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

CHRISTOPHER FAIN, individually and on behalf of all others similarly situated, Plaintiffs, vs. WILLIAM CROUCH, et al., Defendants.	Case No. 3:20-cv-00740

REMOTE 30(b)(6) DEPOSITION OF
WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES

by and through their corporate representative

FREDERICK LEWIS

DATE: April 4, 2022
TIME: 9:00 a.m. (Eastern)
PLACE: Veritext Virtual Videoconference

JOB NO.: MW 5129863
PAGES: 1 to 136
REPORTED BY: Merilee Johnson, RDR, CRR, CRC, RSA

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EXHIBITS

REPORTER'S NOTE: All quotations from exhibits are reflected in the manner in which they were read into the record and do not necessarily indicate an exact quote from the document.

(PROCEEDINGS, 04/04/2022, 9:00 a.m.)

FREDERICK LEWIS,

duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. PRAKASH:

Q. Good morning, Mr. Lewis. My name is Anna Prakash. I am one of the lawyers that is representing Christopher Fain and Shauntae Anderson in this lawsuit. I am an attorney with the law firm of Nichols Kaster in Minneapolis. And my pronouns are she/her.

I'm going to be asking you some questions today and the one rule that I want you to really remember is that if you don't understand what I am asking, can you please ask me to clarify?

A. I sure can.

Q. Okay. Great. And if you answer my question, I'm going to assume that you understood it. Does that make sense?

A. Yes.

Q. Okay. Great.

A. Fair enough.

Q. Can you state your full name for the record?

A. Frederick Samuel Lewis.

Q. Great. And do you go by Fred?

A. I go by Fred. Thank you.

Q. And, Fred, do you have -- do you use he/him pronouns?

A. Yes.

Q. Okay. And you understand, Mr. Lewis, that you're designated to testify today on behalf of the West Virginia Bureau for Medical Services, right?

A. I do.

Q. Okay. And you are designated with respect to certain topics. One of them is the relationship with Mountain Health Trust, UniCare, The Health Plan, Aetna, and the Rational Drug Therapy Program. Does that sound right to you?

A. Yes.

Q. Okay. And are you prepared to testify about that today?

A. I believe so.

Q. Okay. And then you are also designated to testify about the decision to stop excluding hormone therapy from coverage in 2017 and the Bureau's experience covering and/or denying coverage for hormone therapy before and after 2017. Does that sound right to you?

A. Yes.

Q. And are you prepared to testify about that today?

A. I believe so, yes.

Q. Great. And then you are also designated to testify about certain discovery responses, written responses, that were submitted on behalf of the Bureau for Medical Services. Do you recall being designated for that?

A. Yes.

Q. Okay. And are you prepared to talk about that today?

A. Yes.

Q. Great. So I understand that you are the deputy commissioner of Plan Management and Integrity at the West Virginia Bureau for Medical Services; is that right?

A. That's correct.

Q. Okay. And the "Plan" in your title refers to the West Virginia State Medicaid Plan?

A. It refers to the MCOs that we contract with.

Q. Okay.

A. Arguably, it could be the state Medicaid Plan too. I have always related it to the MCOs. We called them plans.

Q. I see. And the MCOs are managed care organizations?

A. Yes.

Q. Bureau for Medical Services I'm going to refer to as "BMS" today so if I say that, will you understand what I mean?

A. Yes.

Q. Okay. Great. And how long have you been the deputy commissioner at BMS?

A. Today, I am 10 days shy of four years.

Q. And though you referenced the MCOs in describing what the "Plan" in your title refers to, are you familiar with the operation of the West Virginia Medicaid Plan?

A. I am, for the most part. There's still areas I'm learning. I came from outside of Medicaid, but I think I've learned a lot in the last four years. So I'm going to give you my best and if I don't know, I'll tell you.

Q. Great. And BMS is within the West Virginia Department of Health and Human Resources, correct?

A. Correct.

Q. And that is a state agency, the Department of Health and Human Resources is?

A. Yes.

Q. BMS is responsible for the administration of West Virginia's Medicaid program?
A. Yes.
Q. Mountain Health Trust is the managed care program for West Virginia Medicaid, right?
A. That's correct. It also is the umbrella for CHIP participants.
Q. And you referenced MCOs earlier. Enrollees in West Virginia Medicaid who are also in the managed care program of Mountain Health Trust need to sign up with an MCO; is that right?
A. That's correct.
Q. And there are three of them: Aetna Better Health of West Virginia, The Health Plan, and UniCare; is that right?
A. That's right.
Q. And how would you describe the role of those three MCOs with respect to West Virginia Medicaid?
A. They all are here to manage the Medicaid membership that has been placed in their custody, and that happens through the -- through the members' election to participate with whichever one of those they may choose. And if they don't choose, there's an auto selection criteria.

The MCOs are here to manage the healthcare of their members within the parameters of the state program and consistent with federal and state law and regulations and the contract.
Q. And that's the contract between BMS and the MCOs?
A. Correct.
Q. You mentioned auto selection criteria. If a member doesn't elect one of the MCOs, can you describe what happens with respect to auto selection criteria?
A. It's basically an eeny meeny miny moe. We have an enrollment broker that is a neutral party that will -- they have a computer logic that basically distributes these members evenly around all of these plans, trying to keep family units together.
So that's the reason it's maybe not just strictly, you know, directing each sequential member to a different plan and continuing, you know, in a circular fashion. They try to keep family units together.
Q. Got it. What's the name of the enrollment broker?
A. It's called Maximus.

Q. And it sounds like -- let me make sure that I understand this. It sounds like when members do not select an MCO, then it's basically random -- they're basically randomly assigned to one of the three MCOs so that the numbers remain even as between the three MCOs, with the exception being trying to keep families together; is that right?
A. Not quite. The members that are not making a selection, those are divided evenly. The ones that are electing to -- you know, the members themselves are deciding to go to, say, UniCare or whatever, they will stay with UniCare and they will not be counted in this logic. So --
Q. I see. Okay.
A. -- yeah. And the idea is to allow -- to foster the sense of competition between the plans. They're competing for the members. It's the member that has their attention, and the member gets to choose and the member's not locked in. The member can decide that they don't like UniCare anymore and maybe go to one of the other plans, so -- and they can do that at any time.
Q. Okay. And there are -- in your example, if they don't like UniCare, the only other options available to them are The Health Plan or Aetna; is

that right?
A. That's typically the case. We do carve out -- there are members in the fee-for-service Medicaid program and they tend to have special circumstances. I mean, such as, you know, maybe they need a transplant or they're a transplant recipient, things like that.
So members that are in nursing homes, members that are on our -- any of the three waiver programs, those are -- those are in the fee-for-service program, which I have little to do with more than the pharmacy -- oversight of the fee-for-service pharmacy program, which supports the entire Medicaid population --
Q. Okay.
A. -- they're a point of sale pharmacy.
Q. And the fee-for-service program, setting aside the pharmacy for a second, is a much smaller portion of the Medicaid program at West Virginia, yes?
A. Yes. Less than -- I just treated this the other day. It's like 17 percent. Something -- approximately.
Q. Okay. And where does Mountain Health Promise fit in with all of this?

A. Mountain Health Promise is our plan for members that are in foster care or have been adopted and it has -- it is not part of Mountain Health Trust. It has its own contract. These are children in need of...
Q. And --
A. I think -- well, I'm not certain of the age limit. I think it goes to 21.
Q. And is the only contract with Mountain Health Promise with an -- with an MCO with Aetna?
A. Yes.
Q. I want to return to something you said about keeping families together when somebody doesn't select an MCO. Do you know how that is accomplished?
A. It's accomplished via some kind of computer algorithm. And beyond that, I can't say, but --
Q. Okay. Do you know what the -- well, let me ask you this: Do you know whether the computer algorithm takes into account anything other than the last name of the individuals in keeping families together?
A. I don't know how that's accomplished. I don't know that it's looking at the last name, for that matter. It may be according to how the family

unit is identified in the eligibility file. But I'm not sure how that's accomplished.
Q. And when you talk about an eligibility file, is that something that BMS keeps or is that something the MCO keeps?
A. BMS keeps it.
Q. And what's the purpose of an eligibility file?
A. It's to identify the members that have coverage and what type of coverage they have, identify who they are, and their member ID. That sort of information.
Q. And the eligibility file is used to determine whether they are eligible for Medicaid and not which specific services they're eligible for; is that right?
A. That is mostly correct. We do have the alternative benefit plan in Mountain Health Trust, which is -- I don't think I can sit here today and contrast that with -- for you from the normal benefit package.
But let me say in the generic. When we carved in the ACA expansion population, or the Medicaid expansion population, we had a slightly different benefit package for those members.

And over time, some services have been added to that package and things have been done to try to take the differences away. And at this point, I understand there is no-to-little difference between the benefit packages.
So to that extent, the eligibility file identifies -- I guess it would identify the expansion members, the members that are in the alternative benefit plan and the members that are in the regular plan. I don't think there is really a tangible -- or much difference between the two.
That's a question -- line of questioning that might -- you might pursue with any of several other people from the Bureau. But I have not really had to delve into that, my going on four years yet.
Q. Okay. When you say -- I just want to make sure I understand what you described as alternative benefit plan. Is that Mountain Health Promise or is that something else?
A. That is -- no. It's in Mountain Health Trust.
Q. Okay.
A. The main program -- Medicaid managed care program.

Q. And when you talked about the alternative benefit package, where is that?
A. That's in Mountain Health Trust.
Q. Got it. Okay. And that was for the ACA carve-in folks that --
A. Yes. You've got it. You've got it. Yes.
Q. Okay. So in its eligibility files, you mentioned "member ID." I assume the eligibility files are kept electronically; is that right?
A. Yes.
Q. And this might be a question for tomorrow's witness so tell me if you don't know the answer, but do you know if those electronic files, if the member ID links to other systems within BMS?
A. You're leading me into some areas that I'm less knowledgeable about. I'm certain that it probably does. I mean, this is a key element in administering our program. This is -- this is a data key, you know, the member ID.
The member eligibility file is a standardized EDI report. I can't remember the number off the top of my head, but it's -- we take a standardized approach there and it makes it easy for the MCOs to ingest and for communication all around with our partners.

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Q. Got it. And in the eligibility file, does it note each member's gender?
A. I don't know if it gets into that level of detail or not.
Q. Okay. Do you know who might know that?
A. Probably any of our data people. For -- I would probably look to Brandon Lewis, for one. I think he's on the witness list.
Q. Yeah, okay. No relation to you?
A. No -- well, we joke about it, but to the best of my knowledge, we are not blood relatives.
Q. Okay. So we're going to be discussing care that transgender people receive for treatment of gender dysphoria. This care can include hormone replacement therapy, surgery, medical appointments, and therapy. And I'm going to collectively refer to that type of treatment as "gender confirming care." So if I use that term "gender confirming care," will you understand what I mean?
A. Yes.
Q. Okay. And we're also going to be talking about the exclusion of care in Medicaid coverage for transgender people. Are you familiar with the exclusions that are at issue in this case?
A. I'm familiar with -- I'm going to call them

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alleged -- there is one exclusion I will concede the -- I'm aware of the alleged exclusions, yes.
Q. And is that for surgical care for the treatment of gender dysphoria?
A. Surgical care, yes.
Q. So I want to talk a little bit about the MCOs. They are -- the relationship between BMS and each MCO is created by contract; is that right?
A. That's right.
Q. Okay. And the contracts do not let the MCOs deem something covered by insurance if it is excluded by BMS; is that right?
A. Not necessarily. I think the contract defines what it is we expect the plan to cover as a part of the capitated relationship between BMS and the plan. In other words, we're paying premium for these identified benefits, not these.
And those other things -- the plans actually provide -- and part of what managed care is about, it's supposed to be encouraging innovation -- innovated, you know, value-based care relationships. It's -- it empowers the plans to go above and beyond if they can and if they provide these value-added -- or value-add benefits that are not part of our baseline expectations, which are

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what you were just referring to -- our baseline expectations are those coverages that you're talking about, those covered services.
And the noncovered services are things that -- we're saying this is not something we're expecting you to provide in exchange for the capitation we are paying you, if that makes sense.
Q. I'm into sure I totally understand so let me ask you this: When you say "capitated relationship," what do you mean?
A. Well, we pay each of the plans a per-member per-month amount to provide for -- and this is how managed care differs from fee-for-service. They are supposed to provide for all medically necessary care within the parameters of the contract for that payment.
So it's -- it's a situation where we're saying, here is your -- it's kind of like a bank account. Here's the bank account for Plaintiff Fain or Plaintiff Anderson and -- only it's pooled with all the other members and certainly their care could -- the cost of their care regularly exceeds the amount that we pay in a given month.
On the whole, those capitations cover the cost of care. It's not based upon the

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individual -- we're not reimbursing them for claims.
Q. So it's kind of like a budget that each MCO gets?
A. Exactly. Yeah.
Q. Okay. And do you happen to know what that budget is for each MCO on a yearly basis?
A. I don't. It's not hard to come to that information but I don't have it off the top of my head. I think it averages around 250-ish dollars per-member per-month, but I'm not full- -- I'm not fully confident that that's even right. I think that's the number.
Q. Okay.
A. And it differs -- it differs by member, you know. It relates to -- there are a lot of different rate cells that determine what capitation is paid for that given member. So I'm talking at a high level here.
Q. So when I described capitation as a budget for each MCO, is it fluid? In other words, it's not a set number but rather it fluctuates?
A. It is -- it can be a set number. It is actuarially determined. Our actuaries look at the plans, administrative expenses, at least what we

will recognize of them. They look at the healthcare spending patterns and they project what it will take to provide coverage to that individual in the coming year.

And they consider all -- you know, rate changes and plan modifications and all that kind of stuff and weigh that in. And they produce rates that are then -- you know, it's quite a process. So a lot of back-and-forth.

The plans -- we get data back from the plans, even. We -- the actuaries prepare all of this information and the rates. And, you know, they openly state their assumptions.

We have meetings with the plan management and actuaries and there's a lot of back-and-forth about what the assumptions are and what data was considered and how data might be interpreted differently.

And all of that is taken into account. Ultimately the rates are produced, draft rates, and they're submitted to CMS along with the contract. CMS reviews the contract and the rates in the context of the contract and certifies the rates.

After the rates are certified, we may -- at some point during the year, we often have a midyear

rate cycle -- although we don't necessarily have to. We're trying to get away from it. But a lot of times we'll have, like, an implementation of a new plan or new provider rates, things like that, midyear that weren't reflected in the original rates. And so that midyear rate adjustment would be to account for things like that.

Q. When you are talking about the work that the actuaries do to determine rates, is that on a per-person basis?

A. No. No, it's -- well the rates are on a per-person basis. The actuaries are looking at more big-picture data, I would say. But still, they're looking at -- I mean, they're looking at every claim. They're looking at the encounters that come in from the MCOs in setting the rates. But we don't have a different rate for each individual, no.

It's done by rate cell that is -- you know, it's related to age and some other demographical factors, not -- well, like -- there's a rate cell for, like, pregnant women, for one thing, and it's to provide -- we pay for them differently than we do other members.

There's something called a kick payment

that essentially is a way to fund the cost of the prenatal care and the delivery, all of that. So the -- the rate -- it's the rate cell level, I think, that you're looking for. Yeah.

Q. Okay. And are there any rate cells that are specific to a diagnosis of gender dysphoria?

A. I don't believe so.

Q. Are there any rate cells that are specific to a person being transgender?

A. No.

Q. And are there any rate cells that are based solely on gender?

A. I believe so. I mean, for example, the pregnant mothers -- yes. That would be -- that would be solely on gender. That's the only one I can think of, though, offhand.

Q. Okay. So the rate cell is specific to pregnancy; is that right?

A. Correct. Yes.

Q. And other than that, you aren't aware of any rate cells that are directly or indirectly tied to gender?

A. I don't recall any others.

Q. Okay. And are the actuaries BMS employees or are they employed by another entity?

A. They are consulting actuaries. We do not have staff actuaries. We have -- we're between firms right -- well, right now we are with -- we are using Myers and Stauffer and they are subcontracting with Milliman for the actuarial services. We just transitioned in February from Guidehouse actuaries.

Q. And were Guidehouse actuaries contracting with anybody? Sorry. Subcontracting with anybody? For example, you just gave this example of Milliman.

A. Well, they were originally the subcontractor of Lewin. I need to be a little bit more precise.

Guidehouse, when -- the people at Guidehouse that we were working with, or are still closing out some business with, some scopes of work, when they first came to do work for us, they were known to us -- doing business as Aon, A-o-n. They were acquired by a company called Navigant, which is a direct competitor of Lewin.

We had some issues between Lewin and Navigant at the time that probably related to the nature of -- you know, suddenly Lewin found their subcontractor to be their competitor and it created

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some issues.
Later, we had a conflict. Lewin -- there were people at Optum, which is in the Lewin corporate family -- I'm not sure how they're related now; I knew at the time -- that were doing work for one of the plans. And we saw this as a conflict so Lewin assigned their work to Navigant, who later became Guidehouse.
And so Guidehouse started as a subcontractor and then they came to be -- to become -- to assume the prime role in that contract work.
Does that make sense?
Q. I think it will when I read the transcript and sort it all out. That was very thorough.
Prior to that last set of contractors before the one that you currently have, were there any other contractors or consultants doing actuarial work for BMS that you're aware of?
A. Well, Lewin provided actuarial work to us when I first came here in 2018. And I understand that it was Lewin probably all the years before, going back to the beginning of managed care. Lewin was our managed care consultant and actuarial -- consulting actuary for that period of time.

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Q. And are you the person at BMS who is in charge of contracting with the consulting actuaries?
A. I'm one of them. I feel like I share this with Becky Manning, the Deputy of Finance. We have overlap in this area. But, yeah, Becky and I are over this contract. I think I actually signed the SOWs this time around.
Q. And do you know if BMS has ever asked or -- asked for or received from the actuaries any calculations on how much it would cost to provide surgery as a treatment for gender dysphoria?
A. We have not asked for that in my time here.
Q. Are you aware of BMS asking for it at any point in time prior to you coming to the agency?
A. I am not aware. I'm not aware of a lot of things, though, so...
Q. All right. So I understand that the MCOs must follow coverage limitations required by Medicaid and can't use Medicaid dollars to authorize noncovered care. Is that right?
A. I think they could use Medicaid dollars as long as, you know, they're coming from profit or something. But that's right. We're not providing -- we're not providing funding to them

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for the purpose of providing anything more than what is basically our -- what we recognize as our base level bene- -- our fee-for-service benefit is sort of the guiding issue.
Q. Okay. And so that -- just so I'm clear, that benefit does not include surgical care for the purpose of treating gender dysphoria, correct?
A. Correct.
Q. Okay. And so the MCOs could not use Medicaid dollars for the purpose of treating gender -- surgical care for the purpose of treating gender dysphoria, correct?
A. They could, as a value-add benefit, which means, you know, they -- it's not our expectation that they will pay for it, but, you know, maybe they have a marketing strategy or something: They want to differentiate their plan from the others by providing a benefit -- a benefit that wouldn't otherwise be covered. They could do that, but it would be from -- it would not be something we have built into that capitation, that budget, as you'd say --
Q. Okay.
A. -- for them to pay for. It would be coming from their managed care savings, for example. When

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you manage a member, you're going to identify some services that -- you're going to avoid services, first of all, because you're going to keep the member healthier. And you're going to be able to manage the services and provide for those that are medically necessary and not services that aren't medically necessary.
So there are savings that come from all of that. That and profits -- you know, there's profit-building with the capitation. All of that could be used by the MCO to pay for the value-add service.
Does that make sense?
Q. Well, let me ask you this: Has any MCO -- any of the three that BMS contracts with, have any of them used that -- those savings or created a value-added benefit that is surgery for the treatment of gender dysphoria?
A. No, none of them have, to date, provided for those dollars to be used for those surgeries, to the best of my knowledge.
Q. All right. How would you describe value-added benefit? You've said that a few times so I just want to know how you're defining that.
A. It is a benefit that is not considered --

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the cost of which is not considered in building the capitation rate and a benefit that is not available to the Medicaid fee-for-service population. It's sort of an extra.
Q. Got it. When you say, "Medicaid fee-for-service," is that -- I guess I'm a little bit confused because we talked about Mountain Health Trust and the three MCOs and that sort of managed care program. When you're talking about fee-for-service, are you still talking about that or are you talking about something else?
A. No, I'm talking about the non-Medicaid part -- the nonmanaged care part of program.
Q. Got it.
A. When I say, "fee-for-service," I'm typically talking about those members that are not in Mountain Health Trust --
Q. Got it.
A. -- or Mountain Health Promise.
Q. Okay. So if we go back to the managed care program, Mountain Health Trust, is it true that the MCOs there cannot use Medicaid dollars to authorize noncovered care?
A. They could, but only to the extent they're deriving those dollars from either their profit

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administrative savings or from -- or from managed care savings, which is coming through, you know, providing -- preventing disease, providing for the -- whatever it takes, to keep their member healthy. But that's it.
They could, in the technical sense, use Medicaid dollars, but it would -- it would have to come from one of those other sources for there to be money available.
Q. I see. And so I think I asked this question with respect to -- and you answered with respect to fee-for-service, but the same question within the managed care program: You're not aware of any MCO using that extra money for the purpose of covering surgery for the treatment of gender dysphoria?
A. Yes, I am not aware of any of the plans providing for the treatment of -- well, providing for the treatment of -- for the surgery for these members and it's not their -- it's -- since we provide pharmacy on the -- and I'm going to use "fee-for-service" in a different context this time. Our pharmacy benefit is fee-for-service.
Q. Right.
A. It's carved out of managed care.

