UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

CODY FLACK, SARA ANN MAKENZIE, MARIE KELLY, and COURTNEY SHERWIN, Plaintiffs, v. WISCONSIN DEPARTMENT OF HEALTH SERVICES and LINDA SEEMEYER, in her official capacity as Secretary of the Wisconsin Department of Health Services, Defendants.	Case No. 3:18-cv-00309-wmc Judge William Conley

SUPPLEMENTAL EXPERT WITNESS DECLARATION OF JACLYN WHITE HUGHTO, PhD, MPH

I, Jaclyn White Hughto, PhD, MPH, declare as follows:

1. I have been retained by counsel for Plaintiffs as an expert in the above-captioned lawsuit. I submitted an expert witness declaration [Dkt. No. 26] ("Hughto Dec.") with Plaintiffs' Motion for a Preliminary Injunction in this case [Dkt. No. 18]. I prepared this supplemental declaration to be submitted with Plaintiffs' motion for a class-wide preliminary injunction. In this supplemental declaration, I address the potential cost impact to the Wisconsin Medicaid program if the exclusion on gender-confirming surgical care is lifted or enjoined. I also respond to the report of David V. Williams submitted to this Court by Defendants on August 23, 2018 regarding the estimated cost to the State of Wisconsin of covering gender-confirming surgeries for Wisconsin Medicaid enrollees [Dkt. No. 74-1] ("Williams Report").

2. My background, qualifications, and compensation for my services in this case, and the basis for my opinions in this case are described in my original declaration and in my C.V. attached to that declaration.

3. In preparation for this declaration I consulted the following sources: (1) reports from leading governmental agencies (e.g., Center for Disease Control and Prevention, National Institute of Health) and non-governmental organizations (e.g., Kaiser Family Foundation) documenting the prevalence and costs associated with various health outcomes, including suicide, violence, and substance use, as cited in the list of references to this report (attached as Exhibit A); (2) the Williams Report; and (3) a number of reports estimating the costs of gender-confirming care (attached as Exhibits B-E).

4. I have actual knowledge of the matters stated in this supplemental declaration.

Summary of Opinions

5. In my professional opinion, the elimination of the Medicaid exclusion for gender-confirming surgeries would result in minimal short-term costs to the State of Wisconsin and would lead to significant longer-term cost savings for the State.

6. The removal of Wisconsin's categorical exclusion of Medicaid coverage for gender-confirming surgeries would have a minimal impact on the state budget. According to the State's own expert, Mr. Williams, the estimated annual cost of covering gender-confirming surgeries would be approximately $300,000, which represents only 0.008% of the State's share of annual Medicaid spending, which is approximately $3.9 billion.[1]

[1] The total annual Wisconsin Medicaid expenditures are approximately $9.7 billion, including the federal contribution, which comprises approximately 59.6 percent of the total. *Flack v. Wis. Dep't of Health Servs.*, No. 18-CV-309-WMC, 2018 WL 3574875, at *3 (W.D. Wis. July 25, 2018); Williams Report at 3.

7. Further, the State's expert failed to account for the short- and long-term cost savings associated with covering gender-confirming surgeries under Wisconsin Medicaid. It is my opinion that coverage of these services would provide significant benefits for transgender individuals on Wisconsin Medicaid, including reductions in gender dysphoria, depression, anxiety, suicidality, substance abuse, HIV transmission and acquisition, and physical and sexual assault, as well as improvements in socioeconomic status. Reducing these social, psychological, and physical health harms is anticipated to offset the cost of providing gender-confirming surgeries to eligible Medicaid beneficiaries in Wisconsin, ultimately producing savings for the State.

Evaluating the Estimated Costs of Covering Gender-Confirming Surgeries

8. The Williams Report estimated that 63 of Wisconsin's 1.2 million Medicaid beneficiaries (0.005%) will undergo some form of gender-confirming surgery in a given year.[2] Drawing on an expected cost to the State per surgical patient of $5,998, the Williams Report estimated that the total cost of treating transgender surgical patients under Wisconsin Medicaid would be approximately $300,000 a year. That figure represents only 0.008% of Wisconsin's annual Medicaid expenses.[3] For the reasons explained below, even this minimal cost impact is likely overstated because Williams did not account for the short- and long-term cost savings associated with covering medically-necessary, gender-confirming care.

9. Exclusionary state Medicaid policies not only create inequitable access to needed care for transgender Medicaid recipients but, as documented in my initial declaration, such

[2] Although his report is not clear, I assume for purposes of my analysis that this estimate refers to the number of beneficiaries who would obtain surgery if they had Medicaid coverage to do so.
[3] The State's share of the $9.7 billion annual Wisconsin Medicaid expenditures is 40.6% (the other 59.4% is covered by the federal contribution). Williams Report at 3. Accordingly, the State pays approximately $3.9 billion annually in Wisconsin Medicaid expenses. The State's cost estimate for covering gender-confirming surgery is $300,000, which equals approximately 0.008% of the State's portion of the Wisconsin Medicaid budget.

policies have the potential to place affected transgender individuals at risk for a variety of negative physical and mental health outcomes (Cole, O'boyle, Emory, & Meyer III, 1997; Haas, Rodgers, & Herman, 2014; White Hughto & Reisner, 2018). Consistent with data provided in other estimates of the costs of providing insurance coverage for gender-confirming surgical care (e.g., Exhibits C, D, E), eliminating coverage exclusions for gender-confirming surgical care under Wisconsin Medicaid would lead to significant cost savings for the Wisconsin Medicaid program via reductions in the morbidity and mortality-related costs of being denied access to medically-necessary care.

10. Indeed, a recent national study analyzed the cost-effectiveness of insurance coverage for medically necessary transition-related treatments and services for gender dysphoria, including surgery (Padula, Heru, & Campbell, 2016) (attached as Exhibit E). In addition to calculating the direct financial costs of gender-confirming medical care, the study accounted for cost savings associated with reductions in negative health outcomes, including HIV, depression, suicidality, drug abuse, and mortality. The study found that while insurance coverage for medically-necessary services came at a greater cost than no health benefits, there was also greater effectiveness. Specifically, providing insurance coverage for gender-confirming medical care was deemed cost-effective, relative to no health benefit for gender-confirming care, over a 5- and 10-year period. These estimates demonstrate that the removal of transgender exclusions is affordable and cost-effective.

11. **Mental Health.** Denying access to medically-necessary, gender-confirming therapies has the potential to exacerbate gender dysphoria and lead to intense emotional suffering, anxiety, depression, self-harm, and suicidality (Bauer, Scheim, Pyne, Travers, & Hammond, 2015; Cole et al., 1997; Haas et al., 2014; Rotondi et al., 2013; White Hughto &

Reisner, 2018). Conversely, utilization of gender-confirming medical therapies is associated with improvements in psychological functioning and quality of life among transgender individuals (Murad et al., 2010; White Hughto & Reisner, 2016).

12. Examining the cost impact of suicidality alone, the Centers for Disease Control and Prevention (CDC) reports that suicide and suicide attempts cost society about $70 billion annually in medical and work loss costs (Centers for Disease Control, 2018). The CDC also estimates that the average medical costs of a single suicide completion was $2,596 and a suicide attempt was $7,234 in 2010 (Centers for Disease Control, 2012). Notably, these values represent the low end of estimated costs as they only include acute care and hospitalization costs and are not inclusive of medical costs following a suicide attempt such as mental health treatment. Given that 41% of U.S. transgender individuals in a national study had attempted suicide in their lifetime (Grant et al., 2011), and longitudinal research documents a 24% reduction in suicide attempts among transgender patients who received gender-confirmation surgery (De Cuypere et al., 2006), providing access to gender-confirming surgical care under Medicaid would likely lead to reductions in Wisconsin Medicaid expenditures associated with suicidality.

13. **Substance Use.** Research documents a disproportionately high prevalence of substance use among transgender individuals relative to the general population (James et al., 2016) and research shows that transgender individuals frequently engage in substance use as a means of coping with gender dysphoria and the mental health harms of stigma (Reisner et al., 2015; White Hughto, Reisner, & Pachankis, 2015). Tobacco, alcohol, and illicit drug use in the U.S. cost an estimated $230 billion in annual healthcare-related costs (e.g., substance use-related injuries and deaths, prevention, and treatment) alone – a value that increases to $740 billion

when the costs of crime and lost work productivity are included (National Institute of Drug Abuse, 2017).

14. Several studies have demonstrated lower levels of substance use among transgender individuals who have received gender-confirming treatments (i.e., hormones and/or surgery) relative to those who have not obtained such care (Cole et al., 1997; Rehman, Lazar, Benet, Schaefer, & Melman, 1999; Wilson, Chen, Arayasirikul, Wenzel, & Raymond, 2015). Thus, covering gender-confirming surgeries under Medicaid would likely result in the Wisconsin Medicaid program spending less on costs related to substance use (See National Institute of Drug Abuse, 2017).

15. **Physical and Sexual Assault.** Transgender individuals also experience high levels of physical and sexual assault due to the stigma of having a gender non-conforming expression or identity (James et al., 2016; Stotzer, 2009; White Hughto et al., 2015). Individuals who have accessed gender-confirming surgeries have been shown to be more visually gender conforming (Spiegel, 2011; Transgender Law Center, 2016), and visual gender conformity is associated with a lower prevalence of physical and sexual assault (Jauk, 2013; Sperber, Landers, & Lawrence, 2005). Examining intimate partner violence alone, the National Center for Injury Prevention and Control estimated that the mean cost of medical care for those who sought treatment after a physical assault by an intimate partner was $2,665 per incident in 1996 (McLean & Bocinski, 2017). For individuals seeking mental health services related to a single act of partner violence, the mean cost was $1,017 per incident in 1996 (National Center for Injury Prevention and Control, 2003). Moreover, the increased annual costs for victims may continue for up to 15 years after the cessation of abuse (Rivara et al., 2007).

16. While greater gender conformity would not necessarily prevent a transgender individual from being abused by an intimate partner, gender-confirming treatments (i.e., hormones and surgery) have been linked to reduced gender dysphoria, improved body image, and greater self-esteem (Murad et al., 2010; Nelson, Whallett, & McGregor, 2009; Sineath et al., 2016), and individuals with greater self-worth may be less vulnerable to entering into and staying in abusive relationships (Kim & Gray, 2008). Additionally, with greater visual gender conformity as a result of access to gender-confirming surgery, the physical and mental health costs of violent harassment, hate crimes, and related health systems costs are likely to decrease (Jauk, 2013). Thus, increased access to gender-confirming surgeries would likely reduce the costs to the Wisconsin Medicaid program associated with stigma-related violence for transgender Wisconsin Medicaid beneficiaries who access such surgeries.

17. **HIV/AIDS.** Transgender people have significantly higher rates of HIV than the general population. Much of the burden of HIV in the transgender community is carried by transgender women who have an estimated 21.7% laboratory-confirmed HIV prevalence (meta-analysis) and a 34.2-fold increased odds of HIV relative to the U.S. population (Baral et al., 2013). The prevalence of HIV is particularly high for low-income transgender individuals and those of color (Herbst et al., 2008). Biomedical advances such as daily medications to prevent and treat HIV (i.e., Pre-Exposure Prophylaxis ("PrEP") and antiretroviral therapies ("ART"), respectively) have the ability to prevent HIV acquisition and transmission (Cohen et al., 2011; Grant et al., 2010). However, these medications require optimal adherence in order for them to be effective in curbing the spread of HIV (Bartlett, 2002; Grant et al., 2010; Paterson et al., 2000; Singh et al., 1999). Notably, research shows that engagement in gender-confirming medical care (i.e., hormones and/or surgery) has been linked to greater engagement in HIV prevention and

treatment services, as well as better adherence to medications (Deutsch et al., 2015; Radix, Sevelius, & Deutsch, 2016; Reisner et al., 2017; Sevelius, Patouhas, Keatley, & Johnson, 2013). The Wisconsin Medicaid program spent $45,228,025 in 2013 on 1,900 enrollees with HIV/AIDS, which equated to $23,804 per enrollee (Kaiser Family Foundation, 2014). Given the enormous costs associated with the HIV epidemic, preventing new infections and reducing HIV-related morbidity and mortality through increased engagement in gender-confirming surgery and HIV-related medical care would likely lead to cost savings for the Wisconsin Medicaid program.

18. **Socioeconomic Status.** Many transgender individuals face employment discrimination as a result of their gender non-conforming identity or expression (James et al., 2016; White Hughto et al., 2015), which can lead to unemployment, low income, and Medicaid eligibility (Herman, 2011). In fact, a 2017 report estimated that the costs of job loss due to discrimination among transgender individuals in Massachusetts was $3 million dollars annually for Medicaid and Commonwealth Care, a state-funded program that provides subsidized premiums for low-income Massachusetts residents to purchase private health insurance coverage (Herman, 2011).

19. Lack of employment and financial resources may lead transgender individuals to engage in illicit activities such as sex work in order to meet basic needs, as well as to obtain the money to undergo gender-confirming treatments (Garofalo, Deleon, Osmer, Doll, & Harper, 2006; James et al., 2016). In addition to the known health risks associated with sex work (e.g., HIV infection, violence) (James et al., 2016; Nemoto, Bodeker, & Iwamoto, 2011), such activities also carry social costs for transgender individuals, such as arrest and incarceration (Grant et al., 2011; James et al., 2016). To that end, a 2016 study found that the aggregate

economic and social cost of incarceration in the U.S. exceeded $1 trillion dollars annually (Pettus-Davis, Brown, Veeh, & Renn, 2016).

20. Research finds that transgender patients who received hormonal and surgical treatment have higher socioeconomic status and are more likely to be employed following treatments than individuals without such care (Beckwith, Reisner, Zaslow, Mayer, & Keuroghlian, 2017). Moreover, a 5-year longitudinal study demonstrated improvements in socioeconomic status and employment following gender-confirming treatments (Bodlund & Kullgren, 1996). Improvements in socioeconomic status may be explained by reduced employment discrimination on account of better visual gender conformity (Begun & Kattari, 2016; James et al., 2016). Transgender individuals who feel more affirmed in their gender identity following surgery may also be more likely to pursue employment opportunities due to lessened fears of stigma-based rejection (Gagné & Tewksbury, 1998; James et al., 2016). Access to gender-confirming surgery for Medicaid beneficiaries may, therefore, lead to social and economic benefits for transgender patients, the Wisconsin Medicaid program, and the broader public, including reductions in unemployment, sex work, and related criminal justice and health system costs. Improved socioeconomic status could also lead to fewer transgender individuals needing Wisconsin Medicaid coverage following appropriate gender-confirming treatments for gender dysphoria.

Number of People Affected by the Challenged Exclusion

21. Before concluding, I want to provide additional detail on the estimated size of the transgender Wisconsin Medicaid population included in my original declaration. Hughto Dec. ¶ 49. In my declaration, I estimated that "at least 5,000 Wisconsin Medicaid recipients are transgender adults who may be affected by the surgical exclusion at some point in their lives."

While I provided some of the background data in my earlier declaration, I fully explain how I arrived at that estimate here.

22. There are approximately 1.2 million adult Medicaid beneficiaries in the state of Wisconsin. National estimates using CDC surveillance data indicate that approximately 0.43% of the Wisconsin adult population identifies as transgender (Flores, Herman, Gates, & Brown, 2016). Applying that proportion to the Wisconsin Medicaid population, it is estimated that 5,160 transgender adults in the state are on Medicaid. Given that approximately 97% of transgender adults in a nation-wide study indicated a desire for some form of gender-affirming surgery in their lifetime (Grant et al., 2011), for which a gender dysphoria diagnosis is typically a prerequisite, I estimate that approximately 5,000 transgender adults are currently affected by the Medicaid exclusions that deny transgender people access to medically-necessary, gender-affirming care.[4] This estimate does not include transgender individuals not currently on Wisconsin Medicaid who may later enroll and need treatments for gender dysphoria in the future.

