenses will not be paid for by The Health Plan. Procedures, services and supplies related to sexual dysfunction will not be paid for by The Health Plan.
- Special services not approved by The Health Plan will not be paid for.
- Provider and medical services outside the service area will not be paid for if you knew you would need these services before you left the service area. If you know you will need services and you may be traveling soon, tell your PCP or The Health Plan.
- Hearing aid evaluations, bone-anchored hearing aids, cochlear implants, hearing aids, hearing aid supplies, batteries and repairs will only be covered for members under the age of 21. Coverage depends on hearing loss and The Health Plan guidelines.
- Exams for insurance, sports physicals, camp physicals, or daycare physicals will not be paid for unless it is part of your yearly physical exam given by your PCP.
- Medical and surgical treatment for *all* infertility services will not be paid for by The Health Plan.
- Abortions will not be paid for by The Health Plan but are covered by FFS Medicaid. Use your medical card.
- Long-term cardiac and pulmonary, physical, respiratory, occupational or speech therapy will only be paid for in certain situations, such as for children.
- Services for acupressure, hypnosis, electrolysis, Christian Science treatment and autopsy. Any education or training classes including Lamaze and to quit tobacco use (unless under RFTS) will not be paid for by The Health Plan. Estrogen and androgen pellet implants, arch supports, massage, and paternity testing are not covered.
- Liposuction, panniculectomies or abdominoplasty, such as surgery to remove fatty tissue ("tummy tucks"), will not be covered by The Health Plan.
- Work hardening programs, including functional capacity evaluations will not be covered by The Health Plan.
- Services at non-medical weight loss clinics and diet centers, mini-gastric bypass surgery, and gastric balloon for treatment of obesity will not be covered by The Health Plan. Consideration for bariatric surgery and related services require prior authorization. Also included are wiring of the jaw, weight control programs, screening for weight control programs, and similar services.
- Organ transplants and related expenses will not be covered by The Health Plan. These are covered by FFS Medicaid through your medical card.
- Vision services for members over age 21 are limited to medical treatment only and require an approved referral to a participating ophthalmologist.
- Practitioner and medical services that are not medically necessary or appropriate as determined by The Health Plan will not be paid for.
- Other limitations specifically stated in the provider and medical benefits list in this handbook.

UniCare Health Plan of West Virginia, Inc.

Member Handbook

Mountain Health Trust
West Virginia Health Bridge
West Virginia Children's Health Insurance Program

UWV-MHB-0022-20

UNICARE®
An Anthem Company

CFAIN0001686

UNICARE®

Please note this change to your handbook.

Thank you for being a member. We have important updates to your UniCare Health Plan of West Virginia, Inc. benefits. Starting July 1, 2021, mothers and their newborns can continue to receive Medicaid benefits for up to one year postpartum. Extending coverage for you and your baby helps ensure continued access to care for your health-related needs.

It is important you provide UniCare with your newborn's name. This helps us stay up to date and provides UniCare with the right details for your health coverage. To provide a name, call your Department of Health and Human Resources (DHHR) or tell the Change Center at **877-716-1212**.

Please keep this insert with your UniCare handbook.

Questions? We're here to help. Call the Customer Care Center at **800-782-0095**, Monday through Friday from 8 a.m. to 6 p.m. Eastern time, or visit **unicare.com/wv**.

Enclosure(s): Get help in another language
HHS nondiscrimination notice

1033803WVMENUNC 06/21

unicare.com/wv

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SERVICES NOT COVERED

Some services are not available through UniCare, Medicaid, or WVCHIP. If you choose to get these services, you may have to pay the entire cost of the service. UniCare is not responsible for paying for these services and others:

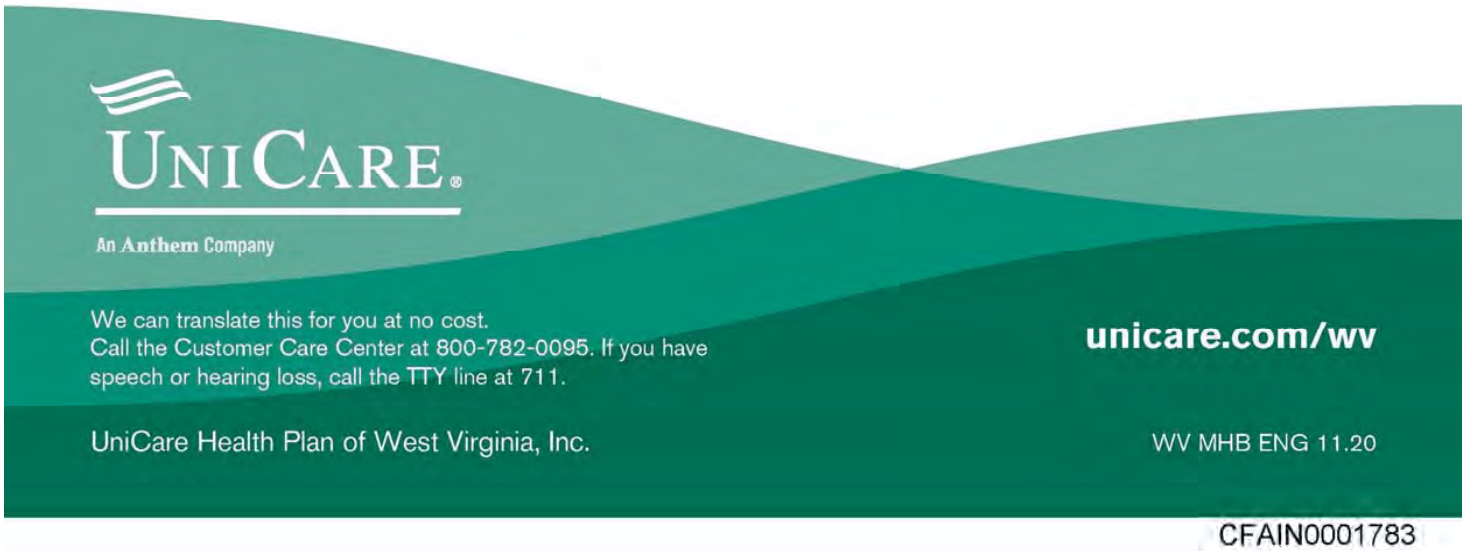
Medicaid non-covered services:

- All non-medically necessary services and those not listed as covered
- Autopsy and other services performed after death
- Care from a provider not in our plan when you didn't get the needed OK from us before you got the service
- Coma stimulation
- Cosmetic or reconstructive surgery when not required as a result of accidental injury or disease, or not performed to correct birth defects; services resulting from or related to these excluded services also are not covered
- Daily living skills training
- Dental services other than those listed as covered
- Duplicate testing, interpretation, or handling fees
- Education, training, and/or cognitive services, unless specifically listed as covered services
- Emergency evacuation from foreign country, even if medically necessary
- Expenses for which you are not responsible, such as patient discounts and contractual discounts
- Expenses incurred as a result of illegal action while incarcerated or while under the control of the court system
- Experimental, investigational, or unproven services
- Fertility drugs and services
- Foot care (routine, except for diabetic patients)
- Genetic testing for screening purposes — except those tests covered under the maternity benefit are not covered
- Sterilization of a mentally incompetent or institutionalized individual
- Except in an emergency, inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner, acting within the scope of practices, who is responsible for the diagnosis or treatment of a particular patient's condition
- Organ transplants, except in some instances
- Treatment for infertility and the reversal of sterilization
- Sex transformation procedures and hormone therapy for sex transformation procedures
- All cosmetic services, except in the case of accidents or birth defects
- Care given outside of the U.S.
- Medical equipment, prescriptions, services, and supplies that are:
  - Used only for your comfort or hygiene

  - Used for exercise
  - Personal or comfort items
  - Used for the same function as another service we have already paid for
  - Changes to your house or car, including ramps, stair glides, vehicle lifts for wheelchairs, vehicle safety devices (such as EZ Vests, transit systems, or car seats)
  - Equipment that needs replacement due to neglect or misuse
- Service animals
- Emergency room visits for routine care
- Payment for care you got for health problems that were work-related if they can be paid for by workers' compensation insurance, your employer, or by a disease law that has to do with your job
- Acupuncture
- Experimental or investigational services
- Christian science nurses and sanitariums
- Homeopathic medicine
- Hospital days associated with non-emergency weekend admissions or other unauthorized hospital days prior to scheduled surgery
- Hypnosis
- Incidental surgery performed during medically necessary surgery
- Orientation therapy
- Orthotripsy
- Screenings, except those specifically listed as covered benefits
- Sensory Stimulation (SS) therapy

WVCHIP non-covered services:
Some services are not covered by WVCHIP regardless of medical necessity. Specific exclusions are listed below.

- All non-medically necessary services and those not listed as covered
- Acupuncture
- All expenses incurred at a facility when a patient leaves against medical advice
- Ancillary services and/or services resulting from an office visit not covered by WVCHIP
- Aqua therapy
- Autopsy and other services performed after death
- Behavioral or functional type skills training except for applied behavior analysis (ABA) treatment
- Biofeedback
- Coma stimulation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InterQual®

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Penectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then go to question 2
   > • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   > • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   > • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

> • If 1 or more options A or B selected and option C not selected, then go to question 4
> • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

> • If option C selected, then go to question 5
> • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

> • If the number of options selected is 4 and option E not selected, then go to question 6
> • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

> • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here **(Outpatient)** [20]
> • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

4:
According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).
Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

Association for Transgender Health. 2011, 7: 1-112).

5:
Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

6:
These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

7:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:
Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:
The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:
Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:
The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:
Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:
Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0VTS0ZZ, 0VTS4ZZ, 0VTSXZZ, Other _____

CPT® (circle all that apply): 54125, 54130, 54135, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Phalloplasty for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then go to question 2
   > • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   > • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   > • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option A selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [20]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

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Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

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These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

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InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

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This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

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Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

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The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

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Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

CPT® (circle all that apply): 55899, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Orchiectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then go to question 2
   > • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   > • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   > • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option C selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here **(Outpatient)** [20]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

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It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0VT90ZZ, 0VT94ZZ, 0VTB0ZZ, 0VTB4ZZ, 0VTC0ZZ, 0VTC4ZZ, Other _____

CPT® (circle all that apply): 54520, 54690, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Ovariectomy/Salpingo-oophorectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then go to question 2
   > • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   > • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   > • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: (9)
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital (10, 11)
   - ☐ B) Female-to-male surgery, other (10, 11)
   - ☐ C) Male-to-female surgery, genital (12, 13)
   - ☐ D) Male-to-female surgery, other (12, 13)
   - ☐ E) Other clinical information (add comment)

   • If option A selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery (14, 15)
   - ☐ B) Persistent and well-documented gender dysphoria (14)
   - ☐ C) Capacity to make fully informed decisions and to consent (14)
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled (16, 17)
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated (18)
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity (19)
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here (20)
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

4:
According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).
Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

Association for Transgender Health. 2011, 7: 1-112).

5:
Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

6:
These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

7:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:
Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:
The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:
Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:
The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:
Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:
Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

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Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0UT00ZZ, 0UT04ZZ, 0UT08ZZ, 0UT0FZZ, 0UT10ZZ, 0UT14ZZ, 0UT18ZZ, 0UT1FZZ, 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT50ZZ, 0UT54ZZ, 0UT57ZZ, 0UT58ZZ, 0UT5FZZ, 0UT60ZZ, 0UT64ZZ, 0UT67ZZ, 0UT68ZZ, 0UT6FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, Other _____

CPT® (circle all that apply): 58661, 58700, 58720, 58953, 58956, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Vaginoplasty for Gender Affirmation Surgery

Age: Age ≥ 18

Exhibit
Ex 0018

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then go to question 2
   > • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   > • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   > • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option C selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [20]
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Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

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Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

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Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

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Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

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These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

7:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:
Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:
The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:
Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:
The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:
Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:
Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

CPT® (circle all that apply): 57335, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Hysterectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then go to question 2
   > • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   > • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   > • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
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   • If option A selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
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6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

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Reference

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Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

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The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:
Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:
The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:
Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:
Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

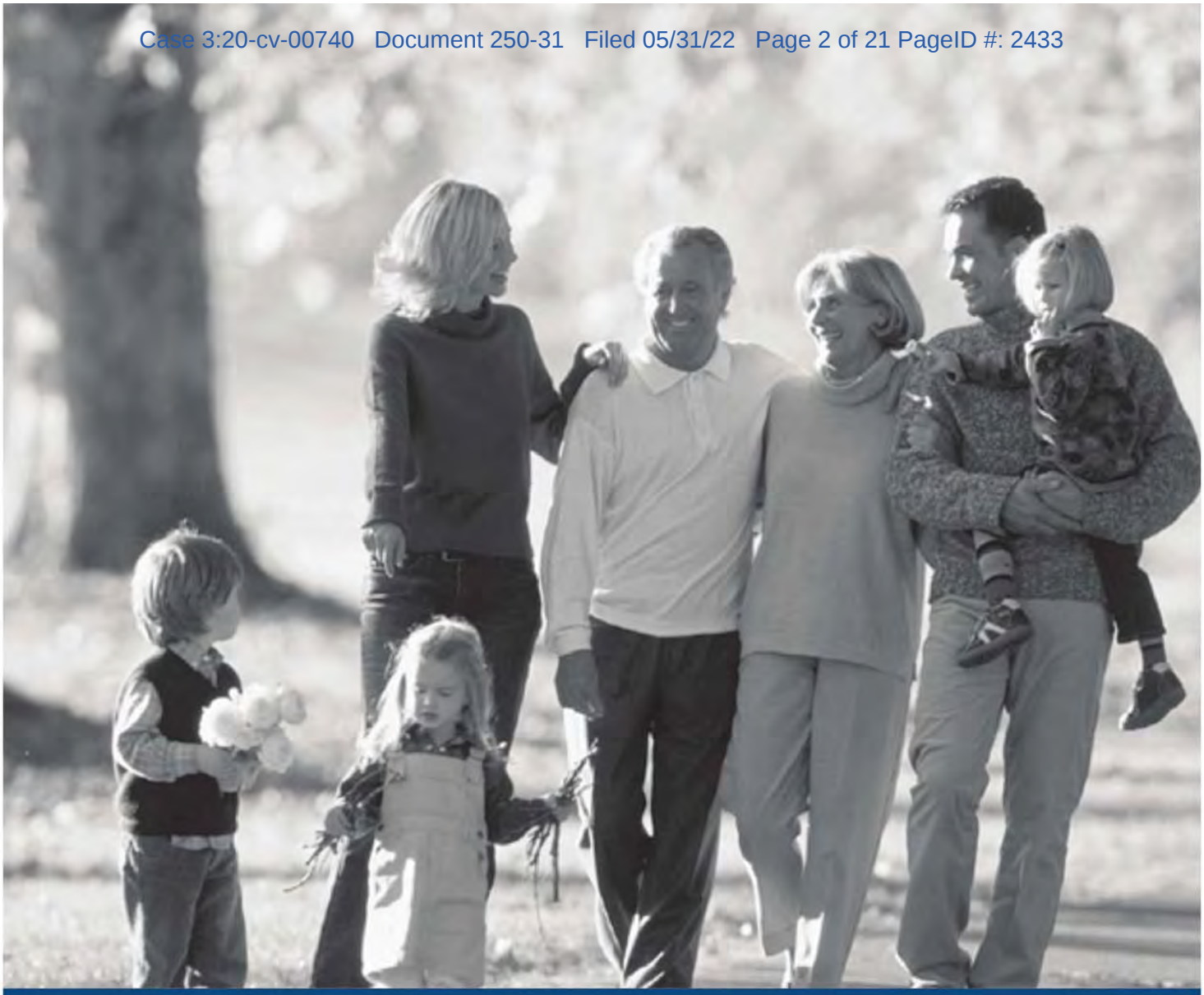
19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58180, 58260, 58262, 58275, 58290, 58291, 58541, 58542, 58543, 58544, 58552, 58553, 58554, 58570, 58571, 58572, 58573, Other _____



MEDICAID 101

An Overview of West Virginia's Medicaid Program

WEST VIRGINIA Department of Health & Human Resources
BUREAU FOR MEDICAL SERVICES

Exhibit 03

Medicaid: The Basics

Medicaid is a public benefit program that provides health insurance and medical services to eligible individuals. Medicaid is financed by state and federal governments and is administered by states. In West Virginia, the Bureau for Medical Services (BMS) within the West Virginia Department of Health and Human Resources (DHHR) is the single state agency responsible for administering the West Virginia Medicaid program.

Across the country, Medicaid is the nation's single largest health insurer, covering more than 73 million individuals in May 2018, or about 22% of the US population.[1] Medicaid contributes substantially to the financing of the US health care system, supporting local public health infrastructure, hospitals, mental health centers, at-home-care, community clinics, nursing homes, physicians, and many other health professionals and administrators.

The Medicaid program is critical to the health and well-being of hundreds of thousands of West Virginians. This manual is intended to provide you with a brief overview of the West Virginia Medicaid program, including how the Medicaid program is financed, Medicaid care delivery models, covered services, and trends in Medicaid enrollment and spending. The information in this manual should not be considered Medicaid policy. Rather, this manual is intended to serve as an accessible resource to answer frequently asked questions related to the Medicaid program. Every effort was taken to document data sources used in the creation of this book. If you have additional questions related to Medicaid program, or any of the information in this manual, please see the contact information in the Appendix.

MEDICAID VS. MEDICARE

Medicaid: A public assistance program that serves low-income people of all ages. Medicaid is jointly funded by states and the federal government but is administered by states. Patients with Medicaid usually do not have out-of-pocket costs related to covered medical expenses.

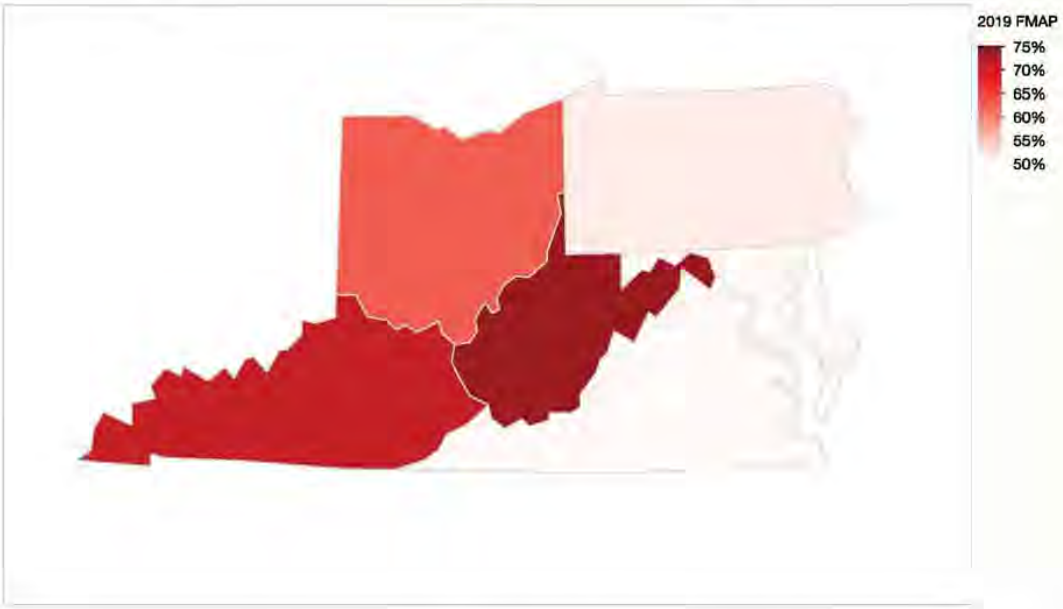
Medicare: An insurance program funded and administered by the federal government. Medicare provides health insurance for hospital and medical care to seniors age 65 and older and some individuals under age 65 with disabilities. Medicare beneficiaries typically have some out-of-pocket costs.