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Q. Got it.
A. Since we provide for that through the fee-for-service program, that's not their responsibility, either.
Q. Okay.
A. But I am not aware of an MCO providing for surgery or providing for hormone therapy. Doesn't mean that it couldn't have happened somewhere. You know, maybe -- maybe there was a mastectomy that was provided and -- but it's not -- it's not their intent to provide for -- those services for that purpose -- the surgical services for that purpose.
Q. Got it. Have you ever -- are you aware of any of the MCOs pushing back against the exclusion on coverage for surgery related to gender dysphoria?
A. No.
Q. Are you aware of any of the MCOs raising compliance concerns with respect to the lack of coverage for surgical care related to gender dysphoria?
A. No. And nor have we gotten such from CMS, to the best of my knowledge.
Q. When you say "CMS," that's the Center for Medicaid Services?

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A. Yes.
Q. Does BMS -- well, let me ask you this: So --
Actually, you know, I think I'd like to go to our first exhibit. So if you could go into Exhibit Share and I will pull up an exhibit.
(Exhibit 1 was marked for identification.)
Q. If you go to the Marked Exhibits folder, there should be an exhibit in there. And if you open it -- there should just be one and it should say Exhibit FL 1 at the bottom of it.
Do you see that document?
A. Yes, I have it open here.
Q. Okay. Great. So, for the record, this is FL 1, and the Bates number is DHHRBMS001121 through 1390.
Okay. So is -- this document that you're looking at, Mr. Lewis, is this one of the contracts between BMS and Aetna?
A. It is. Internal to BMS, this document, formally known as the Model Purchase of Service Provider Agreement, is what we informally call "the contract." Although the concept of contract is much broader, to include, you know, the RFP and the

response to that RFP and other procurement documents, this is -- this is the -- what we, within BMS, typically refer to as "the contract."

And my earlier testimony about making changes to the contract -- I don't know how much I got -- we talked about rates. But where we were talking about making program modifications and whatnot, this is the body of -- this is the contract we're talking about.

Q. Okay. And you described it as a "model contract" a bit earlier. Is it safe to say that this is the language that is used for all of the MCOs that BMS contracts with?

A. It is. It's the same agreement for each of the three and Mountain Health Trust.

Q. Okay.

A. If we were talking about Mountain Health Promise, there would only be one contracting MCO.

Q. And that's Aetna, correct?

A. That's Aetna right now.

Q. And Mountain Health -- does Mountain Health Promise use the same model contract?

A. No. No, it has some other variations. I think it contains some of the same -- the same language that you're going to be concerned with as

we talk through this.

Q. Okay. Great. Well, that makes my job a little bit easier.

Could you scroll down to what is page 19 of the contract. And, for the record, the Bates number is DHHRBMS001147. So just tell me when you are there. The page number of the document in the bottom right-hand corner is 19 and then there should be a smaller printed number that ends in -1147.

A. I'm there.

Q. Okay. Great. So under Utilization Review and Control, there's a second paragraph there that starts with, "BMS will have the authority to override any MCO utilization management guideline on a case-by-case basis."

Do you see that?

A. I do.

Q. Okay. What does that mean, that first sentence?

A. That means that we -- we have the ability to say -- let me go back. The biggest concern in managed care: Because you're paying for all the services up front in a lump sum -- I mean, you're paying to manage the member, you're not paying for

individual services.

The biggest risk to the State of West Virginia in entering an agreement such as this is that we will pay for something and not receive it at that -- members will not receive the benefit that we feel the contract provides.

And so this sentence says, if the MCO is imposing a strict utilization guideline that is denying medically necessary care to a member, we may get involved and direct them to provide the care.

Q. And --

A. I'll give you an example. I remember a case where there was a very costly eye medication. This was not a point of sale throughout. This was a treatment provided in a provider's office or in a surgical setting where the very precious, expensive drug was being injected into someone's eyeball -- or was to be injected into someone's eyeball.

And there were differences between the medical director of a given plan and our own medical director about what was clinically necessary for that member to receive. And we had to direct the plan to provide that expensive service to our member.

Q. Got it. And has BMS ever directed an MCO to provide surgical care for the treatment of gender dysphoria for any member?

A. I don't believe so.

Q. Okay. And has -- this sentence that I focused on, "BMS will have the authority to override any MCO utilization management guideline on a case-by-case basis," does it ever go the other way? In other words, the MCO would -- their guidelines would have them providing a service and BMS says no?

A. I don't believe that would ever happen. I don't know how we would find out about -- no. I mean, they make their own decisions and the only time we're likely to get involved is if a provider or a member is reaching out and, you know, making a complaint with us for more of a -- you know, we have our own denials and appeals processes. The plans have them and then they later can be escalated to Bureau level.

But aside from that, we still may get a call from more of a contract enforcement perspective. And we can sometimes get involved -- and often do get involved in, you know, looking to see if the plans are following through on their

commitment to us. And it can come via direct call to us, call to the governor or the secretary's office. Lots of different avenues.

(Nicole Schladt joined the proceedings.)

Q. And on this specific paragraph in this sentence that I read to you, has that always been the case with respect to each iteration of the contract? Has that language been there? At least during the time that you have been at BMS?

A. I can't say for certain. I believe so. Seems like essential language to me. I believe it's been there the whole time I've been here and likely pretty far back, but I can't -- I can't say for certain. But it wasn't something I prepared.

Q. Okay. And that language, I assume, because this is a model contract, is the same for the other MCOs, correct?

A. Correct.

Q. Okay. And is it the same for Mountain Health Promise, for that contract?

A. I believe so.

Q. Okay. Can you keep scrolling down to the section on Noncovered Services, which is page 65 of the document and, for the record, the Bates number

ends with -1193. Let me know when you're there.

A. I'm here.

Q. Oh, okay. Great. So Noncovered Services starts at the bottom of the page, Section 1.4, and it goes into the next page. Is that list an accurate list of the noncovered services?

A. I guess it depends on how you're viewing it. I mean, for example, all non-medically necessary services, the plans provide lots of non-medically necessary services. I mean, those -- they'll provide value-add benefits, such as free produce to members to encourage healthy diets. Again, it's all in the name of prevention, things like that.

Q. Well, let me ask you --

A. Is that medically necessary? No. So, I mean, the -- I guess I need to understand how you mean, is it an accurate list --

Q. So let me -- let me define that for you.

A. Okay.

Q. If you set aside the value-added services and we are talking about what is considered in the capitated rate that you've described, is this an accurate list of the noncovered services?

A. It's an accurate list of things we're not

paying the plan with the -- for, with the expectation that they will be providing these to the members. It is an accurate list.

Let me footnote that with number 6, "...hormone therapy associated with sex transformation procedures," that's being provided on the fee-for-service side through our point of sale pharmacy program.

So the contract governing the relationship between BMS and the plans, it is -- it is accurate from that standpoint, in the context of what we're paying the capitation for them to do.

MS. PRAKASH: And I wonder, Merilee, if you could read back the beginning of that answer for me because I am not sure I heard it correctly and I'm not quite sure of the follow-up.

(The requested portion was read back by the court reporter:

"ANSWER: It's an accurate list of things we're not paying the plan with the -- for, with the expectation that they will be providing these to the members. It is an accurate list.

Let me footnote that with number 6, '...hormone therapy'") --

MS. PRAKASH: Okay. Thank you. That's good.

BY MS. PRAKASH:

Q. So I want to follow up on that, Mr. Lewis. You said with the expectation that we will be providing these to the members? Is that what you said?

A. We would -- we would not have the expectation that the plans would be providing this list of services to the members as mandatory benefits under the contract. Does that help?

Q. Got it. Yep, that makes sense to me.

A. I'm sorry if I misspoke earlier.

Q. Nope. Just wanted to clarify that.

And the Medicaid program itself, just Medicaid, only covers medically necessary care, right?

A. Correct. I can't think of an example of where we don't, anyway.

Q. Okay. And the noncovered services, this provision is the same in the contract with the other MCOs, right?

A. It's -- yeah, it's the exact same.

Q. And is it the same with respect to Mountain Health Trust? Or, sorry. Mountain Health Promise?

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A. Yes. Yes.
Q. Okay. And to your knowledge, has this list in previous iterations of the contract ever excluded or not had on it what is currently number 6, sex transformation procedures?
A. No. But I will add that in the coming contract year, plan year, 2023, I'm striking the "hormone therapy associated with," that phrase -- this document controls -- it guides our relationship with the plan. I mean, that's what this is about.
But just for the purposes of not confusing somebody that might be reading the plan's contract, we're taking it out. It won't change anything, but it will -- it will -- it will help avoid confusion.
Q. Got it. So the upcoming contract will not include the exclusion for hormone therapy but it will still retain what is listed here as sex transformation procedures?
A. Correct. It won't be a practical -- it won't lead to --
Q. In practice, nothing will change?
A. Nothing will change, but I think -- I think it will make more sense to people that are reviewing the contract and making inferences.

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Yeah.
Q. Okay. So keep scrolling down, please, to page 128, and the Bates number on that ends with -1256.
A. Okay. I'm there.
Q. Okay. I need to catch up with you then. I scrolled too fast.
So under Utilization Management, which is at the bottom of that page, the last sentence of the first paragraph says, "The MCO must meet BMS-specified standards for utilization management (service authorization) listed in this contract."
Do you see that sentence?
A. I do.
Q. Okay. Can you tell me what -- well, first let's start with this: What does "utilization management" mean?
A. It's controlling -- these are -- this is management of utilization. It is the MCO's efforts to limit the consumption or access to medical services and -- you know, there's a lot that happens within the definition of medical necessity and all of that.
But it's also being able to have -- like step therapies, where the plan may say, before you

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access B, you have to do A. Right? So we're going to try this therapy before we send you for the MRI, or whatever.
Q. And --
A. Basically --
Q. Go ahead.
A. It's those kinds of controls on utilization that we're talking about when we're talking about UM.
Q. So the earlier part of that sentence references BMS-specified standards for utilization management.
Does BMS have its own standards for utilization management or do they follow some pre-established guidelines? What is that referencing?
A. We do have our own standards, and this would be a better question probably for Sarah Young or someone -- maybe Jennifer Myers, someone on the fee-for-service side. But we have extensive policies in the policy manual laying out some of these kinds of things.
And, again, I think where this would come into play is if we feel that one of our members providing -- or receiving care from an MCO is

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getting less than a member that is in our fee-for-service program might be getting, we would get involved.
Q. And so that was --
A. That goes back to that body of policy. That's probably the main thing, but there may be others -- other source -- like in the pharmacy program, for some drugs, there are -- these are PA drugs.
There are drug criteria, so there may be comparable policies for certain types of care that's being provided under the program in the fee-for-service environment here for which there may be policy, even beyond what's in the policy manual. I'm not 100 percent sure of that. But that's something you might want to ask about.
Q. Okay. So I have -- when we were talking a bit earlier, you referenced Milliman, and I have seen in some of the document productions documents labeled "InterQual" at the top. Are you familiar with those two companies, generally speaking?
A. I'm familiar with Milliman. The other company is called what? InterQual?
Q. InterQual.
A. InterQual? No, I don't work with

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InterQual.
Q. Okay. And are you aware of any of the MCOs using guidelines established by Milliman for the purpose of utilization review?
A. Any of the MCOs using guidelines established by Milliman for the purpose of utilization review. I am not aware of such...
Q. Okay. And the guidelines under the contract that the MCOs should be utilizing are the BMS-specified standards for utilization management, right?
A. That's right. That's right.
Q. And somebody else, perhaps Jennifer Myers, is the person to ask about what those specific standards are?
A. There may be some I don't know about or haven't communicated. The policy manual would be the key one. I've thought of other sources while we've been sitting here, but mainly there are some policies that are memorandums and such that are hosted on the BMS website. And we've had several that have gone up during COVID, for example, that may direct some of this.
Q. Okay. And when you say "the policy manual," are you referring to BMS's Medicaid policy

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manual?
A. Correct.
Q. Okay. And this section on utilization management, this -- because this is a form contract, this is in the contract with the other two MCOs as well, right?
A. Yes.
Q. And for the entire period that you've been at BMS, the utilization management standards that the MCOs must follow are those that are the BMS-specified standards, right?
A. That's right. Or at least we reserve the right to get involved and provide direction to them if we disagree about something they're doing, yes.
Q. Okay. And is this language the same for the contract with Mountain Health Promise and Aetna?
A. I believe so. Yes.
Q. Okay. Thank you. You can set that aside.
In terms of the contracts being awarded to the MCOs, is that a competitive bidding process?
A. Bidding might give the wrong impression but it is a competitive process. They each respond to the RFP that we put out and they are scored -- this last procurement cycle, however, we only had three

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MCOs that applied and we -- and we were -- our target number of MCOs was three.
We were going to award to three so no one lost out, but we've had a lot of interest by external MCOs that want to come in here and -- we try to foster an environment where -- you know, we try to encourage competition so they are competing on more of a quality basis.
It's not so much that they are in a bidding war from the -- in terms of dollars because it's the actuaries that are setting the rates, if that makes sense.
Q. Yeah. So --
A. So we're determining the rates through the rate-setting process. So we -- we sometimes are required by our purchasing people to give consideration to the cost side. But there's little room to differentiate when we're setting the price.
Q. Got it. And does BMS have a budget within which that price must fall?
A. If we're talking about the procurement process, we may technically identify a budget for all procurements. That's not really within my area of expertise. But I don't see that as really binding us. This -- the budget we have to live

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within is what's provided by the state legislature, not what is put forward by the -- or at the beginning of the MCO procurement cycle.
And keep in mind that procurements tend to be for several years at a time. I think the current one is, I don't know, four or five years. Something like that. Counting all of the renewals, optional renewals. So...
Q. So the actuaries that we talked about, those consultants, they come in during the procurement cycle; is that right?
A. No. They function outside of the procurement cycle, mostly. Actually they're kind of with us year round. I mean, they're here during the procurement cycle, but they're basing their work on past experience, on changes in policy and rates, things like that, trends. They are not trying to come up with a new rate for -- you know, because it's a new procurement or whatever.
Q. So when they're setting the rates, are those in any way connected to the overall budget? You know, does that come into account when they're setting rates?
A. No, we don't tell them, hey, this is the budget. You have to set a rate that will keep us

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within this budget. No.
Q. And are you aware of them ever setting rates that exceed the budget or that end up exceeding the budget?
A. I am not, but -- well, and I tend to think of the budget as a more global amount that BMS has to operate under than that given, you know, line item, if you will, that would be for managed care.
But I'm not aware of a rate coming back to us that would cause us to not be able to live within the bigger budget of BMS, but there are a lot of other -- I mean, there's a lot to -- there's a lot of other things that are paid out of the greater BMS budget, as well.
So that would be a better question for Becky Manning who has experience as our CFO and finance deputy. She may have encountered something like that, where we had to fundamentally go back and rework the budget a little bit. But I would not have been as much in the middle of that.
Q. Okay. And you mentioned, like, a line item for managed care. Do you happen to know what that is?
A. I don't even know for sure that there is one.

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Q. Okay. All right.
A. I was talking in the abstract.
Q. All right. So those budget questions are better suited to somebody else.
A. Yes.
Q. All right. So I -- well, is it right that with respect to managed care and -- the managed care program and the three MCOs that we've been talking about, that they each have a provider procedural manual?
A. I believe each of the MCOs has a provider manual, yes.
Q. Okay. And do you have any role with respect to those?
A. I don't know if we review those or not. We review a lot of the MCO's policies and documents. In the case of the member handbook, you know, we even provide a template in that case. And I'm not sure it's --
That would be something that we rely on this consultant that I spoke of earlier. In this case, it would be Myers and Stauffer or it would have, in the past, been Guidehouse and, before them, Lewin, to -- if there is a responsibility to review the provider manual, it would have been on

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them.
I don't think I've ever had occasion to review it personally. I don't recall being drawn into that.
Q. Okay. And when the consultants are reviewing the provider procedural manuals, does BMS give them any guidelines for the purpose of review?
A. I'm not 100 percent sure that we are reviewing that manual. So I don't know.
Q. Okay. Do you know who would know?
A. I would ask my Chief of Managed Care, Susan Hall.
Q. And do you -- does BMS have access to the provider procedural manuals?
A. Certainly we could request them from the plans if we don't already collect them.
Q. Okay. You talked about -- you referenced a template for the handbooks. I want to just go back and see if I can understand that a little bit better. So I understand that each of the MCOs has a member handbook that is distributed to members. Is that right?
A. Correct.
Q. And does BMS provide the MCOs with a template for that handbook?

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A. We do. They get to add to it, but the template includes sort of a base level of information that we want the plans to convey to the members.
Q. And who at BMS has responsibility for coordinating, you know, the template distribution and receipt of the handbooks?
A. So that would be Susan Hall, the director of managed care, who is my direct report, and we typically work with the managed care consultant on some of that review as well. They're integrated into that process in hosting...
(Court Reporter requested clarification due to distorted/muted audio.)
A. The managed care consultant is integrated into that process of reviewing the member handbook and working with the Center for Managed Care to put the template together, and then review the member handbooks that come together by the plans. I believe we approve those, as well, beyond.
And there's a lot that's taken into account there: reading levels and -- or, I'm sorry, not reading levels. The writing needs to support a certain reading specification.
Q. So if I understand the process right, the

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handbook template is distributed from BMS to the MCOs; the MCOs work on the handbook, they may add to the template; and then it comes back to BMS for final review and approval?
A. That's how I understand it to work, yes.
Q. Okay. So I want to talk a bit about the Rational Drug Therapy Program. And I think you said you're prepared to testify about that today, correct?
A. Sure. Yeah.
Q. Okay. The Rational Drug Therapy Program is a part of West Virginia University's School of Pharmacy, right?
A. That's correct.
Q. And they provide the prior approval system for the BMS Medicaid prescription drug program, right?
A. Correct.
Q. Okay. And the Rational Drug Therapy Program needs to follow the rational drug use criteria established by BMS, right?
A. Say that again.
Q. The Rational Drug Therapy Program needs to follow the rational drug use criteria established by BMS; is that right?

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A. That's correct.
Q. And if a member has a dispute about coverage with respect to drugs that are coming through the Rational Drug Therapy Program, they have the right to appeal; is that right?
A. They do.
Q. And the first appeal goes to the Rational Drug Therapy Program, right?
A. That's correct.
Q. And then if they are still dissatisfied, they can appeal again, but that goes to BMS, correct?
A. Correct. Correct.
Q. And let's say it just stays at that first level of appeal to the Rational Drug Therapy Program. On appeal, the Rational Drug Therapy Program still has to adhere to the BMS criteria, correct?
A. Correct.
Q. And are those criteria listed someplace?
A. Well, we have -- oh, jeez. We have the drug criteria for PA drugs that are posted on the BMS website.
Q. Can I ask you a question? When you say, "PA drugs," can you just explain what that means?