Conclusion

23. Based on the evidence presented above, it is my professional opinion that removal of Wisconsin's categorical exclusion of Medicaid coverage for gender-confirming surgeries would have a relatively minimal economic impact on the Wisconsin Medicaid budget. Specifically, the State's own expert, Mr. Williams, estimated that the direct costs to the State of covering gender-confirming surgery for the treatment of gender dysphoria would be a tiny

[4] Existing estimates regarding the prevalence of gender dysphoria in the U.S. (American Psychiatric Association, 2013; Zucker, 2017) likely underestimate the size of the population. These estimates capture the number of transgender people who have been diagnosed with gender dysphoria *and* received hormone treatment and surgery at specialty clinics, resulting in a likely sizable underestimate of the size of the transgender population with a diagnosis of gender dysphoria since many people with the diagnosis have not or cannot obtain these treatments.

percentage of the overall Wisconsin Medicaid budget. Further, Williams did not account for any savings associated with providing coverage for gender-confirming surgeries. Enabling coverage for gender-confirming surgeries under Medicaid will provide significant benefits for transgender people via anticipated reductions in gender dysphoria, depression, anxiety, suicidality, substance abuse, HIV transmission and acquisition, and physical and sexual assault, as well as improvements in socioeconomic status for many transgender individuals. Reducing these social, psychological, and physical health harms by covering gender-confirming surgery is, therefore, anticipated to yield long-term cost savings for the State Medicaid program. Accordingly, even assuming Mr. Williams' annual cost estimate of $300,000 is accurate, the overall annual cost impact to the Wisconsin Medicaid program is likely to be even lower than $300,000.

24. Weighing the estimated direct costs against the potential savings from improved health outcomes described above, it is my professional opinion that the elimination of the Medicaid exclusion for gender-confirming surgeries will result in minimal short-term costs and ultimately lead to longer-term cost savings for the Wisconsin Medicaid program.

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 October 2018.

Jaclyn White Hughto, PhD, MPH

EXHIBIT A

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EXHIBIT B

State of California, Department of Insurance,
Economic Impact Assessment: Gender Nondiscrimination in Health Insurance

STATE OF CALIFORNIA
DEPARTMENT OF INSURANCE
300 South Spring Street
12th Floor, South Tower
Los Angeles, CA 90013

ECONOMIC IMPACT ASSESSMENT

GENDER NONDISCRIMINATION IN HEALTH INSURANCE

REGULATION FILE NUMBER: REG-2011-00023 **Dated April 13, 2012**

ACTUARIES: Ali Zaker-Shahrak, Lai Weng (Carol) Chio
ECONOMIST: Rani Isaac
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Description of Proposal

The proposed regulation clarifies the prohibition against discrimination on the basis of gender or sex. AB 1586 (2005) prohibits plans and insurers from denying an individual a plan contract or policy, or coverage for a benefit included in the contract or policy, based on the person's sex, defined as "includ[ing] a person's gender identity and gender related appearance and behavior whether or not stereotypically associated with a person's assigned sex at birth."

The proposed regulation specifies forms of gender discrimination that are a violation of the discrimination prohibition in California Insurance Code (Ins. Code) section 10140 including:

- Denying or cancelling an insurance policy on the basis of gender identity;
- Using gender identity as a basis for determining premium;
- Considering gender identity as a pre-existing condition; or
- Denying coverage or claims for health care services to transgender people when coverage is provided to non-transgender people for the same services.

The California Department of Insurance (the "Department") has determined that denying claims as listed in the bullet points above is a violation of the discrimination prohibition in Ins. Code section 10140. The proposed regulation clarifies the obligation of insurers to refrain from discriminatory practices and results in a prohibition on the denial of claims solely due to an individual's transgender status. Furthermore, the proposed is consistent with recently enacted legislation, AB 887 (Atkins, 2011), which specifically prohibited discrimination based on gender identity and gender expression. This document constitutes the Department's Economic Impact Assessment (EIA), which considers the economic impact of this prohibition and assesses whether and to what extent the proposed regulation affects the criteria set forth in Government Code Section 11346.3(b)(1).

Economic Impact Findings

The Department has determined that the adoption of the proposed regulation would have an insignificant and immaterial economic impact on the creation or elimination of jobs, the creation or elimination of new businesses, and the expansion of businesses in the State of California.

Prohibiting the four types of discrimination listed in the bullets above will be of significant benefit for transgender people and should thereby potentially improve their health and welfare since they have been targets of discrimination and violence.[1] The regulation may also have a positive impact on transgender worker safety. Since these workers will have improved access to health care coverage, under the proposed regulation, they should be in better health and more productive at work. However, while the proposed regulation may have a positive impact on the health, welfare and worker safety of the transgender population, which is a very small subset of California residents, the aggregate cost to the state population as a whole will be very insignificant (see "Prevalence of the Transgender Population" section).

The Department finds that nothing in the proposed regulation prohibits an insurer from using objective, valid, and up-to-date statistical and actuarial data or sound underwriting practices. While insurers may use someone's health status to determine their premium, analysis of the potential increase in claim costs from the proposed regulation shows that any such costs are immaterial and insignificant.

To arrive at these conclusions, Department staff conducted a thorough literature review, analyzed existing data, and obtained cost and premium data from employers. Department staff used a variety of data sources to reach these conclusions, including actuarial and utilization data related to potential increased claim costs resulting from the prohibition of the four types of discrimination listed in the bullets, above.

Impact on Employment and Business

Based on the very small size of the population that may be impacted by the proposed regulation, the Department has concluded that the proposed regulation will have an insignificant and immaterial impact on the creation or elimination of jobs, the creation of new business or the elimination of existing business, and the expansion of business currently doing business in California (see "Prevalence of the Transgender Population" section below).

Department staff have determined that the adoption of the proposed regulation will have an immaterial impact on extra demands for treatments, because of the low prevalence of the impacted population. Consequently, there will be immaterial changes in the labor force.

In addition, the proposed regulation requires equality of treatment. If a medically necessary treatment is not available to any insured, the insurer is not obligated to provide that treatment to transgender individuals. Because no new treatments are required, there is no impact on the creation or elimination of existing businesses, nor the expansion of established businesses in California.

Prevalence of the Transgender Population

Because the proposed regulation will give transgender Californians access to the same treatments offered to non-transgender Californians, the Department's analysis included a review of the number of the individuals in the California population that could contribute to increased claim

[1] See the "Impact on Health and Welfare" section.

costs. The transgender population is much smaller than the overall lesbian, gay, and bisexual population and is more difficult to track and follow due to the significant disenfranchisement and discrimination that transgender individuals face.[2] The Department has published a range of estimates (see table below).

The classic estimate for prevalence of transgender individuals (using gender identity disorder as a measurement) comes from the 1994 Diagnostic and Statistical Manual, Fourth Edition (DSM-IV), which reported 1:30,000 natal males and 1:100,000 natal females.[3] More recently, a 2009 review by Zucker and Lawrence concluded that the prevalence may be 3 to 8 times the numbers reported in the DSM-IV, based mostly on reports from Western European clinics.[4, 5]

In 2007, De Cuypere, et al., reviewed ten studies from eight countries; plus, they conducted their own study. "The prevalence figures reported in these ten studies range from 1:11,900 to 1:45,000 for male-to-female individuals and from 1:30,400 to 1:200,000 for female-to-male individuals. Some scholars have suggested that the prevalence is much higher, depending on the methodology used."[6]

Department staff utilized data from these studies, and estimates of the uninsured population, to arrive at a range of estimates for the insured transgender population in California based upon 2010 Census figures.[7]

Out of the 37.3 million California residents, transgender people make up between 0.0065 and 0.0173 percent of the total population in California, using the two highest estimates in order to be conservative (see the last two columns of the table below). When the rate of uninsured Californians (19 percent) is factored in, only 0.0052 to 0.014 percent of the state population would be impacted by the proposed regulation — or between 1,955 and 5,214 people. [8]

		Estimated Number of Transgender Individuals				
Total California Population	**Source**	**DSM-IV**	**De Cuypere - Low End**	**De Cuypere - High End**	**Zucker and Lawrence - 3 times DSM-IV**	**Zucker and Lawrence - 8 times DSM-IV**
18,517,830	Male	617	412	1,556	1,852	4,938
18,736,126	Female	187	94	616	562	1,499
37,253,956	Total	805	505	2,172	2,414	6,437
100%	Percentage of Total California Population	0.0022%	0.0014%	0.0058%	0.0065%	0.0173%
	Total Insured* (Total X .81)	652	409	1,760	1,955	5,214
	Percentage of Total California Population	0.0017%	0.0011%	0.0047%	0.0052%	0.0140%

[2] (Baker, Kesteren, Gooren, & Bezemer, 1993)
[3] (American Psychiatric Association, 1994)
[4] (Zucker & Lawrence, 2009)
[5] (Olson, Forbes, & Belzer, 2001)
[6] (The World Professional Association for Transgender Health, 2011)
[7] (U.S. Census Bureau, 2010)
[8] (The Kaiser Family Foundation, 2009)

Since the number of transgender people in the general population is so small, the subpopulation of insured individuals is even less significant. The following estimates by the Department of costs and utilization are conservative, considering that the transgender population has higher than average rates of poverty and unemployment and lower rates of insurance coverage. A 2008 survey conducted by the Transgender Law Center indicates that transgender people are twice as likely to live below the poverty line.[9] Because transgender people have less access to insurance coverage than average Californians, they are more likely to be covered by a public program and would not contribute to increased claims against private insurers.

Utilization and Impact on Claim Costs and Premiums

While there is limited actuarial data publically available on the impact that the Department's proposed regulation would have on claim costs and premiums, the Department has identified enough existing data to make conclusions about the economic impact of the regulation. Department staff reviewed data from five employers that have internal policies prohibiting discrimination in health care coverage and reviewed their related cost studies. For reasons discussed in the following section, the Department has concluded the impact on costs, due to the adoption of the proposed regulation, would be immaterial.

Utilization

Utilization data is important because it is used by insurers to calculate expected claim costs and then premiums. As utilization increases, the expected claim costs increase and in general the increase will be reflected in setting premiums. In this section, the Department presents data that indicates extremely low utilization resulting from elimination of gender discrimination, as would be expected with such a small population.

Once again, the proposed regulation requires that treatments available to non-transgender insureds not be denied based on an insureds actual or perceived gender identity or transgender status, as defined. If a medically necessary treatment is not available to any insured, the insurer is not obligated to provide that treatment to transgender individuals. Department staff used utilization data from employers that offer transgender employees equal health care benefits as a proxy for increased utilization that we may expect to see as a result of implementing the proposed regulations. Department staff determined that this data most closely represents the kind of increased utilization that we can expect based on prohibition of the four types of discrimination listed in the first section of this assessment.

While the move to eliminate this type of gender discrimination in health policies was rare among employers ten years ago, many more employers are adopting internal policies offering equal access to health care services for their transgender employees. The number of Fortune 500 companies that have eliminated discrimination in health care benefits offered to their transgender employees has increased from 49 in 2009 to 207 in 2012.[10] Presenters at the Out & Equal Workplace Summit 2011 indicated that the utilization, and thus costs, for prohibiting discrimination are very low. "[M]any employers around the country have eliminated the

[9] (Transgender Law Center, 2008)
[10] (Human Rights Campaign, 2012)

exclusions in their health plans…Utilization is very low and there has been little or no impact to premiums."[11]

Existing utilization data is limited due to extremely low utilization coupled with the concern that releasing this data could be traced back to individuals and violate health privacy laws. However, Department staff obtained and reviewed three sources of utilization data: (1) The City and County of San Francisco; (2) The University of California; and (3) Jamison Green and Associates report on utilization and costs to private companies with voluntary internal nondiscrimination policies similar to the proposed regulation.

The City and County of San Francisco (San Francisco) prohibited gender-based discrimination in 2001 for all City and County employees and their dependents. In the following five years, there were only 37 claims. A report by Jamison Green and Associates estimated that utilization rates (claimants per employee) ranged from 0.0325 to 0.104 claimants per thousand employees per year.[12]

In March 2012, the University of California (UC) released utilization and cost data from one of its health plan insurers, for the 6.5 years since UC first prohibited discrimination against transgender employees in its health care plans.[13] The utilization rates, as summarized in the table below, ranged from 0.011 to 0.093 claimants per thousand covered lives per year.[14] In order to make comparisons with other utilization data, the Department converted the UC data to utilization rates per 1,000 covered employees. Using a member-to-employee ratio of 2:1, Department staff arrived at utilization rates per 1,000 employees, from a minimum of 0.022 in CY 2006 to a maximum of 0.187 in CY 2009 (see far right column in table below).

Coverage Period	Number of Claimants	Average Covered Lives	Est. Average Number of Employees*	Utilization Rates per 1,000 covered lives	Utilization Rates per 1,000 employees*
Jul - Dec 2005	-	92,470	46,235	-	-
CY 2006	1	91,705	45,853	0.011	0.022
CY 2007	3	86,868	43,434	0.035	0.069
CY 2008	9	120,905	60,453	0.074	0.149
CY 2009	11	117,945	58,973	0.093	0.187
CY 2010	10	115,087	57,544	0.087	0.174
CY 2011	8	111,571	55,785	0.072	0.143
Total	42				
			Average utilization rates (excl. 2005 data)	0.062	0.124
			Min utilization rates (excl. 2005 data)	0.011	0.022
			Max utilization rates (excl. 2005 data)	0.093	0.187
*Estimated number of employees based on a member-to-employee ratio of 2:1					

[11] (Green, Wilson, & Fidas, 2011). Slide #5.
[12] (Wilson, 2012); Slide # 11
[13] (Manning, 2012)
[14] ibid.

Further underscoring evidence of extremely low utilization, the insurer reported that only 27 individuals sought treatments, some with multiple claims, over the period of 6.5 years.[15] Using the number of (distinct) members, rather than the number of distinct claims, Department staff obtained an average utilization rate of 0.039 per thousand covered lives per year. Department staff made the conversion because utilization data relying on covered lives is a more accurate representation of actual utilization. As expected, the average utilization rate per thousand covered lives (0.062 per thousand) is significantly lower than the utilization per thousand employees (0.124) because the rate per covered lives represents utilization spread across all insureds.

In addition, a report issued by Jamison Green and Associates estimated utilization rates in the range of 0.0015 to 0.325 per thousand employees per year, based on interviews with fifteen Fortune 500 companies who have eliminated the discriminatory policies.[16] Their broader estimates discussed below included the experience of San Francisco.

The table below summarizes the utilization rates from all three sources mentioned above.

	Utilization Rates per 1,000 employees per year		
Case	City and County of San Francisco	University of California	Sample of Private Employers
Minimum	0.0325	0.022	0.0015
Maximum	0.104	0.187	0.325

The utilization rates for San Francisco and UC fall within the range of utilization estimates of Jamison Green and Associates discussed above.

Claim Costs and Premium History

The Department augmented the limited claim cost and utilization data available by reviewing premium data from several employers to determine the additional amount their insurers have been charging to extend equal coverage to transgender employees and dependents.

For San Francisco, the initial cost per employee was $1.70 per member per month (PMPM) in 2001. Due to low utilization, San Francisco reduced the PMPM to $1.16 in 2004-2005 and the city's self-insured plan reduced its charge to $0.50 PMPM. As of July 1, 2006, the cost data demonstrated that no separate rate was required, so the charge was removed entirely. Initial claims were first subject to a lifetime maximum of $50,000 then increased to $75,000 in 2004.[17]

[15] There were 27 unduplicated individuals who received treatment during this time period. There were 42 claimants because some procedures for the same individual occurred over more than one year.
[16] (Wilson, 2012) Slide #13
[17] (The City and County of San Francisco Human Rights Commission, 2007)

The University of California eliminated transgender discrimination in 2005 without being charged an additional premium.[18] Claim cost data from the UC health plan with the largest enrollment shows that the claim costs PMPM attributed to the elimination were very low. The maximum of claim costs during the 6.5 years was $0.20 PMPM, or 0.05 percent of the total premium.

