IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.,
Plaintiffs,
V.
DALE FOLWELL, et al.,
Defendants.

No. 1:19-cv-272-LCB-LPA

DEPOSITION
OF
DALE FOLWELL

AUGUST 12, 2021

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NORTH CAROLINA STATE HEALTH PLAN
3200 Atlantic Avenue, First Floor
Raleigh, North Carolina

Reported by: Michelle Maar, RDR, RMR, FCRR

Q. What are your responsibilities as Treasurer?

A. Well, there are lots.

Q. Let me rephrase that because I understand -- what are your main responsibilities?

A. To put this in context, the, the State Treasurer's Office of North Carolina, as of this week, is, manages nearly a quarter of a trillion dollars. That's almost 250 million billion dollars. And just the Pension Plan is the 26th largest pool of public money in the entire world.

So I'm sometimes asked if I signed the one dollar bill. That's where people see the word treasurer. And it's an obvious question. But I don't do that. But we manage one of the largest pools of that, those in the world.

And to put that in context, that is 10 times larger than the state budget that's being debated as we sit here.

So I would be glad to go down and answer your question if I may.

Q. Please do.

A. Okay. I would say that, that it includes the State Pension Plan, which manages the pension assets for nearly 1 out of 10 adult North Carolinians, those that teach, protect, and otherwise serve, with nearly 900,000 participants.

That Pension Plan is considered one of the best-funded pension plans in the United States. I'm not sure where you're from, but I can probably compare ours to wherever you are from.

And the Pension Plan has, as well-funded as it is, which should give you a little bit of fear of how some of these other pension plans are doing, as well-funded as we are, it has tremendous headwinds.

And most of these headwinds that I'll mention to you are blessings. Zero interest rates is a blessing when you're investing in your life or buying a house or buying a car or starting a business. It's not a blessing for pension plans.

Increased life expectancies, that's obviously a blessing on the face of it.

When I was in high school in 1977, there were about 300 people over the age of 90 who were getting a pension check. Last week, it was 7000 people over the age of 90.

And then somewhere along the way of the last 35 years, the minimum retirement age was taken out of the Pension Plan.

So this is not political or emotional, it's mathematical -- especially for the certain life expectancies. We're now in the situation that, because

people can retire when they're 50 years old, we have the majority of our members who are going to be receiving more retirement checks than paychecks. And the plan was never really designed for that.

So all of our focus and the number one responsibility has to do with my pledge to the participants in these plans because of my fiduciary responsibility, which includes being loyal and exercising a duty of care to preserve, strengthen, but figure out how to sustain this plan for this and the next generation of public service workers.

The Plan is paying out nearly 550 million dollars gross every 30 days. The amount of gross dollars leaving the plan is twice as high as the state debt. So it's kind of a big deal and a big responsibility.

The second is the Defined Contribution Plan, which has over 15 billion dollars in it today. Just this week, we received two national awards.

Both of these plans have recently been designated being in the zero percentile -- which is where I spent most of my school career, which is not a good thing.

But when it comes to scoring it, the efficiency of a Pension Plan, it's a great thing.

And so the Defined Benefit Plan, as well as the Defined Contribution Plan have, are getting national

accolades for what we've tried to do to simplify these plans and to cut expenses.

The Defined Contribution Plan is made up of a 401, 457, and a 403. And it, I think the 457 Plan is not as large in total dollars as the California plan is, but it has more enrollees.

So when you go from the Pension Plan, the Defined Contribution Plan, then the next level would be the State Health Plan, which is the largest purchaser of healthcare in North Carolina, and the State Pharmaceutical Plan, which is, for public service workers, also the largest in North Carolina.

When I was sworn in as keeper of the public purse, that was, I inherited a broke and broken State Health Plan.

And the broke part is something that was brought to my attention in 1993 actually, before -- if you can believe it's been that long.

And I'll be glad to explain why if you like.

Q. Please do.

A. A person that is considered by most around these parts to be possibly the best banker in history is a fellow by the name of John Medlin.

Now, I'm sure I've cleaned John Medlin's toilets at a gas station or I've pumped gas in his car or cooked food for him at Mayberry's. But I didn't know who he was.

A. The most important person in the whole place.

Q. I will agree with you generally because most executive assistants are.

And we already know who Ms. Crabtree is, right? We've talked about her.

A. I don't dispute this timeline or this time stamp. I'm just surprised that Sam Hayes was working here in February of 2017, but that's what it says.

I thought Blake stayed here until April or May of that year.

It's not here nor there -- I'm just -- I thought Blake was here for several months as the interim General Counsel, which means Sam would not have been working here.

Q. Right. And it may have been habit, I know people type in e-mails after they --

A. This person didn't even work for -- anyway, mental curiosity.

Q. Getting back to Exhibit 7 -- so Ms. Moon is e-mailing you.

A. Yes.

Q. And the first line says you've asked several times for a list of requirements associated with the Plan's participation in the federal Retiree Drug Subsidy (RDS) Program.

Do you see that?

A. I do.

Q. Why were you asking for a list of requirements associated with the Plan's participation in the RDS Program?

A. I believe I was asking regarding matters that had nothing to do with the basis of this case.

That is, that, at that point, the previous treasurer had flipped the PBM, prescription drug benefit manager, on January 1, 2017 from Express Scripts to CVS Caremark.

So as you can imagine, when people have been, retirees especially, have been on Express Script for many, many years, that when they're flipping over to a new manager, there's different tiering, there's different this, there's different formulas, there's different all these things that none of us like regarding drug costs or figuring out what they pay for.

I was asking this question specifically in relation to a notion that I got -- was the State Health Plan participating in what we, I think is known as the 40B Program.

The 40B Program, it's my understanding, is a program that allows the, other governmental entities to get the same drug prescription rates as the Federal Government negotiates through CMS and EA.

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MAXWELL KADEL, et al.,
Plaintiffs,
V.
DALE FOLWELL, et al.,
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No. 1:19-cv-272-LCB-LPA

DEPOSITION
OF
DEE JONES

IN HER INDIVIDUAL CAPACITY
and
30(b)(6) DESIGNEE FOR NC STATE HEALTH PLAN

AUGUST 3, 2021

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PNC PLAZA DOWNTOWN
301 Fayetteville Street, Suite 1700
Raleigh, North Carolina

Reported by: Michelle Maar, RDR, RMR, FCRR

Q. And in 2016, did the Plan's benefits coverage provide for blanket exclusions for treatment of gender dysphoria?

A. Yes.

Q. I would like to show you what I'm marking as Plaintiffs' Exhibit 1.

(Exhibit 1 is marked for identification.)

MS. RAVI: I'll give you a moment to review the document. I know it's lengthy.

MR. RULEY: You've seen it before.

THE WITNESS: I've seen it once or twice.

BY MS. RAVI:

Q. Do you recognize this document?

A. I do.

Q. What is this?

A. It is the 80/20 PPO Plan Benefits Booklet for the period January 1 through December 31 of 2016.

Q. Would you turn to the page marked as PLAN DEF2711.

In the 2016 Plan Year, did the Plan exclude from coverage treatment or studies leading to or in connection with sex changes or modifications and related care?

A. Yes.

Q. If you could turn to the page marked PLAN DEF2699.

In the 2016 Plan Year, did the Plan exclude from coverage psychological assessment and psychotherapy treatment in conjunction with proposed gender transformation?

A. Yes.

Q. If I refer to these two exclusions from coverage today as the exclusions, will you know what I'm talking about?

A. Yes.

Q. All right. When was this exclusion language added to the Plan documents?

A. As I understand it, back into the '90s in some capacity.

Q. And with the exception of Plan Year 2017, has the exclusion been in place continuously since it was introduced?

A. As I understand it, yes.

Q. And is that correct for the 80/20 PPO Plan?

A. Yes.

Q. Is that also correct for the 70/30 PPO Plan?

A. Yes.

Q. And for the High-Deductible Health Plan?

A. Yes.

Q. Who is eligible to enroll in the State Health Plan?

A. State employees, teachers, public school teachers, employees of the University Systems of North Carolina, employees of the Community College System, lawmakers, and former lawmakers, some charter schools, some municipalities, and, of course, state agencies.

Q. Okay. And by that, you mean employees of charter schools, municipalities, and state agencies?

A. Yes.

Q. Anyone else?

A. No.

Q. And what is the plan year?

A. January 1 through December 31st.

Q. All right. Can you generally describe the process by which the Plan determines benefits for a subsequent plan year?

A. We start with the existing benefits. And unless there are any material, or changes that the Plan has decided to add, it will be the same booklet or same benefits going forward.

Q. How does the Plan decide whether to make changes going forward?

A. Starting with the overarching goal of providing healthcare for its members, and recognizing that we are a government plan, and recognizing that we have limited funding all provided by taxpayers, we start with that.

Q. Did you discuss this recommendation with the State Treasurer?

A. No.

Q. Is it correct that care must be medically necessary to be covered by your Plan?

A. Yes. But the Plan does not cover all medically necessary treatment.

Q. At the time of this draft resolution, was it the Plan's position that gender transition services were medically necessary care?

MR. RULEY: Objection, form.

THE WITNESS: Again, a lot of things are medically necessary that the Plan doesn't cover. And a lot is not, it's maybe a little bit of a loaded word. But that is what it says here.

BY MS. RAVI:

Q. I'm sorry -- could you clarify when you say that is what it says here?

A. It says here in the resolution that the board approve medically necessary coverage.

Q. Medically necessary coverage of gender transition services?

A. Yes.

Q. Regarding the position on whether or not gender transition services are medically necessary coverage, has

A. That is correct.

Q. What was the basis for that reference?

A. This is the Treasurer's words. I'm not aware of what he was referring to. I don't disagree with it. But these are his words.