Who pays for Medicaid?

A state-federal partnership

Medicaid is jointly funded by state and federal governments. The majority of Medicaid funding is provided by the federal government. The federal government shares financial responsibility for the Medicaid program by matching state spending with federal dollars. The federal share of those costs is determined by the Federal Medical Assistance Percentages (FMAP). The FMAP is calculated annually using a formula set forth in federal statute and is inversely proportional to a states per capita income relative to the US average. States with lower per capita incomes have higher FMAPs. As seen in Figure 1, West Virginia has the highest FMAP in the region.

Figure 1: Fiscal year 2019 FMAP in West Virginia and surrounding states



In fiscal year 2019, West Virginia's FMAP is 74.3%.[2] This means that the federal government pays for 74.3% of the costs for eligible Medicaid services, while BMS is only responsible for 25.7% of the costs. In practice, if a Medicaid member has a hospital stay that results in $1,000 in costs, the federal government will pay $743, while BMS will pay only $257. In this sense, the FMAP acts as a multiplier for state spending. For example, in West Virginia, every $100 in state spending on Medicaid services will bring in $290 in matching federal funds. States may also receive an enhanced FMAP for covering certain services or populations. Perhaps most notably, states currently receive a 94% FMAP for the Medicaid expansion population.[3] These matching funds directly benefit patients receiving medical care while also helping to finance the healthcare infrastructure in areas with large Medicaid populations.

State Medicaid programs are often seen as low-hanging fruit when financially strapped states are forced to make budget cuts. However, thanks to the FMAP, Medicaid spending acts as a tremendous financial boon for the state. The Kaiser Commission on Medicaid and the Uninsured recently compiled findings from 29 different studies examining the economic impact of Medicaid spending and found that in all studies examined Medicaid spending had a positive impact on local economies.[3] These studies also found that Medicaid spending generates economic activity within the state by providing jobs, personal income, and state tax revenues. While most state government expenditures reallocate spending from one sector to another, Medicaid is one of the few state government spending opportunities that is guaranteed to pull in money from outside the state and directly benefit the local economy.

Medicaid care delivery systems

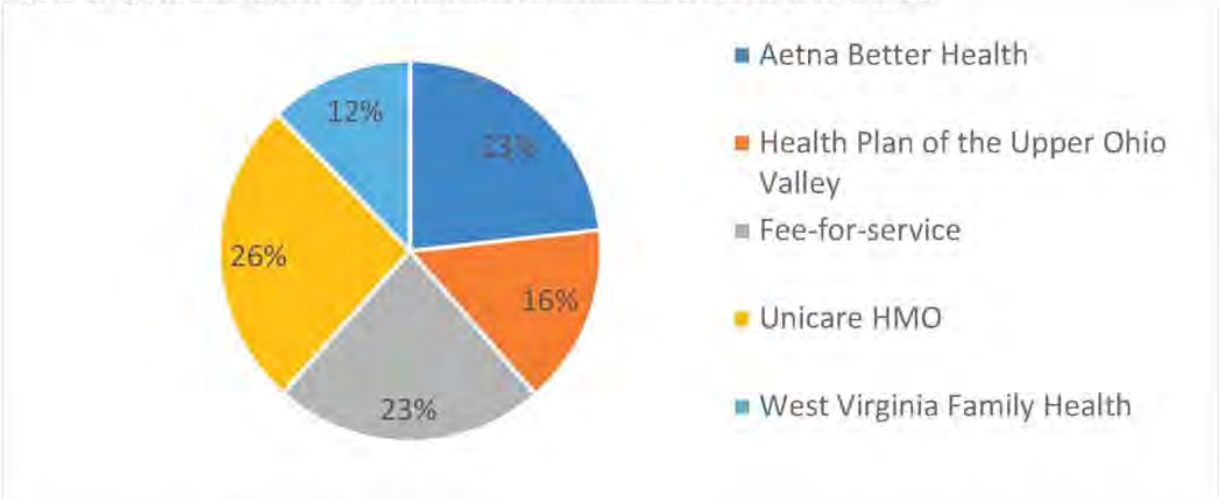
States are generally given leeway to set standards and policies for how they deliver medical and pharmacy services to Medicaid enrollees. States are also able to choose how services are purchased and payments distributed to Medicaid providers. The two most common care delivery systems are fee-for-service and managed care.

Fee-for-service: States directly pay providers a flat fee for each service delivered.

Managed care: States contract with health plans or managed care organizations (MCOs) and pay these groups a monthly per member capitation payment to provide all covered Medicaid services.

More than 75% of West Virginia Medicaid beneficiaries receive their benefits via the managed care delivery system through the Mountain Health Trust program. The Mountain Health Trust program contracts with four Managed Care Organizations (MCOs) for the provision of medical benefits. The four MCOs contracted through the program include Aetna Better Health of West Virginia (formerly Coventry Health Care of West Virginia), Health Plan of the Upper Ohio Valley, Unicare, and West Virginia Family Health. Individuals who are not covered by an MCO receive all benefits via the fee-for-service delivery system and are typically eligible for Medicaid through a waiver program such as the Intellectual/Developmental Disabilities Waiver or the Traumatic Brain Injury Waiver. Importantly, some Medicaid benefits, including pharmacy benefits, long-term care services, and non-emergency medical transportation are still paid via the fee-for-service delivery system for all Medicaid beneficiaries.

Figure 2: Approximate percent of Medicaid beneficiaries enrolled in each MCO



Covered benefits and services

The federal government requires every state Medicaid program to cover a specific set of benefits and services. The services that programs are required to cover have changed greatly since the Medicaid program's inception in 1965, given advancements in medical technologies and changes in the makeup of the Medicaid population. In addition to the required covered services, states are allowed some flexibility in terms of offering additional benefits so long as services are equitable in terms of availability and scope for all Medicaid beneficiaries.

Medicaid programs are required to cover the following services:

- Inpatient and outpatient hospital services
- Physician services
- Nursing facility services
- Early periodic screening, diagnostic and treatment services for children, including dental services
- Laboratory and x-ray services
- Home health services including nursing services, home health aides, and medical supplies and equipment
- Rural health clinic services
- Federally qualified health center services
- Transportation to medical care
- Certified pediatric and family nurse practitioner services
- Emergency medical services for certain noncitizens, also known as emergency medical assistance
- Family planning services, including nurse midwife services
- Tobacco cessation counseling for pregnant women

West Virginia's Medicaid program also covers the following optional services:

- Alcohol and drug treatment
- Chiropractic services
- Emergency dental care for adults
- Orthodontics for children
- Emergency hospital services
- Post-cataract eyeglasses for adults
- Hearing aids for children
- Home care including personal care assistant services
- Hospice care
- Medical equipment and supplies
- Prescriptions and medication therapy management
- Both physical and mental rehabilitative services
- Inpatient and outpatient substance use disorder treatment
- Case management
- Care coordination
- Autism spectrum disorder services

Who is eligible for Medicaid in West Virginia?

West Virginia Medicaid provides health insurance to a diverse population of individuals. All individuals who meet federally established income eligibility requirements are guaranteed Medicaid coverage. However, states are also allowed some flexibility in terms of eligibility requirements and can extend coverage to certain optional populations. The vast majority of Medicaid beneficiaries in West Virginia fall into one of the following categories:

Pregnant women and children

It is extremely important that women receive adequate medical care while they are pregnant. Fortunately, Medicaid provides prenatal care to many pregnant women without other forms of insurance. More than half of all births in West Virginia are paid for by Medicaid. Medicaid is also the primary health insurance program for low-income children from birth to age 18. Nearly half of all West Virginia children receive health care and important developmental services through Medicaid. Ensuring the health and developmental success of pregnant women and children is a sound investment in West Virginia's future.

Aged and disabled population

Medicaid is the primary insurer for many individuals with mental or physical disabilities. Individuals who are aged, blind, or disabled, and who have limited assets to support themselves may be eligible for supplemental security income (SSI) from the federal government. In West Virginia, all individuals who receive SSI automatically become eligible for Medicaid. Once enrolled, these individuals may receive health care, therapy, and long-term care services with few or no out-of-pocket costs. Medicaid also supports seniors in West Virginia by paying for some low-income Medicare beneficiaries' co-pays, deductibles, and premiums as well as certain medical services. For example, Medicaid pays for the majority of all nursing home care for West Virginia seniors.

Expansion adults

Historically, adults aged 19-64 without dependent children were not eligible for Medicaid coverage. However, with the passage of the Patient Protection and Affordable Care Act, states were given the option of expanding Medicaid eligibility to adults with incomes up to 133% of the federal poverty level. West Virginia is one of 36 states to expand Medicaid eligibility to this population. Importantly, the federal government pays an enhanced FMAP for Medicaid services provided to this population.

MEDICAID VS. CHIP

While Medicaid insures many children in West Virginia, some children receive benefits through the Children's Health Insurance Program (CHIP). Medicaid is intended to provide health benefits to the poorest children in the state. CHIP expands health insurance coverage to children in families who have incomes above the Medicaid eligibility threshold who do not have commercial insurance. Services provided through CHIP are generally comparable to those offered under the Medicaid program, however states have more flexibility in determining the breadth of coverage for CHIP services.

How is Medicaid eligibility determined?

Medicaid eligibility is dependent on a host of factors including household income, family size, age, disability, and citizenship status. The specifications for these criteria vary by eligibility category. For example, pregnant women may make up to 158% of the federal poverty level (FPL) and qualify for Medicaid eligibility, while adults in the expansion population may only

make up to 133% of the FPL. West Virginia Medicaid's income eligibility thresholds, as a percentage of the FPL, for various groups are displayed in Figure 3. Figure 4 displays the 2018 FPL designations for different family sizes; families that make less than this amount are deemed in poverty. Regardless of eligibility group, individuals must pass an annual asset test to become eligible for Medicaid benefits. Assets include items such as a car above a certain value, personal savings, and life insurance policies. Notably, a family home is not considered an asset for Medicaid eligibility.

Figure 3: Eligibility thresholds as a percent of the FPL for various Medicaid groups[5]

Population	**Eligibility threshold as a percent of FPL**
Children	
Ages 0 – 1	158%
Ages 1 – 5	141%
Ages 6 – 18	133%
CHIP	300%
Adults	
Aged and Disabled*	Up to 300% of SSI Limit
Expansion population	133%
Pregnant Women	158%

*Eligibility for the aged and disabled population is based on social security income (SSI) limits. Certain individuals can make up to 300% of the SSI limit and qualify for Medicaid benefits

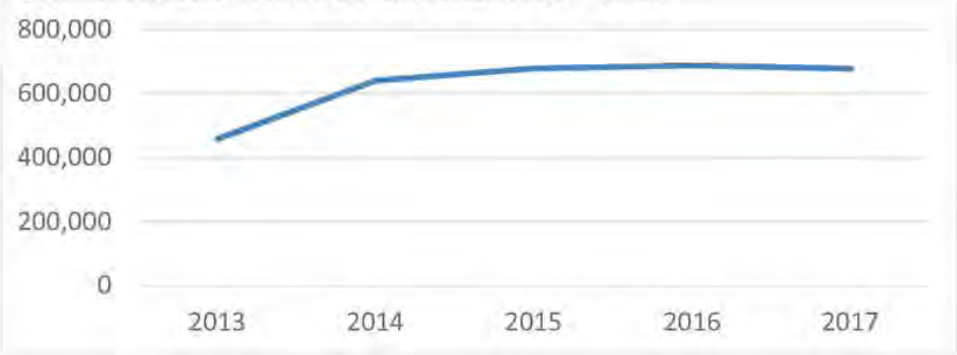
Figure 4: 2018 FPL by family size[6]

Family Size	**FPL Threshold**
Individuals	$12,140
2	$16,460
3	$20,780
4	$25,100
5	$29,420
6	$33,740
7	$38,060
8+	$42,380

Medicaid enrollment by the numbers

Figure 5 displays the number of individuals enrolled with West Virginia Medicaid at any point in a calendar year from 2013 – 2017. Please note that the number of individuals enrolled with Medicaid on any given day will be significantly less than the number enrolled at any point in the calendar year. For example, there are about 530,000 individuals enrolled in Medicaid on any particular day of the month, while there are generally more than 650,000 individuals enrolled at some point over the course of an entire year.

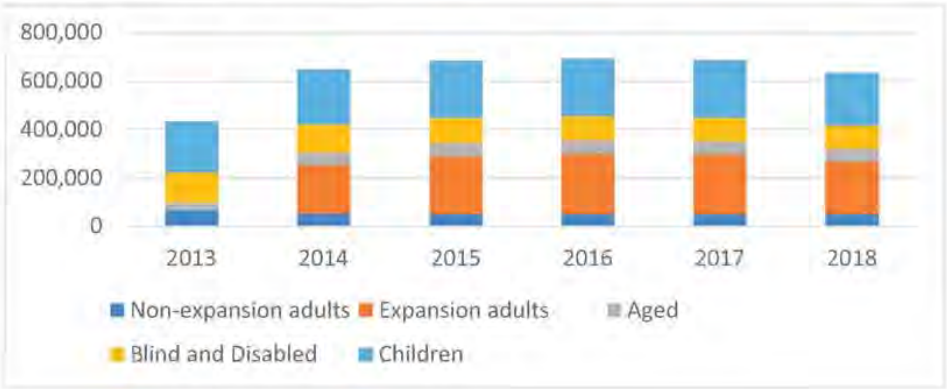
Figure 5: Total annual Medicaid enrollment 2013 – 2017



In 2017, more than 675,000 West Virginians were enrolled in Medicaid at some point during the year. This represents approximately one third of the state's total population in 2017. West Virginia chose to expand Medicaid eligibility under the Affordable Care Act in 2014. From 2013 to 2014, Medicaid enrollment increased by more than 50%, and has remained relatively stable since then.

Figure 6 displays trends in Medicaid enrollment from 2013 – 2017 by Medicaid eligibility category. Changes in Medicaid enrollment from 2013 – 2017 have been driven almost entirely by the adult expansion population. The number of blind and disabled individuals enrolled in Medicaid has decreased slightly over this time period.

Figure 6: Annual Medicaid enrollment by eligibility group 2013 – 2017



Given the dramatic increases in Medicaid enrollment over the last five years, West Virginia now has one of the lowest uninsured rates in the country. Figure 7 displays trends in the percentage of West Virginians with Medicaid coverage relative to the percent of uninsured West Virginians. While more than one-third of the state's population was enrolled with Medicaid at some point in 2017, only about 6% of the state's population was uninsured for the majority of the year.

Figure 7: Percent of West Virginians with Medicaid relative to percent uninsured 2013 – 2017[7,8]

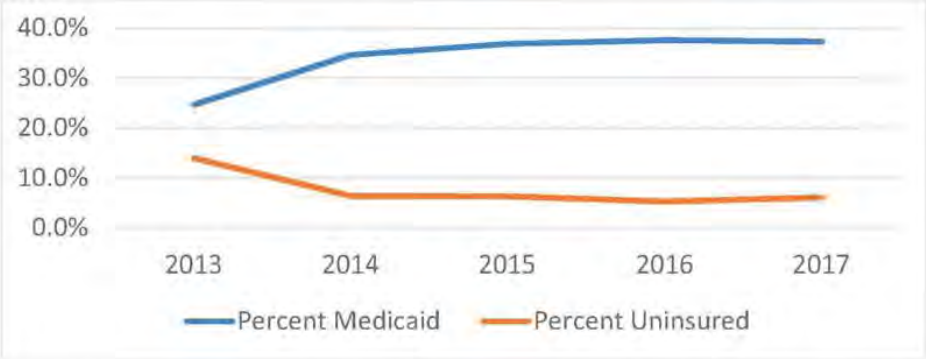
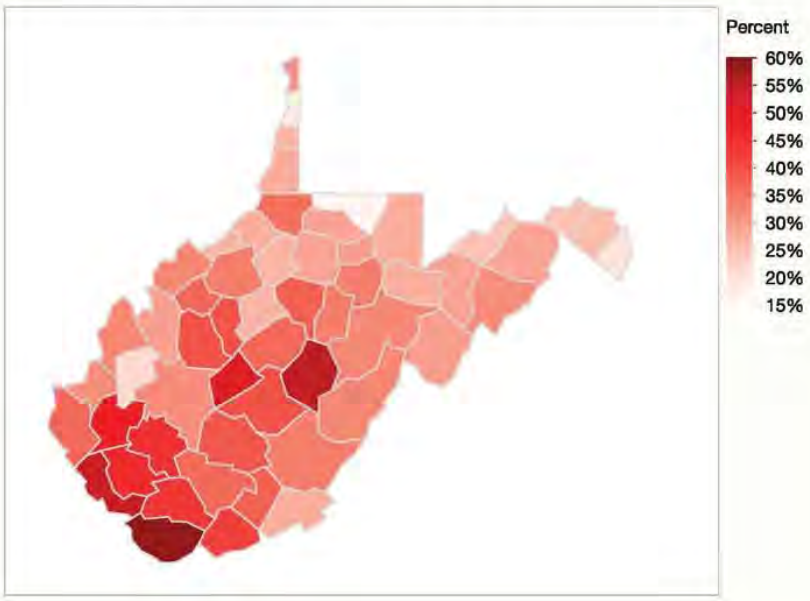


Figure 8 displays the percent of individuals enrolled in Medicaid in each county in West Virginia during calendar year 2017. Generally speaking, counties in the southern region of the state had higher rates of Medicaid coverage relative to counties in the Northern region or Eastern Panhandle.

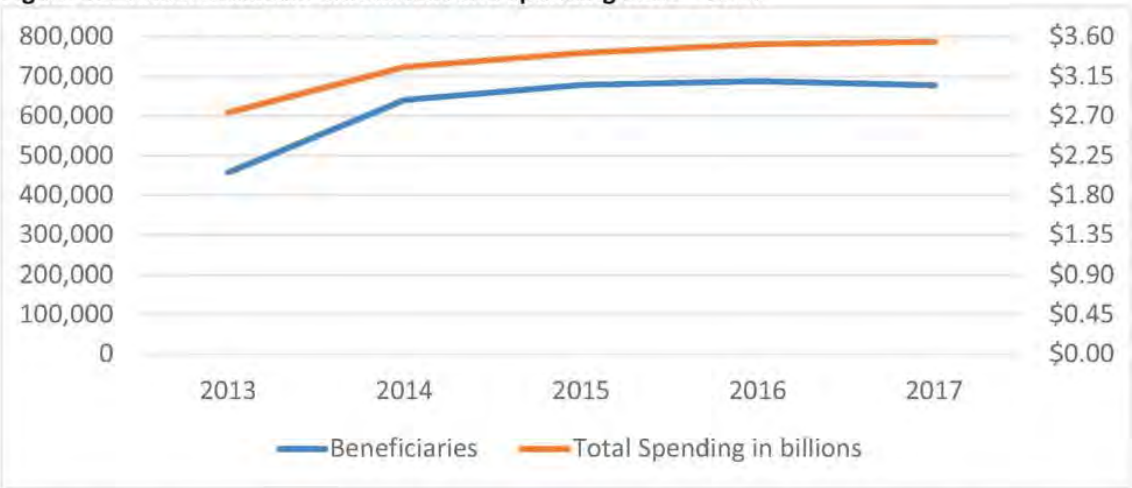
Figure 8: Percent of individuals with Medicaid in each county in calendar year 2017



Medicaid spending by the numbers

Annual Medicaid enrollment increased substantially following implementation of Medicaid expansion under the Affordable Care Act. Understandably, Medicaid spending also increased over this time period, however it was outpaced by increases in Medicaid enrollment. Figure 9 displays trends in annual Medicaid enrollment and spending from 2013 – 2017.