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A. Prior approval -- drugs requiring prior approval.
Q. Okay.
A. We have a drug criteria that we develop ourselves that is posted to the BMS website.
Q. Okay. And so the criteria that BMS develops itself, what is that based on?
A. It's based on the -- and this has gone by our pharmacist, but it's based on the -- what do they call it? -- the drug insert, information about the drug from the manufacturer, and sometimes other research. We have some other services we subscribe to that provide some information that maybe support some of those decisions.
But based on medical literature, pharmacy literature, but primarily it's based on the manufacturer's drug insert.
Q. So you said that the pharmacist does this. Is that a BMS employee?
A. It has traditionally been. We recently migrated the position. We call it our -- oh, shoot -- our drug utilization pharmacist, I believe. We migrated it over to Rational Drug Therapy just within the past year.
Q. Okay.

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A. And to give you a little context on that, part of the reason for it was we had a star in that role. She was incredible. Her husband was a specialty physician -- I can't remember the area -- but moved to Texas. She was going to have to leave. She wasn't going to be able to continue working for us.
But it was a way to get her to move over to Rational Drug Therapy and become an employee on their payroll but continue to support us in the way she always has.
So that was a little bit unusual, but it was -- it was a way that we could maintain the high level of performance that we've had with --
Q. And what's that person's name?
A. Priya Shah.
Q. And so Priya Shah was the drug utilization pharmacist employed by BMS and then she stayed in that position but the position moved to fall under the employ of the Rational Drug Therapy Program; is that right?
A. That's correct. Yes.
Q. And has she been in that role as drug utilization pharmacist during the entire time that you have been at BMS?

A. No, no.
Q. Okay. Who was in that role before?
A. The current director, Brian Thompson, was in that role for a very significant amount of time. Probably the whole -- the whole time that we're considering here under the lawsuit.
Q. And we talked -- you talked about the criteria being based primarily on the drug insert and you did reference other research and other services. So let me just ask you if you are aware of the criteria consulted or considered -- or the research consulted or considered in coming up with the criteria include the international statistical classification of diseases and related health problems, or the ICD-10? Do you know?
A. I believe it probably would include that.
Q. How about the DSM-5?
A. Likely. Yes. I'm having to speculate. I really am not involved at that level.
Q. Okay. And is that -- so when you reference other research and other services, do you have anything specific in mind?
A. Nothing specific, but I just know that the pharmacy staff would be wanting to weigh in the really high-quality research and findings. A lot

of times -- I mean, the insert only, of course, deals with on-label use. And what we're talking about here is off-label use. But we do have -- accepted off-label uses of a lot of drugs. It's kind of commonplace in pharmacy.
So the insert is going to be of limited value in this case. It really has to be supplemented if the criteria is going to delve into off-label uses.
Does that make sense?
Q. Well, sitting here today, you don't know what any of those supplements are; is that right?
A. What any of the supplements -- the hormone supplements?
Q. No. You talked about -- so let's back up. You talked about --
A. Oh, the supplemental source of information?
Q. Hang on. Let me just finish the question.
A. Okay.
Q. So you talked about the inserts, the drug use inserts, and then you said because of off-label use, that information needs to be supplemented. And so I am asking you, you know, sitting here today, do you know what those supplements are?
A. One might be -- I know we subscribe to a

service called First Databank. I think I have that name right. There's something else called a RED BOOK that may be something that we use.
These are better questions to ask of Brian Thompson. He is going to be the authority here.
Q. Okay. And I'm asking you: Like beyond those two, you're not aware of any others?
A. I'm not aware of -- I'm not aware of any others that are like regular sources of that kind of information.
Q. And are you familiar with the term "EPSDT"?
A. Mm-hmm.
Q. And that stands for Early and Periodic Screening Diagnostic and Treatment, right?
A. Correct.
Q. And I understand that that is a set of standards that allows a bit more flexibility when dealing with coverage for children. Is that your understanding?
A. That's correct.
Q. Okay. And do you know whether BMS considers those -- considered those standards in coming up with the criteria that the Rational Drug Therapy Program uses?
A. I believe so.

Q. Okay. And is that -- are those set of standards or criteria based on that another way you could authorize puberty delaying treatment?
A. I don't know. I don't know what's in those standards as they apply to that treatment.
Q. Okay. Do you know who would know or who would be a better person to ask those questions of?
A. We have a sister agency that administers that program that has been Jim Jeffrey's forever. I think he is retiring soon or maybe just retired. I'm not sure who is stepping into that position.
Q. Can I ask you a question about that? So you talk about a sister -- you said "a sister agency" and "that program." What is the program that --
A. The EPSDT program --
Q. Okay. And --
A. -- and what services are provided through managed care, but the administration of the EPSDT program is through -- I think it's through the Office of Maternal and Child Health under the Bureau for Public Health.
Q. Okay. And is that within the Department of Health and Human Services?
A. It is.

Q. Okay. So it's on the same level -- I think you called it a sister agency with BMS, both under DHHR, but essentially like on the same level in terms of departmental structure?
A. Yes. Yes.
Q. And then does BMS get involved at all with EPSDT or is that entirely within the purview of the Office of Maternal and Child?
A. Oh, no, we do get involved with EPSDT and we try to find ways for the program to provide enhanced services to our members. And for that matter, for that program to be able to fund costs of our program. So...
Q. And with respect to the specific costs, that is something that, I think you said, Becky Manning is better able to testify to?
A. Yes.
Q. Okay. So the Rational Drug Therapy Program, in processing claims, they use BMS's claims processing system, right?
A. Yes. The -- it's the MMIS -- it's actually operated by our fiscal agent, Gainwell, but it's our -- it's our system.
Q. Is that the same as the point of sale system or is that different?

A. It's the point of sale system, yes. And they have -- I believe they have their own interface for the -- some of their PA work and stuff. They have their own enterprise system to kind of manage some of that work on the front end.
Q. What does MMIS stand for, do you know?
A. A Medicaid Management Information System.
Q. Got it. Okay. And that's something BMS has access to?
A. Correct. The point of sale system would be part of that.
Q. Got it. Okay. So why is it that BMS chose the University of West Virginia's Rational Drug Therapy Program to provide this service?
A. Well, we had been working with the program for years in providing the same services for our fee-for-service population. Those people that weren't in managed care. You know, this was how we met that need. They always did a good job.
And we even had special dispensation to contract with -- I don't know if we did at that time. We do now. But at some point, we got special ability to contract with WVUM Marshall for certain kinds of services without going through all of the formality that we go through for other

competitive procurements.
And they have been just excellent to work with. They have been terrific partners. We could have never managed the carve-out of pharmacy from the MCOs without them. That's really one of West Virginia Medicaid's bigger success stories, is -- and we're kind of known nationally for moving away from the managed care PBMs to carving out the pharmacy program and overseeing that and how some --
We're kind of the envy of a lot of other states for being able to get there. And a lot of it had to do with having the right people on our own staff, having Rational Drug Therapy in place, with them being able to scale up to do what they had been doing for us all along. And then having the right people with Gainwell, the fiscal agent. The pharmacy team with Gainwell is top notch.
Q. So at some point in time, pharmacy benefits were handled in-house as part of the managed care program, right?
A. That's correct.
Q. And at what point in time or what year, if you recall, did that split off and become separate?
A. It happened in July of 2017.

Q. Okay.
A. So the first of that fiscal year -- it would be fiscal year 2018, but July 1, 2017, we carved pharmacy out of managed care.
Q. Okay. And the Rational Drug Therapy Program at the University of West Virginia was the place it was carved out to, correct?
A. It was carved out to our staff here, but they provided the prior authorization support.
Q. Okay. So it was carved out to -- well, let me ask it this way. The pharmacy services for the managed care program were handled by BMS even after July 1, 2017; is that what you're saying?
A. Yes. Yes. BMS has handled the point of sale pharmacy for the entire Medicaid program, starting with -- starting on July 1, 2017, with the help of Rational Drug Therapy administering that prior approval process and with the help of -- at the time they were called Molina but we call them Gainwell now. They were called DXC for a while. We've had a lot of name changes here, but the people have been the same.
Q. So when did the Rational Drug Therapy Program -- which year did it start administering the pharmacy benefits for the managed care program?

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MS. BANDY: Object to form.
You can answer.
THE WITNESS: Okay.
A. The Rational Drug Therapy began -- well, they had been serving us before, but they began working on the managed care point of sale -- what would have otherwise been the managed care point of sale pharmacy benefit on July 1, 2017, forward.
Q. And prior to that, who was doing the administration of the managed care pharmacy benefits?
A. Each MCO had their own respective pharmacy benefit manager or they maybe did their own pharmacy benefit management in-house, but -- so those plans or their subcontracting PBMs did that.
Q. Got it. And at the time before Rational Drug Therapy Program became the administrator, the MCOs still had to follow the BMS criteria for prior approval, right?
A. Correct.
Q. Okay. The director of the Rational Drug Therapy Program is employed by the University of West Virginia, not BMS, right?
A. Correct.
Q. And the director of pharmacy services, on

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the contrary, is employed by BMS, right?
A. Correct.
Q. Okay. And is the director of the Rational Drug Therapy Program Angela Wowczuk?
A. Yes.
Q. Did I say her name right?
A. I think you did.
Q. Okay. For the record, it's W-o-w-c-z-u-k.
And then I think you said Brian Thompson is the director of pharmacy services for BMS; is that right?
A. Correct. Correct.
Q. Okay. So I would like to go back to Exhibit Share and enter an exhibit.
MS. PRAKASH: Why don't we go off the record and take a little break because this is still loading over here.
(Break: 10:54 a.m. to 11:03 a.m.)
BY MS. PRAKASH:
Q. So, Mr. Lewis, we've been taking your depo this morning remotely, over video, so you and I are not in the same place. I understand you and the court reporter are not in the same place. Where are you physically today?
A. I'm in my office today.

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Q. Okay. And is anybody in the room with you right now?
A. I've been by myself all day.
Q. All right. Thank you.
So I understand that hormone therapy for -- as a treatment for gender dysphoria was not always covered for West Virginia Medicaid participants. Is that right?
A. I have the same understanding, yes.
Q. Okay. And I understand that that changed in November of 2017; is that right?
A. Yes. Well -- yes. I think it was the 7th of 2017. I'm sorry. November 7, 2017, or thereabouts.
Q. So on or around that date, hormone therapy as the treatment for gender dysphoria started being covered for West Virginia Medicaid participants, right?
A. Correct.
Q. Okay. And that was across all three of the MCOs, right?
A. Well, by then, the pharmacy benefit was a fee-for-service benefit, so, yes, correct. And it would have also encompassed the fee-for-service population outside of managed care too.

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Q. Got it. So the entirety of West Virginia Medicaid, the entirety of that population of people would have been eligible for a covered benefit -- that's a terrible question. Let me just start again.
So on November 7th -- on or about November 7, 2011, hormone therapy as a treatment for gender dysphoria was a covered service regardless of which MCO a participant had and regardless of whether they were in managed care or fee-for-service?
A. You said 2011 --
MS. BANDY: Object --
(Simultaneous crosstalk clarified by the court reporter.)
MS. BANDY: I was just going to object to the form.
Q. I meant to say November 7, 2017.
A. Okay. That's right. Yeah.
Q. Okay. So with that correction, you agree with my statement about the coverage for hormone therapy?
A. I do.
Q. Okay. And so since that time, is it true that insurance coverage for West Virginia Medicaid

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participants has not been denied for hormone therapy on the basis that it is a treatment for gender dysphoria?
A. That's true. Yes.
Q. Do you know if BMS provides coverage for hormone therapy when it's medically necessary to treat other conditions?
A. It does provide coverage for hormone therapy when it's necessary to treat other conditions.
Q. Okay. And do --
A. But there are limitations of -- one limitation being: I understand that we do not provide estrogen- and testosterone-based therapies to treat libido, unless there's some other issue happening and libido is also improved as a consequence of the other treatment. So...
Q. Okay. Can you think of -- or do -- are you aware of what those other medically necessary conditions would be where BMS provides coverage for hormone therapy?
A. I can give you some of them. For example, hypogonadism; that would be one example. Menopause would be another. Those are probably the two most prevalent, but I can't be sure. Brian Thompson

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could talk ad nauseam on this topic, I know.
Q. And do you know what, if anything, is considered in making a coverage determination for hormone therapy?
A. Do I know if anything is considered?
Q. Well, that's also a terrible question that I asked. Aside from drug inserts, which we have talked about, do you know what, if anything, is considered by way of research or studies or guidance in terms of making coverage determinations for hormone therapy?
A. Well, I know, for example, they will look to the drug insert with respect to dosing. Even though we're talking about an off-label use here, they want to see that the dosing is not going to be harmful to our member.
So that's the primary consideration there. And I don't know if there are other external sources that they might weigh into that.
Q. Okay. So to the extent that there is independent medical literature, studies, guidelines from other organizations, that's not something you have knowledge of?
A. It's not. But I know that Brian Thompson will be able to give you everything you could want

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on that same line of questioning.
Q. Okay. At any time, are you aware of gender markers being considered when making coverage determinations for hormone therapy?
A. At any time am I aware of gender markers being used?
Q. Yeah, in pre-November 2017, post-November 2017. I'm not limiting the date here. At any point in time, are you aware of gender --
A. Oh, sure. Sure. Prior to 2017 -- let's see. I think it was maybe somewhere from November 2010, powdered testosterone, there was an edit put on that so it would only be available to men.
And then, I think, January 2011, other testosterone, there was an edit placed on that so that men could only access that.
And there may well be other examples, but -- and those continued until all of those edits were taken off, as evidenced in the discovery packet, with system changes taking those edits back off.
Q. Do you know -- so let's talk about the 2010 powdered testosterone. Do you know why that gender

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edit was placed at that time?
A. I only know the conversations with the former pharmacy director -- I'm sorry, the last former pharmacy director, Vicki Cunningham, and she's talking about -- her director at the time, when I say this, she felt that Peggy -- and I'm forgetting Peggy's last name -- was concerned that -- she was concerned that there could be detrimental health effects to the member.
I may be getting this wrong. I think Vicki's story to me was -- you're asking specifically about powdered testosterone and I was wrong to wade into -- this was not a story that was conveyed to me in the context of that.
It was a male receiving a female hormone, I think, and there was concern that it may cause, like, a heart attack or stroke. It was putting the member at risk and so she felt like there needed to be an edit. That was how the story was told to me at one time. That's about all I know.
Q. Let's back up a little bit.
A. Okay.
Q. I asked about whether there were ever gender markers used as a basis for considering coverage for hormone therapy. You gave me two

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examples. One example was an edit added in 2010 with respect to powdered testosterone. Another was in 2011 with respect to other testosterone.

So sticking just with the 2010 powdered testosterone, do you know why the gender edit was added?

A. I don't. I would be projecting to tell you. I don't know why.

Q. And who would know that?

A. I think the person to ask would be the pharmacy director at the time, Peggy -- I'm forgetting her last name. I know it.

Q. And Peggy -- so Peggy, whose last name we don't know, was the pharmacy director at the time. At that point in time, that was a position within BMS, right?

A. It's always been -- it still is a position within BMS, yes.

Q. Okay. And who does the pharmacy director report to?

A. The pharmacy director reports to me currently. Back then, I'm not sure. It may -- I don't know.

Q. Would it have been the person that was in your same position in 2010?

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A. Well, my position didn't exist until I came here. So there was some restructuring of the Bureau and I was the first person to have exactly the responsibilities I have. So...

Q. So moving to your example of other testosterone having a gender edit added in 2011, do you know why that was done?

A. I don't.

Q. Okay. And for both those examples, 2010 and 2011, it would have been the director of pharmacy who had authority over whether gender edits were added, or would it have been someone else?

A. The director of pharmacy definitely had authority over it. I don't know if she might have consulted with the medical director. I would like to think so, that the pharmacy director and the medical director might have had some conversation about it. But the pharmacy director certainly can put those kind of controls on certain drugs.

Q. Other than those two examples, 2010 powdered testosterone and 2011 other testosterone, are you aware of any other time that a gender edit has been considered or a gender marker considered for the purpose of determining coverage for hormone therapy?

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A. No.

Q. But at some point in time, a member's sex was considered or their gender marker was considered when making a determination for hormone therapy with respect to treatment for gender dysphoria, right?

A. Correct. Correct.

Q. Okay. And do you know why that was?

A. I do not.

Q. And do you know who made the determination that that gender marker should be considered for the purpose of hormone therapy as a treatment for gender dysphoria?

A. That would have been the former director, Peggy -- and I may think of her name before we're done here today. I hope I do. I've met her. She's very nice. I just can't think -- I can see her face. I just can't think of her name -- her last name. I apologize. I think it's in the record somewhere -- in the documentation here somewhere.

Q. And in 2017, when the gender edit was removed, who made the decision to remove it?

A. And that was the director at the time,

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Vicki Cunningham, in consultation with the medical director, Jim Becker. And I don't know if -- again, that -- all of this predates me and my involvement here.

I don't know if it came up through the leadership structure of BMS or not. I think it was just decided by Vicki, who had some conversations with the medical director, Jim Becker. And I know that from conversations I've had with Vicki concerning this action.

Q. Did those conversations take place in the presence of your counsel?

A. No.

Q. Okay. What did you and Vicki discuss?

A. We talked about why -- I just asked her why -- what was the justification for the decision, you know, what -- I just wanted to know what she could tell me about the history of this whole thing.

Some of the same questions you've asked me about how did we come to the decision to put the edits there and then why did we remove them. And really, the most meaningful thing I got from it was, she related to me her experience before coming to BMS -- which she worked for HealthRight; she was

a pharmacist for HealthRight, which provides charity care here in the Charleston area.

And she worked with some folks that had gender dysphoria and were just distraught and they -- you know, they couldn't get access to hormone therapy, they couldn't get access to surgery.

And she thought that this -- our understanding of how these hormones work and how this therapy can be administered was far enough along that she was comfortable with it. She spoke with Dr. Becker and they both felt like we could do more -- Dr. Becker may be able to tell -- he may not even remember this conversation. This is how it came to me from Vicki.

She felt that there -- we can at least do this much. If we're not going to provide the surgery, we can at least provide access to this therapy and it may help these folks. And so it -- it's a story of compassion, and that's how the edit was turned off for these instances.

Q. Is there something that was a catalyst for the change to happen in November of 2017?

A. She said that we've been fielding -- we've been getting calls about, you know, what's the

criteria? What's the -- you know, why -- you know, why are you -- why is it this way? And she felt like we didn't have good answers.

And so maybe there were some calls at the time, but she indicated that it was always something we were being asked about. And so that was a big part of it.

Q. And were those questions coming from members?

A. Coming from members and maybe providers as well.

Q. Did Vicki handle those calls or did somebody else?

A. I don't know. We didn't get into -- I think she probably handled some, but I don't know for sure.

Q. And so I think you described it as compassion, which I appreciate. Why didn't that compassion extend to surgical care for gender dysphoria?

A. I don't know the answer to that.

Q. Do you know if Vicki ever raised that question with anybody at BMS?

A. I don't.

Q. Have you ever raised that question with

anybody at BMS?

A. I haven't.

Q. Are you aware of anybody at BMS raising that question?

A. No.

(Exhibit 2 was marked for identification.)

Q. Okay. I'd like to go to an exhibit -- it should be loaded now -- and it will be in the Marked Exhibit folder if you refresh. It's FL 2.

A. Okay. I have it open.

Q. Okay. Great. I understand that this is the state Medicaid plan, and it's very long. Is that your understanding of what this document is?

A. I'm not sure. This is the state plan you're telling me?

Q. Well, that's what I think it is and so I'm asking you if you agree with me.

A. Okay. This is a differently formatted version than what I've worked with in the past. It may be. I'm scrolling here a little bit just to see if I recognize things.

Okay. Here we go. Yes, this looks like -- this looks like the state plan.

Q. Okay. For the record, the Bates number is

DHHRBMS 203 to 1002. This may take a while to get there, so let me see if I can make this faster. I am trying to go to page DHHRBMS000346. Tell me when you get there. I realize loading and scrolling might take some time.

A. I think I am there.

Q. Okay. At the top, does it have the number 74?

A. Yes.

Q. Okay. Great. And then it looks like there is a Section 4.26 labeled Drug Utilization Review Program. Are we looking at the same thing?