As of January 1, 2012, the City of Berkeley removed discriminatory provisions within its health plans. Berkeley's insurers charged a premium of 0.2 percent of the total annual budget for healthcare benefits. The total projected monthly increase was 0.25 percent (223 covered lives in one plan) and 0.19 percent (938 covered lives in another plan) as of March 2012.[19]

Two other cities have had experiences similar to Berkeley's. The City of Portland removed discriminatory policies beginning July 1, 2011. The cost projection for Portland was $32,302 out of a total $41,615,000 health care budget – a 0.08 percent increase.[20] The City of Seattle absorbed a premium increase of $200,000 per year of a total $105 million health care budget – just 0.19 percent of total health costs based on insurer estimates of increased utilization.[21]

It is a standard practice for insurers to charge a premium to cover expected claim costs of the proposed regulation, administrative expenses, taxes, profit and any provisions for adverse deviation. When credible cost and utilization data is absent or limited for new benefits, insurers tend to be conservative by including a larger provision for adverse deviation. This is evidenced by San Francisco's experience, where "[f]rom July 2001 through July 2006, the grand total of reported monies collected (for this purpose) is $5.6 million. The grand total of reported monies expended is $386,417."[22] Since cost assumptions were nearly 15 times higher than actual claims, the city eventually eliminated the additional premium.

Using the impact on premiums as a proxy for anticipated increased claim costs, the range of the impact on costs for the proposed regulation would be a minimum of no increase (the case of San Francisco and the University of California), to a maximum increase of 0.2 percent in expected claim costs (the cases of Berkeley and Seattle). However, changes to policies in Berkeley and Seattle were recent, limiting data availability. As stated before, the 0.2 percent estimate may very likely include a large provision for adverse deviation. The Department's conclusion is supported by the actual claims data collected for the UC system, which shows the claims costs accounted for only 0.05 percent of premiums.

In addition to the employer information, Department staff also reviewed the Sylvia Rivera Law Project white paper discussing the impact of a similar prohibition for Medicaid in the State of New York. "A preliminary estimate by the New York State Department of Health in 2010 approximated that it would cost about $1.7 million to cover gender-confirming care through

[18] (Manning, 2012)
[19] (Hodgkins, 2012)
[20] (The City of Portland, Oregon, 2011)
[21] (Freiboth, 2012)
[22] (The City and County of San Francisco Human Rights Commission, 2007)

Medicaid. As the state Medicaid budget totals $52 billion, this represents only 0.003 percent of the total budget."[23]

Based on evidence of low utilization and prevalence rates shown above, the Department has determined that the impact on costs or increases in premiums due to the adoption of the proposed regulation would be immaterial.

Utilization Assumptions
There are a number of assumptions that contribute to lower-than-expected utilization seen in San Francisco. Like any other condition, treatment options for GID vary greatly and not all transgender people with the diagnosis will undergo surgical intervention. It appears that utilization projections are made with:

> …the belief that all transgender people undergo genital surgery as the primary medical treatment for changing gender. In fact, gender-confirming healthcare is an individualized treatment that differs according to the needs and pre-existing conditions of individual transgender people. Some transgender people undergo no medical care related to their expression of a gender identity that differs from their birth-assigned sex. Others undergo only hormone therapy treatment or any number of surgical procedures.[24]

The assumption that treatment utilization and costs are the same for each transgender person is reflected in the significant difference between premium charges by insurers and actual utilization costs and evidenced in the wide range of claims costs reported by the University of California. The claims varied from $67 to $86,800 with an average cost of $29,929 per transgender person requiring treatment.

Additional factors that impact utilization and cost include, but are not limited to:

- Transgender insureds may have already undergone treatment;
- Surgical treatment for gender identity disorder (GID) is usually a once-in-a-lifetime event, and many costs are spread over a lifetime, and do not occur in just a single year;
- Transgender people do not always have a diagnosis of GID and thus have no medically necessary indication for treatment;
- Almost all surgical treatments for treatment of GID are treatments that are provided to non-transgender insureds for other indications; and
- Other health factors can contraindicate treatment.

[23] (The Sylvia Rivera Law Project, 2011)
[24] (Spade, 2010)

A detailed analysis of the impact of each of these assumptions on utilization is beyond the scope of this assessment, but is illustrative of what may be the reasons for the apparent gap between premiums charged to employers for prohibiting health care discrimination against transgender insureds and the actual reported utilization and cost.

In addition, the Department believes that there may be a possible spike in demand for such services in the first few years after the adoption of the proposed regulation due to the possible existence of some current unmet demand. This may lead to higher costs, in the near-term, following the adoption of the proposed regulation. While this is possible, this was not the experience of the University of California or San Francisco. In any case, the small size of the impacted population will likely make the magnitude of such an increase insignificant and immaterial.

Impact on Health and Welfare

As discussed in the *Prevalence* and the *Utilization and Claims* sections, prohibiting the four types of discrimination listed in the bullets on page one will be of significant benefit for a very small class of California residents who are directly impacted. The proposed regulation should thereby potentially improve their health and welfare since transgender people have been targets of discrimination and violence.[25] The proposed regulation may also improve worker safety, as explained above. However, while the Department found that the proposed regulation may have a significant beneficial impact on the health, welfare and safety of the transgender population, the aggregate costs will be very insignificant. The Department has determined that the benefits of eliminating discrimination far exceed the insignificant costs associated with implementation of the proposed regulation. Based on this assessment, the Department has determined that there are no significant adverse impacts of the regulation to the health and welfare of California residents, nor will it impact overall worker safety, and the state's environment.

Further, the Department's evidence suggests that benefits will accrue to insurance carriers and employers as costs decline for the treatment of complications arising from denial of coverage for treatments. The evidence suggests that there may be potential cost savings resulting from the adoption of the proposed regulation in the medium to long term, such as lower costs associated with the high cost of suicide and attempts at suicide, overall improvements in mental health and lower rates of substance abuse, as discussed in the following section.

The Benefit and Cost Savings of Suicide Reduction[26]

One of the most severe results of denying coverage of treatments to transgender insureds that are available to non-transgender insureds is suicidal ideation and attempts. The Centers for Disease Control and Prevention estimate the average acute medical costs of a single suicide completion or attempt in the United States is $2,596 and $7,234 respectively.[27] This only includes acute care and hospitalization costs. While there are studies that provide higher estimated costs per suicide attempt and completion, we choose to conservatively use the lower bound cost to keep estimates

[25] (Tannis, Grant, & Mottat, 2010)
[26] (Gorton, 2011)
[27] (The Centers for Disease Control, 2010)

as relevant to health insurers as possible.[28,29] A more in-depth analysis might include the costs of mental health treatment or other medical costs following a suicide attempt.

A meta-analysis published in 2010 by Murad, et al., of patients who received currently excluded treatments demonstrated that there was a significant decrease in suicidality post-treatment. The average reduction was from 30 percent pretreatment to 8 percent post treatment.[30]

De Cuypere, et al., reported that the rate of suicide attempts dropped dramatically from 29.3 percent to 5.1 percent after receiving medical and surgical treatment among Dutch patients treated from 1986-2001.[31]

According to Dr. Ryan Gorton, "In a cross-sectional study of 141 transgender patients, Kuiper and Cohen-Kittenis found that after medical intervention and treatments, suicide fell from 19 percent to zero percent in transgender men and from 24 percent to 6 percent in transgender women.[32])"[33]

Clements-Nolle, et al., studied the predictors of suicide among over 500 transgender men and women in a sample from San Francisco and found a prevalence of suicide attempts of 32 percent.[34] In this study, the strongest predictor associated with the risk of suicide was gender based discrimination which included "problems getting health or medical services due to their gender identity or presentation."[35] According to Gorton, "Notably, this gender-based discrimination was a more reliable predictor of suicide than depression, history of alcohol/drug abuse treatment, physical victimization, or sexual assault."[36]

A recent systematic review of largely American samples gives a suicide attempt rate of approximately one in every three individuals with higher rates found among adolescents and young adults.[37] According to Dr. R. Nicholas Gorton, MD, who treats transgender people at a San Francisco Health Clinic, "The same review also noted that while mental health problems predispose to suicidality, a significant proportion of the drivers of suicide in the LGBT population as a whole is minority stress." He continues to conclude that, "[f]or transgender people such stress is tremendous especially if they are unable to 'pass' in society. Surgical and hormonal treatments — that are [also] covered for non-transgender insureds — are specifically aimed at correcting the body so that it more closely resembles that of the target gender, so providing care significantly improves patients' ability to pass and thus lessens minority stress."[38]

These studies provide overwhelming evidence that removing discriminatory barriers to treatment results in significantly lower suicide rates. These lower rates, taken together with the estimated

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[28] (Yang & D.Lester, 2007)
[29] (Corso P, 2007)
[30] (Murad M, 2010)
[31] (DeCuypere, 2006)
[32] (Kuiper M, 1988)
[33] (Gorton, 2011)
[34] (Clements-Nolle K, 2006)
[35] (Clements-Nolle, Marx, & and Katz, 2006)
[36] (Gorton, 2011)
[37] (Haas, 2011)
[38] (Gorton, 2011)

costs of a suicide attempt and completion, demonstrate that the proposed regulation will not only save insurers from the costs associated with suicide, but prevent significant numbers of transgender insureds from losing their lives.

Additional Benefits

Overall improvements in mental health. Transgender insureds who have access to treatment see rates of depression drop and anxiety decrease. Evidence supporting this conclusion comes from a meta-analysis of 28 studies showing that 78 percent of transgender people had improved psychological functioning after treatment.[39] In another recent study, transgender women who had had any relevant surgeries had mental health scores comparable to women in general, while those who were not able to access care scored much lower on mental health measures.[40] In another study, participants improved on 13 out of 14 mental health measures after receiving treatments.[41] This overall improvement in mental health and reduction in utilization of mental health services could be a source of cost savings for employers, insurers, and insureds.

Substance abuse rates decline. There are numerous studies that provide evidence that substance abuse rates decline including one where participants, "describe how substance use was a coping mechanism for their gender dysphoria before they had access to treatment."[42, 43] Another study found an overall reduction in substance use after receiving treatment.[44]

Further, the Sylvia Rivera Law Project suggests that treatment for GID could combat other types of substance abuse since it is well known that "[i]ncreased smoking and drug and alcohol use correlates with increased rates of lung cancer, heart disease, stroke, and liver disease."[45]

HIV Rates and Care. Transgender people have significantly higher rates of HIV than the general population (28 percent in a meta-analysis[46] as compared to a general population rate of 0.6 percent).[47] It is also significant that studies show "high rates of adherence to HIV care for trans people when combined with hormonal treatment."[48, 49] This is particularly relevant to insurers because it provides evidence that offering treatment may reduce the long-term costs of treatment for HIV/AIDS. It is particularly relevant for the welfare of all Californians because, "[w]hen compliant with care, HIV-positive people stay healthier longer and are far less likely to transmit the virus to others."[50]

Other Benefits. Transgender people who are denied access to treatment and suffer from dysphoria associated with gender identity disorder sometimes turn to self-medication for relief.

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[39] (Murad M, 2010)
[40] (Ainsworth & Spiegel, 2010).
[41] (Smith Y, 2005)
[42] (The Sylvia Rivera Law Project, 2011)
[43] (Cole, 1997)
[44] (Rehman, 1999)
[45] (The Sylvia Rivera Law Project, 2011)
[46] (Operario D., 2010)
[47] (United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO), 2007)
[48] (The Sylvia Rivera Law Project, 2011)
[49] Grimaldi J; Jacobs J. (1998.) "The HIV/Hormone Bridge, *Int Conf AIDS; 12*: 981, abstract no. 571/44225.
[50] (The Sylvia Rivera Law Project, 2011)

Silicone injections, for example, are sometimes used in lieu of medically available treatments. Prevalence of this has been documented in needs assessments in Washington D.C., Chicago, and Los Angeles, where respondents reported having injected silicone into their bodies at a rate of 25, 30, and 33 percent of the time, respectively.[51, 52, 53] Construction-grade silicone is used to alter body shape sometimes resulting in deadly consequences.[54] Several researchers suggest that lack of early access to GID treatments and care costs more.

Increased socioeconomic status for transgender insureds. Lack of access to treatment due to coverage denials also results in a greater likelihood of adverse socioeconomic consequences for the insured. A single group pre- and post-study demonstrated improvements in socioeconomic status or employment status in transgender patients after hormonal and surgical treatment.[55] Additional studies conclude that transgender persons have higher employment rates after they have access to treatments.[56]

For the reasons cited above, Department staff concluded that ending these four types of discrimination will cost little or nothing in the short run and may produce longer-term cost savings and improved health benefits for transgender people.

[51] (Xavier, 2000)
[52] (Bostwick, 2001)
[53] (Reback, Simon, Bemis, & Gatson, 2001)
[54] (Komenaka, 2004); (Fox, 2004); (Hage, 2001).
[55] (Bodlund O, 1996)
[56] (Grant, 2010); (Murad M, 2010); (Rakic, 1996).

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EXHIBIT C

Oregon Health Authority, Minutes of June 12, 2014 Meeting of Health Evidence Review Commission's Value-based Benefits Subcommittee

Oregon Health Authority

Health Evidence Review Commission's Value-based Benefits Subcommittee

June 12, 2014
8:30 AM

Meridian Park Hospital
Community Health Education Center, Room 117B & C
19300 SW 65th Avenue, Tualatin, OR 97062

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
June 12, 2014
8:30am - 1:00pm
Meridian Park Room 117B&C
Community Health Education Center
Tualatin, OR 97062
A working lunch will be served at approximately 12:00 PM
All times are approximate

I. Call to Order, Roll Call, Approval of Minutes – Lisa Dodson 8:30 AM

II. Staff report – Ariel Smits, Cat Livingston, Darren Coffman 8:35 AM

III. New discussion items – Ariel Smits 8:45 AM
A. Hearing loss issues
    A. Biennial review deletion of audiant bone conductor for conductive hearing loss line
    B. Unilateral hearing loss
    C. Bone anchored hearing aids
B. Physical therapy for urinary incontinence

IV. Previous Discussion Items – Ariel Smits, Cat Livingston 9:45 AM
A. Electroconvulsive therapy (ECT) guideline
B. Applied behavioral analysis for autism spectrum disorders
C. Gender dysphoria
    A. Cross sex hormone therapy
    B. Sex reassignment surgery

V. Guidelines – Ariel Smits, Cat Livingston 11:15 AM
A. Bariatric surgery guideline clarifications
B. Rehabilitation guideline clarifications
C. Lymphedema guideline
D. Treatment of hepatitis C

VI. Public comment 12:55 PM

VII. Adjournment – Lisa Dodson 1:00 PM

Treatment for Gender Dysphoria 2014

Question: What therapies should be included for treatment of gender dysphoria on the Prioritized List?

Question Source: HERC staff, OHA

Issue:
The October 1, 2014 Prioritized List includes Gender Dysphoria as a new, covered line (413). Currently, the only treatments on this line are office visits, psychotherapy and puberty suppression medication for transgender and gender-questioning youth. Other treatments for gender dysphoria include cross-sex hormone therapy and sex reassignment (gender reassignment) surgery.

Cross-sex hormone therapy and sex reassignment surgery were reviewed at the May, 2014 VBBS meeting. At that time, literature was reviewed which found that cross-sex hormone therapy, in conjunction with psychotherapy, may offer some benefit in self-reported outcomes for persons with gender dysphoria based on poor quality evidence. Gender reassignment surgery in conjunction with hormone therapy likely improves gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life. Most major professional societies and evidence-based health systems such as the NHS recommend cross-sex hormone therapy and sex reassignment surgery be available for appropriate patients who meet strict eligibility criteria. The evidence for both cross-sex hormone therapy and gender reassignment surgery is of poor quality. Outcomes for gender reassignment surgery appear good, with no patients reporting regrets. Outcomes for cross-sex hormone therapy are generally positive, with some medical complications noted in female to male transitioning patients.

The literature review and expert testimony indicated that people with gender dysphoria had a much higher than average rate of suicide, suicide attempts, IV drug abuse, HIV positivity and other high risk behavior/conditions. Experts testified that treatment of gender dysphoria with a range of options including cross-sex hormone therapy and sex reassignment surgery reduced the morbidity of this condition. Experts also testified that treatment of this condition had been shown in California to have negligible economic impact on the health plans.

HERC staff was charged with finding further information on the morbidity/mortality of gender dysphoria and what, if any, impact treatment of this condition had on morbidity, particularly suicide attempts. HERC staff was also charged with finding information on cost experience in states that have covered treatments of gender dysphoria including cross-sex hormone therapy and sex reassignment surgery.

HERC staff was asked to mock up a line for sex reassignment surgery with appropriate scoring. If the scoring for this line placed it in close proximity to the existing gender dysphoria line, staff should propose a single line with all therapies.