Figure 9: Annual Medicaid enrollment and spending 2013 – 2017



Medicaid enrollment increased by more than 50% from 2013 to 2014, but total Medicaid spending increased by less than 20% over the same time period. While the adult expansion population has largely driven increases in Medicaid enrollment, this population accounts for a relatively small proportion of total Medicaid spending. Figure 10A displays the percent of Medicaid beneficiaries by eligibility category in calendar year 2017, while Figure 10B displays the percent of spending attributable to each eligibility category in the same year.

Figure 10A: Percent of Medicaid beneficiaries by eligibility group in calendar year 2017

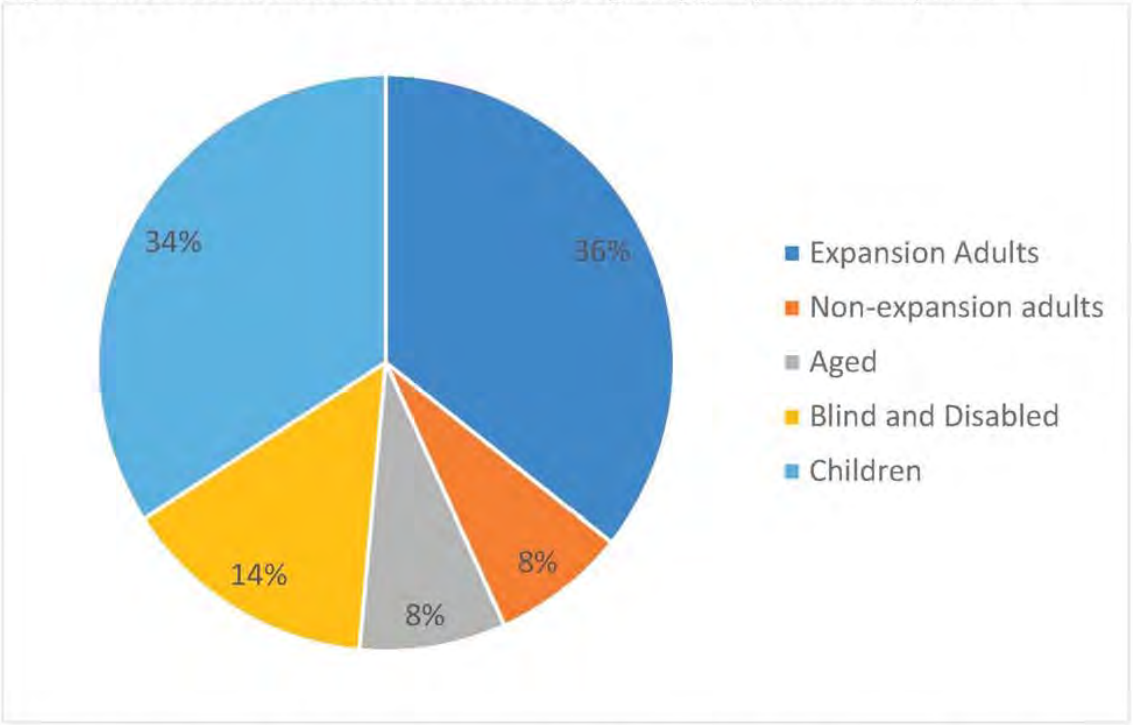
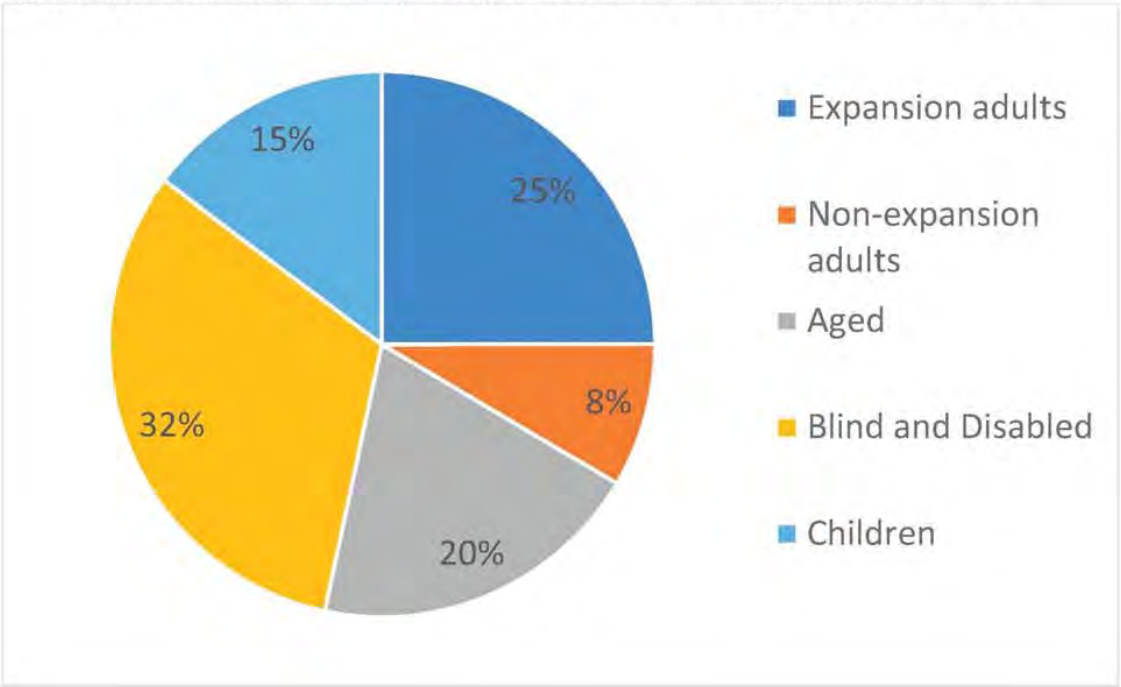


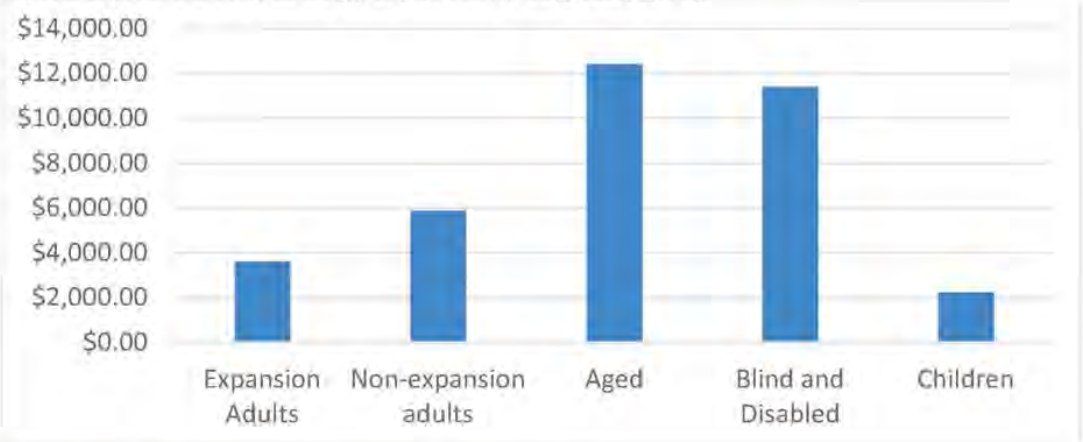
Figure 10B: Percent of Medicaid spending attributable to each eligibility group in 2017



In 2017, more than one-third of Medicaid beneficiaries were part of the adult expansion population, however, these individuals accounted for only about 25% of total Medicaid spending during the calendar year. On the other hand, the aged population and the blind and disabled populations together comprised only about 22% of the Medicaid population in 2017, however they accounted for more than 50% of all Medicaid spending. The aged population and the blind and disabled Medicaid populations tend to have special healthcare needs and require more frequent Medicaid services than other groups. It is understandable that the expansion population accounts for a smaller proportion of Medicaid spending relative to populations with greater healthcare needs.

Figure 11 displays average Medicaid spending per person by eligibility group. Individuals in the aged population and the blind and disabled Medicaid populations account for a much greater share of Medicaid spending than individuals in other eligibility groups. Beneficiaries in the aged population and blind and disabled population accounted for two to four times greater average spending per person relative to beneficiaries in any of the other eligibility groups.

Figure 11: Medicaid spending per person by eligibility group



Medicaid innovations and successes

Innovative approaches to treating Substance Use Disorder

West Virginia has been at the epicenter of the nation's drug crisis. In 2017, West Virginia had the highest drug overdose death rate in the country, with a rate that was greater than double the national average.[9] This crisis has dramatically impacted our Medicaid program, which insures many individuals suffering from Substance Use Disorder (SUD). In the last year, BMS has implemented several innovative policies to improve the quality and availability of SUD treatment for Medicaid beneficiaries. Ultimately, these policies will bolster the SUD care delivery network in the state and improve the health and well-being of West Virginians.

BMS was recently awarded a Medicaid 1115 waiver by the Centers for Medicare and Medicaid Services (CMS) to enhance the continuum of care for beneficiaries with SUD. This waiver is

intended to improve the availability, quality, and coverage of SUD treatment services for Medicaid beneficiaries. The waiver allows Medicaid beneficiaries with SUD to receive the full continuum of care for SUD treatment as defined by the American Society of Addiction Medicine. Medicaid enrollees with SUD are now eligible to receive additional behavioral therapies including peer recovery support and withdrawal management services, as well as short-term residential treatment. The 1115 waiver also expands access to medication assisted treatment (MAT) including methadone treatment services from opioid treatment programs. Additionally, emergency medical service providers can now be reimbursed for administration of naloxone to Medicaid beneficiaries suffering an overdose. Importantly, the new services provided under the 1115 waiver are consistent with the industry standard best practices set forth by the American Society of Addiction Medicine.

In addition to the 1115 waiver, BMS is also taking an innovative approach to treating babies born with neonatal abstinence syndrome (NAS). NAS is a disorder caused by prenatal exposure to opioids or other drugs. Babies with NAS experience a host of symptoms including tremors, vomiting, seizures, excessive crying and sensitivity to stimuli, and these infants require around-the-clock care during the first few weeks of life. BMS is the first Medicaid program in the country to have an approved state plan amendment (SPA) specifically to bolster NAS treatment services. The SPA allows health facilities to be recognized as NAS Treatment Centers, and allows them to receive Medicaid reimbursement for providing NAS treatment. Services that can now be reimbursed under the SPA include comprehensive assessment and care plan development; housing in a low or reduced stimuli environment; pharmaceutical withdrawal management; therapeutic swaddling; rocking; newborn massage; and other services.

Home and Community-Based Services for person-centered care

The Medicaid Home and Community-Based Services (HCBS) waiver program allows state Medicaid agencies to provide services to members in their homes or communities to avoid institutionalization. HCBS programs work to create sustainable, person-centered, long-term support systems for people with disabilities, chronic conditions, and the elderly. The goal of HCBS waiver programs is to improve members' independence, health, and quality of life. Within broad federal guidelines, states can develop HCBS programs tailored to the needs of Medicaid beneficiaries who prefer to receive treatment in their home or communities rather than an institutional setting. West Virginia has three HCBS waiver programs:

1. Aged and Disabled Waiver—This program is a long-term care alternative that provides services that enable an individual to remain at or return home rather than receiving nursing home care. The goals and objectives of this program are focused on providing services that are person-centered, promote choice, independence, respect, and community integration.

2. Intellectual/Developmental Disabilities (I/DD) Waiver—This program provides services that instruct, train, support, supervise, and assist individuals who have intellectual and/or developmental disabilities in achieving the highest level of independence and self-sufficiency possible. The I/DD waiver program provides services in natural settings where the member resides rather than in intermediate care facilities.
3. Traumatic Brain Injury (TBI) Waiver—This program provides services to individuals with a documented traumatic brain injury, defined as a non-degenerative, non-congenital injury to the brain resulting in the need for a nursing facility level of care. The purpose of the program is to prevent unnecessary institutionalization by providing services and supports that are person-centered and promote independence and community integration.

Health Homes for at risk populations

The Affordable Care Act gave state Medicaid programs the option of creating the Health Homes program to provide a comprehensive system of care coordination for Medicaid beneficiaries with multiple chronic conditions. The Health Homes program does not act as a place where patients live, but as a system for holistically providing medical, behavioral, and social support services for individuals with complex healthcare needs. Individuals enrolled in Health Homes are assigned a multidisciplinary team of healthcare providers who collaboratively provide services and supports in a coordinated manner. Health Homes services include comprehensive care management, care coordination, health promotion, and community and social support services. Each patient enrolled in the program is also assigned a personal care manager who is required to contact the patient at least bi-weekly to ensure the patient's needs are being addressed. West Virginia currently has two Health Homes. The first Health Home began in July 2014 for members with bipolar disorder who have, or are at risk of having, hepatitis B or C. The second Health Home

began in April 2017 and is designed for Medicaid beneficiaries with pre-diabetes, diabetes or obesity, who are at risk of also having anxiety or depression.

Reducing pharmacy spending and investing in the state

On July 1, 2017, BMS carved out pharmacy services from the managed care program and began delivering these services as part of the fee-for-service delivery model. With this model, pharmacy benefits are managed by the State Pharmacy Services program, which serves as its own Pharmacy Benefits Manager (PBM). This model unbundles incurred costs and creates a more transparent method of payment for pharmacy services. Claims processing is handled by DXC, the fee-for-service medical/dental claims processor, and processing fees are transparent. Supplemental rebates on preferred drugs are negotiated through a multi-state consortium of Medicaid programs. The collection of federal and supplemental rebates is overseen in-house and the entire amount collected is retained by the Medicaid program. So far, this initiative has paid dividends, with significant cost-savings in the first year alone. In addition to savings on administrative costs and increased rebates, BMS increased the dispensing fee to $10.49 per prescription, providing a significant re-investment back into the pharmacy business community.

Looking to the future

BMS is committed to providing innovative, high quality, and accessible healthcare to the citizens of West Virginia. As part of this commitment, BMS recently completed a strategic planning initiative to more formally establish the Bureau's mission, core values, and major strategic initiatives. This plan will be used to guide the overall direction that BMS will take over the next five years. Development of this strategic plan is only the first step in continuing efforts to improve transparency and better serve the citizens of West Virginia. A copy of the BMS strategic plan can be found on the website: dhhr.wv.gov/bms.

Notes

Notes

Appendix

For additional information about the West Virginia Medicaid program, please contact BMS at: 304-558-1700

For additional information pertaining to preparation of this manual, please contact Nathan Pauly at Nathan.J.Pauly@wv.gov.

References

1- https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html
2- https://www.kff.org/medicaid/state-indicator/federal-matching-rate-and-multiplier/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
3- https://www.kff.org/medicaid/issue-brief/understanding-how-states-access-the-aca-enhanced-medicaid-match-rates/
4- https://kaiserfamilyfoundation.files.wordpress.com/2013/01/7075_02_es.pdf
5- https://www.medicaid.gov/state-overviews/stateprofile.html?state=West-Virginia
6- https://www.healthcare.gov/glossary/federal-poverty-level-fpl/
7- https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-264.pdf
8- https://www.kff.org/other/state-indicator/total-population/?activeTab=graph&currentTimeframe=0&startTimeframe=3&selectedDistributions=uninsured&selectedRows=%7B%22states%22:%7B%22west-virginia%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
9- https://www.cdc.gov/nchs/products/databriefs/db329.htm

Mandatory & Optional Medicaid Benefits

This page outlines mandatory Medicaid benefits, which states are required to provide under federal law, and optional benefits that states may cover if they choose.

Mandatory Benefits

- Inpatient hospital services
- Outpatient hospital services
- EPSDT: Early and Periodic Screening, Diagnostic, and Treatment Services
- Nursing Facility Services
- Home health services
- Physician services
- Rural health clinic services
- Federally qualified health center services
- Laboratory and X-ray services
- Family planning services
- Nurse Midwife services
- Certified Pediatric and Family Nurse Practitioner services
- Freestanding Birth Center services (when licensed or otherwise recognized by the state)
- Transportation to medical care
- Tobacco cessation counseling for pregnant women

Optional Benefits

- Prescription Drugs
- Clinic services
- Physical therapy

DHHRBMS016220

- Occupational therapy
- Speech, hearing and language disorder services
- Respiratory care services
- Other diagnostic, screening, preventive and rehabilitative services
- Podiatry services
- Optometry services
- Dental Services
- Dentures
- Prosthetics
- Eyeglasses
- Chiropractic services
- Other practitioner services
- Private duty nursing services
- Personal Care
- Hospice
- Case management
- Services for Individuals Age 65 or Older in an Institution for Mental Disease (IMD)
- Services in an intermediate care facility for Individuals with Intellectual Disability
- State Plan Home and Community Based Services- 1915(i)
- Self-Directed Personal Assistance Services- 1915(j)
- Community First Choice Option- 1915(k)
- TB Related Services
- Inpatient psychiatric services for individuals under age 21
- Other services approved by the Secretary*
- Health Homes for Enrollees with Chronic Conditions – Section 1945

*This includes services furnished in a religious nonmedical health care institution, emergency hospital services by a non-Medicare certified hospital, and critical access hospital (CAH).

Mandatory & Optional Medicaid Benefits

Twitter YouTube

A federal government managed website by the
Centers for Medicare & Medicaid Services.
7500 Security Boulevard Baltimore, MD 21244

DHHRBMS016222

Centers for Medicare & Medicaid Services

Robert Price
Agree

Todd R. White
Chief Executive Officer

Aetna Better Health® of West Virginia
500 Virginia Street East, Suite 400
Charleston, WV 25301

304-348-2041 T
958-282-1026 F

Exhibit 04

May 6, 2021

Susan Hall, Chief, Center of Managed Care
WV Department of Health and Human Resources
Bureau for Medical Services
350 Capitol Street, Room 251
Charleston, WV 25301
E-mail: susan.l.hall@wv.gov

RE: Mid-Year Contract Change Acknowledgement for the SFY2021 Purchase of Service Provider Agreement for Mountain Health Trust -- Contract No. CMA BMS20*09

Dear Ms. Hall:

This letter serves as the written acceptance by Coventry Health Care of West Virginia, Inc. d/b/a Aetna Better Health of West Virginia of the SFY21 mid-year terms and rates changes set forth in the updated *State Fiscal Year 2021 Model Purchase of Service Provider Agreement for Mountain Health Trust Between State of West Virginia Department of Health and Human Resources Bureau for Medical Services and Coventry Health Care of West Virginia, Inc. d/b/a Aetna Better Health of West Virginia*, effective 1/1/21.

Sincerely,

Todd R. White
Chief Executive Officer

TRW/ago

EXHIBIT 33

STATE FISCAL YEAR 2021

MODEL PURCHASE OF SERVICE PROVIDER AGREEMENT

BETWEEN

STATE OF WEST VIRGINIA

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

BUREAU FOR MEDICAL SERVICES

AND

Aetna Better Health of WV

The MCO must comply with all established criteria required by WV Medicaid before approving the initial coverage of any physician-administered agent which is currently available in a point of sale form. If exceptions to the criteria are considered appropriate or necessary, the MCO must obtain written consent for such variance from BMS Office of Pharmacy Services.

The MCO shall be subject to following provisions of Section 1004 of the SUPPORT for Patient and Communities Act:

- **Claim Reviews:**
  - Retrospective reviews on opioid prescriptions exceeding state defined limitations on an ongoing basis.
  - Retrospective reviews on concurrent utilization of opioids and benzodiazepines as well as opioids and antipsychotics on an ongoing periodic basis.
- **Programs to monitor antipsychotic medications to children**: Antipsychotic agents are reviewed for appropriateness for all children including foster children based on approved indications and clinical guidelines.
- **Fraud and abuse identification:** The DUR program has established a process that identifies potential fraud or abuse of controlled substances by enrolled individuals, health care providers and pharmacies.