Q. All right. Are you aware of the Treasurer's basis for this statement?

A. No.

Q. Does the Plan believe the treatment for gender dysphoria is medically uncertain?

A. Yes.

Q. When did this view develop?

A. Please repeat.

Q. When did this view develop?

A. I would say over several years. In 2016, it's very clear that while the presentations had a lot of supporting documentation, the basis of the sunsetting or the removal of the exclusion was based on the 1557 Rule and the need to keep the federal funding.

And the Plan at the time, the staff used and put forth all sorts of other information when we just went through.

But since that time, we have new staff, we have a small staff, we manage contracts, and we have limited clinical staff.

But the people we work with, and as I already mentioned the journals or whatever that I have reviewed and discussions we've had with current and former board members, there's a lot of uncertainty on whether or not the treatments are effective. And in some cases, maybe they are. But there's discussion in the space of the, more the psychological effects and how much it's important there versus the surgery, the transition surgery.

Q. And what was the basis for Treasurer Folwell's statement regarding the medical uncertainty?

MR. RULEY: Objection, form.

THE WITNESS: I don't know.

BY MS. RAVI:

Q. Did Treasurer Folwell discuss this statement with you?

A. No.

Q. Did Treasurer Folwell discuss this statement with anyone at the Plan?

A. I'm not aware of any conversations he had with anybody at the Plan.

Q. And does this statement from October 25th reflect the views of the State Health Plan?

A. Parts of it might, such as the legal and medical uncertainty.

The Franciscan Alliance opinion came out in

December of 2016. And we know there were various cases in Texas I believe.

So, again, I think there's legal uncertainty. I think there's medical uncertainty. And our thoughts kind of went down that direction.

Plus the fact that this is such, as we already went through, the Blue Cross spreadsheet that was part of the record, where it's such a small part of the Plan membership that this benefit would apply to. It's a niche. I call that a niche, a small population of people.

And the Plan can't cover every requested benefit for every single niche that comes forward, niche population. It happens all the time.

You know, I have to turn down parents who want a special feeding benefit for their infant children who can't process food normally.

I have to turn down hearing aids for a much larger population of people because they're so expensive. There's plenty of efficacy there, right? It helps people hear. But the fact that they have to change hearing aids every five to six years or more frequently, I can't afford that as a Plan.

Because if I -- I have to serve a whole entire population with a very finite amount of money. And so the only thing I can really cover is the current state of

benefits and any benefits that might apply to a broad swath of the population with a not guaranteed but a strong proponent of lower costs in the future.

And so that's where legal and medical uncertainty -- I don't have to cover medically necessary treatment. We cover a lot of it. But in this case, we don't.

Q. Prior to this statement coming out on October 25, 2018, did Plan staff discuss the legal uncertainty that's referenced here?

A. Yes.

Q. Did Plan staff discuss the medical uncertainty that's referenced here?

A. Yes.

Q. Let's turn back to Exhibit 5. And if you can turn to Page 10 of this document.

Plaintiffs' Interrogatory Number 3 asks the Plan to discuss the factual basis for each governmental interest that the Plan contends supports the exclusion.

Is that right?

A. Yes.

Q. And is it correct, turning to the next page, the Plan states that the Plan has not identified any valid, reliable, peer-reviewed longitudinal studies that support the efficacy of the plaintiffs' desired treatment?

A. I'm sorry -- where are you?

Q. I am at the bottom of Page 11, last paragraph.

A. Okay.

That would be true.

Q. Is a peer-reviewed, longitudinal study that supports the efficacy of treatment a prerequisite for the Plan to cover a proposed benefit?

A. Not necessarily. When we evaluate, as I think we said earlier, it's a holistic review. There's no single pathway to coverage. It has to be a broad swath of membership, that there's a benefit for multiple people.

There's a cost component to it. There's a downstream cost component to it. There's got to be some common -- not experimental for sure.

There's got to be some common understanding in the medical community that it is a treatment that will produce a downstream effect that's positive.

So, you know, it's very difficult to come back and say well, peer-reviewed, longitudinal studies -- I'm not a clinician and I'm not a researcher, so it's, you know -- but to the extent that we have not found any real evidence that it's absolutely black and white, this particular issue.

You know, I think it goes, well, it should go without saying this is not a personal issue for me. I don't get, I have no personal opinion about this.

Because I walk through the front door at the office, and I'm a fiduciary. This is all about the cost and maintaining this benefit for 740,000 people who expect it every single day and the retirees that have an expectation of the benefit when they retire.

And so every decision I make -- and I'm speaking for myself -- is about that. It's all about that every day.

It breaks my heart 9 times out of 10 when I have to decline a benefit, 9 times out of 10.

When I see people that need hearing aids, I would love to give them a hearing aid, I would love to.

I have nothing against transgender people. I would be more than happy to provide the benefit. But it's not my decision. I'm a fiduciary first. And I'm responsible for 740,000 people. This is not personal. This is all about money very simply put.

I've been charged with reducing the costs of the Plan to operate since the day I started. And we have done just that.

You know, there's some discussions about how much money the Plan has saved. Well, it's because we've worked really hard to do that. We've taken out all extraneous benefits.

We used to cover benefits for a small population

A. Yes.

Q. So looking at all enrollees in the Plan, 15 percent of those enrollees account for 85 percent of the cost of treatment?

A. Correct.

Q. Can an individual enrolled in the State Health Plan request that the State Health Plan change the pronoun associated with that enrollee?

A. Please rephrase.

Q. Can an individual that's enrolled in the State Health Plan request that the Plan change in its records the pronoun that's associated with that individual?

A. The member can change his or her own pronoun.

Q. How does that process occur?

A. The member logs in to eBenefits or calls into the call center, benefit-focused call center, and either changes it him or herself, or requests that it be changed.

Q. Okay.

A. It's not validated.

Q. What does that mean for it not to be validated?

A. You could put in whatever you want. There's two options, male or female.

And if I were female and put in female, I could do that. Or if I wanted to put in male, I can do that. If I make an error, I can do that too.

Q. And you said an individual can either log in and change that themselves or they can make a request that the Plan make that change?

A. No. They call into the call center, talk to a call center rep who will record the call. And then they can be requested to make that change.

Q. To whom is that request made?

A. The call center rep.

Q. If a call center rep gets that kind of request, what happens next?

A. They comply with the request.

Q. And how does that process occur?

A. They go into the system and check yes or no or male or female or exactly -- I guess it's male or female.

Q. And prior to going into the system, is any validation requested?

A. Absolutely. Whatever -- like the member would call in, and there would be validation questions from the call center rep back to the member to confirm any number of demographic statistics.

Q. What are those validation questions?

A. I don't know them specifically. But it's something that would be similar to what we all do, which is your address, your full name, possibly your Social Security number, you know, phone numbers, whatever, to try to --

they're a vendor. I don't tell them how to do their job. I just tell them they have to validate it. It's not my obligation how to exactly do it.

Q. So is it fair to say that validation is with respect to making sure that the person calling in and making this request is who they say they are?

A. Yes.

Q. Does the Plan require proof of any enrollee's chromosomes before it goes into the system and complies with that question?

A. No.

Q. Does it require proof of an enrollee's anatomy?

A. No.

Q. And does it require proof of an enrollee's DNA?

A. No.

Q. Everything we just talked about with regard to changing the pronoun in the system, does that also apply to a request to change an individual enrollee's gender marker in the system?

A. We don't track gender markers in the system other than male or female. We only have but two options right now.

Q. Is participation in the Plan required for state agency employees?

A. No. They have a choice. I mean the benefit

role, but I would say we have two people, we have a real actuary, Charles Seifert. And we have a financial analyst, Tamera McNeal.

Q. And you said it's a different perspective with regard to how issues are approached with current Plan staff --

A. Uh-huh.

Q. -- as opposed to Plan staff in 2016.

A. Uh-huh.

Q. Can you clarify that?

A. In 2016, there was Mona and Lotta and Caroline. And they seemed to make all the decisions and were supported by staff and maybe some of the clinical perspective that -- they actually had more clinicians back in those days.

Today, we are a flatter staff. And we have a very diverse group of experience and background and skill sets. And so we bring them all to the table.

And we work through -- again, our focus, at the direction of the Treasurer, is about making sure the Plan is in existence tomorrow, in five years, in ten years.

And that's really hard to do when we're being funded at a 4 percent or better or less level, and our trend rates are at 7 percent. The math just doesn't work.

Q. With regard to the Plan's current staff, is there

not personal. This is not something that I get to make a choice about. Because if I had every single group that comes in to ask for a benefit, if I covered that, then I would be completely, completely avoiding my fiduciary responsibility to cover basic health. That's what the Plan Benefits Booklet says, right?

The Plan Benefits Booklet identifies every single thing I cover. And it provides healthcare. We want every member of the Plan to have good healthcare. We want the -- and the reality is we have a lot of members who have diabetes. We have a lot of members who have orthopedic issues. We have a lot of members who have RA. We have really a lot of members who have cancer. And they want to be, they want to be covered.

And so it's really difficult for me to just say, you know, I can take this group of 25 and this group of 10 and these -- if you add all that up -- I'll, I'll totally admit that the cost of this benefit is not going to break the Plan, never was, never will.

But it -- I can't do it for that group and not do it for the group that wants it for their infants, for, you know, for a certain feeding formula for that infant group, and I can't do it for the hearing aid group, and I can't do it for the group that really wants acupuncture.

Because once you start adding those, then I have

to keep going. Everybody who comes in and wants a benefit, I'll have to do it because I can't discriminate.

I'm not discriminating. This is about what the Plan can afford in the environment that we're in today -- which is I have a General Assembly that's funding me at 4 percent when my trend rate is 7 plus. And that's not even absolutely certain.

I have a 28.8 billion unfunded liability for retiree healthcare that I, myself, am ready to have in a few years.

And so, you know, this is all about being a government plan. And I don't get to, I don't get to pick and choose. I'm not a commercial plan.