Treatment for Gender Dysphoria 2014

Evidence Summary

Studies on suicide rates among patients with gender dysphoria

1) **Blosnich 2013**
    a. N=3177, VA patients
    b. The rate of suicide-related events among GID-diagnosed VHA veterans was more than 20 times higher than were rates for the general VHA population.

Effect of gender dysphoria treatment on psychiatric outcomes

1) **Heylens 2014**, prospective cohort study of effects of cross-sex hormone therapy and gender reassignment surgery
    a. N=57, Belgium, 4 yr follow up
    b. The overall psychoneurotic distress scores decreased significantly after hormone therapy, ($P < 0.001$). No further decrease is observed after sex reassignment surgery.
    c. Unlike scores at time of presentation, SCL-90 scores after hormonal treatment and after surgery are similar to the mean SCL-90 scores of a general population.
    d. Significant reductions seen in scores for anxiety and depression after treatment
2) **Colizzi 2014**, cohort study of psychological effects of initiation of cross-sex hormone therapy
    a. N=118 patients, follow up 12 months, Italy
    b. Psychiatric distress and functional impairment were present in a significantly higher percentage of patients before starting the hormonal treatment than after 12 months (50% vs. 17% for anxiety; 42% vs. 23% for depression; 24% vs. 11% for psychological symptoms; 23% vs. 10% for functional impairment).
2) **Gomez-Gil 2012**, cohort study of effects of cross-sex hormone therapy
    a. N=187 (120 treated, 67 not treated)
    b. SADS, HAD-A, and HAD-Depression (HADD) mean scores were significantly higher among patients who had not begun cross-sex hormonal treatment compared with patients in hormonal treatment (p = .038; p = .001; p = .002 respectively). Similarly, current symptoms of anxiety and depression were present in a significantly higher percentage of untreated patients than in treated patients (61% vs. 33% and 31% vs. 8% respectively).
3) **Dhejne 2011**, cohort study of outcomes of gender reassignment surgery
    a. N=324, Sweden, 30 year period
    b. Compared outcomes of patients with gender reassignment surgery to general population; no comparison with persons with gender dysphoria who were not treated
    c. Incidence of suicide: 2.7/1000 person-yrs for patients with gender dysphoria compared to 0.1/1000 person-yrs for controls
    d. Incidence of suicide attempts: 7.9/1000 person-yrs vs 1.0/1000 person-yrs
    e. Incidence of substance misuse: 5.9 /1000 person-yrs vs 1.8/1000 person-yrs

4) **Murad 2010**, meta-analysis
    a. Systematic review and meta-analysis of impact of hormonal therapy and sex reassignment on health outcomes
    b. Included 28 observational studies, N = 1833 participants with GID (1093 male-to-female, 801 female-to male) who underwent sex reassignment that included hormonal therapies
    c. Suicide attempt rates decreased after sex reassignment but stayed higher than the normal population rate.
    a. The average reduction was from 30 percent pretreatment to 8 percent post treatment.
5) **Kuhn 2008**, case control study out outcomes of sex reassignment surgery
    a. N=55 patients with gender dysphoria/20 controls, follow up 15 yrs, Switzerland
    b. Quality of life as determined by the King's Health Questionnaire was significantly lower in general health, personal, physical and role limitations. Patients' satisfaction was significantly lower compared with controls. Emotions, sleep, and incontinence impact as well as symptom severity is similar to controls. Overall satisfaction was statistically significant lower in TS compared with controls.
6) **De Cuypere 2006**, cohort study of outcomes of gender reassignment surgery
    a. N-109, The Netherlands, 15 year follow up
    b. Suicide attempt rate: Although the suicide attempt-rate dropped significantly from 29.3% to 5.1% (McNemar test, N = 58, P = 0.004), it was definitively higher than in the average population (0.15%)
7) **Smith 2005**, prospective cohort study of outcomes of gender reassignment surgery
    a. N=162, United Kingdom
    b. After treatment the group was no longer gender dysphoric
    c. Depression scores improved significantly after treatment (29.3%-22.5%)

Evidence summary

Most, but not all, studies found a significant reduction in depression and anxiety and in gender dysphoria symptoms after treatment for gender dysphoria (hormonal, surgical or a combination). Two studies examined cross-sex hormone therapy alone and one study examined cross-sex hormone therapy separately from gender reassignment surgery. These studies found significant improvement in psychiatric health came from cross-sex hormone therapy alone.

In terms of suicide/suicide attempt reduction, one study found significantly higher rates in treated patients with gender dysphoria compared to the general population. However, this study did not compare treated patients to untreated patients. Two studies comparing treated and untreated patients found a suicide attempt rate reduction of approximately 30% pre-treatment to 5-8% post-treatment (hormone therapy, surgery, or a combination).

Treatment for Gender Dysphoria 2014

HERC staff mock-up of surgical treatment line

Line XXX
Condition: GENDER DYSPHORIA
Treatment: SURGICAL TREATMENT
ICD-9: 302.85 (Gender identity disorder in adolescents or adults)
ICD10: F64.x (Gender identity disorder)
CPT: 19301-19304, 53430, 54125, 54400-54417, 54520, 54660, 54690, 55175-55180, 55970, 55980, 56625, 56800, 56805, 56810, 57106-57107, 57110-57111, 57291-57292, 57335, 58150, 58180, 58260-58262, 58275-58291, 58541-58544, 58550-58554, 58570-58573, 58661, 58720, outpatient medical visit codes
HCPCS:G0396,G0397,G0463

Scoring proposal (scoring for line 413 in parentheses)
Category: 6 (7)
HL: 3 (3)
Suffering: 4 (4)
Population effects: 0 (0)
Vulnerable population: 0 (0)
Tertiary prevention: 3 (3)
Effectiveness: 2 (2)
Need for service: 0.8 (1)
Net cost: 2 (2)
Score: 640
Approximate line placement: 369

Treatment for Gender Dysphoria 2014

Actuarial Estimates

Estimate of number of OHP members with gender dysphoria

The classic estimate for prevalence of transgender individuals (using gender identity disorder as a measurement) comes from the 1994 Diagnostic and Statistical Manual, Fourth Edition (DSM-IV), which reported 1:30,000 natal males and 1:100,000 natal females. Some sources cite rates which are 3-8 times higher than the DSM estimate. Assume 1 in 65,000 persons in Oregon has gender dysphoria (average of male/female DSM estimate)

Oregon population: 3,940,065 (2013 US Census) à 61 persons with gender dysphoria.
Upper end of estimate (using 8x DSM estimate) à 448 persons
Oregon Medicaid population: 935,026 (OHA April 2014 data) à 14 persons with gender dysphoria. Upper end of estimate (using 8x DSM estimate) à 112 persons

Claims data: 175 OHP recipients had claims for ICD-9 302.6 and 302.85 for calendar year 2012

HERC staff estimate 175 enrollees on Oregon Medicaid will have gender dysphoria.

Estimate of utilization of OHP members of treatments for gender dysphoria

The City and County of San Francisco (San Francisco) prohibited gender-based discrimination in 2001 for all City and County employees and their dependents. In the following five years, there were only 37 claims. A report by Jamison Green and Associates estimated that utilization rates (claimants per employee) ranged from 0.0325 to 0.104 claimants per thousand employees per year. The University of California released utilization rates in 2012: Average utilization rates 0.062 covered lives.

HERC staff estimate a utilization (of all treatments for gender dysphoria) in the Oregon Medicaid program of 175 persons. Not all of these persons may seek care in any given coverage period.

Estimate of costs for adding all treatments for gender dysphoria

For San Francisco, the initial cost per employee was $1.70 per member per month (PMPM) in 2001. Due to low utilization, San Francisco reduced the PMPM to $1.16 in 2004-2005 and the city's self-insured plan reduced its charge to $0.50 PMPM. As of July 1, 2006, the cost data demonstrated that no separate rate was required, so the charge was removed entirely. Claim cost data from the UC health plan with the largest enrollment shows that the claim costs PMPM attributed to the elimination were very low. The maximum of claim costs during the 6.5 years was $0.20 PMPM, or 0.05 percent of the total premium. For the City of Berkeley, insurers charged a premium of 0.2 percent of the total annual budget for healthcare benefits. The total projected monthly increase was 0.25 percent (223 covered lives in one plan) and 0.19 percent (938 covered lives in another plan) as of March 2012. The cost projection for Portland was $32,302 out of a total $41,615,000 health care budget – a 0.08 percent increase. The City of Seattle absorbed a premium increase of $200,000 per year of a total $105 million health care budget – 0.19 percent of total health costs based on insurer estimates of increased utilization.

HERC staff estimate of PMPM cost: $0.20-$0.50

A preliminary estimate by the New York State Department of Health in 2010 approximated that it would cost about $1.7 million to cover gender-confirming care through Medicaid. As the state Medicaid budget totals $52 billion, this represents only 0.003 percent of the total budget. The Kaiser Family Foundation estimates that Oregon Medicaid total costs for 2012 were $4,587,000,000 (not including administrative costs). Assuming total non-administrative cost of Oregon Medicaid would increase 0.003% with addition of all treatments for gender dysphoria:

HERC staff estimate total cost of adding all treatments for OHP: $100,000-150,000 per year

The Centers for Disease Control and Prevention estimate the average acute medical costs of a single suicide attempt in the United States is $7,234.

Assuming a reduction in suicide attempts from approximately 30% to 8% among OHP patients with gender dysphoria and assuming the total number of patients with gender dysphoria on OHP is 100, and assuming a suicide attempt rate in this population of 2% a year (based on De Cuypere data), we could expect to reduce the number of total suicide attempts from 2 a year to 0.5 per year.

HERC staff estimate of cost savings from reduced suicide attempts with treatment of about $10,000

Overall HERC staff summary:
Treatment of gender dysphoria with cross-sex hormone therapy, gender reassignment surgery or a combination of these treatments results in a significant reduction in depression, anxiety, and suicide attempts. Data from a limited number of studies indicates that a significant reduction in psychiatric symptoms can be obtained from hormone therapy alone; however, the reduction in suicide attempts was shown in studies with a combination of these therapies. The cost of adding cross-sex hormone treatment for gender dysphoria would likely be minimal to the OHP program. The cost of adding gender reassignment surgery would be higher than that of cross-sex hormone therapy alone, but still very low.

CPT codes for sex reassignment surgery

CPT code	Code description	Current placement
19301-19304	Mastectomy	195 CANCER OF BREAST
53430	Urethroplasty, reconstruction of female urethra	91 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
54125	Amputation of penis; complete	262 CANCER OF PENIS AND OTHER MALE GENITAL ORGANS

Treatment for Gender Dysphoria 2014

CPT code	Code description	Current placement
54400-54417	Insertion/repair/removal of penile prosthesis	529 SEXUAL DYSFUNCTION Some on 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach	98,116,211,249,262,331,333,474
54660	Insertion of testicular prosthesis (separate procedure)	98 UNDESCENDED TESTICLE 249 TORSION OF TESTIS
54690	Laparoscopy, surgical; orchiectomy	98,116,428,474
55175-55180	Scrotoplasty	91, 262, 438 HYPOSPADIAS AND EPISPADIAS
55970	Intersex surgery; male to female	Excluded
55980	Intersex surgery; female to male	Excluded
56625	Vulvectomy simple; complete	291 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS
56800	Plastic repair of introitus	125,211,356,428
56805	Clitoroplasty for intersex state	428 ADRENOGENITAL DISORDERS,638 BENIGN CERVICAL CONDITIONS
56810	Perineoplasty, repair of perineum, nonobstetrical	125 ABUSE AND NEGLECT,428, 471 UTERINE PROLAPSE; CYSTOCELE
57106-57107	Vaginectomy, partial removal of vaginal wall;	291,471
57110-57111	Vaginectomy, complete removal of vaginal wall	291
57291-57292	Construction of artificial vagina	356 STRUCTURAL CAUSES OF AMENORRHEA
57335	Vaginoplasty for intersex state	428
58150, 58180, 58260-58262, 58275-58291, 58541-58544, 58550-58554, 58570-58573	Hysterectomy	Multiple lines, with several guidelines
58661	Laparoscopy, surgical; with removal of adnexal structures	Multiple lines
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral	Multiple lines

Note: Rhinoplasty, face-lifting, lip enhancement, facial bone reduction, blepharoplasty, breast augmentation, liposuction of the waist (body contouring), reduction thyroid chondroplasty, hair removal, voice modification surgery (laryngoplasty or shortening of the vocal cords), and skin resurfacing, which have been used in feminization, are considered cosmetic. Similarly, chin implants, nose implants, and lip reduction, which have been used to assist masculinization, are considered cosmetic.

Treatment for Gender Dysphoria 2014

HSC Staff Recommendations:

1) Add cross-sex hormone therapy and sex-reassignment surgery to line 413
    1) Good evidence found for reduction in psychiatric symptoms and suicide attempts with treatment
    2) Overall cost for full spectrum of treatment expected to be minimal, with some cost savings with reduced suicide attempts, psychiatric care, etc.
    3) Add surgical codes as shown below
        i. Advise DMAP to remove CPT 55970 and 55980 from the Excluded List.
    4) Reprioritize line 413 as a category 6 as shown below
    5) Change the guideline for line 413 as shown below

Line 413
Condition: GENDER DYSPHORIA
Treatment: ~~MEDICAL/PSYCHOTHERAPY~~ MEDICAL AND SURGICAL TREATMENT; PSYCHOTHERAPY
ICD-9: 302.85 (Gender identity disorder in adolescents or adults)
ICD10: F64.1-F64.9 (Gender identity disorder)
CPT: 19301-19304, 53430, 54125, 54400-54417, 54520, 54660, 54690, 55175-55180, 55970, 55980, 56625, 56800, 56805, 56810, 57106-57107, 57110-57111, 57291-57292, 57335, 58150, 58180, 58260-58262, 58275-58291, 58541-58544, 58550-58554, 58570-58573, 58661, 58720, 90785,90832-90840, 90846-90853,90882,90887,96101,98966-98969,99051,99060,99070, 99078,99201-99215,99281-99285,99341-99355,99358-99378,99381-99404,99408-99412,99429-99449,99487-99496,99605-99607
HCPCS:G0176,G0177,G0396,G0397,G0459,G0463,H0004,H0023,H0032,H0034, H0035,H2010,H2011,H2014,H2027,H2032,H2033,S9484,T1016

Scoring proposal (current scoring for line 413 in parentheses)
Category: 6 (7)
HL: 3 (3)
Suffering: 4 (4)
Population effects: 0 (0)
Vulnerable population: 0 (0)
Tertiary prevention: 3 (3)
Effectiveness: 2 (2)
Need for service: 1 (1)
Net cost: 2 (2)
Score: 800
Approximate line placement: 349

Treatment for Gender Dysphoria 2014

GUIDELINE XXX GENDER DYSPHORIA

Line 413

Hormone treatment is included on this line for use in delaying the onset of puberty and/or continued pubertal development with GnRH analogues for gender questioning children and adolescents. This therapy should be initiated at the first physical changes of puberty, confirmed by pubertal levels of estradiol or testosterone, but no earlier than Tanner stages 2-3. Prior to initiation of puberty suppression therapy, adolescents must fulfill eligibility and readiness criteria, and must have a comprehensive mental health evaluation. Ongoing psychological care is strongly encouraged for continued puberty suppression therapy.