1.3.3 Organ and Tissue Transplantations

MCO enrollees receiving services for transplantation of organs or tissues, other than corneal transplants, are covered under FFS Medicaid for the entire duration of their treatment.

The MCO must have the ability to notify the State of any past, present, or future transplant recipient and request transfer to FFS Medicaid. BMS will coordinate with Utilization Management vendor and Medicaid Management Information Systems (MMIS) vendor to transition enrollees to the FFS system and coordinate care at that time. The enrollee will be covered under FFS retroactively to the beginning of the month that the MCO notifies the State. Capitation will be recouped for this month. Any claims paid during the month by the MCO may be reversed and directed to the fiscal agent for payment.

1.4 Non-covered Services

MCOs are not permitted to provide Medicaid excluded services that include, but are not limited to, the following:

1. All non-medically necessary services;
2. Sterilization of a mentally incompetent or institutionalized individual;
3. Except in an emergency, inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner, acting within the scope of practices, who is responsible for the diagnosis or treatment of a particular patient's condition;
4. All organ transplants, except for those specified in Appendix A;

5. Treatments for infertility[5] and for the reversal of sterilization;
6. Sex transformation procedures and hormone therapy associated with sex transformation procedures
7. All cosmetic services, except for those provided as a result of accidents or birth defects; and
8. Christian Science nurses and sanitariums.

The MCO must not reimburse for drugs, drug products, and related services, which are defined as a non-covered benefit by BMS' Outpatient Drug Pharmacy Program.

In accordance with 42 U.S.C. § 1396r-8, the MCO must exclude coverage for any drug marketed by a drug company (or labeler) that does not participate in the federal drug rebate program. The MCO is not permitted to provide coverage for any drug product, brand name or generic, legend or non-legend, sold or distributed by a company that did not sign an agreement with the federal government to provide Medicaid rebates for that product.

The MCO must not provide coverage under any circumstances for drug products that have been classified as less-than-effective by the Food and Drug Administration (FDA) Drug Efficacy Study Implementation (DESI).

MCOs cannot enhance the benefits provided to Medicaid enrollees, with the exception of clinical preventive services, without the prior approval of BMS.

1.5 Other Requirements Pertaining to Covered Services

MCOs must assume responsibility for all covered medical conditions, inclusive of pre-existing conditions of each enrollee as of the effective date of enrollment in the plan. MCOs may not prohibit or otherwise restrict a covered health professional from advising his/her patient about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for that care or treatment are provided under the Contract, if the professional is acting within the lawful scope of practice.[6]

MCOs and their participating providers may not bill or collect any payment from Medicaid enrollees for care that was determined not to be Medically Necessary. Anyone who knowingly and willfully charges for any service provided to a patient under a State Plan approved under Title XIX or under a MCO Contract under 1903(m) of the Social Security Act, money or other consideration at a rate in excess of the rates established by BMS or Contract will be guilty of a

[5] Infertility services are excluded per West Virginia State law, section 33-25A-4(2)(b).

[6] The term "health care professional" means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the Managed Care Plan's Contract for the services. A health care professional includes the following: podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse, registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

UniCare Health Plan of West Virginia, Inc.
200 Association Drive, Suite 200
Charleston, WV 25311
Tel 888 611-9958
Fax 888 338-1320

Agree
Robert Price

UNICARE®

An Anthem Company

May 6, 2021

Exhibit
05

Susan Hall, Chief of Managed Care
WV Bureau for Medical Services
350 Capitol Street, Room 251
Charleston, WV 25301

RE: SFY21 Mid-Year Rate Amendment Acceptance

Dear Ms. Hall:

UniCare has reviewed the SFY21 mid-year Manage Care Contract and Rates amendment under procurement BMS20*08. UniCare accepts the proposed contract and rates amendment. We look forward to our continued partnership with BMS.

Sincerely,

Tadd Haynes
President

EXHIBIT
37

DHHRBMS001682

STATE FISCAL YEAR 2021

MODEL PURCHASE OF SERVICE PROVIDER AGREEMENT

BETWEEN

STATE OF WEST VIRGINIA

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

BUREAU FOR MEDICAL SERVICES

AND

Unicare WV

The MCO must comply with all established criteria required by WV Medicaid before approving the initial coverage of any physician-administered agent which is currently available in a point of sale form. If exceptions to the criteria are considered appropriate or necessary, the MCO must obtain written consent for such variance from BMS Office of Pharmacy Services.

The MCO shall be subject to following provisions of Section 1004 of the SUPPORT for Patient and Communities Act:

- **Claim Reviews:**
  - Retrospective reviews on opioid prescriptions exceeding state defined limitations on an ongoing basis.
  - Retrospective reviews on concurrent utilization of opioids and benzodiazepines as well as opioids and antipsychotics on an ongoing periodic basis.
- **Programs to monitor antipsychotic medications to children**: Antipsychotic agents are reviewed for appropriateness for all children including foster children based on approved indications and clinical guidelines.
- **Fraud and abuse identification:** The DUR program has established a process that identifies potential fraud or abuse of controlled substances by enrolled individuals, health care providers and pharmacies.

1.3.3 Organ and Tissue Transplantations

MCO enrollees receiving services for transplantation of organs or tissues, other than corneal transplants, are covered under FFS Medicaid for the entire duration of their treatment.

The MCO must have the ability to notify the State of any past, present, or future transplant recipient and request transfer to FFS Medicaid. BMS will coordinate with Utilization Management vendor and Medicaid Management Information Systems (MMIS) vendor to transition enrollees to the FFS system and coordinate care at that time. The enrollee will be covered under FFS retroactively to the beginning of the month that the MCO notifies the State. Capitation will be recouped for this month. Any claims paid during the month by the MCO may be reversed and directed to the fiscal agent for payment.

1.4 Non-covered Services

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1. All non-medically necessary services;
2. Sterilization of a mentally incompetent or institutionalized individual;
3. Except in an emergency, inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner, acting within the scope of practices, who is responsible for the diagnosis or treatment of a particular patient's condition;
4. All organ transplants, except for those specified in Appendix A;

5. Treatments for infertility[5] and for the reversal of sterilization;
6. Sex transformation procedures and hormone therapy associated with sex transformation procedures
7. All cosmetic services, except for those provided as a result of accidents or birth defects; and
8. Christian Science nurses and sanitariums.

The MCO must not reimburse for drugs, drug products, and related services, which are defined as a non-covered benefit by BMS' Outpatient Drug Pharmacy Program.

In accordance with 42 U.S.C. § 1396r-8, the MCO must exclude coverage for any drug marketed by a drug company (or labeler) that does not participate in the federal drug rebate program. The MCO is not permitted to provide coverage for any drug product, brand name or generic, legend or non-legend, sold or distributed by a company that did not sign an agreement with the federal government to provide Medicaid rebates for that product.

The MCO must not provide coverage under any circumstances for drug products that have been classified as less-than-effective by the Food and Drug Administration (FDA) Drug Efficacy Study Implementation (DESI).

MCOs cannot enhance the benefits provided to Medicaid enrollees, with the exception of clinical preventive services, without the prior approval of BMS.

1.5 Other Requirements Pertaining to Covered Services

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MCOs and their participating providers may not bill or collect any payment from Medicaid enrollees for care that was determined not to be Medically Necessary. Anyone who knowingly and willfully charges for any service provided to a patient under a State Plan approved under Title XIX or under a MCO Contract under 1903(m) of the Social Security Act, money or other consideration at a rate in excess of the rates established by BMS or Contract will be guilty of a

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Robert Price
Agree

TheHealthPlan

Exhibit
06

April 21, 2021

Susan Hall, Chief of Managed Care
WV Bureau for Medical Services
350 Capitol Street, Room 251
Charleston, WV 25301

RE: SFY21 Mid-Year Rate Amendment Acceptance

Dear Ms. Hall:

The Health Plan has reviewed the SFY21 mid-year Manage Care Contract and Rates amendment under procurement BMS20*10. The Health Plan accepts the proposed contract and rates amendment. We look forward to our continued partnership with BMS.

Sincerely,

DocuSigned by:
471124B160224EC...

Jeff Knight
President & COO

EXHIBIT
41

STATE FISCAL YEAR 2021

MODEL PURCHASE OF SERVICE PROVIDER AGREEMENT

BETWEEN

STATE OF WEST VIRGINIA

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

BUREAU FOR MEDICAL SERVICES

AND

The Health Plan of West Virginia

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To: Beane, Cynthia E (BMS)[Cynthia.E.Beane@wv.gov]
From: Becker, James
Sent: Tue 10/13/2020 5:24:39 PM
Subject: [External] gender dysphoria question
Received: Sat 5/1/2021 1:10:48 PM

Cindy,
We've held off on approving the Vantas implant for this child getting treated at UPMC.
Based on conversations with several experts, it is a standard of care. Dr. Yoost at Marshall said she would have someone with those issues treated in with a comprehensive program at a Center of Excellence.
If this child had a diagnosis of "precocious puberty" we would allow the use of this medicine for that condition.

These are tough issues.

Thanks for your input.
Jim

National Center for TRANSGENDER EQUALITY

Ensuring Nondiscrimination for Transgender People in the West Virginia Medicaid Program

January 2019

West Virginia Medicaid provides essential benefits to the health and well-being of many of the state's most vulnerable residents, including transgender West Virginians. Like you, we believe that all West Virginians should have access to high quality and affordable health care. Therefore, we are confident you will agree that the Department of Health and Human Resources (DHHR) should adopt an affirmative clinical coverage policy to clarify the coverage of medically necessary care for transgender people. Doing so is particularly critical in light of the long history of health care discrimination that transgender people have faced and federal law that prohibits discrimination against transgender people in state Medicaid programs.

West Virginia Medicaid does not expressly exclude health care services needed for gender transition. However, the program has not yet adopted an affirmative clinical coverage policy that confirms that treatment for gender dysphoria—whether mental health services, hormone therapy, or surgery—is medically necessary for many transgender people and thus should be covered. In the absence of clear guidance, transgender Medicaid beneficiaries have struggled to access medically necessary care, leaving beneficiaries, providers and Managed Care Organizations (MCOs) confused about their rights and obligations under West Virginia's Medicaid program. For example, while several MCOs explicitly say that their plans do not discriminated against members based on gender identity, plan booklets still contain broad exclusions of coverage for transition-related care.[1]

Adopting an affirmative coverage policy will ensure that beneficiaries, providers and MCOs understand that these medically necessary health care services are covered and ensure that all transgender West Virginians enrolled in Medicaid can consistently access the care that they need without discrimination. Doing so is particularly critical in light of the long history of health care discrimination that transgender people have faced, and is recognized as a best practice among other state Medicaid programs.

Adopting an affirmative coverage protocol is consistent with the mission of DHHR to provide a system of high-quality and cost-effective health care services to West Virginians and their families and improve their quality of life. This memorandum explains the medical and legal need to ensure that West Virginia Medicaid covers medically necessary procedures, services, and treatments for transgender individuals. Thank you again for your consideration and efforts to promote health equity.

Health treatment for gender dysphoria is widely recognized as medically necessary, but until recently was commonly excluded from coverage.

Medical consensus has established that gender identity is an inherent aspect of human identity.[2] Transgender people are those whose innate gender identity is different from that typically associated with their assigned sex at birth. An estimated 0.6 percent of the U.S. adult population—at least 1.4 million adults—are transgender, including 6,100 West Virginians.[3] Sources such as the

[1] See, e.g.: Aetna Better Health, West Virginia Medicaid Managed Care Member Handbook, p. 30, https://www.aetnabetterhealth.com/westvirginia/assets/pdf/members/Final%20ABH%20WV%20Model%20Member%20Handbook_SFY%2019%20082918.docx.pdf; Unicare Health Plan of West Virginia, Inc, Member Handbook, p. IV and 43, http://mss.unicare.com/DocumentLibrary/UWV-MHB-0011-18-WV-Model-Handbook-Combined_ENG-508.pdf; The Health Plan, West Virginia Medicaid Managed Care Member Handbook, p. 27. https://www.healthplan.org/sites/default/files/documents/resources/medicaid/Revised_Member%20Handbook%20SFY19.pdf; West Virginia Family Health, Member Handbook, p. CP4 and p. 37, https://www.wvfh.com/Portals/4/members/WV-Member-Handbook.pdf

[2] *See, e.g.*, World Prof'l Ass'n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, Seventh Edition, 16 (2011).

[3] Andrew R. Flores et al., *How Many Adults Identify as Transgender in the United States?* (2016), available at: http://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf.

Institute of Medicine,[4] Healthy People 2020,[5] the Substance Abuse and Mental Health Services Administration,[6] and the *National Healthcare Disparities Report*[7] indicate that transgender individuals experience significant disparities in health indicators such as experiences of abuse and violence, mental and behavioral health concerns, and HIV infection. This in turn links to higher levels of poverty, uninsurance, stigma, and discrimination[8]—particularly when seeking health care.[9]

The estimated 6,100 transgender people in West Virginia, like everyone else, need acute care when they are sick and preventive care to keep from becoming sick. In addition, many transgender West Virginians need access to medically necessary care related to gender transition. For many transgender people, their identity—the essence of who they are—is closely connected with a medical condition known as gender dysphoria (formerly known as gender identity disorder).[10] The American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM 5) defines gender dysphoria as: (1) a marked incongruence between one's experienced/expressed gender and assigned gender (manifested in at least two of six specific symptoms), which (2) is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.[11]

Necessary treatment for gender dysphoria may include mental health care, hormone therapy, and a variety of possible surgical treatments.[12] These medical services are not unique to transgender people. The same hormone therapy used for transgender patients, for example, is provided to patients with endocrine disorders and menopausal symptoms. The surgical procedures that may be used in gender transition, such as breast removal or augmentation, hysterectomy, oophorectomy, orchiectomy, salpingectomy, and various reconstructive procedures, are regularly covered by Medicaid programs for non-transgender individuals for purposes such as treating injuries or for cancer treatment or prevention. The use of this range of treatments to treat gender dysphoria is commonly referred to as "transition-related care."

It is the overwhelming consensus among medical experts that transition-related treatments, including surgical procedures, are medically necessary, effective, and safe when clinically indicated to alleviate gender dysphoria.[13] According to the American Medical Association (AMA), untreated gender dysphoria "can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and

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[4] Inst. of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.
[5] Dep't of Health & Human Servs., *Healthy People 2020: LGBT Health Topic Area* (2015), http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health.
[6] Substance Abuse & Mental Health Servs. Admin, *Top Health Issues for LGBT Populations* (2012), http://store.samhsa.gov/product/Top-Health-Issues-for-LGBT-Populations/SMA12-4684.
[7] Agency for Healthcare Research & Quality, *National Healthcare Disparities Report* (2012), http://archive.ahrq.gov/research/findings/nhqrdr/nhdr12/index.html.
[8] Joint Comm'n, *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide* (2011), http://www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf.
[9] Sandy E. James et al., The Report of the 2015 U.S. Transgender Survey 96–97 (2016), www.ustranssurvey.org/report (finding that one-third of transgender respondents who saw a health care provider in the year prior to the survey were denied treatment, turned away or suffered mistreatment or discrimination for being transgender) Center for American Progress, Discrimination Prevents LGBTQ People from Accessing Health Care (2018) https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/ (finding that among transgender people who had visited a doctor in the past year, 29% said a doctor or other health care provider refused to see them because of their actual or perceived gender identity)
[10] *See, e.g.*, Schwenk v. Hartford, 204 F.3d 1187, 1193 (9th Cir. 2000) (referring to "gender dysphoria [as] the technical diagnosis for transsexuality"); Farmer v. Haas, 990 F.2d 319, 320 (7th Cir. 1993) (using "transsexualism" and "gender dysphoria" as interchangeable); Glenn v. Brumby, 724 F. Supp. 2d 1284, 1304, n.5 (N.D. Ga. 2010) *aff'd*, 663 F.3d 1312 (11th Cir. 2011) (stating that "GID and transsexualism are closely related and are sometimes used as synonyms").
[11] AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 452 (5th ed., 2013).
[12] *See* World Professional Association for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People 16 (7th edition, 2011).
[13] *See, e.g.*, Am. Academy of Fam. Physicians, Resolution No. 1004 (2012); Am. Medical Assn., Resolution 122 (A-08), Removing Financial Barriers to Care for Transgender Patients (2008); Am. Psychiatric Assn., Position Statement: Access to Care for Transgender and Gender Variant Individuals (2012); Am. Psychological Assn., Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination (2008); Am. College of Physicians, Lesbian, Gay, Bisexual, and Transgender Health Disparities: A Policy Position Paper, 163 ANN INTERN MED. 135-137 (2015); Am. Coll. of Obstetricians & Gynecologists, Committee Op. 512, 118 OBSTETRICS & GYNECOLOGY 1454 (2011); National Assn. of Social Workers, Transgender and Gender Identity Issues Policy Statement (2008).

treatment, suicidality and death."[14] Numerous studies and meta-analyses —including a recent comprehensive literature review on the issue—[15] have similarly demonstrated the significant benefits of transition-related care in the treatment of gender dysphoria.[16] As such, treatments for this condition cannot be considered "cosmetic" or "experimental." Recognizing this, the Medicare program rescinded its 30-year exclusion of transition-related surgical care in 2014 after concluding that gender confirmation surgery "is safe and effective and not experimental," "has gained broad acceptance in the medical community," and "is an effective treatment option."[17] Following the removal of the exclusion, the Medicare Appeals Council issued a decision in favor of covering transition-related surgery when medically necessary.[18]

Despite the medical necessity of transition-related care for transgender people, some Medicaid programs have historically limited access to care associated with gender transition. Currently, only 11 states continue to have exclusions for coverage of transition-related care,[19] and at least two of them are being challenged in court.[20] These limits—typically exclusions or coverage denials for transition-related care—target transgender people for discrimination by forcing them to forego necessary treatments or to pay out-of-pocket for the same medically necessary services provided to non-transgender people. As the U.S. Department of Health and Human Services noted:

> [M]any health-related insurance plans or other health-related coverage, including Medicaid programs, currently have explicit exclusions of coverage for all care related to gender dysphoria or associated with gender transition. Historically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental. However, such across-the-board categorization is now recognized as outdated and not based on current standards of care.[21]

Even where Medicaid programs have not *explicitly* excluded transition-related care, transgender people are often denied medically necessary care. Such denials may occur if the plan records a "gender mismatch," such as when a transgender man needs a hysterectomy or other type of "sex-specific" service (such as a Pap smear or a mammogram), or because plans continue to justify denials of care by categorizing certain procedures as cosmetic or experimental when needed for transition-related purposes. As a result, the same procedures—such as a hysterectomy—are typically covered for non-transgender people but denied as cosmetic or experimental for transgender people. These types of coverage denials are particularly common in the absence of explicit affirmative coverage protocols and standards. For these reasons, the AMA, American Psychiatric Association, American Psychological Association, and other major medical association have adopted policy statements in support of coverage for medically necessary transition-related care; many of these statements are collected in Appendix A.