So let's start with that. A commercial plan, they have revenues, right? You go out and sell widgets, and you sell a lot of widgets, and then you decide how much you want to put into the benefit. And you can have your member, your staff, your employees pay.

I would bet most employers -- I was paying 100 bucks when I was at Time Warner. I was paying for the family, and I wasn't fully subsidized.

At the State Health Plan, we've got people who, a whole lot of employees have to work one week out of a month just to cover their Health Plan for their family.

And the effort to just institute a 25 dollar

premium for the 70/30 Plan and a 50 dollar premium for the 80/20 Plan was a herculean effort. They had never paid anything until 2018. Employees had never paid anything until 2018 -- which is crazy. I mean I get that.

But we can't just keep adding costs to the Plan.

And the General Assembly, in the 2016 budget, I think it's 2016-94, something like that, said you got to stop, you've got to control your costs, you're not getting more than 4 percent, and you can't go over.

So what happens when I spend more than I've got? I've got to charge employees. And I got to charge employees who, you know, read the, you know employees don't make market rates. They just don't.

And so it is a very tight -- I mean I live in a box. And there's not a lot of room in the box to move because I have the General Assembly describing what I can do. You know, it's all -- eligibility, it's all in statute. My funding is all in statute, in the budget bill. And that's one box.

I work with vendors who I have to make them work together. And, quite frankly, as big as we are, I got at least one vendor that's not real cooperative. And it's really annoying. But it doesn't matter -- apparently, to some vendors, it doesn't matter that we're the biggest Health Plan, you know, one of the biggest in the nation.

-- if that's okay.

MS. RAVI: Alan, I think we're taking another 5 to 10 minute break, and then we'll be back.

(Off the record)

MR. RULEY: I have just a few follow-up questions for you.

EXAMINATION

BY MR. RULEY:

Q. Would you find Exhibit 1 please. Would you turn to Page 50 please.

Page 50 is titled What Is Not Covered? Is that right?

A. That is correct.

Q. And are these basically exclusions, a list of exclusions?

A. Yes.

Q. And would you look at the fourth bullet point.

A. Yes.

Q. What is that exclusion?

A. Any experimental drug or any drug or device not approved by the Food and Drug Administration (FDA) for the applicable diagnosis or treatment.

Q. Then turning the page to Page 51, the fourth bullet point from the bottom, what is that exclusion?

A. Surgical procedures for psychological or emotional reasons.

Q. And would those exclusions also potentially apply to coverage for gender dysphoria?

A. Yes.

Q. Earlier, you mentioned HBRs. What are they again please?

A. Health Benefit Representatives. They are actually defined in statute. And they work at the various employing units. I mentioned there are 408. They are liaisons to the Plan. So the Plan teaches them, keeps them apprised of the benefits being offered. But they're responsible for their employer's employees and getting them enrolled and making sure they understand the processes.

Q. So are they employed by the State Health Plan or by others?

A. By the others.

Q. All right. Thank you.

On costs -- would you get Exhibits 6 and 7 please.

Looking at Exhibit 6, for example, look at the first e-mail on Exhibit 6, Page DEF61647, the January 22, 2017 e-mail.

A. Yes.

Q. And that reports, as of 1-21, a total paid of 287.57.

80/20 and 70/30 Plans
2021 Recommendation

- **Base Premiums:**
  - Base premiums would not change for 2021.
  - Tobacco Attestation wellness surcharge kept flat at $60.
- **Dependent Tiers:**
  - Premiums for the dependent tiers would not change for 2021.
  - The “Subscriber + Family” and “Subscriber + Children” tiers are frozen at the same level since 2018.

Coverage & Tiers	2020 Rates	2021 Rates
80/20 Employees *		
Subscriber Only	$50.00	**$50.00**
Subscriber + Child(ren)	$305.00	**$305.00**
Subscriber + Spouse	$700.00	**$700.00**
Subscriber + Family	$720.00	**$720.00**
80/20 Retirees / Non-Med Dependents		
Subscriber Only	$50.00	**$50.00**
Subscriber + Child(ren)	$305.00	**$305.00**
Subscriber + Spouse	$700.00	**$700.00**
Subscriber + Family	$720.00	**$720.00**

*Assumes "Yes" completion of tobacco attestation

Actuarial Value	
80/20 Active & Non-Medicare Plans	**82.2%**
70/30 Active & Non-Medicare Plans	**77.7%**
70/30 Medicare Plan	**86.6%**

Coverage & Tiers	2020 Rates	2021 Rates
70/30 Employees *		
Subscriber Only	$25.00	**$25.00**
Subscriber + Child(ren)	$218.00	**$218.00**
Subscriber + Spouse	$590.00	**$590.00**
Subscriber + Family	$598.00	**$598.00**
70/30 Retirees/Non-Med Dependents		
Subscriber Only	$0.00	**$0.00**
Subscriber + Child(ren)	$218.00	**$218.00**
Subscriber + Spouse	$590.00	**$590.00**
Subscriber + Family	$598.00	**$598.00**
70/30 Retirees/Med Dependents		
Subscriber Only	$0.00	**$0.00**
Subscriber + Child(ren)	$155.00	**$155.00**
Subscriber + Spouse	$425.00	**$425.00**
Subscriber + Family	$444.00	**$444.00**

*Assumes "Yes" completion of tobacco attestation

WHAT IS NOT COVERED?

Exclusions for a specific type of service are stated along with the benefit description in "*Covered Services*." Exclusions that apply to many services are listed in this section, starting with general exclusions and then the remaining exclusions are listed in alphabetical order. To understand all of the exclusions that apply, read "*Covered Services*," "Summary of Benefits" and "What Is Not Covered?" The *Plan* does not cover services, supplies, medications or charges for:

- Anything specifically listed in this benefits booklet as not covered or excluded, regardless of *medical necessity.*
- Any condition, disease, ailment, injury, or diagnostic service to the extent that benefits are provided or persons are eligible for coverage under Title XVIII of the Social Security Act of 1965, including amendments, except as otherwise required by federal law.
- Conditions that federal, state or local law requires to be treated in a public facility.
- Any condition, disease, illness, or injury that occurs in the course of employment, if the *member*, employer or carrier is liable or responsible for the specific medical charge (1) according to a final adjudication of the claim under a state's workers' compensation laws, or (2) by an order of a state Industrial Commission or other applicable regulatory agency approving a settlement agreement.
- Basic life or work-related or medical disability examinations.
- Benefits that are provided by any governmental unit except as required by law.
- Services that are ordered by a court that are otherwise excluded from benefits under this Plan.
- Any condition suffered as a result of any act of war or while on active or reserve military duty.
- Services in excess of any *benefit period maximum* or *lifetime maximum.*
- Received prior to the *member's effective date.*
- Received after the coverage termination date, regardless of when the treated condition occurred, and regardless of whether the care is a continuation of care received prior to the termination.
- Received from a dental or medical department maintained by or on behalf of an employer, a mutual benefit association, labor union, trust or similar person or group.
- Services provided at request of patient in a location other than physician's office which are normally provided in the physician's office.
- Day care services, chore services, attendant care services, homemaker services, companion care services, foster care services.
- Hair analysis, excluding arsenic.
- Transportation of portable X-ray equipment and personnel to home or nursing home, transportation of portable EKG to facility or other location.
- *Emergency* response systems.
- *Alternative medicine* services, which are unproven preventive or treatment modalities, also described as alternative, integrative, or complementary medicine, whether performed by a physician or any *other provider.*

In addition, the *Plan* does not cover the following services, supplies, medications or charges:

A

- **Acupuncture** and **acupressure.**
- **Administrative** charges billed by a *provider*, including, but not limited to charges for failure to keep a scheduled visit, completion of a claim form, obtaining medical records, late payments, shipping and handling, taxes and telephone charges.
- Costs in excess of the ***allowed amount*** for services usually provided by one *doctor*, when those services are provided by multiple *doctors* or *medical care* provided by more than one *doctor* for treatment of the same condition.

incurred, except in the absence of legal capacity of the *member.*

Clinical Trials exclusions include:

- Non-health care services, such as services provided for data collection and analysis.
- Early feasibility, safety and pilot states of device trials
- CMS Investigational Device Exemption (IDE) Category A devices
- *Investigational* medications and devices and services that are not for the direct clinical management of the patient.

- Side effects and **complications** of non-*covered services*, except for *emergency services* in the case of an *emergency.*
- **Convenience** items such as, but not limited to, devices and equipment used for environmental control, urinary incontinence devices (including bed wetting devices) and equipment, heating pads, hot water bottles, ice packs and personal hygiene items.
- ***Cosmetic*** services, which include the removal of excess skin from the abdomen, arms or thighs, skin tag excisions, skin tone enhancements, cryotherapy or chemical exfoliation for active acne scarring, superficial dermabrasion, injection of dermal fillers, services for hair *transplants*, electrolysis and *surgery* for psychological or emotional reasons, except as specifically covered by the *Plan.*
- Services received either before or after the ***coverage*** period of the Plan, regardless of when the treated condition occurred, and regardless of whether the care is a continuation of care received prior to the termination.
- ***Custodial care*** designed essentially to assist an individual with activities of daily living, with or without routine nursing care and the supervisory care of a *doctor*. While some skilled nursing services may be provided, the patient does not require continuing skill services 24 hours daily. The individual is not under specific medical, surgical, or psychiatric treatment to reduce a physical or mental disability to the extent necessary to enable the patient to live outside either the institution or the home setting with substantial assistance and supervision, nor is there reasonable likelihood that the disability will be reduced to that level even with treatment. *Custodial care* includes, but is not limited to, help in walking, bathing, dressing, feeding, preparation of special diets and supervision over medications that could otherwise be self-administered. Such services and supplies are custodial as determined by the *Plan* without regard to the place of service or the *provider* prescribing or providing the services.
- **Camisoles**, or other clothing, post-mastectomy.
- **Communication** boards or alternative communication devices.
- **Contraception** for males

D

- **Dental services**
  - provided in a *hospital*, except as specifically covered by the *Plan*.
  - *Treatment for the following conditions:*
    - Injury related to chewing or biting.
    - Preventive dental care, diagnosis or treatment of or related to teeth or gums.
  - Periodontal disease or cavities and disease due to infection or tumor.