Cross-sex hormone therapy is included on this line for treatment of adolescents and adults with gender dysphoria who meet appropriate eligibility and readiness criteria. To qualify for cross-sex hormone therapy, the patient must:

1) have persistent, well-documented gender dysphoria
2) have the capacity to make a fully informed decision and to give consent for treatment
3) If significant medical or mental concerns are present, they must be reasonably well controlled
4) have a thorough psychosocial assessment by a qualified mental health professional

Sex reassignment surgery is included for patients who are sufficiently physically fit and meet eligibility criteria. To qualify for surgery, the patient must:

1) Have persistent, well documented gender dysphoria
2) Have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
3) Have completed twelve months of living in a gender role that is congruent with their gender identity
4) Be 18 years of age or older
5) Have any significant medical or mental health concerns reasonably well controlled
6) have two referrals from qualified mental health professionals who have independently assessed the patient

EXHIBIT D

Expert Report of Joan C. Barrett and Elaine T. Corrough Submitted in *Boyden v. Conlin*

EXPERT REPORT OF JOAN C. BARRETT AND ELAINE T. CORROUGH SUBMITTED ON BEHALF OF THE PLAINTIFFS

Alina Boyden and Shannon Andrews, Plaintiffs
v.
State of Wisconsin Department of Employee Trust Funds et al., Defendants

CASE NO. 17-CV-264 IN the United States District Court for the Western District of Wisconsin

May 31, 2018

Presented by:
Joan C. Barrett, FSA, MAAA
Senior Consulting Actuary
Axene Health Partners, LLC

Elaine Corrough, FSA, FCA, MAAA
Partner and Consulting Actuary
Axene Health Partners, LLC

This report has been prepared solely for the use of the American Civil Liberties Union of Wisconsin Foundation and the American Civil Liberties Union Foundation (the ACLU) for the purpose of providing expert information and analysis for the above mentioned lawsuit.

axene health partners
HEALTH ACTUARIES & CONSULTANTS

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Executive Summary

The American Civil Liberties Union of Wisconsin Foundation and the American Civil Liberties Union Foundation (the ACLU), on behalf of Alina Boyden and Shannon Andrews, plaintiffs, engaged Axene Health Partners, LLC (AHP) to provide an expert report in rebuttal to the expert report of David V. Williams submitted on behalf of the State defendants in Case No. 17-CV-264 in the United States District Court for the Western District of Wisconsin. In addition to this report, AHP has agreed to provide expert testimony in depositions and at trial as necessary.

In preparation for this report, AHP reviewed the expert report of David V. Williams ("the Williams Report"), submitted on behalf of the defendants and the supporting information referenced in the Williams Report as well as other related sources of information. We did not attempt to duplicate the calculations described in the Williams report due to time constraints. We do reserve the right to perform that analysis at a later date, however. We did test the calculations and assumptions Mr. Williams describes for reasonability and consistency with standard actuarial principles. Similarly, we did not attempt to provide an independent estimate of the costs. As part of our review, however, we did compare Mr. Williams' estimate to independent sources of cost estimates.

The purpose of the Williams Report was to estimate the healthcare costs associated with removing the exclusion (the "Exclusion") in the Wisconsin State Employees Benefit Plan (the "State Plan") that excludes coverage for "surgical procedures, services and supplies related to surgery and hormone therapy associated with gender reassignment." Mr. Williams' work was done in support of the State defendants in the civil rights case of Boyden, et al., v. State of Wisconsin Group Ins. Board, et al., No. 17-CV-264 (United States District Court for the Western District of Wisconsin).

Conclusions

In our expert opinion, the methods used by Mr. Williams are generally appropriate, but his estimate of a cost of $0.15 per member per month (PMPM) is on the high end of the range we would consider reasonable. Although it was not explicitly stated, we assume that this estimate represents the cost in 2016 based on Mr. Williams' description of his work. Based on that estimate, however, it is our opinion that the cost to cover this benefit is immaterial. Based on the information described in the Interrogatories, we estimate that the average 2016 cost for covered services under the state plan is $495 PMPM, which would make the cost of removing the exclusion 0.03 % of total costs. In our expert opinion, any benefit that is less than 0.1% of total cost is considered immaterial, since it amounts to a rounding error.

Professional Qualifications

This report has been prepared by Joan C. Barrett, FSA, MAAA and peer-reviewed by Elaine T. Corrough, FSA, FCA, MAAA in accordance with the following Standards of

Practice as promulgated by the Actuarial Standards Board of the American Academy of Actuaries:

- Actuarial Standards of Practice No. 1, "Introductory Standard of Practice"
- Actuarial Standards of Practice No. 5, "Incurred Health and Disability Claims"
- Actuarial Standards of Practice No. 17, "Expert Testimony by Actuaries"
- Actuarial Standards of Practice No. 23, "Data Quality"
- Actuarial Standards of Practice No. 25, "Credibility Procedures Applicable to Accident and Health, Group Term Life, and Property/Casualty Coverages"
- Actuarial Standards of Practice No. 41, "Actuarial Communication"

Compensation

The billing rates for Ms. Barrett and Ms. Corrough are $400 per hour and $445 per hour respectively. The compensation is not dependent on the outcome of the case or on the opinions contained in this report.

Personal Qualifications

Both Ms. Barrett and Ms. Corrough are Fellows of the Society of Actuaries (FSA) and Members of the American Academy of Actuaries (MAAA) in good standing and are qualified to perform this work.

Before joining AHP, Ms. Barrett led the National Accounts Actuarial area for UnitedHealth Care. In that role Ms. Barrett and her team provided pricing and benefit strategy work for large self-insured groups, including developing the complex actuarial systems underlying this work. As part of that work, she often estimated the cost of specific benefits like transgender surgery.

Ms. Corrough provided similar support during her tenure at Aon/Aon Hewitt. In that position, she frequently reviewed the work of other actuaries. Since joining AHP, Ms. Corrough has provided expert witness services and developed a measurement system for a targeted condition management program.

Brief biographies and curricula vitae, which include a list of publications in the past ten years, are included in the appendix of this report. Neither Ms. Barrett nor Ms. Corrough has provided expert testimony.

Background

We relied on our knowledge of actuarial pricing principles in reviewing the Williams Report. In this section we describe those principles and their application to the circumstances of this case.

We reviewed the following documents in performing this review: the second amended complaint; the Defendants' Responses to Plaintiffs' First Set of Requests to Admit, Interrogatories and Requests for Production ("Interrogatories"); the Williams Report; the expert report of Stephanie Budge, Ph.D.; two reports by Segal Consulting on the costs of providing surgical and related services for treatment of gender dysphoria; the Terms and Conditions for Comprehensive Medical Plan Participation in the State of Wisconsin Group Health Benefit Program and Uniform Benefits for the 2016 Benefit Year; the World Professional Association for Transgender Health (WPATH) Standards of Care; and each of the references listed in Mr.Williams' bibliography, with the exception of the Diagnostic and Statistical Manual of the American Psychiatric Association. In addition to the sources included in the discovery process, we reviewed the Behavioral Risk Factor Surveillance System website https://www.cdc.gov/brfss) and the American Society of Plastic Surgeons website (https://www.plasticsurgery.org).

The Estimation Process

The general formula for calculating the estimated net cost of adding a benefit to a plan or removing an exclusion reflects:

- The direct costs associated with adding the benefit
- The incremental costs in currently covered benefits due to the new benefit
- Savings in currently covered benefits as a result of adding the benefit
- A risk premium

A few comments on this concept:

- Costs are based on a specific time period, usually a calendar year.
- Costs are typically calculated on a per member per month (PMPM) basis, where the definition of a member includes employees and dependents.
- The formula for calculating a PMPM = [expected number of claims during the year] x [average cost per claim]÷[average number of members covered]÷12.
- Cost of a benefit may also be expressed as a percent of total costs, in which case both the numerator and denominator need to be consistent in terms of time period and applicable population.
- The estimate should reflect typical clinical treatment patterns and accepted standards of care for the procedure or underlying condition in question.
- Similarly, the estimate should reflect the plan provisions regarding which services are covered, which services are excluded as well as any limitations or exceptions to those services.
- Whenever possible, the starting point for the estimate should be the plan's own historical experience. To the extent that is not possible, the experience of similar plans may be used, with appropriate adjustments.
- Other sources of information, like published papers and data, should be used to test the reasonableness of the estimate.
- The determination of the risk premium depends on the purpose of the estimate. If the purpose of the estimate is to provide a best estimate, then the value of the risk premium should be zero. If the purpose of the estimate is to reflect some

measure of risk, then the risk premium should be greater than zero. Typically, the risk premium does not reflect the "worst case" scenario. Instead, it is calculated assuming that there is about an 80% to 90% chance that the actual costs will not exceed the estimate.

- The final value of the risk premium should reflect potential overstatements and understatements in the best estimate calculation.

There are always uncertainties in estimating the cost of a new benefit, so approximations are necessary. In reviewing the Williams Report we consistently looked to see if the general principles described above were followed, if the approximations were reasonable and the potential impact on the risk premium.

Clinical Considerations

Clinical care for transgender individuals may include:

- Counseling and therapy before reassignment surgery, after the surgery or instead of the surgery
- Hormone replacement therapy
- Surgical procedures to feminize or masculinize the chest and genitals
- Other gender confirmation surgeries to alter the body to feminize or masculinize the patient's physical appearance

The World Professional Association for Transgender Health (WPATH) has established standards of care which include both eligibility and readiness requirements. The transition process may take multiple years to complete.

The State Plan

The State Plan currently excludes "procedures, services and supplies related to surgery and sex hormones associated with gender reassignment". In addition to this exclusion, the plan excludes cosmetic and experimental procedures, but covers other medically necessary surgeries. Our interpretation of this language is that the State Plan currently covers surgeries like mastectomies, hysterectomies, breast reconstruction and similar procedures unless there is a diagnosis code or other indicator that implies that the procedure is related to gender confirmation. We have no way to validate that with the information available but that interpretation is consistent with our knowledge of typical claims-payment policies and procedures.

If the Exclusion is removed, then the State plan may attempt to specify whether or not members under age 18 are eligible for coverage and whether or not related procedures to masculinize or feminize appearance are covered. For purposes of this analysis, we assume that there will be coverage for members under age 18 and that all gender confirmation surgeries will be covered.

Baseline Numbers

In our review we assumed that all numbers relate to calendar year 2016 unless otherwise noted. Using the answers to Questions 6 and 7 in the Interrogatories, we further assumed:

- The number of employees with individual coverage in 2016 was 26,168 and the number with family coverage was family coverage was 43,054 for a total of 69,222.
- Assuming 1 member per employee for individual coverage and 3.2 for family coverage, we estimated that there were 165,000 members in total.
- The total cost for the employer portion of the plan was $979,741,313.30, which results in a PMPM cost of $495.

Claims-Based Analysis

In preparing his report, Mr. Williams relied primarily on a claims-based analysis described in this section. AHP reviewed Mr. Williams' description of the steps that he used to calculate his estimate and we compared these steps to the general principles described above.

Methodology

The specific steps he described are:

- Define the benefit. Mr. Williams states that he used a broad approach in defining the benefit for his initial estimate. Specifically, he included individuals with a diagnosis of gender dysphoria and services that may be related to gender reassignment surgery, both in preparation for surgery and for post-surgical treatment as a starting point for his analysis. Later in his analysis, he adjusted the initial estimate to account for a potential overstatement.
- Define criteria for identifying individuals with relevant claims. The first step in Mr. Williams' analysis was to determine which individuals submitted a gender dysphoria claim. To do that, he compiled a list of diagnostic and procedure codes that indicate a potential diagnosis of gender dysphoria. To compile the list, Mr. Williams relied on the Blue Cross and Blue Shield of Massachusetts (BCBSMA) medical policy for gender dysphoria since that policy included extensive information about coding procedures. He then compared the substance of that policy to the policies used by the State Plan third-party administrators, Dean Health Plan and WPS. He concluded that the policies were similar enough that he could rely on the BCBSMA coding procedures for his analysis.
- Gather data. Using the criteria described above, Mr. Williams identified 8,200 individuals with a diagnosis of gender dysphoria using the 2016 Truven MarketScan commercial data base. Based on his description of the process, it appears that this process was HIPAA-compliant. He then assumed that the groups associated with those 8,200 individuals and only those groups covered

transgender surgery benefits. Using that assumption, he calculated the total number of members for those groups (20,037,382) and the corresponding gender dysphoria claims.

While we are familiar with the Truven data at a high level, we relied on Mr. Williams' work regarding the quality of the data and the accuracy of his calculations. We did not attempt to duplicate his work, but we do reserve the right to do so at a later date.

Findings

The following table summarizes the findings in Tables 1A and 1B of the Williams Report.

		Individuals	Total Costs	% of Costs	Cost Per Person	PMPM
Non-Surgical Patients	Counseling	4,260	$ 7,411,724	51%	$ 1,740	$ 0.03
	Hormone Therapy	4,072	$ 2,717,390	19%	$ 667	$ 0.01
	Other	6,515	$ 4,332,024	30%	$ 665	$ 0.02
	Sub-total	7,731	$ 14,400,221	100%	$ 1,863	$ 0.06
Surgical Patients	Counseling	259	$ 424,909	4%	$ 1,641	$ 0.00
	Hormone Therapy	417	$ 229,705	2%	$ 551	$ 0.00
	Reassignment Surgery	469	$ 7,318,440	73%	$ 15,604	$ 0.03
	Other	458	$ 2,017,564	20%	$ 4,405	$ 0.01
	Sub-total	469	$ 9,990,618	100%	$ 21,302	$ 0.04
All Patients	Counseling	4,519	$ 7,836,633	32%	$ 1,734	$ 0.03
	Hormone Therapy	4,489	$ 2,947,095	12%	$ 657	$ 0.01
	Reassignment Surgery	469	$ 7,257,523	30%	$ 15,474	$ 0.03
	Other	6,973	$ 6,349,588	26%	$ 911	$ 0.03
	Total	8,200	$ 24,390,839	100%	$ 2,974	$ 0.10

From this table, the total cost of covering all gender dysphoria benefits is $0.10, with $0.04 being the direct cost for gender reassignment surgeries and $0.06 for all other gender dysphoria claims, even if those claims are currently covered under the terms of the State Plan. Translating these numbers to the State Plan, the total cost would be approximately $200,000 for 68 individuals. The direct cost of the surgery would be about $85,000 for 4 surgical patients.

Mr. Williams used the midpoint of the $0.04 to $0.10 range ($0.07) as his best estimate before adding the risk premium as discussed below. In effect, his final estimate reflects a $0.04 PMPM for gender reassignment surgical services and a net increase of $0.03 for gender dysphoria services not currently covered under the Uniform Benefits provision of the State Plan. The difference between the $0.10 originally calculated for all gender dysphoria claims and the $0.07 represents the net effect of accounting for services already covered under the State Plan and the potential clinical savings associated with fewer claims for services that would be rendered unnecessary if the patients' gender dysphoria is effectively treated by hormones or surgical procedures.

Review

Overall, Mr. Williams followed sound actuarial principles and made appropriate use of the available data. That said, we have a few observations:

- Mr. Williams stated that his determinations might have overstated the average number of members which would have understated the costs. While that may be true, it is also likely that some groups with coverage had no claims, which would have resulted in an understatement in the number of members and an overstatement of the costs per member.
- It appears Mr. Williams' analysis corresponds to our assumptions about coverage described earlier.
- We reviewed several published sources, including those listed in the Williams Report, and did not find a source that helped us to quantify the potential savings associated with removing the Exclusion or the percent of gender dysphoria claims already being covered. That said, based on the expert witness testimony of Dr. Budge, transition-related care is considered cost-effective because "denial of care is associated with increased disparities in depression, drug abuse, HIV and additional conditions that are costly to treat." Based on that, we assume savings exist, even though they cannot be quantified precisely.
- In theory, the $0.03 difference between the $0.10 and the $0.07 mentioned above represents the net impact of potential savings and the overstatement from services already covered.

In addition to the review described above, we looked at the January 17, 2017 estimate provided to Lisa Ellinger by Segal consultants, Kirsten R. Schlatten, ASA, MAAA and Kenneth C. Vieira, FSA, MAAA. They estimated the impact to be in the $0.05 to $0.13 range. In addition, in a letter to Ann Timmons dated March 3, 2014, Segal consultants estimated the cost to be between 0.02% and 0.03% of total costs. Both estimates are consistent with Mr. Williams' estimate.

Given all the considerations described above, we agree that Mr. Williams' best estimate of $0.07 is an appropriate starting point. Under that scenario, the net impact to the State Plan would be $140,000 or 0.01% of total costs.

Final Estimate and Materiality

Although we agree that Mr. Williams' best estimate is appropriate, we believe his risk premium represents a "worst case" scenario as opposed to a more reasonable scenario.

Risk Premium and Final Estimate

Mr. Williams' final estimate was $0.15 PMPM. For the State Plan this translates to a total cost of 0.03% of total costs. He derived this estimate by including a risk premium of 50% for utilization and 50% for costs. In effect, he doubled the best estimate.