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[14] Am. Med. Ass'n House of Delegates, *Removing Financial Barriers to Care for Transgender Patients* (2008).
[15] Cornell University, Public Policy Research Portal, *What does the scholarly research say about the effect of gender transition on transgender well-being?*, https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/
[16] William Byne et al., *Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder*, 41 ARCHIVES OF SEXUAL BEHAVIOR 759 (2012); Marco Colizzi, Rosalia Costa & Orlando Todarello, *Transsexual Patients' Psychiatric Comorbidity and Positive Effect of Cross-Sex Hormonal Treatment on Mental Health: Results from a Longitudinal Study*, 39 PSYCHONEUROENDOCRINOLOGY 65 (2014); Audrey Gorin-Lazard et al., *Hormonal Therapy is Associated with Better Self-Esteem, Mood, and Quality of Life in Transsexuals*, 201 J. Nervous & Mental Disorders 996 (2013); M. Hussan Murad et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 CLINICAL ENDOCRINOLOGY, 214 (2010); Griet De Cuypere et al., *Sexual and Physical Health After Sex Reassignment Surgery*, 34 ARCHIVES OF SEXUAL BEHAVIOR 679 (2005); Giuloio Garaffa, Nim A. Christopher & David J. Ralph, *Total Phallic Reconstruction in Female-to-Male Transsexuals*, 57 EUROPEAN UROLOGY 715 (2010); Caroline Klein & Boris B. Gorzalka, *Sexual Functioning in Transsexuals Following Hormone Therapy and Genital Surgery: A Review*, 6 J. OF SEXUAL MEDICINE 2922 (2009).
[17] Departmental Appeals Board, *NCD 140.3, Transsexual Surgery*, Decision No. 2576 (2014), available at: http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.
[18] Dep't of Health and Human Services, NCD 140.3, Transsexual Surgery, 12 (2014); HHS Department Appeals Board, Decision of Medicare Appeals Council, Docket Number M-15-1069, United Healthcare/AARP (January 21, 2016)
[19] These states are: Alaska, Georgia, Illinois, Iowa, Maine, Missouri, Nebraska, Ohio, Tennessee, Wisconsin and Wyoming.
[20] See: Flack v. Wisconsin Department of Health Services, No. 3:18-cv-00309-wmc (W.D. Wis. July 25, 2018) and Good/Beal v. Iowa Department of Human Services, No. CVCV054956 (Iowa District Court for Polk County, 2018).
[21] Nondiscrimination in Health Programs and Activities; Final Rule, 81 Fed. Reg. 31375, 31429 (May 13, 2016).

Federal law requires equal treatment of transgender beneficiaries in the design of Medicaid benefits

Denials of coverage that are based solely upon gender identity, transgender status, or related diagnoses constitute unlawful, arbitrary discrimination against transgender people under federal law, including the Medicaid Act and the Affordable Care Act. Claims that are submitted for transition-related care must be considered under the same standards of medical necessity and clinical appropriateness, utilizing current clinical standards, as when such claims are submitted by other enrollees for other indications. To ensure compliance with these protections, we strongly urge DHHR to clarify that medically necessary health care services for gender transition are covered under West Virginia Medicaid.

i. State coverage policies must comply with nondiscrimination in benefit design under the Medicaid Act and federal Medicaid regulations

State coverage policies must comply with the federal Medicaid Act. In *Cruz v. Zucker*, a federal district court ruled that a New York regulation that categorically excluded coverage of specific procedures for the treatment of gender dysphoria violated the Medicaid Act.[22] The court held that under the Medicaid Act's availability provision, "a state may not place an outright ban on medically necessary treatments for a particular diagnosis," including gender dysphoria.[23] The Court also found that the exclusions violated the Medicaid Act's comparability provision, which "prohibits discrimination among individuals with the same medical needs stemming from different medical condition," as New York Medicaid provided coverage for the same procedures for people diagnosed with other medical conditions, but not for people diagnosed with gender dysphoria.[24] In response to the ruling, New York adopted rules to eliminate its exclusions for transition-related procedures, replacing them instead with a policy of case-by-case coverage determinations for services outside of a defined list.[25]

Additionally, federal regulations for Medicaid Managed Care Organizations explicitly prohibit MCOs from discriminating against beneficiaries on the basis of gender identity and from adopting any policies or practices that have the effect of discriminating on the basis of gender identity.[26]

To comply with the federal Medicaid Act and federal regulations, we urge DHHR to ensure that transgender West Virginians have equal access to the coverage of procedures that have been identified by the World Professional Association of Transgender Health (WPATH) Standards of Care as medically necessary for the treatment of gender dysphoria. In particular, we urge DHHR to adopt a clinical coverage policy for the treatment of gender dysphoria. This policy can be used when such care is clinically indicated as determined by a qualified health care professional based on the WPATH Standards of Care.

ii. Nondiscrimination in benefit design under the Affordable Care Act

Section 1557 of the Affordable Care Act prohibits prohibits discrimination against transgender beneficiaries in state Medicaid programs.[27] Federal courts have specifically found that

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[22] 195 F.Supp.3d 554, 571 (S.D.N.Y. Jul. 5, 2016) (applying 42 U.S.C. § 1396a(a)(10)(A)).
[23] *Id.*, citing DeSario v. Thomas, 139 F.3d 80, 96 (2d Cir.1998).
[24] *Id.*, citing Davis v. Shah, 821 F.3d 231, 258 (2d Cir. 2016).
[25] New York State Reg., Dec. 7, 2016, I.D. No. HLT-40-16-00030-P, Transgender Related Care and Services.
[26] 81 FR 27497 ("The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation gender identity, or disability.")
[27] 42 U.S.C. § 18116(a). *See, e.g., Rumble v. Fairview Health Servs.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (holding that discrimination against hospital patient based on his transgender status constitutes sex discrimination under Section 1557 of the Affordable Care Act); *Flack v. Wis. Dep't of Health Servs.*, No. 3:18-cv-00309-wmc (W.D. Wis. July 25, 2018) (holding that a Medicaid program's refusal to cover treatments related to gender transition is "text-book discrimination based on sex" in violation of the Affordable Care Act and the Equal Protection Clause of the Constitution); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. 2016) (holding exclusion invalid under the Medicaid Act and the Affordable Care Act); *Prescott v. Rady Children's Hosp.-San Diego*, 265 F.Supp.3d 1090 (S.D. Cal. Sept. 27, 2017) (holding that discrimination against transgender patients violates the Affordable Care Act); *Tovar v. Essentia Health*, No. 16-cv-00100-DWF-LIB (D. Minn. September 20, 2018) (holding that Section 1557 of the Affordable Care Act prohibits discrimination on the basis of gender identity); *Boyden v. Conlin*, No. 17-cv-264-WMC, 2018 (W.D. Wis. September 18, 2018) (holding that a state employee health

discriminatory health insurance and coverage practices, such as exclusions of transition-related care, violate the Affordable Care Act.[28] For example, in *Flack v. Wisconsin Department of Health Services*, a federal court found that an exclusion of transition-related care the state's Medicaid program amounted to illegal discrimination by treating transgender individuals differently on the basis of sex when it comes to coverage, in violation of the Affordable Care Act and the Equal Protection Clause.[29] Even in the absence of a blanket exclusion of transition-related care, certain coverage exclusions of specific services may constitute illegal discrimination. For example, Courts have similarly found that even when a Medicaid program generally covers gender dysphoria treatment, maintaining medically unsupported exclusions of *specific* treatments for transgender beneficiaries could constitute discrimination,[30] including when programs deny coverage for services used in the treatment of gender dysphoria when similar services are covered for the purpose of treating other conditions.[31]

As noted above, all procedures potentially used in gender transition—including hormone therapy or reconstructive surgical procedures—are used to treat both transgender and non-transgender people. However, historically, such procedures had often been covered only for *non-transgender* people under state Medicaid programs. Under the Affordable Care Act, denying coverage for substantially similar procedures simply because those procedures are used for the treatment of gender dysphoria would constitute unlawful discrimination against transgender people. Further, services may only be limited based on "a neutral, nondiscriminatory reason."[32] Automatic coverage denials for certain treatments for gender dysphoria—in spite of a medical provider's determination of medical necessity—discriminate against transgender beneficiaries.

The nondiscrimination requirements of the Affordable Care Act also apply to any limitation on coverage that "results in discrimination against a transgender individual."[33] In particular, Medicaid programs may not employ discriminatory benefit designs or policies that create onerous and unjustifiable barriers to coverage that make it impossible or highly impractical for transgender people to access essential care. For example, a program cannot impose standards that are not supported by sound medical evidence for determining eligibility or medical necessity of transition-related procedures. And, as noted above, state Medicaid programs cannot deny coverage for services used in the treatment of gender dysphoria when similar services are covered for the purpose of treating other conditions for non-transgender people. To ensure that these rules are clear and understood by providers, claims handlers, and others, we urge DHHR to clarify its policies on the coverage of medically necessary transition-related care.

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plan refusal to cover transition-related care constitutes sex discrimination in violation of Title VII, Section 1557 of the ACA, and the Equal Protection Clause). Other federal courts have found that similar federal sex discrimination laws also prohibit anti-transgender discrimination. *See, e.g., Whitaker v. Kenosha Unified School District*, No. 16-3522 (7th Cir. 2017) (Title IX and Equal Protection Clause); *Dodds v. U.S. Dep't of Educ.*, 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); *Glenn v. Brumby*, 663 F.3d 1312 (11th Cir. 2011) (Equal Protection Clause); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); *Smith v. City of Salem*, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); Grimm v. Gloucester County School Board, No. 4:15-cv-54 (E.D. Va. May 22, 2018) (holding that denying a transgender boy access to school restrooms matching his gender violated Title IX and the Equal Protection Clause of the U.S. Constitution); M.A.B. v. Board of Education of Talbot County, 286 F. Supp. 3d 704 (D. Md. March 12, 2018) (holding that prohibiting a transgender boy from boys' locker room based on transgender status is a Title IX sex-discrimination claim as well as a gender-stereotyping claim).

[28] *See, e.g., Flack v. Wis. Dep't of Health Servs.*, No. 3:18-cv-00309-wmc; *Cruz v. Zucker*, 195 F.Supp.3d 554; *Tovar v. Essentia Health*, No. 16-cv-00100-DWF-LIB; *Boyden v. Conlin*, No. 17-cv-264-WMC, 2018.

[29] *Flack v. Wis. Dep't of Health Servs.*, No. 3:18-cv-00309-wmc

[30] *Cruz*, 195 F.Supp.3d at 571; Jesse McKinley, *For Transgender Youths in New York, It Would Be a Health Care Milestone*, N. Y. TIMES (Oct. 5, 2016), https://www.nytimes.com/2016/10/06/nyregion/new-york-moves-to-allow-medicaid-to-cover-hormone-therapy-for-transgender-youth.html.

[31] *Id.* State nondiscrimination laws applicable to insurance have also been interpreted similarly. *See, e.g.*, 10 Cal. Admin. Code § 2561.2(a)(4) (prohibiting exclusion of services for gender transition "if coverage is available for those services under the policy when the services are not related to gender transition"); Oregon Insurance Division Bulletin INS 2012-1 ("A health insurer may not deny or limit coverage or deny a claim for a procedure provided for [gender dysphoria] if the same procedure is allowed in the treatment of another [non-gender dysphoria] condition").

[32] Nondiscrimination in Health Programs and Activities; Final Rule, 81 Fed. Reg. 31375, 31433 (May 13, 2016).

[33] *Cruz v. Zucker*, 195 F.Supp.3d; 45 C.F.R. § 92.207. *See also*, generally: *Rumble v. Fairview Health Servs.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015); *Prescott v. Rady Children's Hospital-San Diego*, 265 F.Supp.3d 1090 (S.D. Cal. Sept. 27, 2017),

Affirmative coverage of transition-related care is increasingly routine in state Medicaid programs, federal health programs, and private health insurance coverage

Seventeen states and the District of Columbia have adopted affirmative coverage standards for transition-related care to help ensure that their Medicaid programs do not discriminate against transgender beneficiaries.[34] These states have updated their regulations or issued new guidance to 1) remove transgender-specific exclusions and 2) adopt affirmative coverage standards for the coverage of transition-related care. State coverage protocols typically address the scope of covered services (including hormone therapy, mental health services, and surgeries) and direct providers to provide treatment in accordance with the latest version of the nationally and internationally recognized WPATH Standards of Care. As noted above, even affirmative coverage standards—such as that in New York—have been successfully challenged under federal law as discriminatory against transgender people where they maintain categorical, medically unsupported exclusions of specific services for transgender beneficiaries.[35] A number of other states, such as Illinois and Virginia, are actively considering similar guidance.

The standards set by the Medicaid programs in Colorado, Connecticut, Montana, and Pennsylvania reflect best practices to ensure that transgender people receive the medical care they need. We urge you to consider a similar approach as these states in developing an appropriate affirmative clinical coverage policy for the treatment of gender dysphoria. We have included direct references to their policies in Appendix B of this memorandum. This policy would affect covered services under physician services, behavioral health, reconstructive surgery, and pharmacy services. Additionally, we urge you to direct MCOs to remove blanket exclusions for transition-related care currently outlined in Medicaid member handbooks. Finally, DHHR should amend existing current clinical coverage policies—such as those related to, at a minimum, hysterectomy, outpatient pharmacy, mental health drug management, breast surgeries, reconstructive and cosmetic surgery—to ensure that these policies do not limit access to medically necessary transition-related care.

There are also 19 states and DC that prohibit transgender exclusions in private health insurance. Insurance regulators and state officials in many of these states have interpreted or adopted state nondiscrimination statutes and statutory prohibitions on unfair trade practices in private health insurance to prohibit insurers from discriminating against transgender enrollees.[36] Federal health programs also cover transition-related care. As previously mentioned, the Medicare program eliminated a national exclusion for transition-related surgeries in 2014, based on the recognition that it was not supported by the overwhelming medical evidence demonstrating that transition-related surgeries are safe, effective and medically necessary when indicated.[37] The Office of Personnel Management directed Federal Employee Health Benefit plans to eliminate blanket exclusions for transition-related care in 2015.[38]

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[34] Cal. Code Regs. tit. 10, § 2561.2 (2011) (*see also* State of Cal., Dep't of Health Care Servs., Medi-Cal Update, Gen. Medicine, Bulletin 465, Policy Clarification: Gender Identity Disorder (September 25, 2013)); Comm. Health Network of Conn, Gender Reassignment Surgery (2016); Col. Health Program Benefits and Operations, Rule MSB 17-03-21-B, Revision to the Medical Assistance Benefits Rule Concerning Transgender Services, Section 8.735 (July 14 2017); D.C. Dep't of Health Care Fin., Non-Discrimination in the District's State Medicaid Program Based on Gender Identity or Expression (Feb. 27, 2014) (*see also* D.C. Dep't of Health Care Fin., Gender Reassignment Surgery Policy (Mar. 1, 2016); Hawaii. H.B. 2084 (2016); 130 Mass. Code Regs. 450.202; 42-2 Md. Reg. 181; Minnesota Department of Human Services, Gender-Confirming Surgery Protocol (February 2, 2017); Montana Department of Health and Human Services, Federal Final Rule, "Nondiscrimination in Health Program and Activities" and Implication for Coverage of Services Related to Gender Transition (May 26, 2017); Nevada, Division of Health Care Financing and Policy, Medicaid Services Manual Transmittal Letter, December 21, 2017; New Hampshire, Amend He-W 531.06, effective 3/29/14 (Document #10561), September 2017; New Jersey, Assembly Bill 4568, Approved P.L.2017, c.176.; 2015-10 N.Y. St. Reg. 19 ; New York State Reg., Oct. 5, 2016, I.D. No. HLT-40-16-00030-P, Transgender Related Care and Services; Proposed Rule Making; Or. Admin. R. 410-141-0520, *See also:* Prioritized List: Guideline for Gender Dysphoria; Penn. Department of Human Services. Medical Assistance Bulletin, July 18, 2016; State of R.I., Exec. Office of Health & Human Services, Gender Dysphoria/Gender Nonconformity Coverage Guidelines (October 28, 2015); Dep't of Vt. Health Access, The Department of Vermont Health Access Medical Policy (May 13, 2016); Washington State Health Care Authority, Physician-Related Services/ Health Care Professional Services Billing Guide, July 1, 2016

[35] Jesse McKinley, "For Transgender Youths in New York, It Would Be A Health Care Milestone," *New York Times* (Oct. 5, 2016).

[36] These states include California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Illinois, Maryland, Massachusetts, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington.

[37] Dep't of Health and Human Services, NCD 140.3, Transsexual Surgery, 12 (2014).

[38] FEHB Program Carrier Letter No. 2015-12, Covered Benefits for Gender Transition Services, (June 24, 2015).

Similar guidance from DHHR clarifying the availability of coverage for medically necessary transition-related care would ensure that all transgender West Virginians enrolled in Medicaid are protected from discrimination.

Transition-related care coverage does not impose significant costs while significantly enhancing the well-being of beneficiaries.

Where state Medicaid programs have assessed the cost of covering transition-related care, minimal costs have been observed. The Oregon Health Authority, for instance, spent an estimated $435,000 on transition-related care, a number that will likely reduce significantly in subsequent years after catching up with the initial demand.[39] Overall, a report issued before the announcement of benefits stated that the cost of adding hormone therapy "would likely be minimal to the [Medicaid] program" and the cost of adding gender confirmation surgery would be "higher than that of cross-sex hormone therapy alone, but still very low."[40] Policymakers also noted the potential for cost savings through reduced suicide attempts.[41]

Private and public employers that have covered transition-related care for their employees have similarly found it to be highly cost-effective. When San Francisco eliminated its exclusion in 2001, the city responded to cost concerns by limiting the scope of the benefit and implementing a $1.70 premium surcharge for all employees. Actual cost and utilization data were so much less than expected that the surcharge produced a multi-million-dollar surplus. The city eventually raised the dollar cap and ultimately eliminated the surcharge entirely.[42] This example has led other states and cities such as California, Massachusetts, Minnesota, Nevada, New York, Oregon, Pennsylvania, Washington, the District of Columbia, Atlanta, Austin, Bloomington, Chicago, Cincinnati, Columbus, Dayton, Detroit, Minneapolis, Missoula, Orlando, Phoenix, Rochester, and St. Louis to eliminate exclusions in their employee plans.[43]

In an Economic Impact Assessment of its 2012 rule that prohibited insurance discrimination against transgender people, the California Department of Insurance concluded that "any such costs are immaterial and insignificant."[44] Similarly, the removal of transgender exclusions from the Massachusetts Group Insurance Commission was found to be highly cost-effective, with a budget impact of $0.016 per member per month that was offset by a reduction in negative health outcomes, such as HIV infection, depression, and suicidality.[45] More recently, in August 2018, the Wisconsin Group Insurance Board voted to remove the exclusion of treatment of gender dysphoria from its state employee plan. Memos from the Wisconsin Department of Employee Trust Funds to the Board cited positive developments in employer coverage of transition-related care and low costs of implementation, which they estimated to be between 0.007% and 0.018% of the $1.3 billion in state health plan premiums.[46]

Private companies also report minimal economic impact from providing equal coverage for transgender employees. The Human Rights Campaign's Corporate Equality Index reports that for the 750 employers who did so, eliminating exclusions "comes at an overall negligible cost to the

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[39] Lost In Transition: Oregon's promise to aid low-income transgender people comes up short. Oregon Live, Updated Jan 23, 2017, https://www.oregonlive.com/transgender-health/2016/04/oregon_health_plan_transgender.html.
[40] *Id.*
[41] *Id.*
[42] San Francisco Human Rights Comm'n, *San Francisco City and County Transgender Health Benefit* (Aug. 2007), available at: http://www.hrc.org/files/assets/resources/San_Francisco_City_and_County_Transgender_Health_Benefit_-_2007-08-10.pdf.
[43] Human Rights Campaign & Equality Federation Institute, *2016 State Equality Index* 20 (2016), http://assets.hrc.org//files/assets/resources/SEI-2016-Report-FINAL.pdf; Human Rights Campaign, *Municipal Equality Index: A Nationwide Evaluation of Municipal Law* (2016), http://assets.hrc.org//files/assets/resources/MEI-2016-Final-Online.pdf.
[44] Cal. Dep't of Ins., *Economic Impact Assessment. Gender Nondiscrimination in Health Insurance* (2012), available at: http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.
[45] William V. Padula et al., "Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis," 31 *Journal of General Internal Medicine* 394 (2015).
[46] State of Wisconsin, Department of Employee Trust Funds. *Correspondence Memorandum* (August 14, 2018), http://etf.wi.gov/boards/agenda-items-2018/gib0822/item6a1.pdf; State of Wisconsin, Department of Employee Trust Funds. *Correspondence Memorandum* (January 30, 2017), http://etf.wi.gov/boards/agenda-items-2017/gib0208/item4.pdf

employers' overall health insurance plans. This holds true across industries."[47] A survey of employers by the Williams Institute at the UCLA School of Law found that transition-related health care benefits have "zero or very low costs" and low utilization rates estimated at 1 per 10,000 to 20,000 employees.[48] Overall, the report finds that "transition-related health care benefits have very low costs, have low utilization rates by employees, and yet can provide benefits for employers and employees alike."[49] More than 86 leading universities and colleges, including state universities in at least 28 states, have similarly found that it is cost-effective to provide this coverage in their student health plans.[50]

Failing to adequately treat gender dysphoria can result in negative outcomes for individuals as well as society—but the opposite is equally true and attainable. Affirming transgender individuals by ensuring nondiscriminatory coverage significantly improves the lives of these individuals and society at large. While the costs to ensure trans-related care provisions are minimal, the benefits are significant.[51] The California Economic Impact Assessment has similarly found that eliminating transgender exclusions results in "lower costs associated with the high cost of suicide and attempts at suicide, overall improvements in mental health and lower rates of abuse," and "will not only save insurers from the costs associated with suicide, but prevent significant numbers of transgender insureds from losing their lives."[52] Finally, failing to provide coverage for transition-related care can lead to higher costs as a result of litigation. For example, the state of Wisconsin was recently ordered by a jury to pay almost $800,000 in damages for two transgender state employees for denying coverage of medically necessary care. Only a small fraction of the total paid was for the actual cost of the procedures (around $80,000), with $720,000 constituting reparations for the discrimination suffered.[53]

Conclusion

To ensure that transgender West Virginians can access the care they need without discrimination, we urge DHHR to adopt an appropriate affirmative clinical coverage policy for the treatment of gender dysphoria to be used when such care is clinically indicated as determined by a qualified health care professional based on the WPATH Standards of Care. For best practices for such policies, please refer to Appendix B of this memorandum.