A. Yeah. I think it looks like 4.25. I'm not trying to argue. Maybe it is a 6. I think it is a 6. I apologize.

Q. Nope. No worries. And just so that I make extra sure, you're looking -- the number at the bottom of that page ends in -346, right?

A. Yes.

Q. Okay. Great.

So going back to the top, in selecting a drug utilization review program, the state is required to select a -- to the extent the state is selecting a program, is what is stated in number 2 on that page correct, in that the program needs to

assure that prescriptions for outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical results?

A. You're asking me what about that list? If this is accurate?

Q. Yes.

A. Yes.

Q. That's an accurate requirement for a drug utilization review program that the state would use?

A. That's correct. Yeah.

Q. Okay. And --

A. And I would add: There would likely be some consideration for, you know, lower cost alternatives maybe being tried first and stepping up. I mean, that's kind of standard in healthcare today.

Q. Okay. And is --

A. That may be part of what's appropriate, if you will. Sorry to interrupt.

Q. No worries. I just want to make sure you're done with your answer.

And then Section B on that same page, is that an accurate statement of requirements for a drug utilization review program that the state

would use?

A. (Reviewing document.) Yes, I think that's entirely accurate.

Q. And the same question for subpart (c) on that page.

A. (Reviewing document.) Yes, I agree.

Q. Thank you. I'm going to enter another exhibit. Just bear with me.

(Exhibit 3 was marked for identification.)

Q. So if you go back to the Marked Exhibit folder, FL 3 should appear in there. Just let me know when you have that open, please.

A. Okay. It's open.

Q. Great. And these are the answers that BMS provided to requests for admission that the plaintiffs served.

Are you prepared to talk about number 8, which is on page 2?

A. (Reviewing document.) I am. Yes.

Q. Okay. So I want to ask you about the portion of that response that says "it is possible that coverage has been denied on other criteria, therefore, it cannot be admitted or denied that 'all' such therapy has been covered."

A. Okay.

Q. With respect to hormone therapy for treatment of gender dysphoria, what are some of the reasons that it may -- coverage may be denied.

A. Well, it may be there could be a lack of a prior approval or a problem with a prior approval that's in place. Or a drug might have been -- it may be the member is trying to fill the drug too early or it may be a dosing concern: It's a nonstandard dose or a dose that exceeds what the pharmacists think will be safe in their best professional judgment.

I mean, a lot of times, it's -- you know, this is a dialogue between the provider and the PA reviewer and -- or, sorry, between the pharmacy and the PA reviewer and sometimes the provider has to get involved to answer questions or provide additional information.

So for all of those reasons, drugs routinely deny. I know in the case of Mr. Fain, there were concerns about the -- he was required to have a PA because this was an injectable drug. And the fact that the drug's injectable, I mean, that's -- once it's injected, we cannot take it back out of the member.

So this is an opportunity to -- kind of an audit upon the provider, if you will. An opportunity to say -- just to check and balance to say, yes, this is going to be okay and the member's going to be safe and we consent.

So there are a lot of reasons that -- coverage might be denied for, you know, some of these reasons I just mentioned.

(Simultaneous crosstalk clarified by the court reporter.)

A. I'm sure I haven't given a comprehensive list of the possibilities there, either.

Q. So my question relates to you using the phrase "checks and balances" just now. Are checks or audits on hormone therapy coverage done on any kind of systematic basis?

A. Well, yeah, I mean, with respect to the dosing, I mean, we would want to see that the dose that's being administered is something that has been established in peer-reviewed work or in the -- in the drug insert.

If the dose exceeds anything that we have awareness of, we don't know that it's safe. And, you know, if the provider reaches out -- the provider may have some peer-reviewed study to show

that -- or to help establish the case, which can be taken into account. And -- but, you know, that's all -- that's all part of the mix.

Q. So let me go back to this idea of checks and balances. Is there a formal system for BMS making sure that coverage for hormone therapy is being provided consistent with the BMS-set criteria?

A. I believe there is within -- I mean, really, the gist of the question is you're asking me: For that reviewer at Rational Drug Therapy, what are they looking at, what are they wanting to be satisfied --

Q. No.

A. -- with . . .

Q. No. Let me rephrase the question.

So does BMS perform random checks on coverage determinations to make sure that they are consistent with BMS standards?

A. I don't know if that's something that the Office of Pharmacy Services is doing as a matter of routine. I would agree with the sentiment that it would not be a bad practice, but I think issues have a way of being escalated. And if there are mistakes being made, our full-time BMS pharmacy

staff end up reviewing these situations and providing direction to Rational Drug Therapy. And that happens from time to time. I know that happens.

Q. Okay. But to answer my question, you're not aware of any regular practice of checking to make sure that coverage is being -- coverage determinations are being made consistent with BMS standards?

A. I'm not aware -- I respectfully ask that you may ask that same question of Brian Thompson. He's -- he's got a -- really a good perspective of that --

Q. Okay.

A. -- to share with you.

Q. Okay. And going back to the exhibit that's in front of you, FL 3, and Response to Request for Admission 8, are -- do you know whether the BMS standards or criteria for coverage are -- with respect to the dose of hormone therapy, takes the diagnosis into account?

A. The -- I have to say, on the generic, it could. I mean, are we talking about the drug that Mr. Fain was to receive specifically?

Q. No. No. I'm asking about hormone therapy

for the treatment of gender dysphoria. As a general practice, do the guidelines for whether that is covered take into account what the requested dosage is?

A. I think it -- okay. I don't believe the criteria takes the diagnosis of the member into account for what would be the appropriate dosage. That's -- did I respond?

Q. So then let me ask you this: With respect to a hormone therapy for the treatment of gender dysphoria, how are -- well, let me start that question again.

With respect to coverage for hormone therapy, how -- is dosing taken into account with respect to coverage determination?

A. Sure. If it's a PA drug, it would be for any drug regardless of whether it's for gender dysphoria or not.

Q. Okay. And so the proper dosing under the criteria or the preapproved dose doesn't vary with respect to the diagnosis; is that accurate?

A. I believe that is accurate.

Q. Okay.

(Exhibit 4 was marked for identification.)

Q. If you could go back to the Marked Exhibits folder, please. Okay. In the Marked Exhibits folder you should see FL 4. And, for the record, that is an email with the Bates range DHHRBMS014729 through -763.

A. Okay. I'm there.

Q. Okay. Great. The email at the very top of the first page is from you, correct?

A. Yes.

Q. Okay. And can you take a minute to read that, please.

A. (Reviewing document.) Yeah, I remember some of this when it was playing out.

Q. Well, let me ask you a question about it then.

A. Okay.

Q. So that first email is one that you sent on January 29, 2020, right?

A. Correct.

Q. And in that first paragraph, at the end of the first paragraph, you say, "We don't pay for gender reassignment or even hormone treatments for gender dysphoria, for example, but in our view these are medical benes."

What did you mean by that?

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A. Okay. So the bigger issue -- this was a mental health parity bill, and I was trying to say, we're giving our all to mental health parity as it is and we have large amount of oversight by CMS with respect to mental health parity. We have to maintain a mental health parity plan with CMS. And I'm saying, you know, we do all of this stuff.

I didn't understand at the time that -- I didn't understand this issue like I do now. And this is a mistake on my part. I was hired in 2020 -- in 2018, into this role. It takes a long time to learn -- you know, I still have so much to learn.

But that was a mistake where I said we don't pay for the hormones. I think I had that misimpression from reading our contract or from -- I don't know for sure where I got that. But I do remember that light bulb moment later when Vicki and I -- when Vicki told me, "Oh, no, we do."

And, you know, that was when I first learned that there were edits in place and they were taken off and we do cover it. So you are seeing here an example of me learning this policy for myself and, embarrassingly enough, I've copied the deputy secretary on here and everyone else.

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Anyhow --

Q. Well, let me ask you about --

A. -- it was a mistake.

Q. In the To line of that email, there is somebody named Ben Beakes. Who is that?

A. He is the president of the West Virginia Association of Health Plans and the -- effectively the lobbyist of the three MCOs that we work with.

And so this email happened during legislative session and we had a common concern here that something is going to end up requiring us to do -- provide even more reporting around mental health parity, and we already do significant reporting to CMS.

Q. Okay. And so my question was just: Who is Ben Beakes. And I understand that you said that he is essentially a lobbyist for the three MCOs. Is that accurate?

A. That's right.

Q. Okay. And did you do anything -- well, how much later after this email did you learn that your statement about coverage for hormone treatments was inaccurate?

A. Oh, it was probably months later. I don't know.

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Q. And do you know what, if anything, was done to inform Ben Beakes that your statement was inaccurate?

A. By then I'd probably forgotten all about this email. I just remembered learning that I had that wrong.

Q. So you're not aware, one way or the other, if anybody corrected your statement to Ben Beakes?

A. I'm not.

Q. Okay. And Cynthia Beane is the commissioner, correct?

A. Correct.

Q. Who is Jeremiah Samples, who is copied on this email?

A. He is the department deputy secretary.

Q. Okay.

A. He is Cindy's boss, the commissioner's boss.

Q. Okay. And the commissioner is your boss, right?

A. Yes.

Q. Okay. And who is Riley Romeo, who is copied on this email?

A. He is our chief counsel.

Q. For BMS?

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A. Yes.

Q. And who is Jeff Wiseman, who is copied on this email?

A. At the time, he was the assistant to Jeremiah Samples.

Q. Okay. Is Riley Romeo a lawyer?

A. Yes.

Q. And what I would like to do is go to another exhibit so let me pull that up.

(Exhibit 5 was marked for identification.)

Q. If you refresh the Marked Exhibits folder, you should have FL 5 in there and that is Bates stamped DHHRBMS015280 through -283.

Okay. Do you see that email?

A. I do.

Q. Okay. And this is another email from you, correct?

A. Correct.

Q. And that was sent in May of 2019, correct?

A. Yes.

Q. And we have talked about the people listed in the To line. Lori Tyson is listed in the cc line. Who is that?

A. She was my secretary at the time.

Q. Okay. And the email at the bottom of that first page comes from somebody named Christy Donohue.

Do you see that?

A. I do. Yes.

Q. And on the next page, so the second page of this document, is her signature block and it says she's the Assistant VP Medicaid, and it looks like she's at The Health Plan. Is that your understanding?

A. That's correct.

Q. Okay. And in her email that is on the first page of this document, she points to the contract and says, "...it states sex transformation procedures and hormone therapy associated with sex transformations are not covered."

Do you see that?

A. I do.

Q. Okay. And she sent this email to people within BMS, including Vicki Cunningham, right?

A. Correct.

Q. And then Vicki forwarded it to you as well as to Dr. Becker and to Brian Thompson, right?

A. Yes.

Q. Okay. And so then you asked to have a

meeting set up to discuss. Did that meeting actually occur?

A. I don't believe it did. I spoke with Vicki just to kind of back up my own recollection and she said, "I don't think we ever were able to find a time to get together and talk about it," and it sort of fell through the cracks after that.

And it would have been a good meeting to have, for sure. And coincidentally, this email string may speak to how I got to the wrong understanding about what we did cover, because this happened before my prior email to Ben Beakes. And Christy is holding out what's in -- the language of the contract and it may have been part of how I got my erroneous understanding of what our policy is.

Q. Okay. And you aren't aware of any efforts to give -- to tell Christy at this time that hormone therapy associated with what is called "sex transformations" in this email are, in fact, covered?

A. I'm not aware of, yeah, that response.

Q. And Vicki did not correct your misunderstanding at any point in time between when this email was sent and when you sent the email to Ben Beakes that we just looked at, right?

A. Correct. Correct.

Q. And do you know -- well, let me ask you this: How -- was any effort made in 2019, to your knowledge, to inform the three MCOs that hormone therapy as a treatment for gender dysphoria was covered?

A. Prior to 2019?

Q. Well, I'm asking you about in 2019.

A. I'm not aware of any effort to educate the MCOs about what we would cover or what we wouldn't cover.

Q. And outside of the 2019 time period, are you aware of any such efforts?

A. No.

Q. So it's conceivable that the MCOs in responding to member questions would tell them that hormone therapy for the treatment of gender dysphoria is not a covered service or not a covered benefit?

MS. BANDY: Object to the form.

But you can answer.

A. It's conceivable that they might have, but I think more likely they would have deferred the member to us so that we could deliver that bad news, you know. Making clear that we're the bad

guy, not them.

Q. I see. And so when --

A. That's what they understood it to be. I think that they would want us to tell the member that.

Q. When denials are referred to BMS from an MCO, who at BMS does that referral go to?

A. Denials of...

Q. Insurance coverage.

A. For like surgery or whatever?

Q. For anything. And you can let me know if there's a distinction between the type of thing being denied.

A. Denials are -- I know they're reviewed by our EQRO, our External Quality Review Organization. That's another partner we have, a CMS requirement. And so they review them and report anything they may find back to us. Otherwise, if a denial is not -- if there's not an appeal or a grievance, I'm not sure that we're seeing it.

Q. Okay. And when Kepro reviews and then reports back to BMS, who does Kepro report to?

A. That, I'm not sure about. I know it's not me.

Q. Okay.

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A. It may be Sarah -- it likely is Sarah Young, deputy commissioner. Or someone on her team.

Well, Kepro, also, they do review physician-administered drugs. Are these the reviews you're talking about?

Q. I am asking you because this came from your answer to my question about MCOs conceivably responding to member inquiries by saying that hormone therapy is not covered. Your response, as I recall it, was that they would want BMS to be the bearer of bad news.

And so I asked you who at BMS is responsible for that messaging.

A. Okay. Well, that would likely come to Brian Thompson or a member of his staff, the pharmacy -- Office of Pharmacy Services.

Q. And are you aware of anybody in the Office for Pharmacy Services after November 7, 2017, informing members that hormone therapy for the treatment of gender dysphoria is not covered?

A. I'm not aware of that and would be surprised by it.

Q. And on this exhibit, which is FL 5, Brian Thompson is one of the people to whom Vicki

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Cunningham forwarded Cindy's question, right?

A. Right.

Q. And Brian Thompson, at that time in 2019, was he still director of pharmacy services?

A. No. He would have been the DUR pharmacist at that time.

Q. Okay. And the DUR pharmacist is responsible for -- well, what are the pharmacist's responsibilities?

A. Well, he would have been involved in setting drug criteria and working on the preferred drug list, some of that kind of work. That would have been mainly it.

Q. Okay. So he would have knowledge in 2019 of there not being a gender edit with respect to hormone therapy as a treatment for gender dysphoria, right?

A. Yes. Absolutely.

Q. And you're not aware of -- well, he didn't have any conversations with you around the time of this email to inform you that hormone therapy as a treatment for gender dysphoria was, in fact, covered, right?

A. I don't recall so.

Q. When was the first time that you personally

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learned that hormone therapy as a treatment for gender dysphoria was covered?

MS. BANDY: I'm going to object to the form of the question.

You can go ahead and answer.

A. I don't know.

Q. Well, it was certainly after the email to Ben Beakes, right?

A. Yes.

Q. And other than that -- these two instances that we looked at in these emails, have you received any inquiries as to whether hormone therapy as a treatment for gender dysphoria is covered?

A. I don't recall, but I -- I am very firm and confident in my answer now, if I do get that question. I don't recall being asked. But that traffic would typically more come to the Office of Pharmacy Services.

Q. Okay. I'm going to introduce another exhibit.

(Exhibit 6 was marked for identification.)

Q. So if you could go to the Marked Exhibits folder, please. This is FL 6 and, for the record,

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it's DHHRBMS 1 through 5.

A. Okay.

Q. Please let me know when you've got that open.

A. I've got it.

Q. Okay. Great. So this is an interoffice memo, it says at the top, from David Thomas to William Hopkins and Vicki Cunningham, and it copies Cynthia Shelton, Randi Kimes, and Neill Alford. And it is dated November 10, 2017.

Do you agree with me?

A. I do.

Q. Okay. Who is William Hopkins?

A. William Hopkins is a member of -- or employee of the Office of Pharmacy Services. He's a drug tech in training. His title is, I think, director of operations. Or director of pharmacy operations. Something like that.

Q. Okay. And was that true in 2017?

A. Yes.

Q. And who is David Thomas?

A. David Thomas is the lead on the -- what is now the Gainwell point of sale, the pharmacy team, out of Virginia Beach, Virginia.

Q. Was that his role in 2017 at the time of

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this memo?
A. I believe so. There was someone named Donna that had it sometime before I got here, and I'm not exactly sure when it was handed off to David. But I believe it to have been his responsibility at the time this memo was produced.
Q. Okay. Who is Cynthia Shelton?
A. Cynthia Shelton was, at the time, the BMS Gainwell contract liaison. She worked for BMS. I'm not sure what her title was here, but she reported to Sarah Young and helped to follow all of the interactions between BMS and Gainwell, or it was known as Molina back then.
Q. And then Randi Kimes, who's that?
A. I'm not sure who Randi Kimes is, or Neill Alford.
Q. Okay. And then in -- on that first page, the last line of the first paragraph references Molina. That's the predecessor to Gainwell; is that right?
A. That's right. It's just been a name change.
Q. Okay. And can you explain, again, what Molina's role was with respect to West Virginia Medicaid in 2017?

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A. Molina is our fiscal agent so they do all of the claims processing. And so they administer this -- the point of sale system that all of these claims are put through on and -- you know, they were the ones -- for the sake of these edits on gender relating to these drugs, they were the ones that put them on and took those edits off for us at our instruction.
Q. When you say that they do the claims processing, do they make actual coverage decisions?
A. No. They received the claim, they applied the edits and controls that we have built through our interactions with them, but they are -- they are helping to run that system and make it all work.
Q. Okay. Can you scroll down, please, to the next page, which is DHHRBMS 2. And what does "CR" refer to on this page?
A. That is change -- it means change request.
Q. Okay. And is this how change requests are submitted to Molina or Gainwell?
A. This is coming back -- there's something called the RQS -- RQMS system that I'm not a personal user of. But Bill Hopkins would be, in this instance, the one entering the request into

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RQMS that we want to remove these gender edits for estrogen and testosterone. And it creates this number that you see in the left-hand column.
And I'm not familiar with this actual report that's been printed, but this is Bill Hopkins signing off that we are closed on this change request, or these four change requests.
Q. When you say "signing off that we are closed," what does that mean?
A. We are approving closure. That means mission accomplished.
Q. Got it. Okay. So who's -- who actually approves the substance of the change?
A. The substance of the change -- you mean, vets that it actually has been effectuated, that the change has been accomplished?
Q. No. I understand that to be Bill Hopkins' role. Is that not right?
A. Well, it's Bill, but it also happens kind of in a meeting with the whole pharmacy -- Office of Pharmacy team. They have a weekly meeting and they run through the list of these change requests. They talk through them there as a team.
And any person on the pharmacy team that may have particular information could jump in and

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raise a concern. You know, hey, I don't think this is -- this is ready yet. We need to do these -- take these other steps before we could close this item, something like that. Or ask, maybe Dave Thomas, to demonstrate how the -- how a new edit might be functioning, or whatever it might be.
Q. So aside from the technical part of this in the system and, you know, the electronic way that all of that works, when -- who has the discretion to approve or deny requested changes?
A. So Vicki would have made this request as the director of this office. Had her deputy commissioner at the time, who I think was Sarah, been in the point of sale meeting, she would have had the power to say, "Not so fast. I don't want to take those edits off." That obviously didn't happen.
But the director of pharmacy is empowered to have this kind of ownership of the program to be able to make this sort of request of Gainwell and -- or Molina, DXC, whatever they were then, and that's what happens.
So Vicki made the request. If her deputy was in the meeting, there was no objection, it carried forward. She was empowered to do it. And

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that's still the case. It still works this way.
DXC or -- sorry, I'm using these names interchangeably -- Gainwell completed the change and then the pharmacy team would have reviewed the change. It would have heard from Gainwell about the testing around the change and all of that. In that meeting, Bill Hopkins, knowing Bill, would have likely been on his own computer testing it and whatnot. And these --
Q. So let me ask you this: So Vicki made the decision on -- that the change should happen. Does anybody have authority over -- or veto authority over the person in Vicki's position?
A. I would have had, had I been here. Sarah Young, I think, was the deputy over Pharmacy before I got here. She would have had. The commissioner has veto authority over all of us for everything. But the -- there are a lot of decisions made here every day and they don't all go up to the commissioner or even the deputy to make.
Sarah would have been on the guest list for -- would have been -- she would have had the standing meeting on her calendar and if she wasn't in attendance, she could have been. She may well have been in the room for that meeting or on the

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call for that meeting and, you know, just -- agreed. So...
Q. If you scroll down to page 4, can you tell me -- you might have said this -- but do you know what system this is a screenshot of?
A. This is on the inside of the point of sale system. This is not something I use, but I know based on Eric Sears' name being here and I've seen some of this from those meetings. So this looks to me like it's from the point of sale system.
Q. Got it. Okay. And then I would like to enter one more exhibit and then I think we need to take a break.
(Exhibit 7 was marked for identification.)
Q. Okay. If you refresh, please, the Marked Exhibits folder, you should see FL 7. And that is Bates stamped DHHRBMS016288 through -90.
A. I got that. I've got it up here.
Q. Great. You are copied on the email that starts halfway down the page, correct?
A. I am, yes.
Q. Okay. And who is Tadd Haynes who is sending this email?
A. He is the UniCare president.