To put that in perspective, the difference between the best estimate and the final estimate is $160,000 ($300,000 - $140,000). This could happen under scenarios like:

- An additional single reassignment surgery at a cost of $160,000. This would be almost 8 times the average cost of such surgeries.
- 8 additional reassignment surgeries at an average cost of $20,000. This would triple the expected number of surgeries.
- 80 additional non-surgical patients at an average cost of $2,000. This would more than double the number of patients.

Given that the probability of any claim for services is close to zero, each of these scenarios is highly unlikely. Our recommendation would be to use a 25% margin, resulting in a $0.09 PMPM. This would support a scenario where there was one additional reassignment surgery and 16 additional non-surgical patients. The net impact to the State Plan would be $175,000 or 0.02% of total costs.

There were two factors supporting our recommended margin. First, according to the American Society of Plastic Surgeons, there were only 3,200 gender confirmation surgeries of all types performed in 2016 even though the surgical techniques have been around since the 1950's. We expect to see a steady growth over time, but not a doubling of the number of surgeries in the near future. Second, in our experience there is a natural tendency to overstate the cost of a benefit when it is relatively new since there is so little known about costs and utilization initially. Employers have been offering this benefit for over a decade now, so there is no need to be overly cautious.

Materiality

Even at Mr. Williams' estimate of $0.15, the removal of the Exclusion rounds to 0.0%, so it is clearly immaterial. It is standard actuarial practice to assume that any benefit that is 0.1% of total costs or less is immaterial for several reasons, but mostly because it is considered a rounding error. In our experience, no employer has made a benefits decision based on cost for a benefit that costs less than 0.1%. Regardless, there would be no way to validate the the accuracy of a projection of a cost at or below this threshhold after the fact, because normal variance for a group the size of the State Plan is between 3% and 5% based on our experience.

For the State Plan, this 0.1% materiality level translates to a 2016 PMPM of $0.50, or more than triple Mr. Williams' final estimate of $0.15, more than 5 times our final estimate of $0.09 and more than 7 times our mutual best estimate of $0.07.

Actuarial Disclosures

Reliance on Data Supplied by Others

In preparing this report, I have relied on data and reports supplied by the ACLU of Wisconsin including the Williams Report. While we have reviewed the information in detail to determine reasonability, we have not audited the data and report, and do not attest herein to their accuracy.

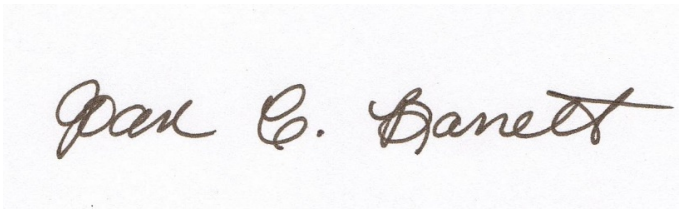
Responsible Actuary

Unless otherwise noted, I am responsible for the assumptions and methodologies presented in this report. Questions regarding this report should be directed to my attention.

Qualifications

I, Joan Barrett, am a Fellow of the Society of Actuaries and a Member of the American Academy of Actuaries in good standing, and am qualified to complete this work.

Respectfully submitted,



Joan Barrett, FSA, MAAA
Senior Consulting Actuary
Axene Health Partners, LLC
May 31, 2018

CURRICULUM VITAE

JOAN C. BARRETT, FSA, MAAA

Axene Health Partners, LLC

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SUMMARY

Seasoned health actuary with over 35 years of professional experience, recognized for technical experience, leadership, communication skills and professional integrity.

CURRENT POSITION

Advisor to Insurers and Employers

Senior Consulting Actuary, Axene Health Partners, LLC, June 2015 – Present

Role: Consulting with health insurers and employers on a variety of actuarial assignments.

Recent projects:

- Rate-making procedures and strategies
- Rate fling support
- Employee benefits pricing and strategy

PREVIOUS WORK EXPERIENCE

National Accounts Actuary

Vice President, National Accounts, UnitedHealthcare. February 1993 – June 2015

Roles: Providing actuarial support to senior management and employers

1. Actuarial support and risk management for senior management
2. Benefit design and strategic consulting for Fortune 500 employers
3. Consumerism and actuarial research
4. Small and large group rate filings and pricing
5. Actuarial support for union negotiations
6. Analysis of self-funded network reimbursement methodologies
7. Rate-filings and pricing

QUALIFICATIONS AND DESIGNATIONS

- FSA – Fellow of the Society of Actuaries (SOA)
- MAAA – Member of the American Academy of Actuaries (AAA)

EDUCATION

- Bachelor of Arts, Frederick College, Portsmouth Virginia (Mathematics)
- Master of Arts, Miami University, Oxford, Ohio (Mathemetics)

PUBLICATIONS IN THE LAST 10 YEARS

- Barrett, Joan. (2018) Time to Update Your Trend Process?. *HealthWatch* (Society of Actuaries).
- Barrett, Joan (2017). Evolution of the Health Actuary: A Health Section Strategic Initiative. *HealthWatch.*
- Barrett, Joan. (2017) Accountability: Rates. *Inspire Accountability Series*. (Axene Health Partners)
- Barrett, Joan. (2017) The Chronic Disease Burden. *Inspire Series on the U.S. Healthcare Sytem*. (Axene Health Partners)
- Barrett, Joan. (2016). Making Predictive Analytics Our Own. *Predictive Analytics and Futurism* (Society of Actuaries)
- Barrett, Joan. (2016). Ch. 34: Medical Claims Cost Trend Analysis. *Group Insurance*, Skwire, Daniel D., 7th Edition.
- Barrett, Joan and Kessler, Emily. (2015) New Directions: The SOA in China. *The Actuary* (Society of Actuaries.
- Barrett, Joan. (2010) Chairperson's Corner. *Expanding Horizons.* (Society of Actuaries)
- Barrett, Joan. (2009) Chairperson's Corner. *Expanding Horizons.* (Society of Actuaries)
- Barrett, Joan. (2008) Timing's Everything: The Impact of Benefit Rush (Society of Actuaries)

EXPERT WITNESS EXPERIENCE

- None

CURRENT AND RECENT SOCIETY OF ACTUARIES (SOA) ENGAGEMENTS, ACTIVITIES AND ACCOMPLISHMENTS

- Vice-President, 2015 to 2017
  - Chair, Value of the Credential Task Force
  - Member, Issues Advisory Committee
  - Member, Policy and Governance Committee
  - Member, Cultivating Opportunities Team
- Elected Board Member, 2011 to 2014
  - Chair, International Committee
  - Chair, Audit Committee
  - Member, Business Analytics Team
  - Academic Partner
- Initiative 18/11: What Can We Do About the Cost of Health Care
  - Planning Committee member
  - Participant
- Section Experience
  - Chair, Education and Research Section Council
  - Board Partner, Health Section Council
  - Board Partner, Predictive Analytics and Futurism Section Council
  - Chair, Evolution of the Health Actuary Task Force, chartered by the Health Section Council
  - Member, Health Section Council
- Basic Education Experience
  - General Officer, General Insurance Curriculum
  - General Officer, Group and Health

- Continuing Professional Development Experience
  - Chair, Health Meeting
  - Board Partner, Continuing Professional Development Committee
  - Frequent speaker
- Research
  - Chair, Project Oversight Group, “Enterprise Risk Management Practice as Applied to Health Insurers, Self-Insured Plans and Health Financial Professionals”
  - Chair, Project Oversight Group, “Risk and Mitigation for Health Insurance Companies”
  - Chair, Project Oversight Group, “Measurement of Healthcare Quality and Efficiency: Resources for Healthcare Professionals”

BRIEF BIOGRAPHY

JOAN C. BARRETT, FSA, MAAA

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Joan Barrett is a Senior Consulting Actuary with Axene Health Partners, LLC. She is a well-known and well-respected actuary. Joan brings great value to AHP clients with a knack for developing strong systems for analyzing network value and core actuarial functions, such as trends and pricing.
Joan joined AHP following a successful career at UnitedHealth Group, where she led the National Accounts Actuarial area for many years. In that role, she was instrumental in developing several innovative concepts in risk analysis and consumer analytics.

In 2017 she completed her service as a Society of Actuaries Vice-President. During her terms on the Board of Directors, she chaired both the International Committee and the Audit Committee. In 2011 she was named one of the Top Ten Volunteers for the Society of Actuaries. In part, this was because of her work as Chair of the Group and Health Curriculum Committee, the group that defines what every aspiring health actuary needs to know.

Joan recently chaired the Evolution of the Health Actuary Task Force which was been charged with defining the needs of health actuaries in the years to come and recommending a path to meet these needs. She is also a frequent speaker and author.

Joan received her Bachelor of Arts in mathematics from Frederick College and her Master of Arts in mathematics from Miami University. She is a Fellow of the Society of Actuaries and a Member of the American Academy of Actuaries.

Joan lives in Tolland, Connecticut near her children and grand-children.

CURRICULUM VITAE

Elaine Corrough, FSA, FCA, MAAA

Axene Health Partners, LLC

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SUMMARY

Seasoned health actuary with over 20 years of professional experience, recognized for technical experience, communication skills and professional integrity.

CURRENT POSITION

Advisor to Health Systems, Insurers, and Related Organizations.

Partner & Consulting Actuary, Axene Health Partners, LLC, January 2016 – Present

Senior Consulting Actuary, Axene Health Partners, LLC, March 2012 – December 2016

Role: Consulting with health systems and health insurers on Medicaid, Medicare, and commercial blocks of business on a variety of actuarial assignments.

Recent projects:

- Expert witness services regarding health actuarial practice and provider payment levels
- Contract review and analysis, cost model development, reimbursement schemes, and risk-based rate analysis
- Actuarial support for provider-payor contract negotiations and network development
- Analysis of self-funded rates for trusts and self-funded employers
- Strategies and structures for alternative payment models
- Evaluation of operational expenses for health plan, including negotiated MSO rates
- Cost analysis for setting network provider reimbursement rates on fee-for-service and risk (capitation) bases
- Claims analysis and payment model development for health systems
- Evaluation of risk readiness for health systems
- Measurement model for targeted condition management program

PREVIOUS WORK EXPERIENCE

Employee Benefits Actuary.

Vice President, Aon/Aon Hewitt, January 2009–December 2011. Employee benefits consulting.

Actuary/Consultant, Hewitt Associates, October 1995–December 2006 and December 2007–December 2008

Role: Consulting with employers on all aspects of their health and welfare benefits.

- Analysis of self-funded network reimbursements and overall health plan performance
- Claims analytics and reserves calculations
- Benefit design and strategic consulting
- Various national roles at Hewitt including national development leader and manager of actuarial operations for the health practice

Staff Fellow.
Health Staff Fellow, Society of Actuaries, January 2007 – November 2007.
Role: Unique national position focusing on the educational and research needs of practicing health actuaries.

QUALIFICATIONS AND DESIGNATIONS

- FSA – Fellow of the Society of Actuaries (SOA)
- MAAA – Member of the American Academy of Actuaries (AAA)
- FCA – Fellow of the Conference of Consulting Actuaries (CCA)

EDUCATION

- Bachelor of Arts 1992, Washington University in St. Louis, Classics (Languages)

EXPERT WITNESS WORK

- None

PUBLICATIONS IN THE LAST 10 YEARS

- Corrough, Elaine. (2017) Data Intermediaries: Pulling Insights from Confidential Data. *Inspire* Series (Axene Health Partners)
- Corrough, Elaine. (2016). Chairperson's Corner. *HealthWatch*. (Society of Actuaries)
- Elaine, Corrough. (2016) Ch. 18: The Affordable Care Act. *Group Insurance*, 7th Edition (Skwire)

CURRENT AND RECENT PROFESSIONAL ENGAGEMENTS, ACTIVITIES AND ACCOMPLISHMENTS

- Project Oversight Group member (Society of Actuaries Research – MACRA), 2018
- Merit Reviewer (multiple grant applications – improving healthcare systems), PCORI, 2018
- SOA Nominating Committee – 2017-18
- Merit Reviewer (multiple grant applications – dissemination & implementation), PCORI, 2017
- Project Oversight Group member (Society of Actuaries Research – Healthcare Fraud), 2017
- Presenter (Health Research), 2016 SOA Annual Meeting – Outstanding Session Award
- Presenter (ACA co-op failures), September 2016 Portland Actuarial Club
- Presenter (ACA marketplace sustainability), 2016 State of Reform-Portland
- Panelist (Actuarial Standards of Practice), 2016 SOA Spring Health Meeting
- Editorial Board member, *HealthWatch*, 2016
- SOA Health Section Council – 2015-16 Chair (elected position)
- Contributing author, *Group Insurance* (textbook, 7th edition)
- Presenter (provider reimbursement models), 2016 State of Reform-Seattle
- Presenter (actuarial communications and writing), 2015 SOA Spring Health Meeting
- Panelist (clinical measures for payment models), 2015 SOA Spring Health Meeting
- Presenter (provider reimbursement models), 2015 State of Reform-Los Angeles
- Moderator (options for small groups under ACA), SOA Webcast, July 2015
- SOA Health Section Council – 2014-15 Vice-Chair (elected position)
- SOA Health Research Committee – 2014-17 member
- SOA Health Research Oversight Committee – 2016-17 member
- CCA – 2015 Health Reform Meeting planning committee member

- Actuarial Standards Board (ASB) MV/AV Task Force and related Actuarial Standard of Practice (ASOP) – task force member
- Joint Discipline Panel – 2016 member
- Panel moderator, 2014 CCA Health Reform Meeting, *State Perspectives on Rate Filing Reviews*
- SOA Public Relations – 2013-2014 media interviews
    - "Is This the Hardest Job in America?" Wall Street Journal, 5/1/2014
    - Commentary on ACA and rate development interviews with media outlets including CNN (11/2013), BloombergBusinessWeek (11/2013), Politico (12/2013), Modern Healthcare (4/2014), Vox.com (4/2014), Kaiser Health News (4/2014), MarketWatch (4/14), Associated Press (4/2014)
- CCA – 2014 Health Reform Meeting planning committee member
- SOA Basic Education – 2013 volunteer, General Insurance track
- Panel moderator, 2013 SOA Annual Meeting & Exhibit, *Healthcare Cost Trends*
- Scorecard committee member, Healthcare Cost Institute, April 2012
- Public testimony, Joint Legislation Audit & Review Subcommittee (State of Washington), February 2011
- SOA Basic Education – 2007-08 volunteer, Health track (wrote original content)

BRIEF BIOGRAPHY

Elaine Corrough, FSA, FCA, MAAA

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O: 503.272.6036 | C: 847.271.1470 | elaine.corrough@axenehp.com

Elaine is a Partner and Consulting Actuary with Axene Health Partners, and has recently opened our new office in Portland, Oregon after working in the Murrieta headquarters for several years. With over 20 years of health actuarial experience, Elaine's recent work has focused on actuarial analysis, cost modeling, and formal certifications for carriers and health systems, including state ACA rate filings; actuarial reviews for the Round 2 Centers for Medicare and Medicaid Innovation (CMMI) Health Care Innovations Awards; and strategic and tactical support for health systems taking on risk. Elaine especially enjoys projects linking regulatory and contractual requirements with actuarial methods.

Prior to joining AHP, Elaine consulted on all aspects of health and welfare benefits for plan sponsors ranging from small public entities to Fortune 100 companies. In addition to traditional consulting activities such as pricing, discount analysis, and claims analysis for self-funded employer plans, her expertise includes actuarial analysis of legislative and regulatory developments; ROI assessments; health risk migration and mapping; and complex model design and development. She was also the national measurement leader for the healthcare consulting practice of a large consulting firm. In addition, Elaine is a past Staff Fellow in health for the Society of Actuaries.

Elaine has presented at multiple industry conferences on a variety of topics. She is a Fellow of the Society of Actuaries, a Fellow of the Conference of Consulting Actuaries, and a Member of the American Academy of Actuaries. In addition to serving on multiple committees for these organizations, she was a member of the Actuarial Standards Board Health Committee's Task Force focused on developing an actuarial standard of practice for determining minimum value and actuarial value under the Affordable Care Act. She was the 2015-16 chairperson of the SOA Health Section Council (elected position), and is also a member of the SOA's Health Research Advisory Committee.