We also urge DHHR to direct MCOs to remove any blanket exclusions for transition-related care included member handbooks and replace them with affirmative coverage language.

DHHR should also amend its own clinical coverage policies —such as those related to, at a minimum, hysterectomy, outpatient pharmacy, mental health drug management, breast surgeries, reconstructive and cosmetic surgery—to ensure that these policies do not limit access to medically necessary transition-related care.

We thank you for the opportunity to discuss this important issue and stand ready to support you in your efforts. If you have questions regarding this memorandum or other opportunities for ensuring

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[47] Human Rights Campaign, *Corporate Equality Index 2018: Rating Workplaces on Lesbian, Gay, Bisexual, Transgender, and Queer Equality* 28 (2018).
[48] Jody L. Herman, *Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefit Plans: Findings from a Survey of Employers*, (2013), available at: http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf.
[49] *Id.* at 17.
[50] Campus Pride, Trans Policy Clearinghouse: Colleges and Universities that Cover Transition-Related Medical Expenses under Student Health Insurance, available at: http://www.campuspride.org/tpc-student-health-insurance.
[51] A systematic literature review study by Cornell University analyzed all peer review articles published in English between 1991 and 2017, and concluded that 93% of the studies on this topic found that gender transition—including transition-related care—improves the well-being of transgender people. The remaining 7% reported mixed or null findings and no studies concluded that gender transition causes overall harm. Cornell University, Public Policy Research Portal, *What does the scholarly research say about the effect of gender transition on transgender well-being?*, https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/
[52] Cal. Dep't of Ins., *supra* note 40 at 9, 11.
[53] *Boyden v. Conlin*, No. 17-cv-264-WMC, 2018 (W.D. Wis. September 18, 2018) (holding that a state employee health plan refusal to cover transition-related care constitutes sex discrimination in violation of Title VII, Section 1557 of the ACA, and the Equal Protection Clause), Think Progress, Transgender women celebrate monumental court win (2018), https://thinkprogress.org/wisconsin-transgender-women-health-care-court-victory-e5ca758264b4/

health equity for transgender people in West Virginians, please do not hesitate to contact [CONTACT INFO].

Thank you for your work to help all transgender people in West Virginia access the health care they need.

Where state Medicaid programs have assessed the cost of covering transition-related care, minimal costs have been observed. The Oregon Health Authority, for instance, spent an estimated $435,000 on transition-related care, a number that will likely reduce significantly in subsequent years after catching up with the initial demand.[i] Overall, a report issued before the announcement of benefits stated that the cost of adding hormone therapy "would likely be minimal to the [Medicaid] program" and the cost of adding gender confirmation surgery would be "higher than that of cross-sex hormone therapy alone, but still very low."[ii] Policymakers also noted the potential for cost savings through reduced suicide attempts.[iii]

Private and public employers that have covered transition-related care for their employees have similarly found it to be highly cost-effective. When San Francisco eliminated its exclusion in 2001, the city responded to cost concerns by limiting the scope of the benefit and implementing a $1.70 premium surcharge for all employees. Actual cost and utilization data were so much less than expected that the surcharge produced a multi-million-dollar surplus. The city eventually raised the dollar cap and ultimately eliminated the surcharge entirely.[iv] This example has led other states and cities such as California, Massachusetts, Minnesota, Nevada, New York, Oregon, Pennsylvania, Washington, the District of Columbia, Atlanta, Austin, Bloomington, Chicago, Cincinnati, Columbus, Dayton, Detroit, Minneapolis, Missoula, Orlando, Phoenix, Rochester, and St. Louis to eliminate exclusions in their employee plans.[v]

In an Economic Impact Assessment of its 2012 rule that prohibited insurance discrimination against transgender people, the California Department of Insurance concluded that "any such costs are immaterial and insignificant."[vi] Similarly, the removal of transgender exclusions from the Massachusetts Group Insurance Commission was found to be highly cost-effective, with a budget impact of $0.016 per member per month that was offset by a reduction in negative health outcomes, such as HIV infection, depression, and suicidality.[vii] More recently, in August 2018, the Wisconsin Group Insurance Board voted to remove the exclusion of treatment of gender dysphoria from its state employee plan. Memos from the Wisconsin Department of Employee Trust Funds to the Board cited positive developments in employer coverage of transition-related care and low costs of implementation, which they estimated to be between 0.007% and 0.018% of the $1.3 billion in state health plan premiums.[viii]

Private companies also report minimal economic impact from providing equal coverage for transgender employees. The Human Rights Campaign's Corporate Equality Index reports that for the 750 employers who did so, eliminating exclusions "comes at an overall negligible cost to the employers' overall health insurance plans. This holds true across industries."[ix] A survey of employers by the Williams Institute at the UCLA School of Law found that transition-related health care benefits have "zero or very low costs" and low utilization rates estimated at 1 per 10,000 to 20,000 employees.[x] Overall, the report finds that "transition-related health care benefits have very low costs, have low utilization rates by employees, and yet can provide benefits for employers and employees alike."[xi] More than 86 leading universities and colleges, including state universities in at least 28 states, have similarly found that it is cost-effective to provide this coverage in their student health plans.[xii]

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[i] Lost In Transition: Oregon's promise to aid low-income transgender people comes up short. Oregon Live, Updated Jan 23, 2017, https://www.oregonlive.com/transgender-health/2016/04/oregon_health_plan_transgender.html.

[ii] *Id.*
[iii] *Id.*
[iv] San Francisco Human Rights Comm'n, *San Francisco City and County Transgender Health Benefit* (Aug. 2007), available at: http://www.hrc.org/files/assets/resources/San_Francisco_City_and_County_Transgender_Health_Benefit_-_2007-08-10.pdf.
[v] Human Rights Campaign & Equality Federation Institute, *2016 State Equality Index* 20 (2016), http://assets.hrc.org//files/assets/resources/SEI-2016-Report-FINAL.pdf; Human Rights Campaign, *Municipal Equality Index: A Nationwide Evaluation of Municipal Law* (2016), http://assets.hrc.org//files/assets/resources/MEI-2016-Final-Online.pdf.
[vi] Cal. Dep't of Ins., *Economic Impact Assessment: Gender Nondiscrimination in Health Insurance* (2012), available at: http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.
[vii] William V. Padula et al., "Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis," 31 *Journal of General Internal Medicine* 394 (2015).
[viii] State of Wisconsin, Department of Employee Trust Funds. *Correspondence Memorandum* (August 14, 2018), http://etf.wi.gov/boards/agenda-items-2018/gib0822/item6a1.pdf; State of Wisconsin, Department of Employee Trust Funds. *Correspondence Memorandum* (January 30, 2017), http://etf.wi.gov/boards/agenda-items-2017/gib0208/item4.pdf
[ix] Human Rights Campaign, *Corporate Equality Index 2018: Rating Workplaces on Lesbian, Gay, Bisexual, Transgender, and Queer Equality* 28 (2018).
[x] Jody L. Herman, *Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefit Plans: Findings from a Survey of Employers*, (2013), available at: http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf.
[xi] *Id.* at 17.
[xii] Campus Pride, Trans Policy Clearinghouse: Colleges and Universities that Cover Transition-Related Medical Expenses under Student Health Insurance, available at: http://www.campuspride.org/tpc-student-health-insurance.

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ORIGINAL RESEARCH & REVIEWS

TRANSGENDER HEALTH

Which U.S. States' Medicaid Programs Provide Coverage for Gender-Affirming Hormone Therapy and Gender-Affirming Genital Surgery for Transgender Patients?: A State-by-State Review, and a Study Detailing the Patient Experience to Confirm Coverage of Services

Michael Zaliznyak, BA,[1,2] Eric E. Jung, MD,[1] Catherine Bresee, MS,[3] and Maurice M. Garcia, MD, MAS[1,2,4,5]

ABSTRACT

Background: To date, a comprehensive state-by-state assessment of transgender transition-related health care coverage for gender-affirming hormone therapy (GAHT) and genital gender-affirming surgery (GAS) has not been reported.

Aims: The aims of this study were 1) to verify which U.S. states' Medicaid systems do/do not cover GAHT and GAS; 2) to assess the ease/difficulty for patients to determine whether GAHT and GAS are Medicaid-covered benefits; and 3) to understand possible state-related predictors of Medicaid coverage for gender-affirming care.

Methods: We reviewed the official Medicaid Handbook and website for all 51 states (+D.C.) and 5 territories to confirm whether GAHT and GAS are covered benefits. When indeterminate, we called the Medicaid office in each state, and for many, Medicaid managed care organizations (MCOs), and individual in-state providers, to confirm coverage. We recorded our experiences, number of, and duration of phone calls to confirm coverage.

Outcomes: The main outcome was a definitive answer from the state/territory's Medicaid program or MCOs regarding whether GAHT and GAS are/are not covered benefits. Secondary outcome measures included responses we received and the total number/duration of phone calls necessary to confirm coverage.

Results: Only 12 of 51 states and 0 of 5 territories featured their policy regarding coverage for GAHT in their Medicaid Handbook/webpages. We confirmed that 34 of 51 state Medicaid programs do cover GAHT, whereas 9 of 51 states' and 2 of 5 territories' do not. We could not confirm coverage of GAHT in 8 of 51 states and 3 of 5 territories. Only 26 of 51 states and 0 of 5 territories featured their policy regarding coverage for GAS in their Medicaid Handbook/webpages. We confirmed that 25 of 51 state Medicaid programs do cover GAS, whereas 22 of 51 states' and 3 of 5 territories' do not. We could not confirm coverage of GAS in 4 of 51 states and 2 of 5 territories. Up to 12 calls, lasting up to 125 minutes, were required to confirm coverage for GAHT/GAS.

Clinical Implications: Our findings indicate that important health care access barriers/disparities exist today and warrant improvement.

Strengths & Limitations: To our knowledge, this is the most comprehensive assessment of transgender transition-related health care coverage. Limitations include possible bias, as it could be that we were more persistent than actual patients would be to determine service coverage, and a lack of specificity regarding which specific hormone formulations or procedures are/are not covered.

Conclusion: Our findings show that only 34 of 51 (67%) states' Medicaid programs include GAHT and 25 of 51 (49%) include GAS as covered benefits. Our experience suggests that the process to confirm coverage can be especially time-consuming and frustrating for patients. **Zaliznyak M, Jung EE, Bresee C, et al. Which U.S. States' Medicaid Programs Provide Coverage for Gender-Affirming Hormone Therapy and Genital Gender-Affirming Surgery for Transgender Patients?: A State-by-State Review, and a Study Detailing the Patient Experience to Confirm Coverage of Service. J Sex Med 2021;18:410–422.**

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Key Words: Transgender; Gender Dysphoria; Medicaid Assistance Program; Gender-Affirming Hormone Therapy (GAHT); Gender-Affirming Surgery (GAS); Sex Reassignment Surgery (SRS)

INTRODUCTION

Transgender is a term for people whose gender identity does not align with or reflect the social-cultural roles associated with the biological sex that they were assigned at birth in the individual's social environment.[1] Flores et al estimated that between 0.6% and 0.7% of the U.S. population (1.4-1.65 million) is identified as transgender, representing a 100% growth from the same study that was published in 2011.[2] A 2015 national survey of transgender individuals found that transgender individuals suffer from health-related disparities at a considerably higher rate than the United States average.[3] The survey found that 29% of respondents were living in poverty,[3] compared with the U.S. poverty rate of 11.8%.[4] This same survey found 40% of surveyed transgender respondents reported attempting suicide at least once in their life, and 7% attempted suicide in the past year[3]—nearly 14 times greater than the U.S. national average of 0.5%,[5] and 39% reported suffering from serious psychological distress [3][3]—compared with the U.S. national average of 3.4%.[6] In addition, 55% of respondents reported being denied coverage for transition-related surgery, and 25% reported being denied coverage for transition-related hormone therapy treatment.[3]

Studies have shown that transgender people with untreated gender dysphoria experience relatively higher rates of depression, anxiety, suicidality, and HIV as compared with cisgender people.[3,7–11] The 3 now well-established treatment domains for gender dysphoria, which include counseling and therapy to help the individual with social transition (full-time life in the gender role they identify with), gender-affirming hormone therapy (GAHT), and gender-affirming surgery (GAS), have been shown to significantly improve quality of life[10,12–15] for transgender people with gender dysphoria. Research has shown that health-insurance coverage for the subset of transgender patients who choose these transition-related treatments is both affordable and cost-effective.[10,16]

Today, with changing social mores and greater visibility of transgender people in popular culture media, there are a growing number of community-based transgender support and resource centers throughout the United States which support transgender youth and adults.[17] We see also an increase in transgender people seeking transition-related health services,[18,19] as transition-related health care has been shown to improve patient quality of life and the efficiency of our health care service system.[10,12–16] A significant proportion of transgender people utilize public health care services (such as Medicaid).[19,20] It was estimated that 152,000 transgender adults (11% of the estimated transgender population in America) are enrolled in Medicaid.[20] This estimate, however, is likely an underestimate as it is 4 years old (2016), and because most epidemiologic studies tend to underestimate the prevalence of individuals that identify as gender non-conforming.[21]

Medicaid is a joint federal and state health insurance program for people of low income or disabilities, and pays the health care provider directly for the entire cost of most health care procedures, doctor's visits, and prescription drugs. In October 2018, approximately 66,000,000 Americans, or one in every 5 U.S. citizens, were enrolled in a state Medicaid program.[22] Given recent unprecedented national unemployment rates related to the COVID-19 global pandemic, the proportion of U.S. citizens that depend on Medicaid for their health care may increase, at least in the short term.

Although Medicaid provides health care insurance, this does not necessarily translate to access to needed health care services. In an effort to address discrimination in access to health care services, section 1557 of the ACA (2010), states are prohibited from denying federal benefits to individuals based on a patient's gender.[23] How Federal Medicaid funding is utilized is controlled by the State legislature and Medicaid Programs. In 2013 California became the first state to issue policies that explicitly include coverage for gender transition—related care under its state Medicaid program.[24] By 2014 California also passed legislation that specifically bans health insurance policy riders that allow for health care to be denied based on gender identity, and explicitly including medically necessary transgender health care. Since then, additional State Medicaid programs have followed suit to include gender transition—related care (including gender affirming surgery) as covered benefits under their Medicaid programs. Despite such precedent, many states continue to deny coverage for gender transition—related health care to transgender citizens within their state Medicaid programs.[20,25,26] Several states, for example, have explicitly written policies that exclude coverage for transition-related care. Many more states have Medicaid policies that simply do not make clear whether they exclude or include gender transition—related services.[20,25,26] This opacity makes it difficult for transgender citizens of those states to, first, know clearly whether such benefits are or are not available to them under Medicaid, and second, lack of clarity makes it difficult for people to make educated decisions regarding which specific Medicaid managed care plan to enroll into (plans can vary regarding what transition-related services they cover). Finally, uncertainty about whether or not highly important services are available is highly anxiety-provoking to most people, which fuels despair and can lead to high-risk behaviors. Altogether, explicit policies that deny access and/or

opaque and indiscernible policies concerning whether transition-related services are or are not covered serve to deny transgender youth and adults' access to vitally important and medically necessary transition-related health care.

To date, a comprehensive state-by-state assessment of transgender transition-related health care coverage under state Medicaid for genital GAS and GAHT has not been reported. In this work, we queried all U.S. Medicaid programs to assess the availability of 2 primary transition-related health care services (GAS and GAHT). We also sought to gain a patient-centered perspective for how easy or difficult it is to confirm Medicaid coverage for transition-related services: we tracked the burden of effort (as number of separate phone calls and total time spent on the telephone) necessary to arrive at a definitive answer regarding whether or not GAHT and GAS are covered benefits under their state's Medicaid program. And finally, we attempted to understand possible state-related predictors as to why states do or do not provide Medicaid coverage for GAS.

METHODS

We queried all 50 U.S. state Medicaid programs, plus the District of Columbia (N = 51), and the 5 U.S. territories (American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and U.S Virgin Islands) to determine whether or not each includes GAHT and GAS as covered benefits to patients who meet the treatment criteria. We used the methodology outlined in Figure 1 to confirm coverage for GAHT, and the methodology outlined in Figure 2, to confirm coverage for GAS. We also queried whether the criteria listed for GAS, as listed on the Medicaid Program Handbook and webpages, aligned with World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) guidelines for GAS.[13]

We included the 5 U.S. territories in our search after consulting the national Medicaid program webpages (www.medicaid.gov) to confirm that federal Medicaid programs operates in all 5 territories.[27]

Methodologic Approach

[Step 1] We Searched Each State Medicaid Program Website/Webpages to Confirm Coverage

We began by first reviewing each state's online Medicaid Handbook and program webpages to determine whether these featured any explicit written policy regarding coverage of gender transition–related GAHT and GAS. We reviewed any content related to eligibility criteria for GAS to determine whether this reflected 4 principal WPATH SOC guideline requirements for GAS: 1. diagnosis of gender dysphoria; 2. use and tolerance of GAHT for ≥1 year before GAS; 3. social transition for ≥1 year before GAS; and 4. two referral letters from mental health providers that support readiness for GAS.[13]

If states had explicitly written policies that indicated that GAHT and/or GAS are covered benefits, we recorded their policy and a URL link to the policy statement both for documentation and to serve as a reference for the public (Supplementary Table 1).

[Step 2] We Called State Medicaid Program Offices Directly

When state and U.S. territory Medicaid program webpages did not have explicit written policies regarding Medicaid coverage for GAHT and GAS, we called the state Medicaid office for each state and spoke with health care services representatives to confirm whether GAHT and GAS were classified as a covered benefit.