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Q. Okay. And then it looks like he is sending this to the commissioner and copying you and Susan Hall. Who is Susan Hall?
A. Susan Hall is the chief of managed care. She's one of my direct reports.
Q. Okay. And the subject is Health Equity Follow-Up. Do you know what that references?
A. I do. I think he's following up on a conversation that was raised by the Aetna Plan president, Todd White, about a similar issue, but this is a conversation that we have been having as we are changing the vision of our Office of Quality Management, which used to be -- it used to be all about only producing -- only working on quality measures. Like the CMS has what we call the core measures. So they would -- they were primarily engaged in that.
We want to turn that office into more of a continuous quality improvement function here at BMS, and to take some ownership over health equity and to start to stratify these measures. I mean, this is in the long-term vision, to start to look at these measures by all of these -- just stratify the measures every way we can to see where disparities may be happening for certain grades.

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Q. What grades?
A. Oh, it could be based on sex. It could be based on gender identity. It could be based on where somebody lives. It could be a race, ethnicity, language. A lot of -- a lot of different things.
And one of the first things we are reckoning with here in West Virginia is we collect -- our members fill out an application for Medicaid that is largely determined by CMS on the front -- CMS said, here's the boilerplate information you need to collect.
And then in putting our application together, we have -- we have those items in there. And it recognizes, like, race and ethnicity as an optional item. And what happens is, our members aren't completing it. So we don't have enough data to sometimes --
I mean, this has created a challenge. This made this really difficult. For COVID vaccinations, we were looking for disparities and we had to work with the health information network locally to try to enrich the race and ethnicity data, to be able to even use it.
So this has been a struggle and this is all

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part of that bigger conversation. So here's Tadd saying, "Here is what the people in our organization think we need to do to collect this other data and we absolutely have to get there."

I don't know that what Anthem is proposing here is the end-all be-all, that this is exactly how we need to collect it, but we need this or something a lot like it. And we're moving in this direction.

But there's a lot of juggling here -- happening here and we have not yet had the meeting that Tadd was propo- -- in fact, I don't know if Cindy responded to this or not. I was waiting for her to respond since it was addressed to her. But I would like to have this meeting and move on with the bigger conversation.

Right now, we collect gender in a binary field. It's male or female. That's how it comes from CMS. And so I don't know if we could -- we may have to ask CMS permission to change it and to make some of these responses mandatory, but maybe give an option to decline to say what race somebody is, or ethnicity, give options for them. I think that's the sticking point. But we're trying to sort these things out so that we can move forward

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with it.

And we've -- we've had a vacancy in the director's role for this office for an extended time and we are currently struggling with that too. So that's been a little bit of a factor for us, frankly, as well.

Q. In the second paragraph of that email, there is a reference to members from Maximus. Do you know what that means?

A. Maximus is our enrollment broker that we talked about early in the call.

Q. Got it.

A. Maximus is administering, in addition to their work as an enrollment broker, like a seven-question social determinants of health questionnaire.

And they're tracking that for us and they're passing the data about our members on social determinants on to the MCOs so the MCOs can know that a member has food insecurity, or is homeless, or whatever it might be, and take that into account when they're helping to manage the member's health.

Q. Got it. So --

A. So Tadd is proposing that we add these

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questions or these items to that social determinants questionnaire that's being administered by Maximus at that stage.

Q. Do you know what the current questionnaire administered by Maximus asks for?

A. I've seen it. But like I said, it -- well, it's been a while. It's been like seven social determinants of health-type questions. It was very carefully crafted to try to maximize response rate, but, I mean, it -- there's a question relating to food security, a question relating to housing security, one about employment. I mean, things like that. And I can't recite off the top of my head what they are. I have it somewhere.

Q. Does the current questionnaire ask about gender identity?

A. No, it does not.

Q. How long has the current questionnaire been in place?

A. Two or three years. Something like that. And it was a new process when we implemented it.

Q. Okay. And it's implemented across all MCOs through the broker?

A. Yes. And that's a disadvantage to this approach in that we wouldn't be able to provide the

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same level of concern to our fee-for-service members if we try to collect it through the enrollment broker.

So that's another challenge for me, is ideally we would ask these questions through the application process so that we would have the answers for all of our members, not just those in managed care.

MS. PRAKASH: Okay. Can we go off the record, please.

(Break: 12:29 p.m. to 12:45 p.m.)

BY MS. PRAKASH:

Q. So, Mr. Lewis, can you describe to me what your job duties are as deputy commissioner of plan management and integrity at BMS?

A. Yeah. I oversee four different areas of -- within Medicaid. One being the Office of Pharmacy Services, as we've been discussing. The other being the Center for Managed Care. And then the Office of Program Integrity is one of my areas. And the Office of Quality Management.

Q. Okay. What does the Office for Program Integrity do?

A. So that office oversees the spending of Medicaid funds to ensure that it's for bona fide

members for bona fide purposes. They look for fraud; they look for overpayments. Broadly, overpayment, it can be a lot of things, but these are -- I mean, any kind of upcoding or a provider -- a scheme, duplicate claims that may have been submitted. These sorts of things. They look for all of that.

Q. Do they oversee any coverage determinations?

A. They don't oversee coverage determinations.

Q. And what does the Office for Quality Management do?

A. That's the office I was telling you about that was originally created to complete certain measures, to maintain the measures. But we are trying to change the focus of that office and get the staffing up to be able to provide for continuous quality improvement to the quality of our care for our members, and then provide for health equity as well.

And I have a vacant -- I have two people there that have been traditionally the staff when they've only been about producing the measures. I have two vacate positions. One for a nurse and one is the director -- going to be the director of the

office, that I'm trying to get filled so that we can move forward with this bigger vision for that office.

Q. Does that office, the Office of Quality Management, deal with coverage determinations at all?

A. A little bit. So one of the things I have been doing is working with the External Quality Review Organization on -- for managed care. And the EQRO is looking at denials a bit and so they're involved in receiving and kind of overseeing that contract work with the EQRO.

Q. What -- are you saying "Kepro"? I'm not sure I totally heard the last part.

A. E-Q-R-O. EQRO. External Quality Review Organization. I'm sorry. We are terrible about using acronyms.

Q. No, that's okay.

A. My apologies.

The External Quality Review Organization is called Qlarant and the Office of Quality Management is engaged with Qlarant in overseeing their contract work in that capacity. But -- you know, one of the things they look at is the -- they call it GAD. It's grievances, appeals, and denials. So

they do some statistical work for us around that and -- that's probably about as close as I can get.

Q. Okay. And when they are looking at grievances and denials, are they looking to make sure that those are consistent with BMS standards?

A. I believe so. And CMS standards as well.

Q. Got it. Are they looking at whether there should be any changes made to the standards?

A. That, I'm not sure.

Q. Who would know that?

A. Tanya Cyrus.

Q. What's --

A. She is -- she is over the Office of Program Integrity and the Office of Quality Management and reports to me.

Q. Who else reports to you?

A. That's basically it. So Brian Thompson, the pharmacy director; Susan Hall, the chief of managed care; and Tanya Cyrus, the chief of quality and integrity.

Q. And --

A. I used to have a secretary. That position is vacate still. I mean, it was a shared position, so I have three people. Direct reports.

Q. Okay. And who do you report to?

A. I report to the Commissioner.

Q. Have you ever been disciplined in your role as deputy commissioner?

A. I've never been disciplined in my role as deputy commissioner.

Q. Okay. Did you receive any counseling or any type of -- was any type of employment action taken against you with respect to your misunderstanding of whether hormone therapy was covered?

A. No. No.

Q. Do you have any medical training?

A. Clinical training, no. I've got a master's in management with an emphasis in healthcare administration. My bachelor's degree is in economics, and I have quite a bit of coursework in finance and assurance and other related fields so -- but medical training, no. And I try to stay out of clinical matters and let the clinicians handle those.

Q. Where did you get your bachelor's from?

A. West Virginia University.

Q. And what year was that?

A. That was 1991.

Q. And where did you get your master's from?

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A. Got my master's from Marshall University. That was as a nontraditional student. I was working full time. And I'm forgetting what year I actually finished it. I apologize.
Q. Was it --
A. I should have my diploma on the wall, but I don't.
Q. Was it before you became deputy commissioner?
A. Oh, yes. Long before.
Q. Okay. More than 10 years ago?
A. Oh, yes.
Q. Okay. So after graduating from college through when you became deputy commissioner, can you give me a summary -- I just need job titles and employers -- of your job history.
A. Oh, sure. Well, let's see. I worked in sales for a while right out of college, struggling to find employment as an economist with a bachelor's degree. So I worked as an admissions rep for a business college for a little while.
And then I went on to security system sales. I didn't do that for very long. I didn't like it. And then I applied to work as a per diem --

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Well, I did some volunteer work with the VA Hospital for a while. And they knew my ambition to get a master's in healthcare administration or something like that. And so I got to work on some policy and some different things. I did that for about a year.
And I came to Charleston in December of 1994 and I worked as a per diem session employee for the House of Delegates, working for the Speaker of the House who was Chuck Chambers, who is presiding over this case as the judge, but he was the Speaker of the House then.
And that was for the session and little period after the session. That job ended, but I made a lot of positive contacts and I went to work for the Legislative Auditor's Office, the Performance Evaluation and Research Division, in the spring, I want to say, of 1995, just after the session. And I think I was there for about seven months and was promoted to senior auditor position.
And then after a couple years or so -- or maybe a year and change, it just worked out that I got promoted to be audit manager. I was managing performance audits there. I did that until the year 2000.

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And in -- for the session of 2000, the House Finance Committee wanted me to come over and work as its policy analyst. I did that in -- I'm probably getting ahead of myself. I did different audits when I worked in Legislative Auditor's Office.
I worked on -- the state had a monopolistic workers' compensation fund. I managed that audit. I worked on that audit before I was a manager. And that was a big, often healthcare-related, audit. I worked on Medicare -- or Medicaid auditing at the time. And different -- I mean, all different subject matter. I mean, we looked at the School Building Authority, lots of things, while I was there.
Then I went to the House Finance Committee in 2000. Worked as policy analyst there. Got a very diverse experience working for that committee. Worked on everything from workers' compensation reform to -- you know, worked on the budget. I worked on all kinds of policy and pension bills.
And I did that for about 18 years. A good long time. I probably overstayed in that job, from a career standpoint, and then I came here in -- directly from that job in 2018. And fortunate

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to -- I mean, especially having stayed in that job for so long, to have been given an opportunity, and I love what I'm doing and I think it's going pretty well. I think we've had a positive impact.
You're seeing the mistakes, but I think it's going well.
Q. Aside from your current position, in any of the past positions that you described for me, did you do work related to the provision of gender confirming care for transgender folks?
A. This is a new experience. No, I did not.
Q. And then if you go back to Exhibit Share, to the Marked Exhibits folder, could you please open FL 8.
(Exhibit 8 was marked for identification.)
Q. It's a single page and, for the record, it is DHHRBMS 385.
A. I'm there.
Q. Okay. And I will represent to you that I took this single page out of the document that we previously marked as the Medicaid State Plan. The date at the bottom of this document, the Approval Date says September 16, 2016. And I want to ask you about the chart on this document.

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I understand this to be an organizational chart of the Department of Health and Human Services, Bureau for Medical Services, at the time this document was approved which is September 2016. What is your understanding of what this document is?

MS. BANDY: I'm just going to object to the -- just object to questioning about this document, but he can answer.

A. I'm not familiar with the document, but it -- I'll take you at your word that it -- that it's from -- you said 2017?

Q. I'm just looking at the date at the bottom of the document.

A. Okay. Okay. I see. Yeah, it looks like it would be the Bureau's org chart, even including some of the department leadership-level stuff at the time.

Q. I noticed that there isn't -- well, actually, let me ask you this: Where would your position go on this chart?

A. It would go under the commissioner -- okay. So Policy and Operations have kind of merged, and if we had a new little -- a new deputy under the commissioner, it would include -- from the

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left-most column, the Quality unit there at the bottom, that is the Office of Quality Management that I mentioned earlier. That would go under the new tree.

The Office of Program Integrity under Finance would go under me, in the next column there.

And then to the right, the Office of Pharmacy Services and Drug Rebate and Managed Care would go under me.

Q. Okay. And aside from that new deputy position that you fill, are there any other deputy commissioner positions that are currently at BMS that are not reflected in this chart?

A. Yeah. So there's Sarah Young's position. She's -- she has -- she is the director of Operations and Policy Coordination. Or she's the deputy commissioner of Operations and Policy Coordination.

And so if you combined those two elements on here and just moved the pieces that I mentioned over to my group, that's how Sarah's role would look.

And then Becky Manning is the deputy commissioner of Finance and Administration. And so

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she would have, you know, the top two boxes under that division.

Q. Anything else?

A. You're asking me for other changes on here? No, I think that -- I think that pretty well -- that pretty well captures it.

Q. Okay. Great. I am trying to introduce another exhibit but it is spinning and spinning on my computer, so let me ask you this: Have you ever been deposed before?

A. This is my first time.

Q. Oh. Well, hopefully it wasn't too painful.

A. It was good.

Q. As the organizational representative for BMS, did you meet with any transgender Medicaid participants to prepare for today's deposition?

A. I did not.

Q. Okay. Did you meet with any mental health providers who provide any care for transgender people to prepare for today's deposition?

A. No.

Q. Did you meet with any medical health providers who specialized in care for transgender people to prepare for today's deposition?

A. None -- no providers outside of the agency.

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I mean, our clinical people internal to BMS is all.

Q. Okay. And who did you meet with at the agency to prepare for today's deposition?

A. I have -- I met with the commissioner. I met with Riley Romeo, the chief counsel. I think I've had some conversations with -- I say "met," it's more conversations, for the most part -- well, actually I have met with Riley.

Met with our counsel. Met with -- or I've had conversations with Susan Hall, the chief of Managed Care; Vicki Cunningham, the former -- the last former Office of Pharmacy Services director; Brian Thompson, the current pharmacy director.

Met with our -- or talked with our procurement director in trying to gather the full versions of the contracts for you-all because I think what we started with were not complete.

That's about all I can come up with.

Q. Okay. Did you meet with the commissioner outside of the presence of counsel?

A. No.

Q. Did you meet with Susan Hall outside of the presence of counsel?

A. I don't think we met. We just probably had a few conversations about it. And, yes, it would

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have been outside of the presence of counsel.
Q. What did you discuss with Susan Hall?
A. I remember discussing with her the -- we talked about the template for the member handbook and our process around that. So I was just firming up my understanding. I mean, these things come up every so often and it's -- it was an opportunity to discuss who does what. That was the nature of the conversation. So...
Q. Did you --
A. And I did actually talk with her about changing the language in the template to remove that -- the hormone therapy language and sent an email this week about the contract language, talking about noncovered services, asking to strike the language that talks about hormone therapy, so -- as we discussed earlier.
Q. Right, yeah. We discussed that with respect to the contracts. With respect to the handbook template, as I understand your testimony just now, the template is going to be revised so that there is not an exclusion for hormone therapy related to gender dysphoria; is that right?
A. That's right.
Q. And the exclusion pertaining to surgical

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care for gender dysphoria will still remain; is that right?
A. That's right.
Q. Why?
A. Are we talking about --
MS. BANDY: I'm just going to object to the question if you're asking him about a policy decision related to that, but he can answer.
A. Well, okay. We're talking -- you're talking in the context of the contract or the hand- -- you're talking about the handbook, right?
Q. Correct.
A. Okay. The -- it is the MCO that would be paying for a surgery. And the surgeries -- it's currently our policy and has been our policy that these surgeries are not something that we're paying the capitations to manage.
If you're proposing that we take the language out and just let the MCO decide whether they want to put something like that in there or not, I'll take that on advisement.
Q. Well, I am not your counsel. But that language about the exclusion is not being removed from the template handbook, as I understand your testimony, right?

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A. Yeah. I was more focused on leaving the misimpression that the hormone therapy would not be available, because it's members using this book and that concerns me.
Q. Right.
A. And the handbook template, that's -- it's something that evolves a little bit every year. We take it -- we account for the changes in the Medicaid program year over year over year, and we try to make those updates to the template.
Q. Why --
A. By the way this played out -- and by the way this played out with the edits being removed by the Pharmacy team, somehow we -- we didn't get word back to the Office of Managed Care that we should remove that language from the -- and the Office of Pharmacy Services also was probably not aware that there's language in the respective member handbooks that talks about the hormone therapies not being covered.
So, really, this lawsuit was an occasion to sort of get all this in order and realize that we should update that. So that's what we're trying to do. We're trying to update that.
If the court might decide something

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relating to surgery in this case, we will also do whatever we need to do to reflect that in the handbook...
(Court Reporter requested clarification due to distorted/muted audio.)
A. ...in the member handbook template.
Q. With respect to your conversations with Brian Thompson in preparation for today's deposition, did you speak with him outside the presence of counsel?
A. Yes, I did some of the time. And you're going to ask me what those conversations were about?
Q. The ones outside of the presence of counsel, yes.
A. Okay. The conversations we had were in -- at one time I -- when we first had this scheduled, I was supposed to answer your questions about the experience that Mr. Fain had in receiving his injectable testosterone. And Brian had to walk me through the meaning of some of the edits that were on there.
I mean, there's -- there are -- as I'm sure you've encountered, there are codes that are used for certain things. I didn't understand all of it

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because I'm not in the middle of that process. And upon relating some of that to -- to Kim and others, and we're probably in the protected stuff --

MS. BANDY: Yeah, I would just jump in and remind the witness of the attorney-client privilege and not to disclose any confidential communications with counsel.

A. Okay. Anyway, it worked out that I was not going to be testifying on that stuff eventually -- later on so -- and it's better to have Brian in that role anyway.

Q. Okay. Did you look at any documents to prepare for today's deposition?

A. I did. I worked my way through the discovery packet and, you know, much of what we've reviewed, I've already -- I've looked at. And other things besides, so I looked at --

Q. Let me ask you this: What is the discovery packet?

A. The records that have been shared with me by the law firm.

Q. Do you know what those documents are? Can you describe them to me?

A. The MCO contracts, the contract with Rational Drug Therapy, emails from and to me.

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There was the preferred drug list.

What else did I see? The RQMS -- the evidence that we closed the CR relating to these gender edits. The -- I think it was the UniCare member handbook. The various health information of Mr. Fain and Ms. Anderson.

That's about all I'm coming up with right now.

Q. And today, while I have been asking you questions, have you been looking at any documents other than the ones that I've shown you through Exhibit Share?

A. No.

Q. So can you go back to Exhibit Share and open what is marked as FL 9, please.

(Exhibit 9 was marked for identification.)

Q. For the record, this is DHHRBMS002742 through 2753, as well as 2785 through 2862.

A. Okay. I have it open.

Q. I understand that these are contracts between BMS and the Rational Drug Therapy Program. Is that right?

A. That's right.

Q. Okay. I got a couple more for you like

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that, so if you could go back to the Marked Exhibits folder, please.

(Exhibit 10 was marked for identification.)

Q. Okay. So shortly you should see FL 10, so please open that once it loads.

For the record, this is DHHRBMS000109 through 144.

Is this the pharmacy benefits manual?