Elaine earned a Bachelor of Arts degree in Classics (with an emphasis on languages) from Washington University in St. Louis.

CURRENT STAFF BILLING RATES

Elaine Corrough, FSA, FCA, MAAA
Axene Health Partners, LLC
503.272.6036 | elaine.corrough@axenehp.com

As of March 2018, hourly billing rates are as follows:

Elaine Corrough, FSA, FCA, MAAA - $445
Project Lead and Lead Actuary

Other team members:
Peer Review - $405-$545
Medical Director/Clinical Consultant - $435-$475
Senior Consulting Actuary - $310-$415
Consulting Actuary - $295-$345
Actuary - $170-$300

EXHIBIT E

Padula & Campbell Article

Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis

Article *in* Journal of General Internal Medicine · October 2015
DOI: 10.1007/s11606-015-3529-6

CITATIONS
16

READS
124

3 authors, including:

William V Padula
Johns Hopkins Bloomberg School of Public Health
68 PUBLICATIONS **454** CITATIONS
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Jonathan D Campbell
University of Colorado
128 PUBLICATIONS **1,146** CITATIONS
SEE PROFILE

Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis

William V. Padula, PhD MS MSc[1], Shiona Heru, JD[2], and Jonathan D. Campbell, PhD[3]

[1]Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; [2]Commonwealth of Massachusetts Group Insurance Commission (GIC), Boston, MA, USA; [3]Center for Pharmaceutical Outcomes Research (CePOR), Department of Clinical Pharmacy, University of Colorado, Aurora, CO, USA.

BACKGROUND: Recently, the Massachusetts Group Insurance Commission (GIC) prioritized research on the implications of a clause expressly prohibiting the denial of health insurance coverage for transgender-related services. These medically necessary services include primary and preventive care as well as transitional therapy.
OBJECTIVE: To analyze the cost-effectiveness of insurance coverage for medically necessary transgender-related services.
DESIGN: Markov model with 5- and 10-year time horizons from a U.S. societal perspective, discounted at 3 % (USD 2013). Data on outcomes were abstracted from the 2011 National Transgender Discrimination Survey (NTDS).
PATIENTS: U.S. transgender population starting before transitional therapy.
INTERVENTIONS: No health benefits compared to health insurance coverage for medically necessary services. This coverage can lead to hormone replacement therapy, sex reassignment surgery, or both.
MAIN MEASURES: Cost per quality-adjusted life year (QALY) for successful transition or negative outcomes (e.g. HIV, depression, suicidality, drug abuse, mortality) dependent on insurance coverage or no health benefit at a willingness-to-pay threshold of $100,000/QALY. Budget impact interpreted as the U.S. per-member-per-month cost.
KEY RESULTS: Compared to no health benefits for transgender patients ($23,619; 6.49 QALYs), insurance coverage for medically necessary services came at a greater cost and effectiveness ($31,816; 7.37 QALYs), with an incremental cost-effectiveness ratio (ICER) of $9314/QALY. The budget impact of this coverage is approximately $0.016 per member per month. Although the cost for transitions is $10,000–22,000 and the cost of provider coverage is $2175/year, these additional expenses hold good value for reducing the risk of negative endpoints —HIV, depression, suicidality, and drug abuse. Results were robust to uncertainty. The probabilistic sensitivity analysis showed that provider coverage was cost-effective in 85 % of simulations.
CONCLUSIONS: Health insurance coverage for the U.S. transgender population is affordable and cost-effective, and has a low budget impact on U.S. society. Organizations such as the GIC should consider these results when examining policies regarding coverage exclusions.

KEY WORDS: transgender health; cost-effectiveness analysis; budget impact analysis; preventive care; health law; health insurance coverage.
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INTRODUCTION

U.S. health insurance plans categorically deny transgender enrollees coverage for medically necessary services such as transition-related and preventive care.[1]

In 2013, the Commonwealth of Massachusetts Group Insurance Commission (GIC), the state's administrator of employment-based health benefits to 420,000 subscribers, prioritized research on whether the cost-effectiveness of providing benefit coverage for transgender enrollees would support the removal of exclusions of coverage for transition-related services. Current evidence indicates that transition-related care is medically necessary and effective for transgender patients.[2,3] Furthermore, recent changes in federal and state laws may place health insurer accreditation status at risk based on absence of coverage for transition-related care.[4,5] Since negative health outcomes are associated with denial of these services, it may be in payers' financial interests to cover transgender health benefits.[2] Payers could increase net monetary benefit and avoid noncompliance with regulations by offering coverage in accordance with guideline-recommended care.[3]

The American College of Physicians' position on the health care of transgender persons is that all services should be covered as they would for other beneficiaries, and that coverage should not discriminate on the basis of gender identity.[6] However, health insurance policies frequently prohibit coverage for transgender people under a clause expressly prohibiting coverage for transitional care, or based on carriers' contract interpretation.[7] Transgender exclusions result in denial of coverage when subscriber gender marker and physiology are incongruent.[8]

In 2014, the U.S. Department of Health and Human Services lifted a 33-year ban on coverage of transitional care for Centers for Medicare and Medicaid Services (CMS) beneficiaries, citing that existing literature demonstrates the efficacy, safety, and effectiveness of "sex reassignment surgery" and that "exclusions of coverage are not reasonable."[4,5] This stance stemmed from the U.S. Department of Justice's interpretation of Title VII of the Civil Rights Act that sex discrimination prohibitions extend to health benefits of transgender people.[9] This federal decision could influence how public and commercial payers define medically necessary services.

The most effective approach to transition uses individualized treatment plans,[10] which may require hormone replacement therapy (HRT), mastectomy, phalloplasty, vaginoplasty, psychotherapy, or other services.[8] The prevalence of sex reassignment surgery is 1:100,000 population, or approximately 3000–9000 in the U.S.[4,8] In 2001, 866 male-to-female (MTF) primary surgeries (bottom surgery) and 336 female-to-male (FTM) primary surgeries (top surgery) were documented in the U.S., and the prevalence has likely increased since then, despite considerable under-reporting.[4,8,11] These procedures are costly to uninsured patients. In addition, many costs for gender-specific preventive care (i.e., prostate screening, mammograms) are not covered by insurance if a patient legally changes their sex on their birth certificate.[11,12] According to Gorton et al., providing insurance coverage would appear cost-effective,[2] whereas negative outcomes associated with denial of coverage could be costly to payers because of increased morbidity.[13] For instance, studies by Lundstrom and by Kuiper and Cohen-Kettenis estimated that suicidality in transmen dropped from 20 % to 1 % after treatment.[14,15] No studies, however, have measured the economic benefit of health insurance coverage to transgender enrollees for medically necessary and preventive services.

Our objective was to analyze the cost-effectiveness of health insurance coverage for medically necessary and preventive services compared to no coverage in the U.S. adult transgender population. This study was designed from a U.S. societal perspective and evaluated outcomes over 5- and 10-year periods.[16] We hypothesized that provider coverage is cost-effective.

METHODS

Study Design

Using a Markov model, we compared the cost-effectiveness of health insurance for provider coverage (i.e., access to primary, secondary, and tertiary services provided by a physician and/or advanced practitioner) of medically necessary services in the U.S. adult transgender population.[17,18] Model parameters were extracted from the National Transgender Discrimination Survey (NTDS) of adults,[1] and provider costs for transition-related care were extracted from the Healthcare Bluebook.[19] Costs were adjusted to 2013 U.S. dollar values and discounted at 3 % along with utilities, and analyzed over 5 and 10 years.[16]

The analysis was conducted from a U.S. societal perspective. Effectiveness was measured as quality-adjusted life years (QALYs) derived from EuroQol Group EQ-5D index scores.[20] Patient costs in the provider coverage arm were considered along with probabilities for negative outcomes and any associated costs for psychiatric rehabilitation. Patients in the provider coverage arm were assumed to receive individualized transition therapy.[7] With no health benefit, patients were assumed to have lower upfront costs, but higher risks for negative outcomes, long-term costs, and lower life expectancy.

Model

The Markov model (Fig. 1) was built using TreeAge (TreeAge Software, Inc., Williamstown, MA, USA; 2009). With provider coverage, 100 % of patients were modeled to have authorized transitional therapy care in accordance with the World Professional Association for Transgender Health (WPATH) standards of care.[3]

Patients could experience a continuous progression of outcomes in escalating stages over 1-year cycles for up to 10 years. Patients in escalated states required costly rehabilitation to cycle through job loss/depression in order to return to a preferable baseline state. Patients who cycled into escalated states had increased risk of drug abuse, suicidality, and HIV.[21] The risk of death included all-cause mortality[22] and specific mortality rates from suicide and drug overdose.[23–25] Following transitional therapy, the model included costs for provider coverage to reduce negative outcomes.

No Health Benefit

The structure of the no health benefit arm accounted for denial of coverage to transgender patients for medically necessary and preventive care, as well as adverse implications. Patients began either at baseline or a job loss/depression state according to the unemployment rate associated with anti-transgender bias.[1] Patients at baseline and in the job loss/depression state were modeled as having high rates of escalating issues, including death.[1] Alternatively, patients at baseline accrued no cost.

Provider Coverage

Patients with health insurance with provider coverage could navigate through transitional therapy or denial. Patients denied coverage following a mental health evaluation transitioned to baseline or escalated states. This sub-tree accounted for variations in policy and practice, including barriers raised through insurance claims and coding processes. For example, if a female-to-male (FTM) patient changed his legal gender marker and then submitted billing for a Pap smear, coverage was modeled as denied based on his gender marker despite the provider's adherence to WPATH guidelines.

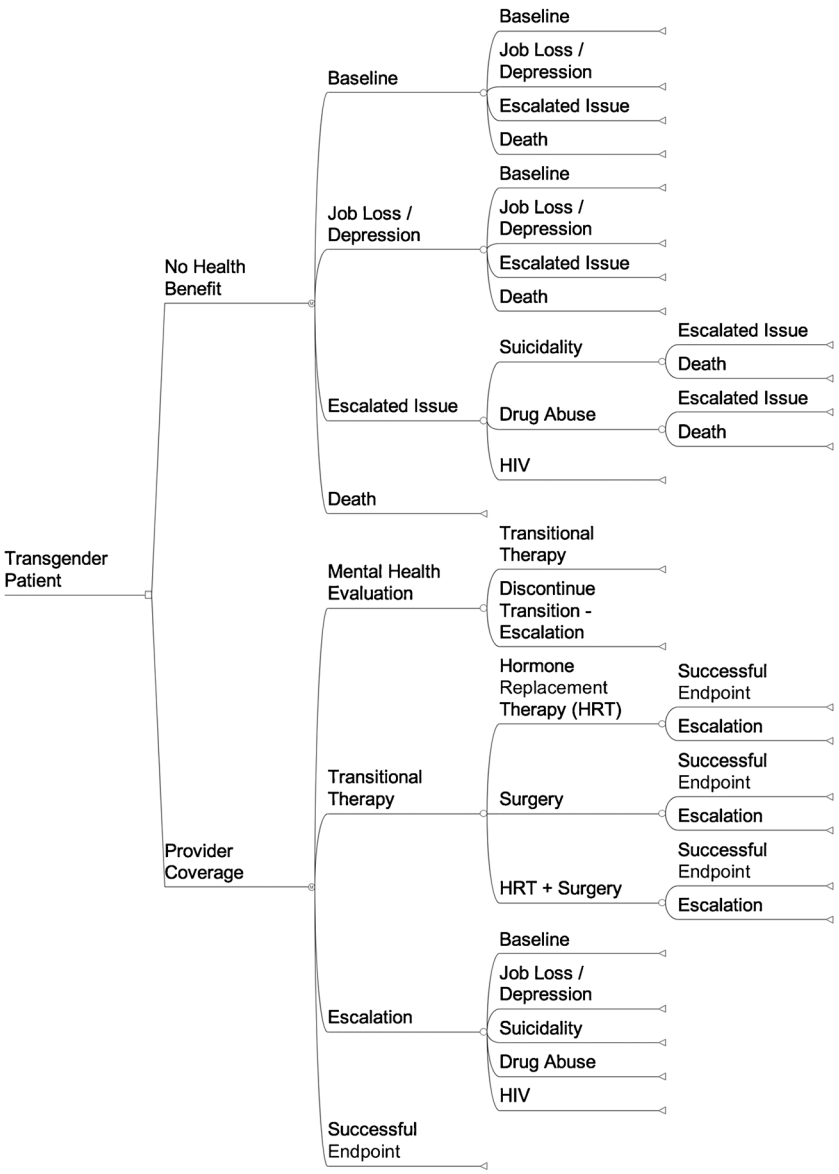

Figure 1 A simplified Markov diagram comparing no health benefit to provider coverage of medically necessary services for the U.S. transgender population.

Provider coverage was modeled as having higher costs and improved quality of life. The model also incorporated probabilities for negative health outcomes. Most patients were assumed to receive a full range of services indicated by WPATH, including reconstructive procedures.[3,7]

Assumptions

The model included several assumptions. First, provider coverage paid for the following procedural combinations: surgery, HRT, surgery and HRT, discontinued transition, and costs associated with baseline prevalence of job loss/depression. Second, costs for provider coverage were equivalent to reimbursed rates for procedural diagnosis-related groups (DRGs). Third, transitional therapy would maintain its baseline utility.

Data Collection

Data were collected from a systematic review of over 30 randomized controlled trials, observational data, and case series detailing types of gender-confirming care, whether transphobic-related events triggered negative outcomes, and the existence of a defined outcome for each related state. Many probabilities were from the NTDS (Table 1).[1]

Costs

Transition costs were gathered from the GIC public record and the literature (Table 2).[11] Existing DRGs weighted by procedural prevalence were used for initial and incremental costs of services. Thus, costs were reflective of the most common procedures (e.g. mastectomy) compared to rare procedures

Table 1 Probabilities for the cost-effectiveness analysis

Probabilities	Base Case	Range for Sensitivity Analyses	Source
No Health Benefits			
Baseline	0.74	0.629–0.851	1
Baseline	0.7	0.595–0.805	1
Job Loss/Depression*	0.199	0.169–0.229	1
Escalation	0.1	0.085–0.115	1
Suicidality*	0.82	0.697–0.943	1
HIV	0.048	0.039–0.053	1
Drug Abuse	0.13	0.1105–0.1495	1
Death	0.00012	0.000102–0.000138	22
Active	0.26	0.221–0.299	1
Baseline	0.58	0.493–0.667	1
Active	0.26	0.221–0.299	1
Escalation	0.13	0.1105–0.1495	1
Suicidality*	0.739	0.628–0.849	1
HIV	0.101	0.086105–0.116495	1
Drug Abuse	0.16	0.136–0.184	1
Death*	0.00012	0.000102–0.000138	22
Death	0.00012	0.000102–0.000138	22
Suicidality			
Job Loss/Depression*	0.47	0.399–0.541	1
Suicidality	0.33	0.281–0.380	24
Drug Abuse	0.08	0.068–0.092	1
Death	0.12	0.102–0.138	24
Drug Abuse			
Job Loss/Depression*	0.383	0.326–0.441	1
Drug Abuse	0.448	0.381–0.515	1
HIV	0.026	0.022–0.030	1
Suicidality	0.14	0.119–0.161	23–25
Death	0.0017	0.0014–0.0019	23–25
Provider Coverage			
Mental Health Evaluation			
Denied Coverage	0.07	0.059–0.081	1
HRT	0.62	0.527–0.713	1
Escalation	0.66	0.412–0.841	1
Surgery*	0.31	0.264–0.357	1
Escalation	0.0895	0.076–0.103	23
MTF	0.5		Assumed
w/HRT	0.8	0.68–0.92	1
w/no HRT*	0.2	0.17–0.23	1
FTM	0.5		Assumed
w/HRT	0.69	0.586–0.793	1
w/no HRT*	0.03	0.025–0.034	1

** Represents a remainder so that all probabilities add up to 1.0; FTM female-to-male transition, HRT hormone replacement therapy, MTF male-to-female transition*

(e.g. phalloplasty).[11,17] There were no costs attributed to baseline state or death. Depression, suicidality, and drug abuse states resulted in rehabilitative costs.[26–28] The U.S. cost of illness for HIV was extracted from Walensky et al.[29]

Cost of provider coverage was dependent on combinations of surgery and HRT. HRT was a fixed cost. The MTF group represented combinations of penectomy, breast augmentation, labiaplasty, and vaginoplasty. The FTM represented combinations of mastectomy, hysterectomy, abdominoplasty, and genital augmentation. Under provider coverage, there was an annual cost of $2175 associated with medically necessary services and preventive care.