- Primary treatment of a psychiatric disorder in a *residential treatment center* (RTC) unless the RTC is licensed as a psychiatric RTC.
- Primary treatment of a *substance abuse* or *substance abuse* disorder in a *residential treatment center* (RTC) unless the RTC is licensed as a *substance abuse* or substance abuse RTC.
- Services by *providers* not currently licensed in the state in which services are provided.
- Psychotherapy as part of artificial means of conception.
- Psychological assessment and psychotherapy treatment in conjunction with proposed gender transformation.
- Psychological testing for those persons with a *substance abuse* diagnosis until 30 consecutive days of abstinence are obtained.
- Therapeutic boarding schools as a psychiatric residential treatment center (RTC) unless the program is licensed for psychiatric RTC in the state in which services are provided, has *registered nurses* who are present on-site 24-hours per day, and holds current national accreditation by a national health care accrediting body approved by the *Mental Health Case Manager.*
- Therapeutic boarding schools as a *substance abuse* or *substance abuse* residential treatment center (RTC) unless the program is licensed as a *substance abuse* RTC in the state in which services are provided and has licensed supervision of all residents 24 hours per day, seven days per week.
- Wilderness camps, wilderness "step-down" components of a residential program, and stand-alone outdoor treatment programs or outdoor "step-down" components of a residential program are not covered as a psychiatric RTC unless the program is licensed for psychiatric residential treatment in the state in which services are provided, has *registered nurse*s who are present on-site 24-hours per day, and holds current national accreditation by a national health care accrediting body approved by the *Mental Health Case Manager.*
- Wilderness camps and stand-along outdoor treatment programs are not covered as *substance abuse* or *substance abuse* RTC programs.
- Academic education during *residential treatment* when charged separately.
- Administrative psychiatric services (e.g., expert testimony, report writing, medical records review and maintenance, case management or case coordination, chart review, etc.)
- Consultation with a mental health professional for adjudication of marital, child support, and custody cases.
- Evaluations, consultations, testing or therapy for educational, professional training, or for investigation purposes relating to employment, insurance, judicial or administrative proceedings.
- Training analysis.
- Treatment for personal or professional growth, development, training or professional *certification.*
- Aversive Treatment.
- Treatment programs based solely on the 12-step Model.
- Erhard Seminar Training (EST) or similar motivational services.
- Bioenergetic, carbon dioxide, confrontational, hyperbaric or normobaric oxygen, marathon, megavitamin, orthomolecular, primal, rebirthing, or sleep therapies.
- Expressive therapies (art, poetry, movement, psychodrama), guided imagery, or stress and relaxation therapy when billed separately.

- Occlusal (bite) adjustments.
- Extractions.

- The following types of **therapy:**
  - Applied Behavior Analysis (ABA) therapy except as specifically identified by the *Plan.*
  - Music therapy, recreational or activity therapy, and all types of animal therapy. Remedial reading and all forms of special education and supplies or equipment used similarly, except as specifically covered by the *Plan.*
  - Massage therapy.
  - Alternative therapy.
  - Hypothermia therapy.
  - Cognitive therapy.
  - Speech therapy for stammering, stuttering, or developmental delay.
  - Treatment of speech, language, voice, communication and/or auditory processing disorder.
  - Pulmonary rehabilitation group sessions.
  - Peripheral arterial disease rehabilitation.
  - Community or work integration training, work hardening or conditioning.
- **Thermography** or **thermograph** examination.
- **Transplant** exclusions include:
  - The purchase price of the organ or tissue if any organ or tissue is sold rather than donated to the recipient *member.*
  - The procurement of organs, tissue, bone marrow or peripheral blood stem cells or any other donor services if the recipient is not a *member.*
  - *Transplants*, including high dose chemotherapy, considered *experimental* or *investigational.*
  - Services for or related to the transplantation of animal or artificial organs or tissues.
- **Travel**, whether or not recommended or prescribed by a *doctor* or other licensed health care professional, except as specifically covered by the *Plan*.
- **Treatment** or studies leading to or in connection with sex changes or modifications and related care.

V

- The following **vision** services:
  - Radial keratotomy and other refractive eye *surgery*, and related services to correct vision except for surgical correction of an eye injury. Also excluded are premium intraocular lenses or the services related to the insertion of premium lenses beyond what is required for insertion of conventional intraocular lenses, which are small, lightweight, clear disks that replace the distance-focusing power of the eye's natural crystalline lens.
  - Routine eye examination services except as specifically covered by the *Plan.*
  - Eyeglasses or contact lenses, except as specifically covered in "*Prosthetic appliances.*"
  - Orthoptics, vision training, and low vision aids.
- For over-the-counter and non-federal legend **Vitamins**, food supplements or replacements, nutritional or dietary supplements, formulas, or special foods of any

- And except as specifically stated as covered:
  - Dental implants or root canals
  - Dentures
  - Dental appliances except when medically necessary for the treatment of temporomandibular joint disease or obstructive sleep apnea
  - Orthodontic braces or devices.
  - Palatal expanders
  - Removal of teeth and intrabony cysts.
  - Procedures performed for the preparation of the mouth for dentures.
  - Crowns, bridges, dentures or in-mouth appliances.
- Evaluation and treatment of ***developmental dysfunction*** and/or learning disability.
- ***Diabetes*** *related services including:*
  - *D*iabetic shoes, including accessories, fittings, and associated services and supplies.
  - Glasses.
- The following drugs or medications:
  - Injections by a health care professional of injectable *prescription medications* which can be self-administered, unless medical supervision is required.
  - Medications associated with conception by artificial means.
  - For prescribed *sexual dysfunction* medications.
  - Take home medications furnished by a *hospital* or *non-hospital facility*.
  - *Experimental* medication or any medication or device not approved by the Food and Drug Administration (FDA) for the applicable diagnosis or treatment. However, this exclusion does not apply to *prescription medications* used in covered phases I, II, III and IV clinical trials, or medications approved by the FDA for treatment of cancer, if prescribed for the treatment of any type of cancer for which the medication has been approved as effective and accepted in any one of the following nationally recognized medication reference guides:
    - The American Medical Association Drug Evaluations;
    - The American *Hospital Formulary* Service Drug Information;
    - The United States Pharmacopoeia Drug Information;
    - The National Comprehensive Cancer Network Drugs & Biologics Compendium;
    - The Thomson Micromedex DrugDex;
    - The Elsevier Gold Standard's Clinical Pharmacology; or
    - Any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services.
- ***Durable Medical Equipment*** including:
  - Appliances or devices that serve no medical purpose or that are primarily for comfort or convenience.
  - Repair or replacement of equipment due to abuse or desire for new equipment.
  - Heel or elbow protectors.
  - Batteries, except as required for operation of *medically necessary* equipment prescribed by a *provider*.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*,

Plaintiffs,

v.

No. 1:19-cv-272-LCB

DALE FOLWELL, in his official capacity as State Treasurer of North Carolina; **DEE JONES,** in her official capacity as Executive Administrator of the North Carolina State Health Plan for Teachers and State Employees; **NORTH CAROLINA STATE HEALTH PLAN FOR TEACHERS AND STATE EMPLOYEES**; and **STATE OF NORTH CAROLINA, DEPARTMENT OF PUBLIC SAFETY,**

Defendants.

DECLARATION OF BLUE CROSS BLUE SHIELD OF NORTH CAROLINA

I, AIMEE FOREHAND, on behalf of Blue Cross and Blue Shield of North Carolina ("BCBSNC"), state that to the best of my knowledge and based on a review of BCBSNC's records, the following is true and accurate:

1. BCBSNC is a non-profit medical services corporation, which is organized and existing under the laws of the State of North Carolina. BCBSNC is headquartered in Durham, North Carolina.

2. BCBSNC is the Third-Party Administrator ("TPA") of the North Carolina State Health Plan for Teacher and State Employees (the "State Health Plan" or the "Plan").

3. The State Health Plan is a self-funded customer of BCBSNC, which means that, in addition to deciding what benefits the Plan will provide to Plan participants each year, the Plan is also solely responsible for paying for all the benefits it has agreed to provide.

4. As TPA for the Plan, BCBSNC has a contract with the Plan to provide administrative services on behalf of the Plan. More specifically, after a participating, in-network healthcare provider provides a medical service to a Plan participant, the medical provider submits a claim to BCBSNC which processes the claim according to the terms of Plan and determines the amount of reimbursement that the healthcare provider will receive by the Plan for that service based on the terms of the Plan and the network participation agreement between BCBSNC and the participating provider.

5. The contract between the Plan and BCBSNC is an Administrative Services Only (hereafter "ASO") contract, which means that BCBSNC provides only administrative services that relate to the processing of the claims. BCBSNC has provided these services to the Plan for more than 30 years.

6. In addition to serving as a TPA for the Plan and other customers, BCBSNC also sells private health insurance to groups and individuals. BCBSNC uses its claims processing system and standards in the same manner for both its private health insurance business and its work as the TPA for the Plan. In both

circumstances, the BCBSNC operates in the manner accepted as the industry standard for the provision of healthcare benefits.

7. In accordance with industry practice, BCBSNC uses industry-standard procedural codes and diagnostic codes to determine whether a claim submitted to it by a healthcare provider for a specific medical treatment is compensable by the Plan. These diagnostic and procedural codes are not created by BCBSNC, but are uniform across the American health care, health benefits plan, and health insurance industries. Diagnostic codes are classification of diseases as provided by the ICD ("International Classification of Diseases"). Medical services and procedures are identified by a distinctive alphanumeric code known as CPT code ("Current Procedural Terminology"). Every medical service has its own unique CPT Code.