A. Yes. The pharmacy policy manual.

Q. Okay. Right. So this is the BMS provider manual and this is the chapter for Pharmacy Services, right?

A. Correct.

Q. Got it. Then just a couple more here.

A. Am I going back to the file share?

Q. Yes, please.

(Exhibit 11 was marked for identification.)

Q. So in a minute you should see FL 11 in the Marked Exhibits folder. And, for the record, this is DHHRBMS000145 through 198.

And is this the Bureau for Medical Services Preferred Drug List With Prior Authorization Criteria as of July 2021?

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A. I'm just looking for the -- okay. There's the date. Yes, it is.

Q. Then I've got one last exhibit for you.

(Exhibit 12 was marked for identification.)

Q. So this will be FL 12, if you go back to the Marked Exhibits folder. It's a single page. It is DHHRBMS015272 and this looks, at the top, like it's an email from you to Vicki Cunningham and Bill Hopkins, correct?

A. Correct.

Q. And then it looks like the email originated -- this chain started with Bill sending around a Washington Post article, right?

A. Correct.

Q. And the -- or actually, the Subject line says, "Federal judge blocks Trump administration from ending transgender healthcare protections from The Washington Post," correct?

A. Correct.

Q. And Vicki Cunningham responds with, "They delight in cruelty." Correct?

A. Yes.

Q. And what did you understand her to mean there?

MS. BANDY: I'm just going to object to questioning about this email in terms of it doesn't seem to relate to the topics he's designated on.

But you can certainly -- if you can answer.

A. So Vicki and Bill and I have -- you know, we've had our share of watercooler conversations about the former president, and you can kind of see where we were with him. But Vicki is saying, you know, it's -- the president is doing this to be cruel. That's how I understood it.

Q. Did you agree with that?

A. Yeah. I think it -- I said it was base pandering and he knew he would lose it when he it did it. I'm saying here that -- first of all, I'm sorry this got into the record. I don't use email this way typically. I must have been in a weak moment, and I had a few weak moments in this four years.

And when I'm talking about base pandering, I think he often used the courts to send dog whistles and to thrill his base. And it really wasn't about winning the case. It was about making everyone think that he was fighting. And so that's where I was coming from with that.

Q. Okay. I have no more questions for you at this time, Mr. Lewis. Your counsel might have some.

MS. BANDY: I don't have any questions for Mr. Lewis. I would just note that he will read the transcript.

MS. PRAKASH: All right. Very good. Thanks very much, Mr. Lewis, and we can go off the record.

(Time Noted: 1:29 p.m.,
April 4, 2022.)

- - -

REPORTER'S CERTIFICATE

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

I hereby certify that I reported the remote deposition of FREDERICK LEWIS, on April 4, 2022, via Veritext Virtual Videoconference, and that the witness was by me first duly affirmed to tell the whole truth;

That the testimony was transcribed by me and is a true record of the testimony of the witness;

That the cost of the original has been charged to the party who noticed the deposition, and that all parties who ordered copies have been charged at the same rate for such copies;

That I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel;

That I am not financially interested in the action and have no contract with the parties, attorneys, or persons with an interest in the action that affects or has a substantial tendency to affect my impartiality;

That the right to read and sign the deposition by the witness was preserved.

WITNESS MY HAND AND SEAL THIS 12th day of April, 2022.

[redacted], CRR, CRC, RSA
Notary Public, Hennepin County, Minnesota
My commission expires January 31, 2026

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

April 15, 2022

To: Ms. Bandy

Case Name: Fain, Christopher Et Al. v. Crouch, William Et Al.

Veritext Reference Number: 5129863

Witness: Frederick Lewis , 30(b)(6) Deposition Date: 4/4/2022

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 5129863
CASE NAME: Fain, Christopher Et Al. v. Crouch, William Et Al.
DATE OF DEPOSITION: 4/4/2022
WITNESS' NAME: Frederick Lewis , 30(b)(6)
In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.
I have made no changes to the testimony as transcribed by the court reporter.

_____ _____
Date Frederick Lewis , 30(b)(6)
Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal

this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 5129863
CASE NAME: Fain, Christopher Et Al. v. Crouch, William Et Al.
DATE OF DEPOSITION: 4/4/2022
WITNESS' NAME: Frederick Lewis , 30(b)(6)
In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.
I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).
I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

_____ _____
Date Frederick Lewis , 30(b)(6)

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:
They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.
I have affixed my name and official seal
this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

ERRATA SHEET
VERITEXT LEGAL SOLUTIONS MIDWEST
ASSIGNMENT NO: 5129863
PAGE/LINE(S) / CHANGE /REASON

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_____ _____
Date Frederick Lewis , 30(b)(6)
SUBSCRIBED AND SWORN TO BEFORE ME THIS _____
DAY OF_____, 20_____ .

_____
Notary Public

_____
Commission Expiration Date

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

Veritext Legal Solutions complies with all federal and State regulations with respect to the provision of court reporting services, and maintains its neutrality and independence regardless of relationship or the financial outcome of any litigation. Veritext requires adherence to the foregoing professional and ethical standards from all of its subcontractors in their independent contractor agreements.

Inquiries about Veritext Legal Solutions' confidentiality and security policies and practices should be directed to Veritext's Client Services Associates indicated on the cover of this document or at www.veritext.com.

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 5129863
CASE NAME: Fain, Christopher Et Al. v. Crouch, William Et Al.
DATE OF DEPOSITION: 4/4/2022
WITNESS' NAME: Frederick Lewis , 30(b)(6)

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

April 27, 2022
Date

Frederick Lewis , 30(b)(6)

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this 27 day of April, 2022.

Kimberly Michelle O'Brien
Notary Public

July 28, 2026
Commission Expiration Date

OFFICIAL SEAL
NOTARY PUBLIC
STATE OF WEST VIRGINIA
Kimberly Michelle O'Brien
WV DHHR Bureau for Medical Services
350 Capitol St. Rm 251, Charleston, WV 25301
My Commission Expires July 28, 2026

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 5129863

PAGE/LINE(S) /	CHANGE	/REASON
23/4 /	strike "plan" and insert "benefit design" in lieu thereof	/ clarity
24/23 /	add "ADDENDUM: Rate cells typically represent an age band, gender, eligibility type (TANF, Pregnant Women, Delivery Kick Payments, CSHCN, SSI, Expansion), and region (North, East, South). Age bands for children 14 and younger are not broken out by gender and for the SSI eligibility type, there is no gender specificity in the rates for the <20 age band."	/ Supplementing response because gender is even a more significant demographic in the identification of rate cells than I recalled in the deposition.
73/6 and subsequent references	The former Office of Pharmacy Services Director's name is Peggy King	/ Completeness
117/17 /	"insurance" not "assurance"	/ Correction

April 27, 2022

Date

Frederick Lewis , 30(b)(6)

SUBSCRIBED AND SWORN TO BEFORE ME THIS 27th

DAY OF April , 2022 .

Kimberly Michelle O'Brien

Notary Public

OFFICIAL SEAL
NOTARY PUBLIC
STATE OF WEST VIRGINIA
Kimberly Michelle O'Brien
WV DHHR Bureau for Medical Services
350 Capitol St, Rm 251, Charleston, WV 25301
My Commission Expires July 28, 2026

July 28, 2026

Commission Expiration Date

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

CHRISTOPHER FAIN; ZACHARY MARTELL; and **BRIAN MCNEMAR,** Individually and on behalf of all others similarly situated,

Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

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

DEFENDANTS' RESPONSE TO PLAINTIFF'S FIRST SET OF REQUESTS FOR ADMISSIONS TO DEFENDANTS WILLIAM CROUCH, CYNTHIA BEANE, AND WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES

REQUESTS FOR ADMISSIONS

1. Admit that Gender-Confirming Care can be medically necessary care for the treatment of gender dysphoria.

   RESPONSE: Upon information and belief, experts may differ in opinion as to whether gender-confirming care is medically necessary, both in general and with respect to a particular patient. This Request is admitted with the understanding that this area of treatment continues to evolve.

Exhibit
FL 3

2. Admit that Defendants partially or fully cover counseling and/or therapy for some diagnoses not related to Gender-Confirming Care.

   RESPONSE: Admitted.

3. Admit that Defendants partially or fully cover mastectomy, breast reduction surgery, and chest reconstruction surgery for sone diagnoses not related to Gender-Confirming Care.

   RESPONSE: Admitted.

4. Admit that Defendants partially or fully cover hysterectomy and oophorectomy surgical procedures for some diagnoses not related to Gender-Confirming Care.

   RESPONSE: Admitted.

5. Admit that Defendants partially or fully cover vaginoplasty procedures for some diagnoses not related to Gender-Confirming Care.

   RESPONSE: Admitted.

6. Admit that Defendants partially or fully cover orchiectomy, penectomy, and /or phalloplasty procedures for some diagnoses not related to Gender-Confirming Care.

   RESPONSE: Admitted.

7. Admit that the Medicaid Plan only covers care that is medically necessary.

   RESPONSE: Admitted. However, these Defendants deny any suggestion that Medicaid covers all care that is medically necessary.

8. Admit that the Medicaid Plan has covered all hormone therapy for the treatment of gender dysphoria from November 2017 to the present.

   RESPONSE: It is admitted upon information and belief that from November 2017 to the present, coverage for hormone therapy has not been denied on the basis that it is for treatment of gender dysphoria. Upon information and belief, "hormone therapy for the treatment of gender dysphoria" may broadly involve several separate medications, doses, and formulations, and it is possible that coverage has been denied on other criteria, therefore, it cannot be admitted or denied that "all" such therapy has been covered.

WILLIAM CROUCH,
CYNTHIA BEANE, and
WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES,

By counsel

/s/ Kimberly M. Bandy
Lou Ann S. Cyrus, Esquire (WVSB #6558)
Roberta F. Green, Esquire (WVSB #6598)
Caleb B. David, Esquire (WVSB #12732)
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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN; ZACHARY MARTELL; and **BRIAN MCNEMAR,** Individually and on behalf of all others similarly situated,

Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

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

Defendants.

CERTIFICATE OF SERVICE

Now come Defendants William Crouch, Cynthia Beane and West Virginia Department of Health and Human Resources, by counsel, and do hereby certify that on the 27th day of August, 2021, a true and exact copy of **DEFENDANTS' RESPONSE TO PLAINTIFF'S FIRST SET OF REQUESTS FOR ADMISSIONS TO DEFENDANTS WILLIAM CROUCH, CYNTHIA BEANE, AND WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES** was served on counsel via electronic means as follows:

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kbandy@shumanlaw.com

INTEROFFICE MEMORANDUM

TO: WILLIAM HOPKINS/VICKI CUNNINGHAM

FROM: DAVID THOMAS

SUBJECT: CR IMPLEMENTATION APPROVAL

DATE: 11/10/2017

CC: CYNTHIA SHELTON, RANDI KIMES, NEILL ALFORD

Please find the Implementation Approval Document attached for the listed CRs. Approval of said TR(s)/CR(s) acknowledges the acceptance of contractual deliverables as delineated in their respective SOWs (if an SOW is applicable). Furthermore, BMS directs Molina to move the solution elements into the production environment.

Upon approval, please sign and fax to (757) 306-4478 within 5 working days of the receipt of this letter to the attention of David Thomas, Neill Alford. Please contact me if you have any questions or comments.

Exhibit
FL 6

EXHIBIT
1

CR APPROVAL/ IMPLEMENTATION Details

BMS hereby confirms agreement to production implementation of the following CRs where a BMS representative has provided initials signifying approval. (CRs lacking customer initials are not approved for implementation under the signature provided.)

	CR Title	Initials
RQ_WV00016468	POS - Remove users (Anita Souder) from getting WVDRGS017, 018, 019, and 020 reports	wbh
RQ_WV00016773	POS - Remove Gender Limits from Estrogen and Testosterone products	wbh
RQ_WV00016780	POS - Remove Korlym drugs from Dohmen restricted contract	wbh
RQ_WV00016826	POS- SMAC Weekly Update 11/07/2017	wbh

Signed for and on behalf of
Bureau for Medical Services (BMS)
By:

Name: **William Hopkins**

Title: **Pharmacy Operations Manager**

Date: 11-15-17

Change_Request:RQ_WV00021101 ▾ Modify

CR | SLATS | MMIS Approval / SOW/CE Details | Project Actuals | Reviews | Relationships | ALM | Due Dates | Attachments | History | Notes

ID: RQ_WV00021101 State: 12-Closed Headline POS - Remove Gender Limits from Estrogen and Testosterone products

Description

Per direction of Vicki Cunningham of BMS, in the 11/02/2017 POS Issues call, remove the Gender limitations from the estrogen and testosterone containing products. This will include a removal of the Gender limits on the following HIC3's and GCNS's: HIC3's: F1A- Androgenic Agents G1A- Estrogenic Agents G1B- Estrogen/Androgen Combinations GCNS's (only found Gender limit for some GCNS's in HIC3 F1A): 021606 024137 031376 045215 045216 057874 061294 062542 067154 067366 068099 070128 070129

Ticket Type: CR

Requires Fiscal Agent Newsletter Publication:

HPAS Component: 07.00-Pharmacy (POS)

Applicable Programs: All Programs

Requires Banner/Portal Updates:

CR Source: External

Claims Reprocessing Required:

CR Type: D Routine OPS

Submitter: SearsEri

Sears, Eric

Reprocessed Claims

BMS Office: Pharmacy – V Cunningham

Owner: SearsEri

Payhold Refresh

Priority Requested:

State Initiatives:

Place Payhold

Severity: 3-Medium

Remove Payhold

Terminate Provider

Submitting Authority: (•)BMS ( )Fiscal Agent ( )BHHF ( )CHIP

Workgroup Approval:

Workgroup Approval Date:

Submit Date: 11/2/2017 3:53:23 PM

Requested Due Date: 11/30/2017

Watch List: No

RQMS User Guide:


CR
SLATS
MMIS Approval / SOW/CE Details
Project Actuals
Reviews
Relationships
ALM
Due Dates
Attachments
History
Notes
New Note:
close per below
Notes Log:
===== State: Closed by:CantleyJ at 11/15/2017 10:28:30 AM ===== close per below ===== State: ClosureRequested by:ThomasDa at 11/15/2017 1:13:37 PM ===== Requesting closure. ===== State: WorkInProgress by:ThomasDa at 11/14/2017 2:22:03 PM ===== All work has been completed. ===== State: Submitted by:SearsEri at 11/7/2017 1:27:51 PM ===== This CR was implemented into production at 1:25 PM on 11/07/2017. Validation screenshots are attached. ===== State: Submitted by:SearsEri at 11/2/2017 3:48:19 PM ===== This Record is not on the State Watch List.

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Bureau for Medical Services

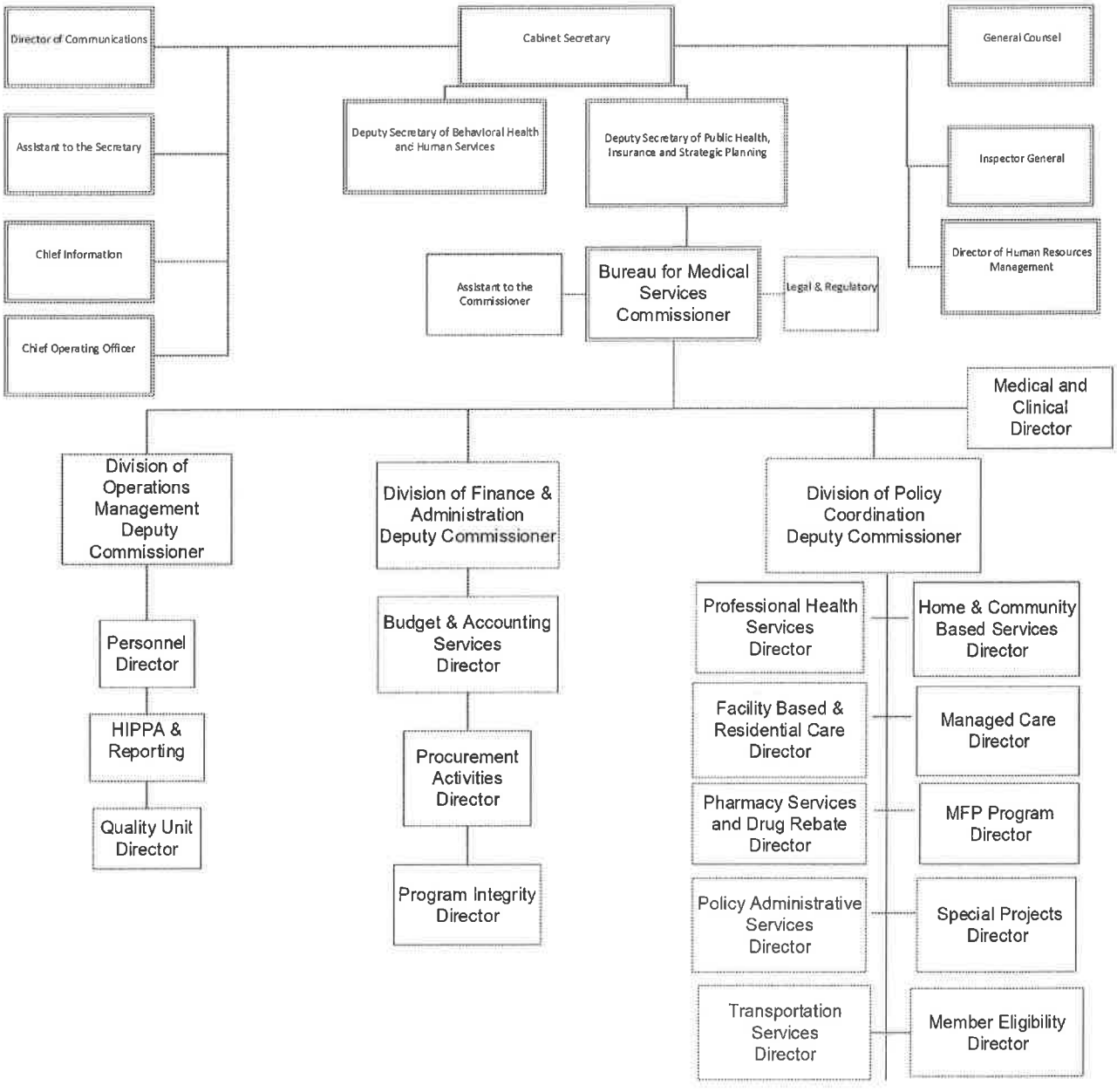

Exhibit
FL 8

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

CHAPTER 518 PHARMACY SERVICES

TABLE OF CONTENTS

Exhibit
FL 10

DISCLAIMER: This chapter does not address all the complexities of Medicaid p and must be supplemented with all State and Federal Laws and Regulations. Contact BMS Fiscal Agent for coverage, prior authorization requirements, service limitations, and other practitioner information.

EXHIBIT
5

DISCLAIMER: This chapter does not address all the complexities of Medicaid policies and procedures, and must be supplemented with all State and Federal Laws and Regulations. Contact BMS Fiscal Agent for coverage, prior authorization requirements, service limitations, and other practitioner information.

DISCLAIMER: This chapter does not address all the complexities of Medicaid policies and procedures, and must be supplemented with all State and Federal Laws and Regulations. Contact BMS Fiscal Agent for coverage, prior authorization requirements, service limitations, and other practitioner information.

CHAPTER 518 PHARMACY SERVICES

DISCLAIMER: This chapter does not address all the complexities of Medicaid policies and procedures, and must be supplemented with all State and Federal Laws and Regulations. Contact BMS Fiscal Agent for coverage, prior authorization requirements, service limitations, and other practitioner information.

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

CHAPTER 518 PHARMACY SERVICES

BACKGROUND

West Virginia Medicaid offers a comprehensive scope of Pharmacy services to Medicaid members as an optional program, subject to medical necessity, appropriateness criteria, and prior authorization requirements. All covered drugs, whether legend or over the counter, must be prescribed by a practitioner qualified under state law within the scope of his/her license and in accordance with all state and Federal requirements.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) mandated major changes in coverage and reimbursement for Medicaid-covered outpatient drugs. West Virginia Medicaid reimbursement is limited to drugs whose manufacturers have entered into and have in effect a rebate agreement with the Secretary, US Department of Health and Human Services.