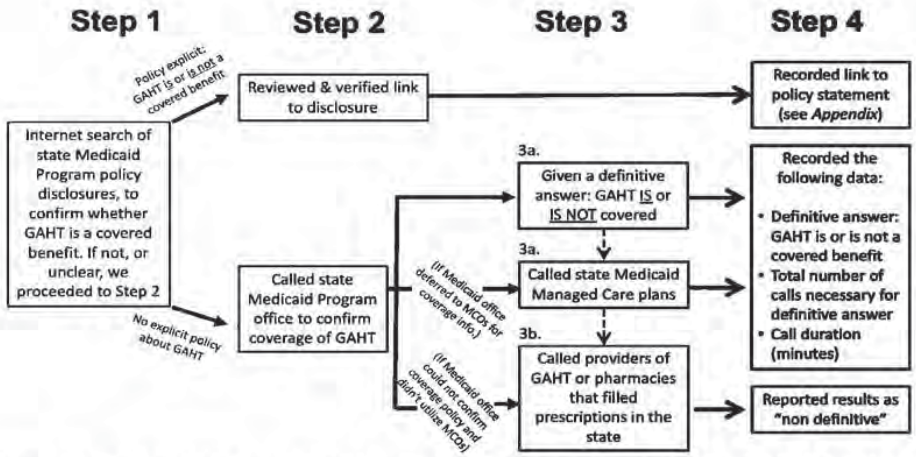

Figure 1. Flowchart outline of our study approach and methods to confirm Medicaid coverage for GAHT on for each U.S. state and territory. GAHT = gender-affirming hormone therapy. Figure 1 is available in color online at www.jsm.jsexmed.org.

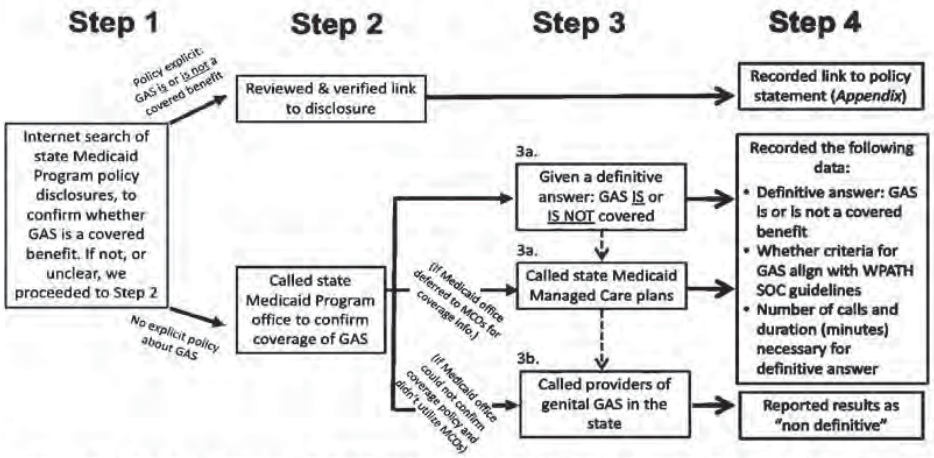

Figure 2. Flowchart outline of our study approach and methods to confirm Medicaid coverage for GAS on for each U.S. state and territory. GAS = gender-affirming surgery. Figure 2 is available in color online at www.jsm.jsexmed.org.

If the Medicaid Program Office was unable to confirm a coverage policy, the state or territory was classified by us as "indeterminate". If the Medicaid program representative requested information that no patient could reasonably provide (eg, surgery current procedural terminology [CPT] or treatment CPT codes), or do (eg, if the representative recommended that we consult a physicians-only hotline to inquire about coverage, or that the patient's surgeon submit a preauthorization request form for GAHT or GAS), we proceeded to classify the state or territory as "indeterminate".

If the Medicaid office representative could not confirm whether CHT or GAS is covered benefits, we proceeded to step 3 (below).

[Step 3] When the State Medicaid Program Office Could Not Confirm Coverage of GAHT or GAS, We Contacted [3a.] Medicaid Managed Care Organizations and/or [3b.] Local Providers to Confirm Coverage

[3a.] Each state Medicaid Program office that could not confirm whether GAHT or GAS is or is not a Medicaid-covered benefit was asked whether their state or U.S. territory Medicaid program defers to managed care organizations (MCOs) for policy regarding coverage of GAHT and GAS. If the answer to this question was either a definitive "no" (eg, because state policy specifically prohibits coverage by Medicaid funds) or "not applicable" (eg, when a given state or territory has no Medicaid MCOs), the state or territory's Medicaid program was classified as "indeterminate" for whether or not GAHT and GAS are covered benefits under Medicaid.

However, if the Medicaid program office was at all uncertain about coverage, before classifying it as "indeterminate", we requested the contact information for any MCO that the state or territory contracts with and we contacted these directly to confirm coverage. We contacted each organization (or up to a maximum of 7) by telephone until at least one responded that they do cover GAHT or GAS, or, until all MCOs confirmed that they do not cover GAHT or GAS.

If any of the MCOs that we contacted deferred confirmation about coverage to completion of a requirement that we believe a patient could not reasonably complete (eg, 1. the patient's physician consult a "physician-only" consultation hotline for further inquiry, or 2. the patient provide specific CPT codes for GAHT and/or GAS), we classified the MCO's coverage of GAHT and GAS as "indeterminate".

Only application of the research methodology described in 1-3a. above resulted in a definitive and final classification of all states/territories' Medicaid programs into one of 3 groups regarding Medicaid program coverage of GAHT and GAS: "does cover", "does not cover", or "indeterminate".

[3b.] For all states/territories whose coverage of GAHT or GAS was still classified as "indeterminate" after completing research method steps 1-3a., we attempted to collect circumstantial evidence of coverage of GAHT/GAS by their state/territory Medicaid programs by contacting individual GAHT/GAS providers to query their own experiences providing these services under Medicaid coverage. We performed an internet-based search for a minimum of 2 GAHT and 2 GAS providers and contacted them by telephone to ask whether they (or colleagues they know personally) have ever successfully provided GAHT and/or GAS under coverage by their state/territory's Medicaid program. When more than 2 providers of GAHT or GAS operated within a state, we would choose to contact the first 2 which appeared through our internet-based search. (For GAHT, we extended the definition of "providers" to pharmacies affiliated with transgender community centers and clinics).

Results from research method step 3b. were recorded, but all states/territories for whom research method step 3b. was performed to query Medicaid coverage for GAHT/GAS were still given a final classification of "indeterminate", given the circumstantial and subjective nature of this research method.

[Step 4] Data Analysis

We recorded and analyzed the following data points for all states/territories:

1. Whether or not a given state/territory's Medicaid program did or did not include GAHT and/or GAS as a covered benefit;
2. For states/territories whose Medicaid programs state explicitly on their webpages that they do cover GAS, we recorded whether the eligibility criteria for these services align with current WPATH SOC guidelines eligibility criteria for GAS;
3. We created a record of any conflicting information or unusual experiences from contacting states/territories' Medicaid program and MCO service representatives.
4. For all state Medicaid programs/MCOs that we contacted by telephone (steps 2-3a.), we recorded the total number of individual phone calls and total call duration (minutes) that was necessary to definitively confirm coverage. We excluded from these calculations any calls/time spent contacting individual providers (ie, step 3b.).

When states/territories' Medicaid Handbook or webpages featured their benefits coverage policy for GAHT/GAS, we recorded the URL to this written policy as a reference tool for patients and providers.

Associations between outcomes were calculated as the nonparametric Spearman rank correlation (r_S), and were considered significant where $P < .05$.

RESULTS

We completed methods steps 1-3b. for 51 U.S. states (includes the District of Columbia) (N = 51 states) and all 5 U.S. territories (American Samoa, Guam, Northern Mariana Islands; Puerto Rico; U.S. Virgin Islands) for GAHT (Figure 3 and Figure 4) and GAS (Figure 5 and Figure 6).

Gender-Affirming Hormone Therapy

Methods, step 1: Our review of each state/territory's Medicaid Program webpages found that only 12 of 51 states listed any explicit policy on their web content regarding whether GAHT is or is not a covered benefit. All 12 states with an explicit policy stated that they do cover GAHT. No state or U.S. territory's web content announced a policy that they do not cover GAHT. Owing to an absence of explicit policy the remaining 39 of 51 states and all 5 territories were classified as "indeterminate" (Figure 3).

Methods, step 2: We began step 2 with 39 states and all 5 U.S. territories still classified as "indeterminate". After telephoning these 39 states' Medicaid program offices, we confirmed that 10 of 39 do cover GAHT, whereas 4 of 39 do not cover GAHT. The remaining 25 of 39 states remained classified as "indeterminate" (Figure 3).

U.S. territories: We called the Medicaid program contact telephone number listed on the Federal Medicaid website for each of the territories.[28] 2 of the 5 territories confirmed that they do not cover GAHT. The Medicaid program office of 1 territory (Puerto Rico) could not confirm whether GAHT is or is not a covered benefit, and for the remaining 2 territories (Guam and U.S. Virgin Islands) there was no answer to our telephone calls. All 3 territories (Guam, Puerto Rico, and U.S. Virgin Islands) were classified as "indeterminate" (Figure 3).

Methods, step 3a: We began with 25 states and 3 U.S. territories still classified as "indeterminate". The Medicaid programs for 20 of these 25 states and for 1 U.S. territory deferred questions about coverage of GAHT to their Medicaid MCOs and directed us to contact their state's MCOs to confirm coverage. Upon calling, we identified 12 of 20 states with at least one MCO that confirmed that they do cover GAHT and 5 of 20 states whose MCOs *all* confirmed that they do not cover GAHT. (There was one exception: for Texas, only 4 of 7 MCOs stated that GAHT was not a covered benefit for their MCO or any other Texas MCOs, whereas the remaining 3 MCOs were "not certain" about coverage ("indeterminate"). We ultimately classified this state as one that does not cover GAHT.) MCOs from the remaining 3 of 20 states (Arkansas; Nebraska; Tennessee): none stated that they do cover GAHT; a small number stated that they do not cover GAS, and the majority from each state could not confirm whether GAHT is or is not a covered benefit. These 3 states were classified as "indeterminate."

U.S. territories: One of Puerto Rico's MCOs confirmed that GAHT is not a covered benefit, but the majority could not confirm whether it is or is not a covered benefit. For this reason, Puerto Rico was ultimately classified as "indeterminate".

Summary of results to confirm coverage for GAHT under Medicaid by methods steps 1-3a: States with an explicit written policy regarding coverage of GAHT as a covered benefit: 12 of 51; States that do cover GAHT: 34 of 51; States that do not cover GAHT: 9/51; States classified as "indeterminate": 8 of 51.

U.S. territories: U.S. territories with an explicit written policy regarding coverage of GAHT: 0 of 5. Territories we confirmed that do cover GAHT: 0 of 5. U.S. territories we confirmed that do not cover GAHT: 2 of 5. U.S. territories classified as "indeterminate": 3 of 5 (Figures 3 and 4).

Methods, step 3b: We began with 8 states and 3 U.S. territories still classified as "indeterminate". We identified at least 2 providers of GAHT per state by internet search and contacted them to confirm whether they have had success providing GAHT under coverage by Medicaid. Providers from 4 of 8 states reported that they have provided GAHT to patients under

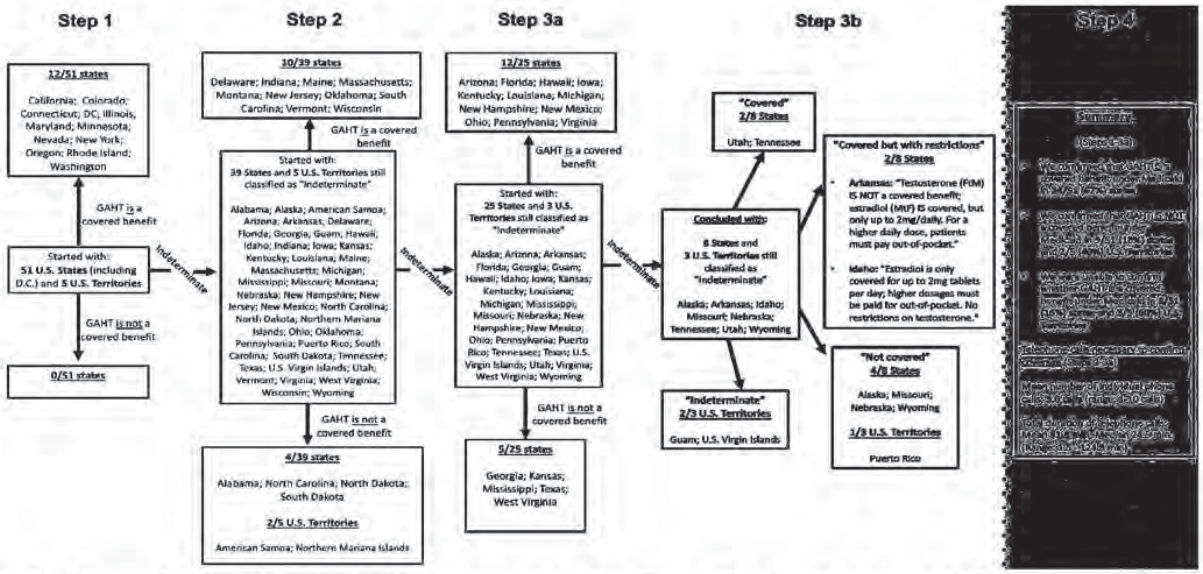

Figure 3. Flowchart outline of our results obtained through our step-by-step methodology to confirm Medicaid coverage for GAHT. GAHT = gender-affirming hormone therapy. Figure 3 is available in color online at www.jsm.jsexmed.org.

Medicaid coverage (although 2 of 4 reported specific restrictions to coverage; see Figure 3), whereas providers from the remaining 4 of 8 states reported they have not had success providing GAHT under Medicaid.

U.S. territories: We were able to identify a single provider of GAHT by internet search in only 1 territory (Puerto Rico); the provider reported that Medicaid in Puerto Rico "does not cover" GAHT (Figure 3).

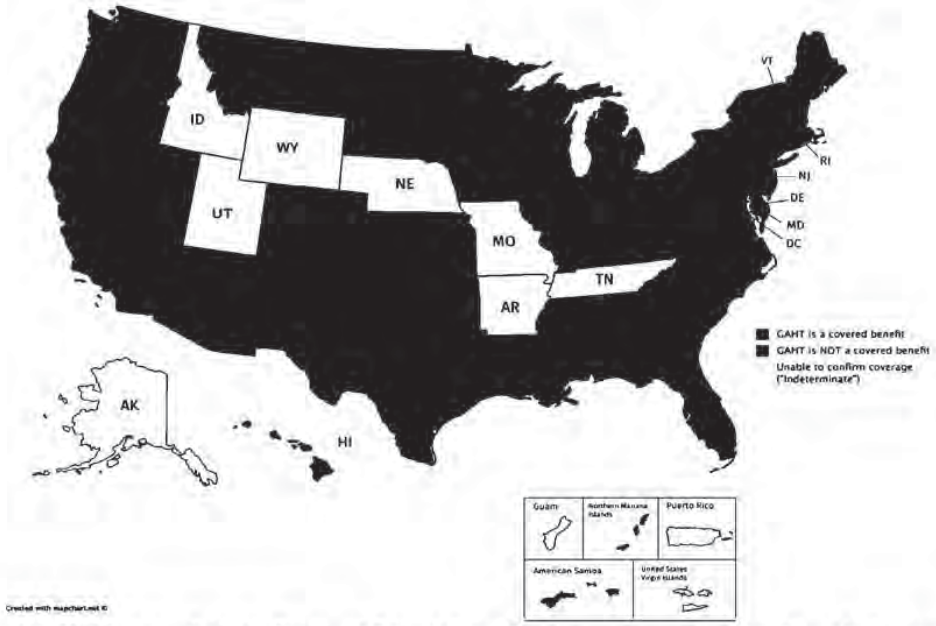

Figure 4. Maps of all 51 U.S. states (includes District of Columbia) and 5 U.S. territories, colored based on whether our work confirmed whether GAHT is a covered benefit (green), is not a covered benefit (red), or whether coverage remains "indeterminate". GAHT = gender-affirming hormone therapy. Figure 4 is available in color online at www.jsm.jsexmed.org.

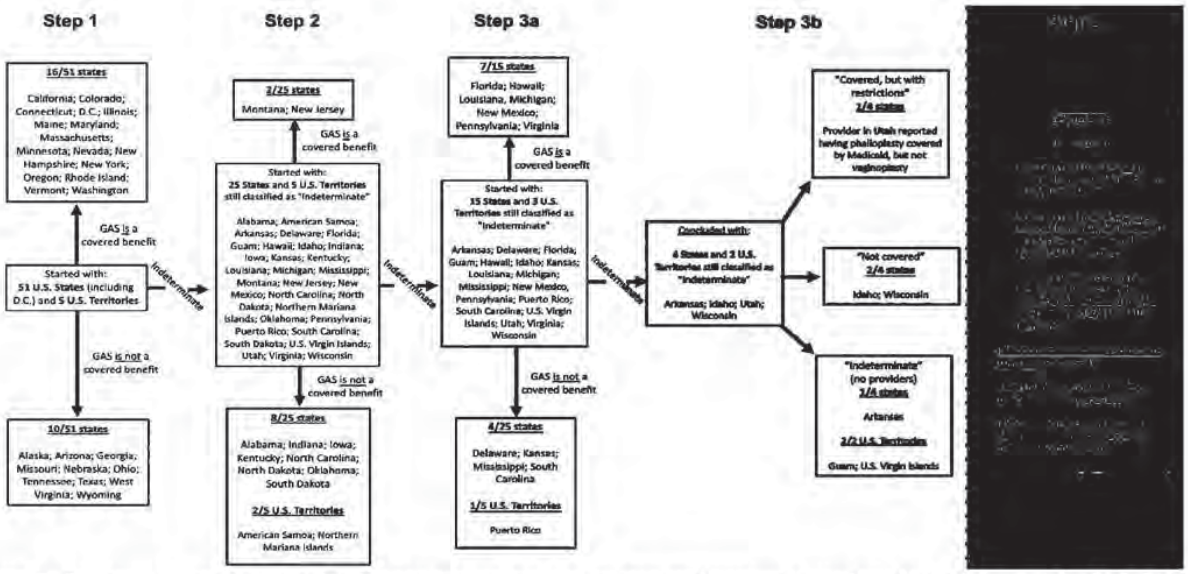

Figure 5. Flowchart outline of our results obtained through our step-by-step methodology to confirm Medicaid coverage for GAS. GAS = gender-affirming surgery. Figure 5 is available in color online at www.jsm.jsexmed.org.

Methods, step 4: The mean number of individual phone calls necessary to complete steps 2-3a. was 3.0 calls (range 1-10). Mean and median call duration were 31.8 min and 24.5 min, respectively; range was 1.5-124.8 min (Figure 3).