8. In order to request reimbursement for the medical service provided to a Plan participant, an in-network health care provider submits a claim to BCBSNC on an established industry form (either a CMS-1500 or UB-04 form depending on the type of provider; copies attached) or through an electronic billing agreement which requires the same information.

9. To receive reimbursement, a healthcare provider must submit a claim that contains both a diagnostic code and a corresponding procedural code (or, for facilities, a revenue code rather than a procedural code), among other information. This is the standard requirement across the national health insurance industry. Failure to submit both a diagnostic code and a corresponding procedural code results in denial of the claim.

10. When BCBSNC receives a claim for reimbursement from a provider, BCBSNC's automated claims systems reviews the claim to determine whether it is for a benefit covered by the Plan. If the medical treatment is a covered treatment, BCBSNC authorizes reimbursement to the healthcare provider by the Plan.

11. Each year, the State Health Plan creates a benefits booklet, which describes the benefits and reimbursement levels offered to eligible Plan participants. As TPA, BCBSNC receives and reviews the final Plan benefit booklet each year. BCBSNC is responsible for implementation of the benefits outlined in the benefit booklet. Because the benefits booklet does not contain or identify either procedural or diagnostic codes, BCBSNC—in consultation with the Plan staff—implements the coding for the benefits covered by the Plan.

12. When a healthcare provider performs a service for a Plan participant, the provider submits a claim to BCBSNC for reimbursement (as a benefit provided by the Plan). For more than 90% of claims submitted to BCBSNC for Plan beneficiaries, the process is automated, meaning it is processed electronically without being separately reviewed by a person.

13. As part of the claim submission, BCBSNC receives the name of the Plan participant, the name of the healthcare provider, the age and sex of the Plan participant, the ICD diagnostic code, and the CPT procedural Code, among other information. This is the industry-standard information required for claims submitted to insurance providers for reimbursement of expenses for medical services, and this information is submitted by the physician or other healthcare provider where the

physician or healthcare provider is a participating, in-network provider. BCBSNC has a publicly available manual for healthcare providers that advises them on what information must accompany a claim, and how to properly submit a claim.

14. As part of the claim submission process, BCBSNC does not request or require that the healthcare provider identify the transgender status of any person seeking medical care. The BCBSNC claim submission process does not include any method for the healthcare provider to submit this information, and the transgender status of any person is not recorded within the BCBSNC databases.

15. Certain claims require approval by BCBSNC before the medical service is provided to the Plan participant. BCBSNC and the State Health Plan jointly decide which claims will be subject to this preauthorization requirement. All inpatient surgical procedures require preauthorization. There is no separate or unique preauthorization requirement for claims submitted on behalf of individuals who identify as transgender.

16. Further, in determining whether to approve or deny a claim, BCBSNC does not consider whether the Plan participant identifies as transgender. More specifically, BCBSNC does not track whether any specific Plan participant identifies as transgender, cisgender, gender non-binary, etc. Thus, the transgender status of any person—or whether any person identifies as transgender—is not a fact that BCBSNC uses at any time to determine whether BCBSNC will approve a claim for benefits for State Health Plan participants.

17. BCBSNC processes claims for medical services provided to an individual who identifies as transgender in the exact same manner as BCBSNC processes claims for medical services provided to an individual who does not identify as transgender. BCBSNC process claims for medical services for gender non-binary individuals in the exact same manner as BCBSNC processes claims for medical services for an individual who identifies as neither transgender nor gender non-binary.

18. As noted above, in excess of 90% of submitted claims are approved by BCBSNC's claims-processing software. Claims not approved in this fashion because, for example, the software has identified a potential duplicate bill, are manually processed by BCBSNC employees. After this employee review, claims are approved or denied. Reasons to deny a claim include: incorrect coding (diagnosis or procedure), duplicative billing, failure to obtain prior authorization when required, or other reasons.

19. BCBSNC will not approve a claim, or preauthorization, for a service not covered by the Plan.

20. To the best of my knowledge, prior to January 1, 2017, in its implementation of the Plan Benefit Booklet, BCBSNC denied preauthorization for 4 specific surgeries, regardless of the diagnostic code.

Table 1

CPT Code	Description of Surgery
55970	Intersex Surgery, Male to Female
55980	Intersex Surgery, Female to Male

57335	Vaginoplasty for Intersex State
56805	Clitoroplasty for Intersex State

21. To best of my knowledge, prior to January 1, 2017, BCBSNC either denied preauthorization or reimbursement for claims for the following procedures when the procedural code is for treatment of one of two diagnostic codes: F64.0 (Transsexualism) or Z87.890 (Personal history of sex reassignment):

Table 2

CPT Code	Description of Surgery
54400	Insertion of Penile Prosthesis; non-inflatable (semi-rigid)
C1813	Prosthesis, Penile, Inflatable
54401	Insertion of Penile Prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of multi-component Inflatable Penile
54408	Repair Components(s) multi-component, Inflatable Penile
54410	Removal and replacement of all components(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal non-inflatable (semi-rigid) /inflatable
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of a non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54660	Insertion of Testicular Prosthesis (separate procedure)
55175	Scrotoplasty (simple)
55180	Scrotoplasty (complicated)
56800	Plastic Repair of Introitus
57291	Construction of artificial vagina (without graft)
57292	Construction of artificial vagina (with graft)
19316	Mastopexy
19318	Breast Reduction
57295	Revision (including removal) of prosthetic vaginal graft

57296	Revision (including removal) of prosthetic vagina graft
19325	Breast Augmentation with implant
17380	Electrolysis Epilation, each .5 hour

22. Although the industry-standard medical claim form requires a healthcare provider to identify the sex of the Plan participant, BCBSNC does not use the sex of the Plan participant to evaluate whether claims for the benefits identified above are covered by the Plan. This is true whether the claim is processed automatically or manually. Approval or denial of a claim is based solely on the procedural and diagnostic codes identified above.

23. Beginning on January 1, 2017, the Plan directed BCBSNC to approve claims when submitted with the procedures listed in Table 1—without regard to the diagnostic code—and in Table 2, when submitted with the two identified diagnostic codes.

24. Beginning on January 1, 2018, at the direction of the Plan, BCBSNC returned to its 1990-2016 claims processing rules, and thereafter denied claims for the above-referenced procedures because they were not included as benefits provided by the Plan.

25. BCBSNC would not approve a claim for cosmetic procedures for any Plan participant, regardless of the diagnostic code. The State Health Plan benefit booklet defines cosmetic services as not covered, and the Plan does not cover cosmetic surgeries. Accordingly, the following procedures, which, under the 1990-2016 claims processing rules described above, are considered cosmetic procedures, are not covered: shoulder shaping, chin contouring and implants, face lifts (unless as a

medically necessary part of other facial procedures), facial bone osteoplasty, forehead reduction and contouring, mandible reduction, mandible contouring or mandible augmentation, and chondrolaryngoplasty (tracheal shave).

26. BCBSNC does not process claims for the vast majority of pharmaceuticals or hormones, although it does process claims for the administration of some pharmaceuticals, e.g. intravenous infusions.

27. BCBSNC has never implemented the portion of the Plan's benefit booklets that excludes "surgery for psychological or emotion reasons." More specifically, BCBSNC does not have diagnostic codes or procedural codes connected to this language from the Plan's benefits book that would prevent any claim from being approved, without regard to whether the Plan participant identified as cisgender, transgender, gender non-binary, or otherwise.

28. BCBSNC processes all claims for behavioral health treatment to be potentially reimbursed by the Plan. For behavioral health treatment, healthcare provider payment requests are not screened by diagnosis. Rather, notwithstanding the language contained in the Plan's benefits book, BCBSNC authorizes payment for all behavioral health services, if they are otherwise within the Plan's benefits, regardless of the submitted diagnosis code. This has been true since at least 1990. BCBSNC claims processing does not distinguish between an individual diagnosed with gender dysphoria or another psychiatric diagnosis. Plan participants with claims for behavioral health treatment are not denied because the submitted claim identified gender dysphoria as the diagnosis.

29. BCBSNC, as TPA of the State Health Plan does not code or track whether Plan participants identify as transgender, cisgender, gender non-binary, or otherwise, and BCBSNC's implements the benefit booklets of the State Health Plan without denying coverage for any healthcare service on the basis of a Plan participant's identification as transgender, cisgender, gender non-binary, or otherwise.

I declare and verify under penalty of perjury that the foregoing is true and correct. Executed on November 30, 2021.

Aimee Forehand (Nov 30, 2021 12:14 EST)

Aimee Forehand
Director, State Health Plan
Blue Cross and Blue Shield of North Carolina

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

PICA

CARRIER

1. MEDICARE ☐ (Medicare#) MEDICAID ☐ (Medicaid#) TRICARE ☐ (ID#/DoD#) CHAMPVA ☐ (Member ID#) GROUP HEALTH PLAN ☐ (ID#) FECA BLK LUNG ☐ (ID#) OTHER ☐ (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M ☐ F ☐

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self ☐ Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street)

CITY | STATE

8. RESERVED FOR NUCC USE

CITY | STATE

ZIP CODE | TELEPHONE (Include Area Code) ( )

ZIP CODE | TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) ☐ YES ☐ NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M ☐ F ☐

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? ☐ YES ☐ NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? ☐ YES ☐ NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? ☐ YES ☐ NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below

SIGNED _____

PATIENT AND INSURED INFORMATION

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24 A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1									NPI	
2									NPI	
3									NPI	
4									NPI	
5									NPI	
6									NPI	

PHYSICIAN OR SUPPLIER INFORMATION

25. FEDERAL TAX I.D. NUMBER SSN ☐ EIN ☐

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) ☐ YES ☐ NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. b.