POLICY

518.1 COVERED SERVICES

Except for certain limitations and exclusions, West Virginia Medicaid will reimburse for the following:

- Outpatient legend drugs;
- Specific over-the-counter drugs;
- Compounded prescriptions;
- Drugs that require prior authorization, when approved by the Bureau for Medical Services (BMS);
- Family planning supplies, including certain over-the-counter supplies;
- Certain diabetic supplies;
- Influenza, pneumonia, Hepatitis A, Hepatitis B, tetanus, tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults 19 years of age and older administered by a pharmacist. Members up to 19 years of age have access to vaccines via the Vaccines for Children Program; and
- Herpes zoster vaccine for adults 50 years of age and older administered by a pharmacist.

Drugs covered under the Medicaid outpatient pharmacy program are those that have been approved for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act, when used for medically accepted indications.

Medically accepted indication means any use that is supported by one or more of the following official compendia:

1. The American Hospital Formulary Service Drug Information
2. The United States Pharmacopoeia Drug Information or its approved replacement
3. The DrugDex Information System

All covered drugs, whether legend or over the counter, must be prescribed by a practitioner qualified under state law within the scope of his/her license and in accordance with all state and Federal requirements.

The West Virginia Medicaid program follows the US Office of Inspector General's (OIG) guidelines in excluding prescribers from participating with West Virginia Medicaid who are barred from participating in Federal health programs. Reimbursement of prescriptions issued by these excluded prescribers is denied.

DISCLAIMER: This chapter does not address all the complexities of Medicaid policies and procedures, and must be supplemented with all State and Federal Laws and Regulations. Contact BMS Fiscal Agent for coverage, prior authorization requirements, service limitations, and other practitioner information.

West Virginia Medicaid also excludes from reimbursement any prescription ordered by a prescriber who is not enrolled with West Virginia Medicaid.

518.1.1 Preferred Drug List (PDL)

The West Virginia Preferred Drug List (PDL) is a list of medications recommended to the BMS by the West Virginia Medicaid Pharmaceutical and Therapeutics (P&T) Committee and approved by the U.S. Secretary of the Department of Health and Human Resources. The P&T Committee is composed of actively practicing physicians, pharmacists, a nurse practitioner, and a physician's assistant. The P&T Committee meetings are held a minimum of three times per year and are open to the public.

The drugs that are designated as "preferred" have been selected for their clinical significance and overall cost efficiencies. All Medicaid-covered drugs noted as "non-preferred" continue to be available through the prior authorization process.

The PDL only contains drugs from certain drug classes. Some classes of drugs will not be reviewed for preferential agents because there are no, or limited cost savings associated with these classes. Drugs that meet the criteria for coverage and have no preferred status are considered covered drugs.

The PDL is updated at minimum annually and as needed. Newly released drugs in classes that are included in the PDL will be considered non-preferred until the new drug has been reviewed.

The complete PDL, criteria for coverage of non-preferred drugs, minutes of P&T Committee meetings, and other pertinent information are available on the BMS website.

518.1.2 Over-the-Counter Drugs

Certain over-the-counter (OTC) drugs are reimbursed for eligible Medicaid members when prescribed by a qualified practitioner. The OTC drugs must be manufactured by companies participating in the Federal drug rebate program and are limited to generic products when available. Any OTC drug available in packaging designed for OTC sale to the public must be dispensed in the original packaging. These products must be billed at the shelf price of the pharmacy. If a pharmacy is not accessible to, or frequented by the general public, or if the OTC drug is not on display for sale to the general public, then the product will be reimbursed at the same rate as legend drugs.

The OTC drugs are not covered for residents of skilled nursing home facilities or intermediate care facilities for individuals with intellectual disabilities (ICF/IID) except for insulin. These drugs are included in the rates paid to these facilities.

A current list of covered OTC drugs is available on the BMS website.

518.1.3 Diabetic Testing Supplies and Syringes/Needles

Certain supplies used by eligible diabetic Medicaid members are covered through the Outpatient Pharmacy program. A prescription issued by a licensed prescriber within the scope of his/her practice is required for coverage of these items. Verbal prescriptions that meet Federal and state regulations are

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permitted. Prescriptions must state the number of tests to be performed per day. Co-payments are not required on prescriptions for these items. Covered supplies include:

- Blood glucose testing strips;
- Urine testing tablets and strips;
- Lancets;
- Insulin syringe and needle combinations for the administration of insulin; and
- Needles for insulin pen systems.

Needle and syringe combinations and disposable pen needles for insulin pens are reimbursed through the Pharmacy Point-Of-Sale (POS) program only for the administration of insulin.

Diabetic testing supplies and syringes/needles are not covered pharmacy services for members residing in skilled nursing or ICF/IID facilities.

The following limits apply for those members who have insulin dependent diabetes:

Urine and blood glucose testing tablets and strips	150 per 30 days
Lancets	200 per 30 days
Insulin syringe and needle combinations	100 per 30 days
Pen needles	100 per 30 days

The following limits apply for those members who have non-insulin dependent diabetes:

Urine and blood glucose testing tablets and strips	100 per 30 days
Lancets	100 per 30 days

Prescriptions for quantities greater than the above referenced amounts require prior authorization through the pharmacy prior authorization vendor.

Dual eligible members have coverage of diabetic supplies through Medicare. Medicaid will not cover these supplies for dual eligible individuals, except for amounts that may be reimbursed on Medicare Part B crossover.

518.1.4 Home Infusion Therapy Pharmacy Services

Drugs used for home infusion therapy services are covered under the West Virginia Medicaid Pharmacy program. These drugs require prior authorization and must be justified by the ordering practitioner, including why oral therapy is unsuitable for the patient. Dual eligible members have coverage of home infusion pharmacy services through their Medicare Part D plans.

Total Parenteral Nutrition (TPN) supplies are considered Durable Medical Equipment (DME) and supplies and are not pharmacy POS covered services.

518.1.5 In-Home Parenteral Therapy (IHPT)

In-Home Parenteral Therapy (IHPT) is a Medicaid-covered service. Medicaid coverage for this service will include drugs and services that are:

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- Medically necessary;
- Prescribed by a licensed physician;
- Administered through central line, peripheral line, infusion port, epidural, intrathecal or subcutaneous site;
- Provided by a licensed pharmacy enrolled with West Virginia Medicaid;
- Billed through electronic transmission according to standard guidelines or on the approved pharmacy paper claim form; and
- Prior authorized as directed by the BMS.

MEMBER REQUIREMENTS

Members receiving IHPT must meet the following requirements:

- The member must reside in either a private home or domiciliary care facility, such as an adult care residence. Members who are residents or patients of hospitals, nursing homes (including ICF/IID group homes), rehabilitation centers, and other institutional settings are not eligible for this service;
- The member must be under the care of a physician who prescribes the in-home infusion therapy and monitors the progress of the therapy;
- The member must have sites available for intravenous catheters or needle placement or have central venous access; and
- The member must be capable of self-administering or have a nurse or a caregiver who can be adequately trained, and is capable and willing to administer/monitor home infusion therapy safely and efficiently following appropriate teaching and adequate monitoring.

PRIOR AUTHORIZATION

All IHPT services require prior authorization. Requests must be made through the pharmacy prior authorization vendor. The approved prior authorization forms are available on the BMS website.

- **Pre-Mixed Solutions or Products Requiring No Compounding:** Pre-mixed solutions or products include those injectable items that do not require compounding by the pharmacist because a) the items are marketed as pre-mixed, thus requiring no dilution and/or compounding, or b) compounding is performed by the patient, the nurse or the caregiver. Commercially prepared products are mandated to be dispensed if available. Compounded products and related professional services shall not be reimbursed when the commercially prepared product is available.
- **Products Requiring Compounding:** Certain injectable products require compounding in order to meet the needs of the member, and are not available commercially.

The request for prior authorization must include the diagnosis, duration of therapy, prescribing physician information, and appropriate documentation. The prior approval will be effective from the date of the physician's original order and continue for the specified length of therapy unless there is a change in prescription or level of care. Changes in therapy require new prior authorizations. Written requests for prior authorization must be submitted via fax or mail to the pharmacy prior authorization vendor on form IV-1. Signed physicians' orders for compounded IHPT medications must be provided to the pharmacy prior authorization vendor if reimbursement for compounding activities is requested.

Please refer to *Chapter 600 Reimbursement Methodologies* for further information on IHPT billing and reimbursement by POS.

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518.1.6 Tobacco Cessation Program

West Virginia Medicaid, in partnership with the Bureau for Public Health (BPH), offers a tobacco cessation program, known as the West Virginia Tobacco Quitline, to assist members to discontinue use of tobacco products. See *Chapter 519.18, Tobacco Cessation Services* for more information on the Quitline, covered cessation agents, and limitations.

Nicotine replacement therapy and other smoking cessation agents are covered for West Virginia Medicaid members enrolled in the Quitline's telephone coaching program. Smoking cessation agents fall in three general categories: Nicotine Replacement Therapy (NRT), Bupropion (Zyban), and Varenicline (Chantix®). All agents are first line therapy and are covered for 12 weeks per calendar year, with additional treatment at the request by the member's physician. Authorization for therapy beyond the initial 12 weeks requires a written appeal from the prescriber with documentation of efficacy and patient compliance. A claims review must confirm compliance with no more than a five-day lapse between pharmacy fills of current therapy. Covered products include:

- Nicotine gum – 24 pieces per day;
- Nicotine patches – 1 patch per day;
- Nicotine lozenges – 20 lozenges per day;
- Nicotine inhaler – 168 inhalers per 30 days;
- Nicotine nasal spray – 4 spray bottles per 30 days (This therapy is reserved for members that have failed other forms of NRT);
- Bupropion – 300 mg per day (NRT and bupropion will not be covered concurrently); and
- Varenicline – 2 mg per day.

Drugs in this category may be combined for concurrent use, unless indicated. All tobacco cessation products must be prescribed by an enrolled practitioner within the scope of his/her license under West Virginia law. Prior authorization is required for coverage of tobacco cessation drugs and is coordinated through the Quitline. If the caller has the prescription information for nicotine replacement therapy available, the coach can send it to Rational Drug Therapy for approval. Women who are pregnant are also eligible for treatment, when appropriate.

Dual eligible members have coverage of legend drugs through their Medicare Part D plans, and coverage of over-the-counter drugs and tobacco cessation counseling services through Medicaid.

518.1.7 Buprenorphine-Naloxone (Suboxone®) / Buprenorphine (Subutex®) Coverage

Buprenorphine-Naloxone and Buprenorphine are covered through the Pharmacy program and must have a prescription written by an enrolled prescriber approved to prescribe these services. Other limitations may apply. Additional information and detailed coverage criteria is available on the BMS website.

518.1.8 Bulk Chemicals

Per CMS Medicaid Drug Rebate Program Release No. 155, bulk chemicals are substances which when used in the manufacturing of a drug become the active ingredient of the drug product. As such they do not meet the definition of covered outpatient drugs as defined in section 1927(k)(2) of the Social Security Act.

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However, bulk chemicals may be considered covered in rare circumstances if prescribed for a Food and Drug Administration (FDA) approved indication and/or medically accepted indication supported in official compendia. Prior authorization is required. All rules, regulations, limitations, and exclusions set forth in the Pharmacy Services manual apply also to bulk chemicals.

A list of covered bulk chemicals and criteria for coverage is available on the BMS website.

518.1.9 Brand Name versus Generic Drugs

Brand name multi-source legend drugs that have therapeutic equivalents available will be denied for payment. Generic drugs must be substituted, if available. In certain instances, pharmacies may indicate brand name drug usage on submitted electronic and paper pharmacy claims by using Dispensed as Written (DAW) codes. The DAW codes that are recognized by West Virginia Medicaid and can be used by providers to explain the dispensing of a brand name product instead of a generic one are as follows:

- **DAW 1:** Prescriber states that the brand name drug is "medically necessary. This information must be supplied in writing by the prescriber via written prescriptions in his or her own handwriting, and must write on the prescription "Brand Medically Necessary. A checkbox or other methods to indicate that the brand should be dispensed shall not be accepted. Approval from the pharmacy prior authorization vendor help desk is required for the use of DAW 1 and appropriate justification must be provided.
- **DAW 4:** A generic equivalent is not available or not stocked at the time of dispensing. This code shall only be used when a generic drug is sold out or a generic drug is unavailable on a wide-spread basis. It shall not be used routinely to circumvent the mandatory generic program for other reasons. A call to the pharmacy prior authorization vendor help desk is required for the use of DAW 4 and appropriate justification must be provided. The brand name rate will be reimbursed when approved.
- **DAW 5:** Pharmacy uses this brand as a generic and realizes it will be paid at the generic rate.
- **DAW 6:** Pharmacy is dispensing a generic drug that has been identified by the drug database as a brand name drug due to pricing issues. These generic drugs have high Average Wholesale Prices (AWP) in relation to other generic drugs that are available. An effort shall be made to obtain lower-priced alternatives.
- **DAW 8:** Substitution not allowed - generic drug not available in marketplace.
- **DAW 9:** Substitution allowed by prescriber, but plan requires brand

For auditing purposes, documentation shall be made on the prescription to justify use of the DAW codes. All other DAW codes that are recognized by the National Council on Prescription Drug Programs (NCPDP) are not active in the West Virginia Medicaid program and will not affect the processing of claims, if submitted. The use of DAW codes is not permitted for non-preferred drugs included in the PDL program.

Completion of an FDA MedWatch form is required for the failure of a generic product to produce the same outcome as the equivalent brand name drug. The MedWatch form shall be sent by mail or fax to the pharmacy prior authorization vendor. The MedWatch form is available on the FDA website.
Please note that some generic drugs may be classified as non-preferred by West Virginia Medicaid and require prior authorization. This occurs when brand name drugs are less expensive to Medicaid due to supplemental rebate negotiations. In this case, the pharmacy will be required to dispense the brand name drug instead of the generic equivalent.

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518.2 PRIOR AUTHORIZATION

Prior authorization for Medicaid-covered drugs is required for reimbursement of certain drugs to assure the appropriateness of drug therapy. Specific prior authorization criteria are based on review of the most current clinical information, FDA-approved indications, and manufacturers' recommendations. These criteria are reviewed by the Medicaid Drug Utilization Review (DUR) Board and recommended to the BMS. These criteria then form the basis of acceptable drug therapy for members with Medicaid pharmacy benefits. Current criteria for coverage of non-preferred drugs and other drugs requiring prior authorization is available on the BMS website. Drugs which require prior authorization and for which prior authorization criteria have not been met are considered non-reimbursable unless, upon appeal by the prescribing provider, the Medicaid medical director determines that the drug meets the appropriateness and medical necessity criteria.

The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization.

Federal regulations state that Medicaid-covered drugs that require prior authorization must have a 24-hour decision turnaround. In emergent situations, a 72-hour supply of medication must be made available to members until the prior authorization process can be completed. No more than a 72-hour supply shall be dispensed. Submitting a quantity greater than a 72-hour supply constitutes an improper claim unless it is for a package that cannot be broken. If a product package cannot be broken, then the whole package may be dispensed, if necessary, to meet the member's needs. Documentation of this action shall be made on the prescription for auditing purposes. Repeated submissions of 72-hour supplies for the same patient and same drug to circumvent the prior authorization process constitute an improper billing method. This practice is subject to audit.

518.2.1 Process of Requesting Prior Authorization

The pharmacy prior authorization vendor is the agency contracted to provide prior authorization services to the West Virginia Medicaid Pharmacy program. Prior authorization may be initiated either by the dispensing pharmacist, the prescriber, or the prescriber's designee. Prior authorization requests from third party vendors or contractors will be denied. Requests may be made by telephone, fax, or mail. If all the necessary information is provided, requests will be addressed within 24 hours. It is the responsibility of the provider of the service, either the physician or pharmacist, to obtain the authorization before rendering the service. Requests for prior authorization after the service is rendered will be denied. In cases of back-dated eligibility, prior authorizations may be considered on a case by case basis using coverage policies in place on the dates the services were rendered. If the service is provided before prior authorization is obtained, the Medicaid member must be informed that he/she will be responsible for the bill. There is a maximum approval limit of one year.

Prior authorization requests shall include the following:

- Member name, address, and Medicaid identification number;
- Name of drug, strength, dosage, and duration of treatment;
- Diagnosis;
- Pertinent laboratory information;
- Justification for the use of the drug;
- Return fax number; and

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- Signature of prescriber or pharmacist.

Prior authorization forms are available on the BMS website. These forms may be duplicated.

518.2.2 Prior Authorization Denial Appeals Process

If a prior authorization request is not approved, the prescriber may appeal the decision to the Pharmacy Prior Authorization Vendor Appeals Department in writing (first level appeal). Requests must include the following information:

- Member name, address, and Medicaid identification number;
- Name of drug, strength, dosage, and duration of treatment;
- Diagnosis;
- Pertinent laboratory information;
- Justification for the use of the drug, including any other treatments that have been tried;
- Supporting literature;
- Return fax number; and
- Signature of prescriber.

Office and/or hospital notes, including signed ones, are not acceptable and do not constitute an appeal. The appeal decision will be returned to the fax number of the *prescriber* on record.

Appeals will be processed within three business days of their receipt. All appeals denied by the pharmacy prior authorization vendor will be sent to the BMS for physician review. Any denial resulting from physician review is final.

The Medicaid member is notified of this denial and of the right to request a fair hearing.

518.3 NON-COVERED SERVICES

The following list of drugs, drug products, and related services are not reimbursable. Non-covered services include, but are not limited to:

- Drugs supplied by drug manufacturers who have not entered into a drug rebate agreement with the Centers for Medicare and Medicaid Services (CMS);
- Agents used for weight loss, anorexia, or weight gain, including binge-eating disorder;
- Agents used for cosmetic purposes or hair growth;
- Drugs identified by the CMS as being less-than-effective (DESI);
- Agents used for fertility;
- Drugs used to treat erectile dysfunction;
- Drugs that are investigational or approved drugs used for investigational purpose;
- Drugs used for off-label indications that are not found in official compendia or generally accepted in peer reviewed literature;
- Drugs dispensed after their expiration date;
- The cost of shipping or delivering a drug;
- Herbal or homeopathic products;

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- Drugs that result in therapeutic duplication, ingredient duplication, early refills, or other DUR events that are not medically necessary;
- Drugs that are not medically necessary;
- Covered outpatient drugs for which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee;
- Nutritional supplements;
- Free pharmaceutical samples;
- Diagnostic agents;
- Vacation supplies;
- Allergenic extracts;
- Excipients except when used in compounded prescriptions containing a covered legend drug. Excipients must be eligible for Federal rebates in order to be eligible for reimbursement;
- Vaccines through the pharmacy POS, except for Influenza, pneumonia, Hepatitis A, Hepatitis B, tetanus, tetanus-diphtheria (Td), and tetanus-diphtheria-and-pertussis (Tdap) vaccines for adults 19 years of age and older administered by a pharmacist; vaccines and vaccine administration approved during a public health emergency declaration, and herpes zoster vaccine for adults 50 years of age and older administered by a pharmacist; and
- Methadone for the treatment of opioid addiction/dependence is not covered as a pharmacy benefit. *See Chapter 504, Substance Use Disorder Services*.

Non-covered services are not eligible for a Department of Health and Human Resources' (DHHR) Fair Hearing. See 42 § 431.220 When a hearing is required for more information.

518.4 SERVICE LIMITATIONS

Service limitations governing the provision of all West Virginia Medicaid pharmacy services will apply for eligible members as follows:

- Covered drugs are limited to their FDA-approved or medically accepted indications and dosing limits.
- When appropriate, PDL-preferred drugs must be tried before non-preferred drugs are approved.
- All covered outpatient drugs must be prescribed by a practitioner qualified under state law within the scope of his/her license and in accordance with all state and Federal requirements.
- Prescriptions may be written or verbal, and must meet all the Federal and state guidelines for legal prescriptions.
- Covered outpatient drugs are reimbursed up to a 34-day supply and may be refilled according to state and Federal Laws. Certain exceptions apply, for example, most oral systemic antibiotics are covered for a 14-day supply with one refill. Exceptions to this policy may apply if the only available package size of the product is one that exceeds the 34-day supply limit.
- Only those legend drugs for the symptomatic relief of cough and colds that appear on the approved BMS list are covered for this therapeutic indication. Certain over-the-counter cough and cold medications are also covered. This list is available on the BMS website. Dual eligible members have coverage of cough and cold medications through Medicaid if these products are not covered by their Medicare Part D or Part C plans.
- Barbiturates are not covered except for phenobarbital and mephobarbital, unless the barbiturate is in combination with another active ingredient. Dual eligible members have coverage of phenobarbital; mephobarbital; and butalbital, acetaminophen, and caffeine combination products

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through Medicaid if these products are not covered by their Medicare Part D plans. (Note: Combination products of butalbital, acetaminophen, caffeine, and codeine will be covered by Medicare Part D or Part C plans for dual eligible members.)