Genital Gender-Affirming Surgery

Methods, step 1: Our review of each state/territory's Medicaid program webpages found that only 26 of 51 states featured any explicit policy regarding whether or not GAS is a covered benefit:

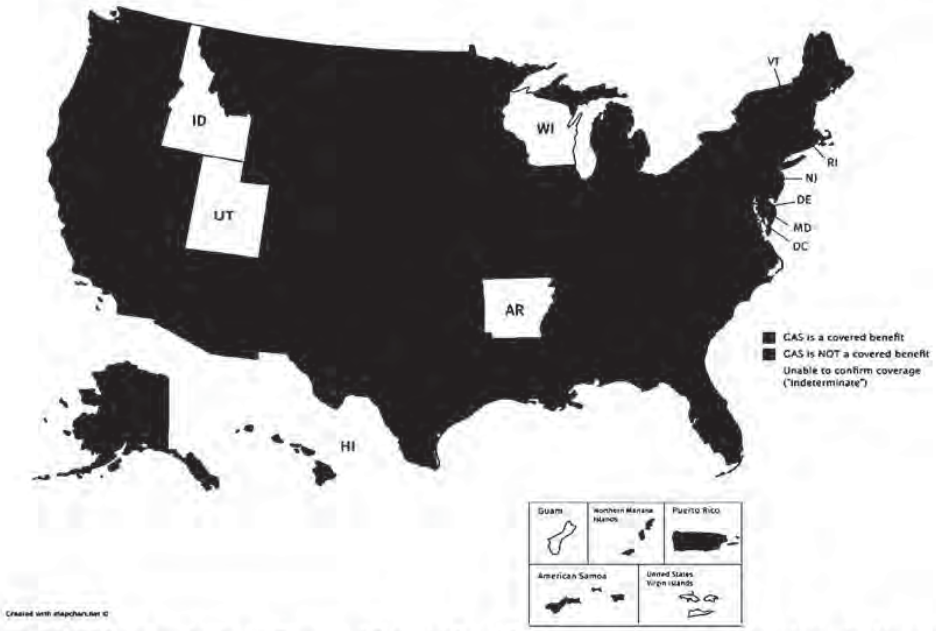

Figure 6. Maps of all 51 U.S. states (includes District of Columbia) and 5 U.S. territories, colored based on whether our work confirmed whether GAS is a covered benefit (green), is not a covered benefit (red), or whether coverage remains "indeterminate". GAS = gender-affirming surgery. Figure 6 is available in color online at www.jsm.jsexmed.org.

16 states had content that clearly states that their Medicaid program benefits do cover GAS, whereas 10 states clearly state that their Medicaid program benefits do not. We found that for the 16 states which do cover GAS, 15 of 16 explicitly specify eligibility criteria that align with the Transgender Health (WPATH) SOC guidelines.

U.S. territories: No territory's Medicaid program web content featured any policy statement regarding transgender health care. The remaining 25 of 51 states and all 5 U.S. territories were classified as "indeterminate" (Figure 5).

Methods, step 2: We began step 2 with 25 states and all 5 U.S. territories still classified as "indeterminate". After telephoning these 25 states' Medicaid program offices, we confirmed that 2 of 25 do cover GAS, and 8 of 25 do not cover GAS. The remaining 15 of 25 states remained classified as "indeterminate".

U.S. territories: We called the Medicaid program contact telephone number listed on the Federal Medicaid website for each of the territories.[28] 2 of the 5 territories confirmed that they do not cover GAS. The Medicaid program office of 1 territory (Puerto Rico) could not confirm whether GAS is or is not a covered benefit, and for the remaining 2 territories (Guam and U.S. Virgin Islands), there was no answer to our telephone calls. All 3 territories (Guam, Puerto Rico, and U.S. Virgin Islands) were classified as "indeterminate" (Figure 5).

Methods, step 3a: We began with 15 states and all 5 U.S. territories still classified as "indeterminate". The Medicaid programs for 13 of the 15 states and 1 U.S. territory classified by step 2 as "indeterminate" deferred questions about coverage of specific services to their Medicaid MCOs and directed us to contact their state's MCOs to confirm coverage. On calling these, we identified 7 of 13 states with at least one MCO that confirmed that they do cover GAS, whereas all* of the MCOs from 4 of 13 states confirmed that they do not cover GAS. (South Carolina was an exception: 4 of the 5 state MCOs stated that GAS is not a covered benefit whereas 1 was "not certain" about coverage ["indeterminate"]. We classified this state as one that does not cover GAS). MCOs from the remaining 2 of 13 states (Arkansas and Wisconsin): none stated that they do cover GAS; a small number stated that they do not cover GAS, and the majority from each state could not confirm whether GAS is or is not a covered benefit. These 2 states were classified as "indeterminate."

U.S. territories: We contacted Puerto Rico's MCOs and confirmed that these do not cover GAS.

Summary of results to confirm coverage for GAS under Medicaid by methods steps 1-3a: States with any explicit written policy regarding coverage of GAS as a covered benefit: 26 of 51; States that we found do cover GAS: 25 of 51; States that do not cover GAS: 22 of 51; States classified as "indeterminate": 4 of 51.

U.S. territories: U.S. territories that do cover GAS: 0 of 5; U.S. territories that do not cover GAS: 3 of 5; U.S. territories classified as "indeterminate": 2 of 5 (Figures 5 and 6).

Methods, step 3b: We began with 4 states and 2 U.S. territories still classified as "indeterminate". We identified only 1 provider of GAS in 3 of the 4 states (Idaho, Utah, Wisconsin) and 0 providers in the fourth state (Arkansas). We found 0 providers in the 2 U.S. territories. The single provider from one of these 3 states (Utah) reported successfully providing GAS to patients under Medicaid coverage, although with restrictions: (masculinizing GAS [phalloplasty] is covered, but feminizing GAS [vaginoplasty] is not covered (see Figure 5). All providers from the remaining 2 of 3 states reported no success providing GAS under Medicaid reimbursement.

U.S. territories: We could not identify any providers of GAS by internet search in the remaining 2 territories (Figure 5).

Methods, step 4: The mean number of individual phone calls necessary to complete steps 2-3a. was 3.3 calls (range 1-12). Mean and median call duration were 33.2 min and 25.1 min, respectively; range was 1.5 - 119.8 min.

We compiled a list of the U.S. states for whom we found explicit policy disclosure in their web content regarding whether or not GAHT and/or GAS is a covered benefit under their state Medicaid program, with an accompanying link to that disclosure (Supplementary Table 1). We also compiled a list of the Medicaid MCOs which confirmed covering GAHT and/or GAS (Supplementary Table 2).

Associations

Currently 25 states have passed non-discrimination laws that specifically outlaw health care plan provisions that allow insurers to refuse outright coverage for gender transition—related health care. There is a significant correlation between Medicaid programs that cover GAHT ($r_S = 0.61$, $P < .01$) and GAS ($r_S = 0.87$, $P < .01$) and states that have passed these non-discrimination laws. In addition, 14 states have not adopted Medicaid expansion per the ACA. We found that there is a significant correlation between states whose Medicaid programs do not provide coverage for GAHT ($r_S = 0.56$, $P < .01$) and GAS ($r_S = 0.62$, $P < .01$) and states that have not adopted the expansion of Medicaid under the ACA.

DISCUSSION

Our work shows that access to GAHT and GAS for people who depend on Medicaid for their health care remains limited and not uniformly distributed throughout the United States. Our research study had 3 aims: first, to provide an assessment that is as definitive as possible regarding coverage for gender transition—related health care in the literature to date; second, to provide a better understanding of the "patient experience" for those who depend on Medicaid and seek to confirm access to transition-related care (ie, how easy or difficult is it to confirm access to care); and third, to try to understand possible state-related predictors as to why states do or do not provide Medicaid coverage for gender-affirming care.

Regarding our first study aim, our approach allowed us to confirm that GAHT is a covered benefit under Medicaid in only ~ two-thirds of the U.S. states (34/51, 67%) (Figure 3), and that GAS is a covered benefit in only close to half (25/51, 49%) of all the U.S. states (including the District of Columbia) (Figure 5), all despite an abundance of evidence based data that shows that gender transition—related care in these domains improves quality of life and decreases health care—related costs.[10,12–15] Such data are cited in the Federal Government's nationwide Medicare policy Handbook as the basis for why care is a covered benefit under Medicare. In addition to how gender transition—related care helps individual patients, access to it serves our health care system and society in immeasurable ways as well, especially when we consider the fact that 1 in 5 Americans depends on Medicaid for health care, as transgender people are significantly more likely to be uninsured[16,29,30] and depend on Medicaid and/or health care from "urgent care" settings. High incidence of depression, anxiety, and status as "medically disabled" (related to depression and anxiety) pre-transition[13,14,31,32] contribute to high rates of unemployment (and as a consequence, dependence on the public health care system), and suggests that access to gender transition health care would help transgender people enter the workforce.[33–35] These findings closely correlate with the results of the 2015 National Transgender Survey which found that 55% of respondents reported being denied coverage for transition-related surgery, and 25% reported being denied coverage for transition—related hormone therapy treatment.[3] Several states indicated to us that coverage for GAS is denied because of the states position that gender reassignment surgery falls into the "cosmetic surgery" or "elective surgery" designation. This argument is contradictory to the position of several professional organizations (including the American Medical Association[36] and American Public Health Association[37]) which have endorsed classifying gender affirming health care such as GAHT and GAS as "medically necessary" treatments for transgender individuals suffering from gender dysphoria.

There were several notable findings from our study that warrant consideration.

Why does Medicaid cover gender transition—related health care in only a limited number of states, whereas Medicare (a federal program) covers it in all states? This is most likely explained by the fact that Medicaid is a combined federal and state program, managed by each state's government policies. Any opposition to coverage must either originate, or at a minimum pass through, each state's policy-making bodies. Although such opposition could be from medical-scientific disagreement with empiric data showing that gender transition—related health care improves quality of life and decreases costs to our health care system, our work found no evidence of writings or debate arguing that these data were incorrect, or, suggesting that transgender people were better served without gender transition—related health care among the states that explicitly deny or are silent about coverage. However, we did find that, by contrast, virtually all states that do cover transition-related care have webpage content which announced to the public that they do so and explained the rationale for their policy. All of these states' Medicaid program web-based content either states explicitly that any policy that denies access to transition-related care is discriminatory, and/or that transition-related care is recognized as "medically necessary".

We have also considered how to explain why, as our work showed, some state Medicaid programs cover gender transition—related services, whereas others do not. Given the abundance of empiric data that supports the benefit to patient quality of life, and cost-savings to state health care systems, it is hard to understand why some states would make such services inaccessible under Medicaid. We cannot answer this question definitively, but, results from our work leads us to conjecture that why some states' Medicaid programs do and others do not cover GAHT and GAS depends on whether or not the state (Medicaid program and state legislators that oversee it) view denial of access to these services as discrimination. For example, our work found that of the 25 states whose Medicaid programs cover GAS, 23 of these states have passed non-discrimination laws that specifically outlaw health care plan provisions that allow insurers to refuse outright coverage for gender transition—related health care.[38,39] This association was found to be significant ($r_S = 0.87$, $P < .01$). This will be an important observation to monitor in light of the June 12th, 2020, U.S. Federal Government policy announcement that it would direct the Department of Health and Human Services to more narrowly define sex discrimination in health care as being based on an individual's biological birth sex, while excluding both gender identity and sexual orientation as bases of discrimination. This policy would make it legal for health insurers to deny coverage for medically necessary gender transition—related health care and services.

Medicaid expansion became effective January 1st, 2014, and allowed for the expansion of Medicaid eligibility to individuals and families with annual incomes at or below 138% of the federal poverty line. The expansion of Medicaid inclusion is of particular importance to the U.S. transgender population as a 2015 national survey of transgender individuals found that 38% of respondents had household incomes that would fall within the Medicaid expansion range.[3] We observed a significant correlation between states whose Medicaid programs do not provide coverage for GAHT and GAS and states who have not adopted the expansion of Medicaid under the ACA.[40] Currently 14 states have not adopted Medicaid expansion per the ACA. Our study found that GAHT and GAS are not covered benefits in 7 of 14 (50%, $r_S = 0.56$, $P < .01$) and 12 of 14 (86%, $r_S = 0.62$, $P < .01$) of these states, respectively.

Another finding from our work which warrants consideration is that among the state Medicaid Programs that do cover GAHT (34/51) and GAS (25/51) (methods, steps 1-3A), only a relatively small fraction of these states advertised their coverage

Table 1. Inconsistent responses regarding coverage for GAS we encountered when it was necessary to call some state Medicaid program offices twice (methods, step 2)

	Responses from state Medicaid office	
State	State Medicaid Office response: FIRST telephone call (*Methods Step 2*)	State Medicaid office response: SECOND telephone call (*Methods Step 2*)
Michigan	Told "GAS *is* a covered benefit if 'medically necessary'"	Told "we cannot confirm if GAS is a covered benefit"
Mississippi	Told "GAS is *probably* not a covered benefit"	Told "procedure codes are required in order to confirm if GAS is a covered benefit"
Utah	Told "GAS is *generally* not a covered benefit, but has been covered in the past"	Told "GAS *is not* a covered benefit"
Virginia	Told "GAS is not a covered a covered benefit"	Told "procedure codes are required in order to confirm if GAS is a covered benefit"

GAS = gender-affirming surgery.

policy on their Medicaid program web content (for GAHT only 12 of 34 states did so, and for GAS, only 16 of 25 states did so). At face value, it makes sense for a program to clearly state their coverage policies, as doing so not only serves the public interest (ie, yields good patient/customer experience), but also reduces un-necessary phone calls with questions to the Medicaid program patient help hotlines. It is possible that the reason that the states whose Medicaid programs do cover these services but do not state doing so on their Medicaid program web content do so under the influence of Medicaid services administrators and/or state legislators, and/or providers opposed to providing these services to transgender people. However, we did consider other explanations too: some state Medicaid programs may not disclose coverage of transition-related health care services because they have "too few" or "no" transgender care—specialized providers. This explanation seems less likely; however, given that most all states today have at least some transgender-dedicated clinics and providers.

A question that no state's Medicaid Program Handbook or webpages addressed is what options patients have when their state Medicaid does cover less commonly offered services such as GAS, but there are either no providers within the state who do GAS, or, there are no providers within the state who accept Medicaid reimbursement for GAS. In such cases, despite benefits "coverage", Medicaid patients will go without care. It would be helpful for patients if Medicaid programs addressed this difficult situation, and offered options such as allowing patients to receive treatment from out of state Medicaid providers.

The second aim of our research was to provide an estimate of how easy or difficult it is for patients to simply confirm whether their state Medicaid program benefits cover transition-related care. How much effort should patients be expected to have to expend to confirm whether or not their insurance covers a medically necessary service? If we assume that a "reasonable effort" constitutes 1. An internet search of their state's Medicaid Program web-based Services Handbook (which is specifically designed for public use to answer such questions), and/or 2. A telephone call to the Medicaid program patient services hotline to confirm coverage (our methods steps 1-2), then our findings suggest that more than half of U.S. states do not meet this standard. For example, by our research methods steps 1-2, we were able to confirm a clear policy regarding coverage of GAHT in only 26 of 51 (51%), and for GAS in only 36 of 51 (71%) of the states. It is our opinion that it is not reasonable to expect patients to have to do more than steps 1 and 2 simply to confirm whether or not they have access to medically necessary transition-related care. It should be noted that the aforementioned statistics do not address the negative impact on patients when the "explicit policy" is to deny coverage for transition-related GAHT and GAS.

The process to confirm access to care is time-consuming. Patients who would have to make telephone calls, as we did, to complete methods steps 2-3A (calling state Medicaid offices and Medicaid MCOs) to confirm services for GAHT (76% of states) and GAS (49% of states) must spend a significant amount of time on the telephone to confirm coverage: for GAHT, an average of 31.8 minutes (range 1.5-124.8) over an average of 3.0 calls (range 1-10) (Figure 4), and for GAS, an average of 33.2 minutes (range 1.5-119.8) over 3.3 calls (range 1-12) (Figure 5). These results do not include the time that was required to review state's Medicaid Program web-based Services Handbooks (methods, step 1) which can also be significantly time-consuming. A recent study found that it can take on average > 50 min to review a private insurance company's online insurance information to determine gender transition—related coverage.[41]

Besides being time-consuming, the process to confirm access to gender transition—related care under Medicaid can be frustrating for patients in other ways. For example, information from the Medicaid office was most often not straight-forward; representatives at state Medicaid offices would often ask us to call other departments (pharmacy/billing), individual state insurance plans, or direct supervisors to obtain coverage information. Such time delays and need for multiple telephone "hand-offs" during a single call disfavors patients who work during normal business hours and cannot afford extended time for telephone calls, and people with language barriers and/or modest communication skills.

The process to confirm access to gender transition–related care under Medicaid can also be opaque and contradictory (Table 1). For example, nearly all states and territories initially classified as "indeterminate" required at least one additional follow-up phone call to confirm coverage (methods, steps 2 and 3A). During these follow-up phone calls, we often received answers/responses regarding whether or not GAHT/GAS are covered benefits that contradicted previous statements from the same Medicaid program office or MCO (Table 1). We estimate that telephone calls to approximately 50% of all states classified as "indeterminate" yielded contradictory information of the types shown in Table 1.

Some telephone call exchanges with Medicaid representatives were notable for responses that were "negatively uncertain". For example, Medicaid program representatives from some states responded that while their Medicaid program has covered GAS in the past, coverage is "typically an exception", and is as such, "not common." Some Medicaid program representatives said that they "have been instructed to say" that GAS and/or GAHT are "generally not covered."

Finally, representatives from some states' Medicaid program offices (Alaska, Georgia, Idaho, Mississippi, Missouri, Tennessee, Texas, Utah, Virginia, and Wyoming) told us by telephone that they could only confirm whether GAHT and/or GAS are covered benefits if we provided CPT (medical procedure) codes, or, unless the patient's physician called a specific telephone hotline to inquire. Opaque, contradictory and/or "negatively uncertain" responses from Medicaid program office representatives are likely frustrating and discouraging for transgender patients, and for some, could possibly encourage distrust of their Medicaid health care system.

Strengths and Limitations

A strength of our study is that our research group has expertise in the very services we were inquiring about, as we are a high-volume tertiary-care center for gender-affirming care that includes genital GAS and GAHT, which regularly provides these services to patients covered by both Medicaid- and Medicaid-managed care plans. As such, we are likely more adept at navigating Medicaid services than the average patient. Another strength of the study design is that to better understand barriers actual patients face, we acted as proxies for real Medicaid patients and approached confirming access to care as a real patient seeking services might: by using the internet and contacting their state's Medicaid program office. However, despite our expertise with transgender health care, we were careful to not leverage this expertise in the course of our inquiries, as this would make the findings we report less representative of what actual patients experience. For example, some Medicaid programs requested surgical procedure CPT codes before they could confirm the availability of surgical services. We did not provide these as doing so would be out of line with what information that an actual patient could be expected to provide.

A limitation of our study design is that in an effort to more definitively determine whether GAS and GAHT are or are not available in a given state, it could be that we were more adept at navigating Medicaid Program office helplines and/or we were persistent than some actual patients would be. If so, this would bias our results to underestimate how long it takes for a real patient to correctly conclude whether GAS and GAHT are or are not covered benefits in their state. Another limitation of our study is that we did not confirm which specific hormone formulations or specific genital gender affirming procedures would or would not be covered by each state's Medicaid programs. Drug formulation and surgical procedure–specific details are not information that a Medicaid office can readily access or share. In addition, these details would presumably vary by provider, as well. It is certainly possible that some Medicaid programs or their MCOs may have distinctions regarding coverage of certain services over others, and potential Medicaid enrollees should continue to work with their insurance carriers and health care providers to ensure that their healthcare needs will be covered.

CONCLUSIONS

By our research approach, we were able to confirm that GAHT and genital GAS are covered benefits under the Medicaid programs in only 34 of 51 (67%) and 25 of 51 (49%) states, respectively, and in none of the 5 U.S. territories. Our work found that the process to confirm coverage of these services by individual state Medicaid programs is opaque, time-consuming, and represents a barrier to care that warrants improvement. We speculate that based on our findings the strongest predictor for whether or not a state's Medicaid program includes gender transition–related care as a covered benefit is whether or not it has legal statutes in place that recognize denial of care based on gender identity as discriminatory. To date, this is the most thorough work to confirm coverage of these services nationwide.

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jsxm.2020.11.016.