33. BILLING PROVIDER INFO & PH # ( )

a. b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

BECAUSE THIS FORM IS USED BY VARIOUS GOVERNMENT AND PRIVATE HEALTH PROGRAMS, SEE SEPARATE INSTRUCTIONS ISSUED BY APPLICABLE PROGRAMS.

NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.

REFERS TO GOVERNMENT PROGRAMS ONLY

MEDICARE AND TRICARE PAYMENTS: A patient's signature requests that payment be made and authorizes release of any information necessary to process the claim and certifies that the information provided in Blocks 1 through 12 is true, accurate and complete. In the case of a Medicare claim, the patient's signature authorizes any entity to release to Medicare medical and nonmedical information and whether the person has employer group health insurance, liability, no-fault, worker's compensation or other insurance which is responsible to pay for the services for which the Medicare claim is made. See 42 CFR 411.24(a). If item 9 is completed, the patient's signature authorizes release of the information to the health plan or agency shown. In Medicare assigned or TRICARE participation cases, the physician agrees to accept the charge determination of the Medicare carrier or TRICARE fiscal intermediary as the full charge and the patient is responsible only for the deductible, coinsurance and non-covered services. Coinsurance and the deductible are based upon the charge determination of the Medicare carrier or TRICARE fiscal intermediary if this is less than the charge submitted. TRICARE is not a health insurance program but makes payment for health benefits provided through certain affiliations with the Uniformed Services. Information on the patient's sponsor should be provided in those items captioned in "Insured"; i.e., items 1a, 4, 6, 7, 9, and 11.

BLACK LUNG AND FECA CLAIMS

The provider agrees to accept the amount paid by the Government as payment in full. See Black Lung and FECA instructions regarding required procedure and diagnosis coding systems.

SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE, TRICARE, FECA AND BLACK LUNG)

In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete, 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law), 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI license #, or SSN) of the primary individual rendering each service is reported in the designated section.For services to be considered "incident to" a physician's professional services: 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills.

For TRICARE claims, I further certify that I (or any employee) who rendered services am not an active duty member of the Uniformed Services or a civilian employee of the United States Government or a contract employee of the United States Government, either civilian or military (refer to 5 USC 5536). For Black-Lung claims, I further certify that the services performed were for a Black Lung-related disorder.

No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations (42 CFR 424.32).

NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF MEDICARE, TRICARE, FECA, AND BLACK LUNG INFORMATION (PRIVACY ACT STATEMENT)

We are authorized by CMS, TRICARE and OWCP to ask you for information needed in the administration of the Medicare, TRICARE, FECA, and Black Lung programs. Authority to collect information is in section 205(a), 1862, 1872 and 1874 of the Social Security Act as amended, 42 CFR 411.24(a) and 424.5(a) (6), and 44 USC 3101,41 CFR 101 et seq and 10 USC 1079 and 1086; 5 USC 8101 et seq; and 30 USC 901 et seq; 38 USC 613; E.O. 9397.

The information we obtain to complete claims under these programs is used to identify you and to determine your eligibility. It is also used to decide if the services and supplies you received are covered by these programs and to insure that proper payment is made.

The information may also be given to other providers of services, carriers, intermediaries, medical review boards, health plans, and other organizations or Federal agencies, for the effective administration of Federal provisions that require other third parties payers to pay primary to Federal program, and as otherwise necessary to administer these programs. For example, it may be necessary to disclose information about the benefits you have used to a hospital or doctor. Additional disclosures are made through routine uses for information contained in systems of records.

FOR MEDICARE CLAIMS: See the notice modifying system No. 09-70-0501, titled, 'Carrier Medicare Claims Record,' published in the Federal Register, Vol. 55 No. 177, page 37549, Wed. Sept. 12, 1990, or as updated and republished.

FOR OWCP CLAIMS: Department of Labor, Privacy Act of 1974, "Republication of Notice of Systems of Records," Federal Register Vol. 55 No. 40, Wed Feb. 28, 1990, See ESA-5, ESA-6, ESA-12, ESA-13, ESA-30, or as updated and republished.

FOR TRICARE CLAIMS: PRINCIPLE PURPOSE(S): To evaluate eligibility for medical care provided by civilian sources and to issue payment upon establishment of eligibility and determination that the services/supplies received are authorized by law.

ROUTINE USE(S): Information from claims and related documents may be given to the Dept. of Veterans Affairs, the Dept. of Health and Human Services and/or the Dept. of Transportation consistent with their statutory administrative responsibilities under TRICARE/CHAMPVA, to the Dept. of Justice for representation of the Secretary of Defense in civil actions, to the Internal Revenue Service, private collection agencies, and consumer reporting agencies in connection with recoupment claims; and to Congressional Offices in response to inquiries made at the request of the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, local, foreign government agencies, private business entities, and individual providers of care, on matters relating to entitlement, claims adjudication, fraud, program abuse, utilization review, quality assurance, peer review, program integrity, third party liability, coordination of benefits, and civil and criminal litigation related to the operation of TRICARE.

DISCLOSURES: Voluntary; however, failure to provide information will result in delay in payment or may result in denial of claim. With the one exception discussed below, there are no penalties under these programs for refusing to supply information. However, failure to furnish information regarding the medical services rendered or the amount charged would prevent payment of claims under these programs. Failure to furnish any other information, such as name or claim number, would delay payment of the claim. Failure to provide medical information under FECA could be deemed an obstruction.

It is mandatory that you tell us if you know that another party is responsible for paying for your treatment. Section 1128B of the Social Security Act and 31 USC 3801-3812 provide penalties for withholding this information.

You should be aware that P.L. 100-503, the "Computer Matching and Privacy Protection Act of 1988", permits the government to verify information by way of computer matches.

MEDICAID PAYMENTS (PROVIDER CERTIFICATION)

I hereby agree to keep such records as are necessary to disclose fully the extent of services provided to individuals under the State's Title XIX plan and to furnish information regarding any payments claimed for providing such services as the State Agency or Dept. of Health and Human Services may request.

I further agree to accept, as payment in full, the amount paid by the Medicaid program for those claims submitted for payment under that program, with the exception of authorized deductible, coinsurance, co-payment or similar cost-sharing charge.

SIGNATURE OF PHYSICIAN (OR SUPPLIER): I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.

NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1197. The time required to complete this information collection is estimated to average 10 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. This address is for comments and/or suggestions only. DO NOT MAIL COMPLETED CLAIM FORMS TO THIS ADDRESS.

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		b. MED. REC. #	
		5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM / THROUGH	7

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38		39 VALUE CODES CODE	39 VALUE CODES AMOUNT	40 VALUE CODES CODE	40 VALUE CODES AMOUNT	41 VALUE CODES CODE	41 VALUE CODES AMOUNT
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	50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	
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	58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.	
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C						C

	63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME	
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66 DX	67	A	B	C	D	E	F	G	H	68
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69 ADMIT DX		70 PATIENT REASON DX	a	b	c	71 PPS CODE		72 ECI	a	b	c	73

74 PRINCIPAL PROCEDURE CODE	DATE	a. OTHER PROCEDURE CODE	DATE	b. OTHER PROCEDURE CODE	DATE	75
c. OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE	

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UB-04 NOTICE: **THE SUBMITTER OF THIS FORM UNDERSTANDS THAT MISREPRESENTATION OR FALSIFICATION OF ESSENTIAL INFORMATION AS REQUESTED BY THIS FORM, MAY SERVE AS THE BASIS FOR CIVIL MONETARTY PENALTIES AND ASSESSMENTS AND MAY UPON CONVICTION INCLUDE FINES AND/OR IMPRISONMENT UNDER FEDERAL AND/OR STATE LAW(S).**

Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts. The following certifications or verifications apply where pertinent to this Bill:

1. If third party benefits are indicated, the appropriate assignments by the insured /beneficiary and signature of the patient or parent or a legal guardian covering authorization to release information are on file. Determinations as to the release of medical and financial information should be guided by the patient or the patient's legal representative.
2. If patient occupied a private room or required private nursing for medical necessity, any required certifications are on file.
3. Physician's certifications and re-certifications, if required by contract or Federal regulations, are on file.
4. For Religious Non-Medical facilities, verifications and if necessary re-certifications of the patient's need for services are on file.
5. Signature of patient or his representative on certifications, authorization to release information, and payment request, as required by Federal Law and Regulations (42 USC 1935f, 42 CFR 424.36, 10 USC 1071 through 1086, 32 CFR 199) and any other applicable contract regulations, is on file.
6. The provider of care submitter acknowledges that the bill is in conformance with the Civil Rights Act of 1964 as amended. Records adequately describing services will be maintained and necessary information will be furnished to such governmental agencies as required by applicable law.
7. For Medicare Purposes: If the patient has indicated that other health insurance or a state medical assistance agency will pay part of his/her medical expenses and he/she wants information about his/her claim released to them upon request, necessary authorization is on file. The patient's signature on the provider's request to bill Medicare medical and non-medical information, including employment status, and whether the person has employer group health insurance which is responsible to pay for the services for which this Medicare claim is made.
8. For Medicaid purposes: The submitter understands that because payment and satisfaction of this claim will be from Federal and State funds, any false statements, documents, or concealment of a material fact are subject to prosecution under applicable Federal or State Laws.
9. For TRICARE Purposes:
   (a) The information on the face of this claim is true, accurate and complete to the best of the submitter's knowledge and belief, and services were medically necessary and appropriate for the health of the patient;
   (b) The patient has represented that by a reported residential address outside a military medical treatment facility catchment area he or she does not live within the catchment area of a U.S. military medical treatment facility, or if the patient resides within a catchment area of such a facility, a copy of Non-Availability Statement (DD Form 1251) is on file, or the physician has certified to a medical emergency in any instance where a copy of a Non-Availability Statement is not on file;
   (c) The patient or the patient's parent or guardian has responded directly to the provider's request to identify all health insurance coverage, and that all such coverage is identified on the face of the claim except that coverage which is exclusively supplemental payments to TRICARE-determined benefits;
   (d) The amount billed to TRICARE has been billed after all such coverage have been billed and paid excluding Medicaid, and the amount billed to TRICARE is that remaining claimed against TRICARE benefits;
   (e) The beneficiary's cost share has not been waived by consent or failure to exercise generally accepted billing and collection efforts; and,
   (f) Any hospital-based physician under contract, the cost of whose services are allocated in the charges included in this bill, is not an employee or member of the Uniformed Services. For purposes of this certification, an employee of the Uniformed Services is an employee, appointed in civil service (refer to 5 USC 2105), including part-time or intermittent employees, but excluding contract surgeons or other personal service contracts. Similarly, member of the Uniformed Services does not apply to reserve members of the Uniformed Services not on active duty.
   (g) Based on 42 United States Code 1395cc(a)(1)(j) all providers participating in Medicare must also participate in TRICARE for inpatient hospital services provided pursuant to admissions to hospitals occurring on or after January 1, 1987; and
   (h) If TRICARE benefits are to be paid in a participating status, the submitter of this claim agrees to submit this claim to the appropriate TRICARE claims processor. The provider of care submitter also agrees to accept the TRICARE determined reasonable charge as the total charge for the medical services or supplies listed on the claim form. The provider of care will accept the TRICARE-determined reasonable charge even if it is less than the billed amount, and also agrees to accept the amount paid by TRICARE combined with the cost-share amount and deductible amount, if any, paid by or on behalf of the patient as full payment for the listed medical services or supplies. The provider of care submitter will not attempt to collect from the patient (or his or her parent or guardian) amounts over the TRICARE determined reasonable charge. TRICARE will make any benefits payable directly to the provider of care, if the provider of care is a participating provider.