Other treatment costs were based on DRGs. Escalated states following baseline were based on employment status. The NTDS found that 78 % of respondents who successfully transitioned reported improved job performance.[1] Conversely, respondents who experienced job loss were 70 % more likely to abuse substances than employed respondents. HIV rates among the transgender population were 400 % higher than in the general population, and doubled with unemployment.

Utilities

QALYs were extracted from U.S.-based sources (Table 3). Baseline utility was taken as the U.S. average according to Sullivan et al.[20] This index also provided utilities for depression (ICD-9 311) and suicidality (assumed as ICD-9 296). Utility for HIV was referenced from Wu et al., and Coffin et al. provided utility data for drug abuse.[30,31] Surgery had a disutility.[32] Benefit coverage for transition and successful endpoints were weighted as 0.867 QALYs, given primary preferences for these outcomes aligned with the U.S. population average.[30,31]

Sensitivity Analyses

Univariate and multivariate sensitivity analyses were used to test model uncertainty. These sensitivity analyses were performed by varying all base case estimates by reported distributions (e.g., confidence intervals, standard deviations) or by varying estimates ±15 % of the mean when distributions were not reported.

In one particular univariate analysis, the probability of patients starting in job loss/depression ranged from 0–29.9 % in the provider coverage arm, since the model assumed some baseline prevalence of depression or unemployment not negated by transition therapy, leading to downstream escalations.

A Bayesian multivariate probabilistic sensitivity analysis applied distributions for each variable to characterize uncertainty on all parameters simultaneously using 10,000 Monte Carlo simulations. Beta distributions were used for probabilities and utilities (i.e., values of 0.0–1.0), and gamma distributions were used for costs (i.e., positive values).

Budget Impact Analysis

The budget impact of transgender coverage was measured relative to the total U.S. population, thereby gauging equity of absorbing costs of coverage in a small population.[33] Budget impact was calculated on a per-member-per-month basis for an approximate 2014 U.S. population of 320 million (U.S. Census Bureau, 2014). The calculation assumed that following implementation of blanket provider coverage, there would be an influx of about 30,000 transgender persons seeking transitional care in the first 5 years (i.e., 6000/year taken as the midpoint of 3000–9000 procedures per year according to

Table 2 Costs for the cost-effectiveness analysis

State	Cost Type	ICD-9 Code	Base Case Costs ($)	Range for Sensitivity Analyses	Source
Baseline		n/a	n/a		Anchor
Job Loss – Depression	Annual	311	565.06	63.00–3781.10	28
Attempted Suicide	Annual	296	21,671.00	18420.35–24921.65	27
HIV (generic therapy)	Annual	042	11,600.00	9860.00–13340.00	29
Drug & Substance Abuse	Annual	304	11,448.00	9730.80–13165.20	26
Cost for Mental Health Evaluation	Fixed	n/a	2175.00	1848.75–2501.25	19
HRT	Fixed	n/a	4350.00	3697.50–5002.50	19
Surgery					
MTF w/HRT	Fixed	n/a	22,025.00	18721.25–25328.75	19
MTF w/o HRT	Fixed	n/a	17,675.00	15023.75–20326.25	19
FTM w/HRT	Fixed	n/a	14,658.00	12459.30–16856.70	19
FTM w/o HRT	Fixed	n/a	10,308.00	8761.80–11854.20	19
Cost for Continuous Coverage	Annual	n/a	2175.00	1848.75–2501.25	19
Death		n/a	n/a		Anchor

FTM female-to-male transition, HRT hormone replacement therapy, MTF male-to-female transition

Walsham).[32] The additional cost would be the difference in cost of benefit coverage from the model.

RESULTS

Expected Cost and Effectiveness

Provider coverage resulted in higher cost and greater effectiveness, and was cost-effective relative to no health benefits at 5 and 10 years from a willingness-to-pay (WTP) threshold of $100,000/QALY (Table 4). These results were driven by the cohort without health benefits, which had less favorable outcomes, including depression, HIV, and death. The 5-year incremental cost effectiveness ratio (ICER) was greater than that at 10 years, since upfront costs for transitional therapy were not yet offset by costly long-term endpoints of excluded coverage (e.g., HIV, drug abuse).

The 5-year budget impact analysis determined a cost of $0.016 per member per month, meaning that if U.S. society assumed the role of paying an additional $10,614 for each person seeking benefit coverage, the U.S. population could absorb these costs for just cents per month.

Table 3 Utilities for the cost-effectiveness analysis

Utilities	ICD-9 Code	Base Case Utility	Range for Sensitivity Analyses	Source
Baseline*	n/a	0.867	0.737–0.997	20
Job Loss – Depression	311	0.732	0.622–0.842	20
Attempted Suicide	296	0.693	0.589–0.797	20
HIV	042	0.800	0.680–0.920	31
Drug & Substance Abuse	304	0.800	0.730–0.900	30
Hormone Replacement Therapy (HRT)	n/a	0.867	0.737–0.997	Assumed
Surgery (transition utility from baseline)	n/a	−0.155	−0.178 to −0.132	32
End-State	n/a	0.867	0.737–0.997	Assumed
Death	n/a	0.0	0.0–0.0	Anchor

**The benefit of having transitional therapy is no disutility from baseline status*

Sensitivity and Threshold Analyses

Variations in expected values of all cost, probability, and utility estimates did not change expected results. Univariate sensitivity analyses indicated that the model was most sensitive to (1) probability of suicidal death, (2) probability of drug abuse, and (3) utilities of baseline, depression, and drug abuse. However, univariate and two- and three-way sensitivity analyses did not alter results.

The results did not change in sensitivity analysis of patients with provider coverage starting at a baseline with job loss or depression. The maximum probability of 29.9 % job loss/depression produced a 10-year ICER of only $20,942/QALY.

The probabilistic sensitivity analysis showed that provider coverage was cost-effective compared to no health benefit in 8477 of 10,000 Monte Carlo simulations at a mean ICER of $8655/QALY (median ICER of $8593/QALY). In 389 of these simulations, provider coverage dominated the alternative (Fig. 2).

DISCUSSION

These findings suggest that the removal of transgender exclusions is affordable and efficient with respect to the U.S. population. Provider coverage is a cost-effective policy at a willingness-to-pay threshold of $100,000/QALY. The ICER of provider coverage for medically necessary services and preventive care at 10 years is about $9300/QALY, which suggests that this policy would be comparatively efficient on a per-patient basis. Even at 5 years, this type of program still holds good value. These findings appear robust to model uncertainty according to sensitivity analyses. In addition, the results of the budget impact analysis imply that this policy is affordable, with a cost of only about $0.016 per member per month.

Table 4 Expected results of the base case cost-effectiveness analysis

	Cost (USD 2013)	Δ Cost	Health Utility (QALYs)	Δ Utility	ICER ($/QALY)
5-Year Time Horizon					
No Health Benefit	10,712.00		3.71		
Provider Coverage	21,326.00	10,614.00	3.98	0.27	39,311.11
Male-to-Female (MTF)*	22,545.00	11,833.00	3.98	0.27	43,825.93
Female-to-Male (FTM)*	20,107.00	9395.00	3.98	0.27	34,796.30
10-Year Time Horizon					
No Health Benefit	23,619.00		6.49		
Provider Coverage	31,816.00	8197.00	7.37	0.88	9314.77
Male-to-Female (MTF)*	33,034.00	9415.00	7.37	0.88	10,698.86
Female-to-Male (FTM)*	30,597.00	6978.00	7.37	0.88	7929.55

(*) Compared to no health benefit; QALY quality-adjusted life year

This case presents an economical coverage policy that can be likened to patients in the U.S. facing similar challenges of access to necessary care, such as those with rare diseases who have access to necessary health technology as a result of the Orphan Drug Act of 1983.[34] For instance, cystic fibrosis (CF) affects a population of only 30,000 individuals in the U.S., but has evolved into a successfully treatable chronic disease with the availability of new pharmaceuticals.[35] While the cost of ivacaftor for CF ($300,000/year) is neither affordable nor efficient (ICER>$ 1million/QALY), this act makes it available to CF patients.[36] By the absorption of the cost of ivacaftor across the U.S. population for people who are uninsured or have annual incomes less than $150,000, the budget impact is only about $0.05 per member per month.[37]

While justice, legality, and a desire to avoid discrimination should drive decisions about benefit coverage, this case for the transgender population also appears economically attractive. The budget impact analysis calculates the expected value of costs for a state with an average population of 700 instances of transition therapy each year. Thus, if state governments require

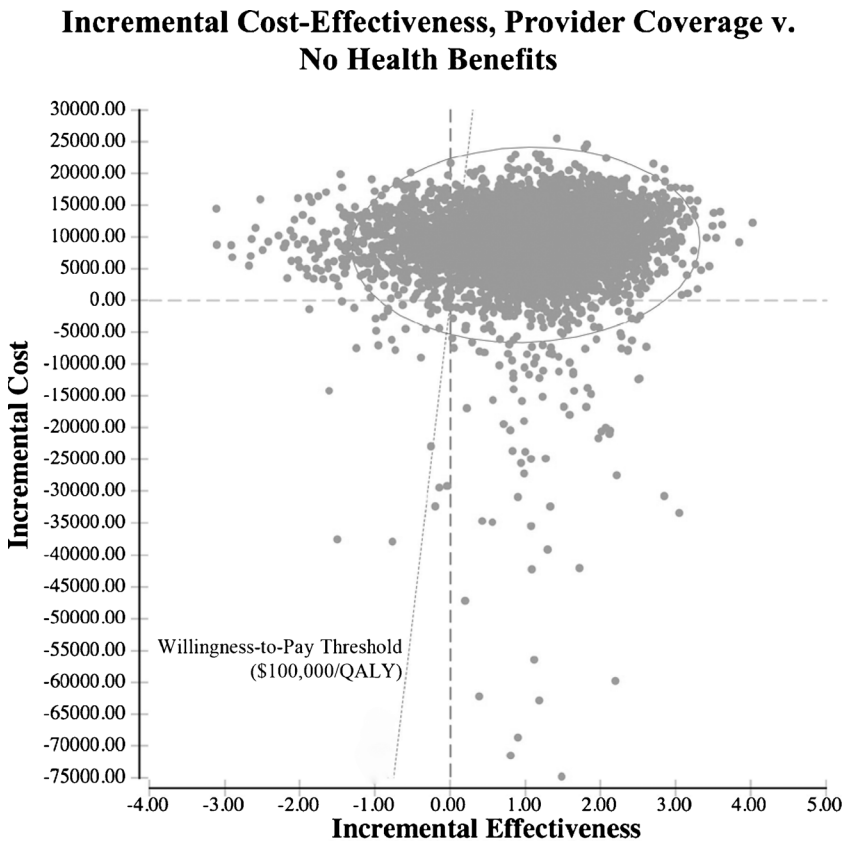

Figure 2 A scatter plot of a Bayesian multivariate probabilistic sensitivity analysis measuring the incremental cost-effectiveness ratios (ICERs) of 10,000 Monte Carlo simulations. Under no health benefit, people who are transgender navigate issues such as employment discrimination and depression, which can escalate to more severe health states such as suicidality, drug abuse, and HIV, according to the 2011 National Transgender Discrimination Survey. A lack of provider coverage under this arm increases the risk of these issues. In the other arm, provider coverage improves access to primary and preventive care, as well as medically necessary services that in most cases lead to transitional therapy such as hormone replacement therapy and surgery. The majority of people with provider coverage achieve preferred health states with greater utility, at an increased cost per year of about $2175. The risks of escalated issues such as depression and suicidality still exist for the provider coverage arm, since not all people qualify for all benefits, and transitional therapy does not completely insulate against these issues.

that payers offer coverage, insurance companies need to account for approximately $7.5 million per state. While cost-effective on a societal level, there is some upfront investment required of payers. A return-on-investment (ROI) calculation for this figure shows that it would take a payer approximately 63 years to break even on an investment in this type of benefit program.

However, legal and administrative barriers can hinder the implementation of new policy informed by these results. First, commercial payers are accustomed to negotiating contracts and benefit packages in ways that may resist change. It may be difficult to instantaneously adopt changes in provider coverage when exclusions are enforced by a third party or if state law defines health services to exclude transgender benefits.[38] Fortunately, transgender exclusions were recently removed by states, commercial payers, and CMS.[4,7]

According to the Human Rights Commission, 57 of the approximately 200 major employers offering at least one transgender-inclusive health care coverage plan were law firms, possibly reflecting the growing legal consensus that transgender exclusions are discriminatory in practice.[7,39] At least 17 major insurance carriers administer or provide coverage for at least one employer or student plan offering transgender benefits (e.g., Aetna, Cigna, Harvard Pilgrim, United Healthcare, and Blue Cross Blue Shield Massachusetts).[40] Additionally, numerous public employers offer provider coverage (e.g., University of California, University of Michigan, City of Minneapolis, City of New York, and City of San Francisco).[15,40] However, most U.S. health insurance policies still contain transgender exclusions, even though treatment of gender identity disorder is neither cosmetic nor experimental.[40,41]

This study has several limitations. First, data were lacking on whether transition-related therapy completely prevents negative endpoints such as depression/suicidality, or whether a baseline prevalence still exists. Second, some data in this analysis were representative not of the transgender population, but of the general population. Third, no empirical evidence exists on the time-dependency of escalated issues, so expert opinion guided transition probabilities. Fourth, no true health utilities were available for outcomes triggered by anti-transgender bias.[11] Fifth, some costs were derived from an ad hoc survey of provider affiliates to the GIC. Although these results should be widely applicable to most institutions, some insurance carriers have third-party payers or self-payers that could change the relevance of these results. Sixth, while depression and job loss are grouped together in the model, there may be some element of exclusivity in these two states that cannot be well-discerned by health utility. Seventh, HIV and drug abuse represent two of many possible negative outcomes; the choice to highlight these in the model was based on reported prevalence in the NTDS.

Finally, this study did not include children or adolescents, and focused on an adult-only population, based on the age of respondents in the NTDS. According to de Vries et al., young adults experience alleviation of gender dysphoria and improvement in psychological functioning following gender reassignment.[42] Given this promise, the field could benefit from additional outcomes research among youth.

Another challenge of this study involves the premise that outcomes research is able to justify transgender benefit coverage. QALYs in this study come from societal preferences for chronic conditions. People are not asked to consider a state of being for a transgender person who is depressed or HIV-positive, for example, nor are transgender individuals represented. According to Lyons et al., there is a stigma attached to the inclusion of transgender-stratified preferences and outcomes in trials and observation,[43] which speaks to the broader issue of gaining consensus within U.S. society in accepting that unique services covered by transgender benefits are as necessary as care for people not seeking a transition.

By removing transgender exclusions, society could change the trajectory of health for all transgender persons. It is worth considering that other costly surgeries (e.g., breast reduction;, spinal fusion for chronic back pain), procedures (e.g., in vitro fertilization), and health technologies (e.g., drugs such as sildenafil citrate for erectile dysfunction) that consensus dictates as not medically necessary are still covered by payers. Overall, payers may provide the motivation for progress in a field when there is the potential of reimbursement for improved performance. This concept could be likened to poor outcomes of phalloplasty in MTF transitions: surgeons might invest in trials that improve outcomes of these complicated procedures if they knew they would be reimbursed.[44] A law protecting transgender benefit coverage is not only medically necessary, but is morally imperative.

Ultimately, removing a clause expressly prohibiting coverage for medically necessary care in the transgender population is economical at a U.S. societal level. State laws that define "health services," thereby dictating benefit exclusions, should be amended to reflect contemporary medical evidence.[4,38,45] Affiliated contracting agencies and bodies should remove their corresponding exclusions given that provider coverage is affordable, efficient, and equitable.

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Compliance with Ethical Standards

Conflict of Interest: *The Authors have no conflicts of interest to declare. Authorship of this manuscript follows ICMJE guidelines; each author is associated with conceptualization, writing, final approval, and accountability for the work.*

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