SEE http://www.nubc.org/ FOR MORE INFORMATION ON UB-04 DATA ELEMENT AND PRINTING SPECIFICATIONS

Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy

SUMMARY

Formularies that include prior authorization and utilization management are widely used by managed care organizations (MCOs), including health plans and pharmacy benefit management companies. Utilization management criteria are essential to optimizing patient outcomes and reducing waste, error, unnecessary drug use, and cost. The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed the following 9 specific concepts for effective prior authorization practices by MCOs: (1) patient safety and appropriate medication use, (2) clinical decision making, (3) evidence-based review criteria, (4) automated decision support, (5) transparency and advanced notice, (6) emergency access, (7) provider collaboration, (8) need for timeliness and avoiding disruptions in therapy, and (9) cost-effectiveness and value. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients receive appropriate and timely access to drugs, devices, and other therapeutic agents.

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Formularies that include prior authorization and utilization management are widely used by managed care organizations (MCOs), including health plans and pharmacy benefit management companies. Utilization management criteria are essential to optimizing patient outcomes and reducing waste, error, unnecessary drug use, and cost. The safety and clinical appropriateness of medication therapy selection for a covered population is the primary goal of formularies. A thorough review of clinical evidence is the cornerstone of managed care formulary decisions.[1,2] For individuals who require medications and treatments not included on formularies, prescribers and health plans can work together through exceptions and appeals processes to provide appropriate access to therapy. Health plans, employers, and government-sponsored health care programs focus on optimizing patient outcomes through the use of medications that have established evidence of efficacy and safety, while providing the highest value. Prior authorization (PA) is a utilization management tool that enables plans to implement patient-focused goals of safe and appropriate medication use. Also known as coverage determinations in the Medicare Part D program, PA coverage criteria are centered on patients' clinical needs and therapeutic rationale.

The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed the following 9 specific concepts for effective PA practices by MCOs. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients receive appropriate and timely access to drugs, devices, and other therapeutic agents. Additionally, these concepts are timely, given recent attention and proposed reforms to PA.[3]

Concept 1: Patient Safety and Appropriate Medication Use

Using clinically sound, evidence-based principles, PA guides safe and appropriate medication therapy for patients. MCOs work with prescribers to ensure that treatment goals are met, while considering the health plan benefit design and all statutory and regulatory requirements. For example, PA can be used to support careful patient selection and manage ongoing medication use for medications with a high potential for misuse or abuse, or those with unknown long-term safety or durability of effect.

Concept 2: Clinical Decision Making

PA guidelines are designed by MCOs to efficiently improve the use of clinically appropriate, affordable medications and therapies. This is especially useful for classes of medications that include multiple agents of varying effectiveness, for which PAs are an additional way to encourage the use of appropriate formulary alternatives. MCOs should regularly confirm that agents on the formulary provide appropriate care across the membership of a plan and that the plan's coverage requirements align with standards of relevant accreditation bodies and quality organizations.

Concept 3: Evidence-Based Review Criteria

Medication utilization management criteria based on an evaluation of clinical trials, peer-reviewed literature, and consensus guidelines are a common part of PA programs. These criteria are developed by a pharmacy and therapeutics (P&T) committee that includes health care providers (e.g., pharmacists, nurses, and physicians) and administrators, quality-improvement managers, and others involved with the medication use process.[4] The P&T committee reviews the safety and efficacy evidence of a medication in comparison with therapeutic alternatives to render a clinical determination for drug formulary placement.[4,5] Furthermore, the P&T committee considers subgroups or special populations of patients for whom the evidence indicates a drug may have differing effectiveness or adverse effect incidence. The P&T committee evaluates all pertinent, accessible medication trial data when making formulary decisions. While cost is an evaluated component, it is used as a comparator when the alternative is therapeutically equivalent or shown to produce similar results. In order of priority, formulary decisions are derived first from safety and efficacy, followed by cost considerations.[4,5]

The intent of a formulary and utilization management is to encourage the use of medically appropriate and cost-effective drug-related products that meet the needs of patient populations.[4] Formularies and utilization management criteria should be updated regularly to keep pace with changes in clinical practice, clinical guidelines, new drugs, evolving health plan designs, and the reality that patients may change health plan coverage.[4,5]

Concept 4: Automated Decision Support

Provider burden and/or dissatisfaction with approval processes has been documented in the literature.[6,7] Health information technology solutions should be used to reduce paperwork and waste, standardize data and processes for utilization management, and improve the patient and clinician experience.[8] For example, adoption of electronic PA (ePA) allows for secure, electronic transmission of patient information to complete a PA review, thus, decreasing the administrative burden for prescribers and MCOs and improving the turnaround time for the benefit of patients.[9-11] According to a national ePA technology vendor, providers who use electronic solutions spend an average of 2.5 fewer hours on PA per week.[12] Best practice guidelines or state regulations should be followed as the industry continues to develop uniform, national industry standards for the electronic exchange of health information. An effective ePA process includes automation at the point of care, point of sale, or any point where a PA originates. To support the decision-making process for patients and providers, the patient's financial responsibility, as well as any potential less costly therapeutic alternatives, should be displayed at the point of care.

Concept 5: Transparency and Advanced Notice

MCOs should provide advanced notice of formulary changes to the provider and patient. Advanced notice is vital to avoid disruptions in care.

MCOs should make current formulary and utilization management requirements available and transparent in a manner that is easily accessible and understandable to patients. Members and providers should be able to easily identify a particular formulary and any changes made, as well as search for drug-utilizing tools such as medication search tools and formulary guides. Details of utilization management criteria should be presented, including required documentation that supports the request for authorization or a formulary exception, the volume of requests, and the approval and denial rates.

Concept 6: Emergency Access

In emergency situations, access to medication therapy without impediments is imperative. This includes situations in which care is sought outside of standard business hours. PA criteria are not applied to medications used in inpatient or emergency care settings. Utilization management tools should not cause delay of care or have an effect on medical treatment during emergency care situations. MCOs should avoid broad or inflexible PA requirements for drug therapies commonly used as part of emergency care.

Concept 7: Provider Collaboration

MCOs should collaborate and communicate clearly with providers throughout the PA process. Utilization reviews should provide detailed explanations for PA denials, including an indication of any missing information. The PA process should support health plan transparency and multidisciplinary collaboration to obtain the best outcomes for the member/patient and the best value for the health care system. Additionally, PA criteria should be subject to continuous improvement, revisions, and, where necessary, removal. This requires dynamic discussion and partnership with providers to ensure that patients are receiving appropriate care without unnecessary hurdles. All PA denials should include the clinical rationale for each determination (e.g., national medical specialty society guidelines and peer-reviewed clinical literature), provide the plan's covered alternative treatment, and detail the appeal process.

In cases where different providers are not aware of all the medications or treatments a patient is receiving, the MCO may act as the care coordinator when reviewing medication regimens or PAs. Ensuring that all providers are aware of the medications being prescribed to a patient can lead to discontinuation of duplicate medications or modifications that optimize the medication regimen. MCOs need to continue bridging any gaps in medication coordination between providers.

MCOs should monitor utilization of medications across the medical and pharmacy benefit, including those administered in a physician's office or outpatient treatment facility. Coverage of medical and pharmacy benefit drugs, devices, or therapies should be coordinated to enable more cost-effective therapy selection and streamlined medication management.

Concept 8: Need for Timeliness and Avoiding Disruptions in Therapy

MCOs should allow for timely PA approval for medically necessary exceptions and for timely handling of denial appeals. When requesting nonurgent care, PAs should be reviewed and acted upon promptly and within statutory and regulatory timelines and accreditation standards. When a provider and the MCO do not agree on the utilization management criteria used for approval of a therapy or a coverage decision for a member, a provider should have access to a peer-to-peer clinical discussion to resolve the matter.

Patients newly enrolled in plans who are stabilized on therapy should be allowed sufficient time for therapy continuation during the PA review process, sometimes referred to as a grandfathering or transition period. Transitional coverage promotes coordinated care and prevents unnecessary therapy changes or gaps in care.

Concept 9: Cost-Effectiveness and Value

As MCOs and providers enter into risk-based arrangements, use of PA as a tool to ensure delivery of affordable, high-quality, patient-centered care must evolve to facilitate shared decision making. When there is shared risk involved in contracts between providers and payers, PA can be a tool to ensure alignment of providers around evidence-based care. The evolution of PA should be a partnership between payers, providers, and administrators of health care contracts to include alignment of incentives, clinical approach, and operational capabilities. As noted in the American Medical Association Reform Principles,[3] collaboration among stakeholders is necessary to achieve cost-effective and value-based care.[13,14]

Conclusions

MCOs should focus on ensuring access to appropriate, evidence-based, and cost-effective medications for their members. These concepts provide a framework to ensure that PA and utilization management are timely, transparent, and collaborative, which is ultimately synonymous with patient-centered care. MCOs have the responsibility and opportunity to incorporate clinical and technology advancements into these processes with a constant goal of improving health outcomes and cost-effectiveness.

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DISCLOSURES

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. 1:19-cv-00272

MAXWELL KADEL, et al.,
Plaintiffs,
vs.
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,
Defendants,

DEPOSITION OF DAN H. KARASIC, M.D.

Remote
September 20, 2021
9:00 a.m. Pacific Time

Prepared by:
Vicki L. O'Ceallaigh Champion, CR
Certificate No. 50534

Prepared for:

(Certified copy)

A. No.
Q. Have you served as a principal investigator on any private grants?
A. No.
Q. Dr. Karasic, what is gender dysphoria?
MR. HASKEL: Objection to the form.
A. So gender dysphoria -- well, first of all, there are a couple gender dysphorias. There is the gender dysphoria, the symptom. You might say small letter "G," small letter "D."
There is also gender dysphoria, capital "G," capital "D," the DSM-5 diagnosis. If for gender dysphoria the symptom, it is distress about the difference between one's identified or lived gender and one's assigned gender.
BY MR. KNEPPER:
Q. Okay. And then what is the diagnosis of gender dysphoria?
A. So the diagnosis of gender dysphoria is a diagnosis that the American Psychiatric Association has put in DSM-5. That includes the presence of persistent gender dysphoria along with -- well, it lists various manifestations of that, but it also -- as potential symptoms and also has that the symptoms cause social or occupational -- impairment of social

occupational functioning or clinically significant distress.

Q. Is it clinically significant distress?

A. Distress.

Q. And how is that distinguished from the distress identified as a symptom? You described it as little-G-little-D dysphoria.

MR. HASKEL: Object to form.

A. So the gender dysphoria as a symptom was -- or has been something that has been described in people long before there was -- the DSM-5 came out in 2013, but for example, WPATH Standards of Care 7 refers to gender dysphoria, not capitalized, and not as -- not as an APA diagnosis, but as this symptom of distress.

BY MR. KNEPPER:

Q. So what -- let me just -- if an individual -- and this is what I'm trying to understand: If an individual suffers from gender dysphoria, little-G-little-D, does that mean that they suffer from gender dysphoria, the psychiatric diagnosis?

MR. HASKEL: Objection to form, foundation. You can answer.

A. Not necessarily. I would say very often

actually a question. I think you were characterizing his testimony, which I don't know if that's a question or you were going to ask a question after --

MR. KNEPPER: Hold on. Hold on. I stopped, because I wanted to let Dr. Karasic speak.

MR. HASKEL: Okay.

MR. KNEPPER: I absolutely will finish my question, but I want to give the Witness -- when he raised his finger and said he wanted to say something, I wanted to give him an opportunity to make sure that I was saying something correctly.

BY MR. KNEPPER:

Q. So go ahead, Dr. Karasic.

A. So on that last answer, I was saying in the example I was giving was a "no" to the question of do all transgender people also have a diagnosis of gender dysphoria, and I was giving an example that related to the difference between gender dysphoria and gender incongruence of ICD-11, so just to clarify my answer --

Q. Thank you. That does -- that does clarify for me.

I'm going to ask you the converse question now. Do all individuals -- are all individuals who

suffer from gender dysphoria, the psychiatric DSM-5 diagnosis, transgender?

MR. HASKEL: Objection to form, foundation.

A. So being transgender is an identity. So there are -- you know, there are different ways to define it. I think we tend to think about people who identify as transgender and then to look at that, you know, another -- if we are looking at differences between the term "transgender" and "gender dysphoria," that gender dysphoria is a symptom or a diagnosis. Transgender is a diagnosis -- I mean, an identity. I'm sorry -- an identity.

And so there may be people who have symptoms of gender dysphoria, but they personally don't identify as transgender. Similarly, to give an example, there can be people who have same-sex attraction, but don't identify as either lesbian or bisexual.

BY MR. KNEPPER:

Q. Are there any peer reviewed studies that attempt to quantify that distinction between the number of individuals who suffer from gender dysphoria and the number of individuals who claim a

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.,	)	
	)	
Plaintiffs,	)	
	)	
-vs-	)	Civil Action No.
	)	1:19-cv-00272
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,	)	
	)	
Defendants.	)	

The videotaped videoconference deposition of RANDI C. ETTNER, Ph.D., reported remotely by JUNE M. FUNKHOUSER, CSR, RMR, and Notary Public, pursuant to the Federal Rules of Civil Procedure for the United States District Courts pertaining to the taking of depositions, commencing at 9:35 a.m. on October 15, 2021.

dysphoria?

A First I'd like to correct the statement that the specific study done at the University of Minnesota is upcoming.

Q Okay.

A It's already been published. It was actually spoken about on Good Morning America. I'm not an epidemiologist, so I cannot really give an answer about prevalence or incidence of any medical condition.

Q Do all transgender individuals suffer from gender dysphoria?

A No.

Q Are all individuals suffering from gender dysphoria transgender?

A Yes.

Q Is there an article that you would cite to support that conclusion?

A Well, gender dysphoria by definition includes a portion of the transgender or gender-nonconforming population.

Q So we've used a couple of terms, and I just would like you to define them as you used them. So what does it mean to be -- the

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

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MAXWELL KADEL, et al.,

Plaintiffs,

vs. Case No. 1:19-cv-272-LCB-LPA

DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,

Defendants.

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Video Deposition of
STEPHEN B. LEVINE, M.D.

September 10, 2021
9:05 a.m.

Taken at:
Veritext Legal Solutions
1100 Superior Avenue
Cleveland, Ohio

Tracy Morse, RPR

substance abuse, they didn't distinguish between trans and -- statistically, but other studies have indicated that everything else, like suicide in the last thirty days, thinking about suicide in the last thirty days, making a suicide attempt, substance abuse, it's all higher in the trans community.

It's not low in sexual minority communities. Either is domestic violence in either of those communities, but it's much less in the trans -- in the lesbian and gay community than it is in the straight -- in the trans community. And it's even less in the straight community, but obviously we have these same problems in the straight community, the cis gender community.

Q. Return to the question. Do you consider surgery for the treatment of gender dysphoria to be experimental?

MR. CHARLES: I object to form.

A. I have the same answer that I had to the hormonal question and for the same reasons.

Q. Do all transgender people suffer from a gender dysphoria?

A. No.

Q. Are there any studies or scientifically valid research that indicates what percentage of transgender people suffer from gender dysphoria?

MR. CHARLES: Object to form.

A. What percentage of transgender people suffer from gender dysphoria? I don't think -- I can't recall a study that asks that question and use -- and had numbers to explain the answer. People like myself get to see individuals who are transgender but not dysphoric or who are dysphoric but not transgender.

Q. That was going to be my followup question. Are there people who are dysphoric who are not transgender?

A. Oh, yes. Oh, yes. Many years ago, before I ever got involved with any lawyer about these issues, I remember recommending to a group of alcohol specialists that they ought to look at the gender identity -- they ought to ask questions about the sexual identity of the people being treated for substance abuse and alcoholism. Because in my limited clinical

experience, I've run into -- I keep running into people who presented with substance abuse and really dangerous degrees of substance abuse that would get them hospitalized.

And then when I talked to them, they tell me stories about their hidden gender dysphoria or their struggles about -- let me just take a man, for example -- the struggles about the sense that they have that they're feminine and they can't -- they have feminine interests, they have feminine interests but social -- and they have a sense of themselves as more feminine than masculine and yet they are too afraid to show it and then they drink themselves into hepatitis or whatever.

Q. But you would not consider those individuals to be transgender?

A. Well, they don't call themselves transgender. They present themselves as cis gender people.

MR. KNEPPER: That's all I have. Carl, do you have any follow up?

MR. CHARLES: What time is your flight?

MR. KNEPPER: 7:15.

UNITED STATES DISTRICT COURT
NORTH CAROLINA MIDDLE DISTRICT

MAXWELL KADEL, et al.,
Plaintiffs,
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DALE FOLWELL, et al.,
Defendants.

THE DEPOSITION OF GEORGE R. BROWN, M.D.
September 23, 2021

PORTIONS ATTORNEYS' EYES ONLY

Reported by:
PATRICIA A. NILSEN, RMR, CRR, CRC
Licensed Court Reporter 717 for the State of Tennessee

Foundation. Object to the extent it's outside the scope of Dr. Brown's opinions.

A. So the short answer is no, but I also want to point out that the presence of symptoms is -- also has to be considered at a particular -- in a particular time frame. So it's not just a simple matter of, does the person experience gender dysphoria if they have transgender identity. They could have last year; they might have it next year; they don't have it today. It depends on where they are in time, and a variety of other parameters specific to the individual.

But it is true that there are transgender people who, sitting here today, if they were sitting here today, do not have gender dysphoria with little G, little D or big G, big D.

Q. Are there studies that identify the portion of -- the portion, prevalence, ratio of gender dysphoria, the diagnosis in transgender individuals?

MR. TISHYEVICH: Objection, to the extent it's beyond the scope of Dr. Brown's opinions.

A. The answer to that is, no one knows the answer to that.