- Vitamins and minerals are limited to:
  - Legend vitamins A, D, K, folic acid, B-12 for injection, iron preparations, and niacin.
  - Minerals including calcium, iron, magnesium, fluoride, and additional mineral requirements for the treatment of End Stage Renal Disease.
  - Multivitamins for children through age 20.
  - Prenatal vitamins for women through age 45.
  - Legend fluoride preparations.
- Other drugs may be limited in quantity, duration, or based on gender. The information regarding these drug products and their limitations is available on the BMS website. Exceptions are considered on a case-by-case basis through the pharmacy prior authorization vendor.
- Additional drugs may have quantity limits to assure accurate billing of units.
- Limitations apply to diabetic testing supplies and insulin syringes/needles depending on the member's diagnosis, i.e. insulin dependent or non-insulin dependent diabetes. Medicaid does not cover diabetic supplies for dual eligible members, except for coverage of Part B deductibles and coinsurance amounts. These individuals have coverage for diabetic supplies either through Medicare Part B or Part D.
- Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:
  - Barbiturates (if not for treatment of epilepsy, cancer, or mental health disorder, as Medicare Part D covers these conditions).
  - Over-the-counter medications.
  - Agents for the symptomatic relief of cough and cold symptoms.
  - Prescription vitamins and minerals.

518.5 DRUG UTILIZATION REVIEW (DUR)

The Omnibus Budget Reconciliation Act (OBRA '90) required that states establish a DUR program which consists of prospective and retrospective components as well as components to educate physicians and pharmacists on common drug therapy problems and assessments of whether usage complies with predetermined standards. In order to meet the requirements of the statute, the DUR program must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. The two primary objectives of DUR systems are to improve quality of care and to assist in containing health care costs.

The establishment of a DUR Board was required by OBRA '90. This Board consists of local pharmacists, physicians, and other healthcare providers from around the state. The Board is charged with making recommendations for educational interventions to prescribers and pharmacists to identify and reduce, for both providers and patients, the frequency of patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care. Specific drugs or classes of drugs may be targeted in regard to:

- Therapeutic appropriateness
- Overutilization
- Under utilization
- Appropriate use of generic products

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- Therapeutic duplication (same or different prescriber)
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage
- Incorrect duration of drug treatment
- Drug-allergy interactions
- Clinical abuse/misuse

The West Virginia Medicaid DUR Board meets quarterly to discuss methods of achieving the goals of assuring the appropriate use of drugs in the Medicaid program. These meetings are open to the public. The DUR Board also assists the BMS in defining criteria for coverage of drugs that require prior authorization.

The DUR Board meeting agendas, minutes, and other DUR information are available on the BMS website.

518.5.1 Prospective Drug Utilization Review (DUR)

Prospective DUR is conducted at the pharmacy POS before delivery of a medication by the pharmacist to the Medicaid member or caregiver. Prescription claims are screened to identify potential drug therapy problems of the following types:

- Therapeutic duplication
- Ingredient duplication
- Adverse drug-drug interactions
- Early refill
- Late refill
- High dosage
- Low dosage
- Incorrect duration of drug treatment
- Age/gender precaution
- Pregnancy precaution
- Breast feeding precaution

Dispensing pharmacists use the information provided by the pharmacy POS and their professional judgment to determine if the prescription shall be filled. The pharmacist determines the appropriateness of the prescribed therapy and intervenes with the prescribing physician and/or member in the event of a suspected problem.

Pharmacists may continue to process claims that contain prospective DUR messages by using DUR outcome and intervention codes. A call to the pharmacy prior authorization vendor help desk may be required in certain instances as determined by the BMS to obtain an edit override. Requests for edit overrides after the service is rendered will be denied, except in cases of back-dated eligibility. More detailed information regarding DUR may be accessed through the Health PAS-RX pharmacy POS User Guide found on the BMS fiscal agent's website.

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518.5.2 Retrospective Drug Utilization Review (DUR)

Retrospective DUR is required in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid members, or associated with specific drugs or groups of drugs. West Virginia Medicaid conducts retrospective DUR with the assistance of a vendor. They provide patient profiles addressing drug use that may be inappropriate based on predetermined standards. A Retrospective DUR Committee, consisting of healthcare professionals, meets monthly to review these patient profiles that are used to generate letters to physicians and pharmacists relating to these issues.

518.5.3 Pharmacy Lock-in Program

Members who use pharmacy services excessively or inappropriately may be assigned to a single pharmacy provider where they receive their Medicaid-covered medications. The purpose of this program is to assist members in using pharmacy services appropriately.

As part of this program, the Retrospective DUR Committee reviews Medicaid member utilization profiles to determine if controlled substances are being used at a frequency or amount that results in a level that may be harmful or not medically necessary. Inappropriate utilization can include frequent use of multiple controlled substances, use of multiple prescribing physicians and/or pharmacies, overlapping prescription drugs within the same drug class and drug seeking behavior, i.e., doctor shopping.

A series of letters is sent to prescribers and/or the member to seek information regarding his/her drug utilization or to warn that continued overutilization may result in restricting the member to a single pharmacy provider. If the pharmacy lock-in criteria are met, the member is given the opportunity to select a pharmacy, but pharmacy participation is voluntary. Pharmacists serving these members are requested to use their professional judgment in regard to filling prescriptions for controlled substances.

Criteria for Lock-in Determination is available on the BMS website. Members, upon discharge from a substance abuse program, or while receiving outpatient substance abuse treatment, will be locked into a single pharmacy provider. Upon admission to a facility for treatment of substance abuse or during the initial visit for outpatient substance abuse services, the member will be required to choose a pharmacy from which to receive all controlled substances.

518.6 PROVIDER PARTICIPATION REQUIREMENTS

Provider enrollment requirements in general are detailed in the BMS Manual *Chapter 300, Provider Participation and Requirements*.

518.7 CERTIFICATION

A pharmacy eligible to participate in Medicaid must hold a current permit from the West Virginia State Board of Pharmacy (BOP) and adhere to all state and Federal regulations. Pharmacies located out-of-state and filling prescriptions for West Virginia Medicaid members must be licensed by the state in which they are located. Pharmacies located out-of-state and are shipping or mailing prescriptions into West Virginia, must be licensed by the state in which they are located **and** hold a permit from the West Virginia BOP. Pharmacies are required to file a copy of their current permits with the BMS annually. Failure to do so may result in the withholding of payments and/or enrollment termination.

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When the current license and/or permit is not on file, the provider shall not be reimbursed by Medicaid until such time as the BMS Provider Enrollment Unit receives a copy of the current license and/or permit.

West Virginia only enrolls providers outside of West Virginia within a 30-mile radius of the state border, unless it is a specialty pharmacy with exclusive distribution rights for certain drug(s). These out-of-state specialty pharmacy providers will be limited to the National Drug Codes (NDCs) requested on their enrollment applications.

518.8 DISPENSING PHYSICIANS

The BMS does not enroll dispensing physicians for reimbursement as a pharmacy provider type. Reimbursement for self-administered prescription drugs is limited to licensed and participating pharmacies.

518.9 IN-HOME PARENTERAL THERAPY PROVIDER REQUIREMENTS AND RESPONSIBILITIES

Pharmacies requesting reimbursement for IHPT compounding services must meet all state and Federal licensure and certification requirements. In order to participate in the West Virginia Medicaid program and receive payment from the BMS, IHPT providers must:

- Submit an IHPT Medicaid Provider Enrollment Form to the BMS; and
- Submit a copy of the provider's West Virginia BOP Sterile Compounding Permit or respective state Board of Pharmacy Sterile Compounding Permit.

Participating pharmacies that bill services for West Virginia Medicaid members shall be subject to the laws and regulations set forth by the West Virginia BOP that govern the requirements to hold a Sterile Compounding Permit.

518.10 PHARMACIES PARTICIPATING IN THE 340B PROGRAM

Pharmacies participating in the program established by Section 340B of the Public Health Services Act of 1992 dispense drugs with discounts generated from participation in the program. These drugs are not eligible for Federal drug rebates.

Actual acquisition costs must be submitted when billing Medicaid. Submission of invoices may be required for audit purposes.

All 340B pharmacy providers for West Virginia Medicaid are required to bill each pharmacy POS claim with the following NCPDP values:

- Claim Segment-Submission Clarification Code (420-DK) - Use value 20 in Position 1 or 2
- Pricing Segment- Basis of Cost Determination (423-DN) - Use value 08

These updates may be found on the updated West Virginia Medicaid Vendor Specification Sheet, D.0. vs.1.7, September 2016.

The NCPDP values above identify claims to be removed from the rebate file which avoids billing manufacturers for duplicate discounts. As per 42 USC 256b(a)(5) a manufacturer may audit and seek

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recoupment of the duplicate discount from covered entities found to be non-compliant with 340B requirements. In these instances, the rebate is due to the State and the duplicate discount will be recouped from the non-compliant covered entity.

The Health Resources & Services Administration (HRSA) maintains a current listing of participating providers who intend to bill Medicaid for 340B drugs on the HRSA website. It is the providers' responsibility to verify that the HRSA listing of their participation is current and accurate. Providers must report any changes in Medicaid 340B program participation to HRSA.

518.11 PHARMACY CHANGE OF OWNERSHIP

Change of ownership policy is addressed in the BMS Manual *Chapter 300, Provider Participation Requirements* and additional information may be found on the fiscal agent's website, see BMS Manual *Chapter 100, General Information*.

518.12 CASH PAYMENTS

Pharmacies are encouraged to report to the BMS when a member pays cash for prescriptions that would otherwise be covered by Medicaid or considered for reimbursement upon a call to the pharmacy prior authorization vendor, or when the pharmacy provider suspects overutilization by the member. The cash waiver form used for this reporting is available on the BMS website. Information collected through this process may be used for member lock-in consideration.

Medicaid reserves the right to deny coverage of controlled substances when the member has been found to be paying cash to bypass Medicaid's prior authorization and/or quantity limit requirements.

518.13 MEMBER COUNSELING

The OBRA '90 requires that pharmacists offer counseling to Medicaid members and must include the following:

- Name and description of the medication;
- The route of administration, dosage form, dosage, and duration of therapy;
- Special directions and precautions for preparation, administration and use by the patient;
- Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- Techniques for self-monitoring prescription therapy;
- Proper storage;
- Prescription refill information; and
- Action to be taken in the event of a missed dose.

The West Virginia Medicaid program relies on the West Virginia BOP to monitor these activities, but the BMS may audit these requirements through routine or special reviews.

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518.14 DOCUMENTATION AND RECORD RETENTION REQUIREMENTS

518.14.1 Tamper-Resistant Prescription Pad Requirement

All prescriptions written for West Virginia Medicaid members must be on tamper-resistant pads/paper which meet all three characteristics set forth in the guidelines from the CMS. The three characteristics to meet the tamper-resistant prescription requirement are:

1. Prevent unauthorized copying of a completed or blank prescription form;
2. Prevent the erasure or modification of information written on the prescription, and
3. Prevent the use of counterfeit prescription forms.

Written prescriptions must contain **ALL** of the following:

Feature	Description
"Void" pantograph	The word "Void" appears when document is photocopied. Pharmacy will need to record on document if received by fax.
Uniform non-white background color – preferably green	Background is one color (preferably green), inhibits a forger from physically erasing written or printed information on a prescription form. If an attempt is made to erase copy – the consistent background color will look altered.
Quantity check off boxes	In addition to the written quantity on the prescription, quantities are indicated in ranges of 25's (or some other, similar range). Box MUST be checked for this feature to be valid.
Refill indicator	Refill indicator (circle or check number of refills or "NR"). Refill indicator must be used to be a valid feature.
Security features and descriptions listed on the front of the prescription	Listing of the security features of the prescription for compliance purposes. This will assist the pharmacist and auditors on what security features are included on the pads/paper.

Computer-generated prescriptions, electronic medical records (EMR), or ePrescribing generated prescriptions may be printed on plain paper and be fully compliant with all three categories of tamper resistance, provided they contain the features listed in the table below. Prescribers are urged to contact their software companies to ensure that computer generated prescriptions have all requirements necessary for tamper resistance.

Computer-generated prescriptions must contain the following:

1.One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.

Feature	Description
"Void" pantograph	The word "Void" appears when document is photocopied. Pharmacy will need to record on document if received via fax. *This requires the purchase of special paper.*

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Feature	Description
OR	
Micro print signature line	Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.

2.One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.

Feature	Description
Uniform non-white background color – preferably green OR "Toner-lock" paper for laser printed prescriptions, or plain bond paper for inkjet printed prescriptions	Background is one color (*preferably green*), inhibits a forger from physically erasing written or printed information on a prescription form. If someone tries to erase copy – the consistent background color will look altered. Toner-lock paper is special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. Note – this is NOT necessary for inkjet printers – as the ink from the inkjet printers is absorbed into normal "bond" paper.
Quantity written and quantity with border characteristics for computer generated printed prescriptions	Quantity written, and Quantity surrounded by special characters such as asterisks to prevent modification, e.g. QTY Fifty ***50****.
Refill written and refill with border Characteristic for computer generated printed prescriptions	Refills written, and Refill surrounded by special characters such as asterisks to prevent modification, e.g. Five refills ****5 refills*****.

3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Feature	Description
Security features and descriptions listed on the prescription	A complete list of the security features of the prescription for compliance purposes. This will assist the pharmacist and auditors on what security features are included on the paper.

Prescriptions for West Virginia Medicaid members written by prescribers that reside outside of West Virginia may meet the Federal tamper-resistant prescription requirement if the prescription addresses the three distinct characteristics outlined above, and may contain the same or other features than those adopted by the BMS.

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518.14.2 Prescriptions Returned to Stock

Claims for prescriptions which have been filled by the participating pharmacy, but not dispensed to the patient, shall be reversed. This shall be done on a timely basis, within 15 days. A log of these returns must be maintained by the pharmacy for a period of five years for auditing purposes.

518.14.3 Nursing Home Returns

Drugs dispensed to nursing home residents that are not used by the member must be either returned to the dispensing pharmacy or destroyed according to applicable rules and regulations. Drugs that are returned unused by the Medicaid member and are available for re-dispensing, per West Virginia State BOP rules and regulations, must be credited to Medicaid. Claims for these returned medications must be reversed and resubmitted for the quantity used by the member.

518.14.4 Medication Dispensing/Shipping/Receiving

Providers shall take all necessary and prudent steps to prevent loss of medications in the shipping process and to assure that the member receives the shipment when needed, as Medicaid will not reimburse for medications not received by the member. In the case of a dispute, the only definitive proof of delivery accepted by BMS shall be a copy of the member's signature on the delivery log. Reimbursement shall be withheld should a dispute arise where proof of signature is not available from the pharmacy. It is recommended that a log of these signatures be maintained by the pharmacy for a period of five years should a dispute of delivery arise.

Claims for medications not received by the member in a timely manner, and which the member was compelled to obtain from a local pharmacy, may be reversed by the fiscal agent, if necessary, in order to allow for billing by a local pharmacy provider to meet the member's needs.

518.15 PHARMACY SERVICES FOR MEDICAID MEMBERS

Medicaid members eligible for pharmacy services have access to legend and over-the-counter drugs as defined in the State Plan filed with CMS. Any person requesting services shall be advised that he/she is responsible for furnishing proof of coverage to the provider prior to services being rendered. Eligibility may be verified through the Medicaid Voice Response System at 1-888-483-0801 or by sending an electronic NCPDP E-1 transaction through the pharmacy POS billing system.

518.15.1 Dual Eligible Members

Members eligible for both Medicare and Medicaid are called dual eligible members. Medicare is the primary payer for dual eligible members. Medicare, a Federal health insurance program for the aged and disabled, covers certain hospital (Part A), outpatient medical benefits and physicians' services (Part B) and prescription benefits (Part D) for participating individuals. Some dual eligible members may participate in Medicare Managed Care plans (Advantage or Part C plans) which include pharmacy services.

Dual eligible members have prescription drug coverage through Medicare Part D, or Part C if enrolled in a Medicare Managed Care plan. Medicaid is not responsible for covering pharmacy benefits for these individuals, except for drugs in the Medicare excluded categories. Medicaid does not reimburse for Medicare Part D or Part C co-payments. Medicaid does not pay as the secondary payer on Medicare Part D or Part C covered drugs.

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518.15.2 Medicaid Members Enrolled in Managed Care Organization Plans

Medicaid members enrolled in the managed care organization plans receive pharmacy benefits from the fee-for-service (FFS) pharmacy program. The FFS pharmacy program covers drugs which are submitted to pharmacies by written, telephonic, or electronic prescriptions.

Drugs that are billed with J Codes or Healthcare Common Procedure Coding System (HCPCS) Codes are covered by the managed care programs and cannot be billed to the fee-for-service program at the point of sale.

518.15.3 Medicaid Members with End Stage Renal Disease (ESRD)

Members diagnosed with End Stage Renal Disease (ESRD) may require additional vitamin/mineral supplements not usually covered by the pharmacy program. In order to accommodate these members, the prescriber must contact the prior authorization vendor (Rational Drug Therapy Program (RDTP)) by fax, phone or mail in order to confirm the ESRD diagnosis.

Once a member receives a kidney transplant, the member is no longer considered as having ESRD, and no longer qualifies for these additional supplements. To allow for clinical stabilization following transplant, a six-month extension of the ESRD coverage will be permitted before being terminated.

518.15.4 Qualified Medicare Beneficiary (QMB)

Qualified Medicare Beneficiary (QMB) members do not receive pharmacy coverage benefits through the Medicaid program. Medicaid does provide coverage of deductibles and co-insurance amounts for Medicare Part B covered drugs and other Medicare covered services with the exception of those covered under Part D.

518.15.5 Children in Foster and Adoptive Placement

Children in state custody and entered into foster, residential, or adoptive placements may be Medicaid eligible and receive a medical identification card. The eligibility number usually begins with "039." Drug claims may be submitted online through the pharmacy POS system or on the approved paper claim form. Medicaid coverage rules apply.

518.15.6 Incarcerated Members

Medicaid members who are incarcerated are restricted from coverage of pharmacy benefits until they are released from the correctional system. Claims submitted with dates of service during a period of incarceration will deny. If the member has been released before the restriction is updated, positive identification is required. A call to the pharmacy prior authorization vendor help desk must be made to request an override.

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518.16 PHARMACY SERVICES FOR NON-MEDICAID INDIVIDUALS

Individuals who do not qualify for the Medicaid program may have pharmacy coverage under other Federal or state-funded programs. These individuals do not receive medical identification cards, but may receive a letter or other form of eligibility authorization.

518.16.1 Limited Pharmacy Services or Ryan White Program

The Limited Pharmacy Services program is funded under Part B of the Ryan White HIV/AIDS Treatment Extension Act in West Virginia, and claims are processed through the BMS claims processing system. The program assists eligible persons with HIV infection in obtaining drugs covered by the Limited Pharmacy Services formulary. To be eligible for the Limited Pharmacy Services program, a person must meet the following criteria:

- Be an HIV infected resident of West Virginia;
- Have family income less than 400% of the Federal poverty level (FPL);
- Not be eligible for other forms of reimbursement such as Medicaid or full insurance coverage; and
- Have completed the Limited Pharmacy Services and Medicaid application at their local DHHR county office.

Limited Pharmacy Services participants do not receive a medical identification card, but do receive a letter that verifies eligibility and includes their identification number with a prefix of "69." All claims except those for vaccines may be submitted online through the pharmacy POS system or by using the approved paper claim form. Covered drugs are limited to a 30-day supply. Claims must be submitted within one year from the date of service. Formulary drugs must be dispensed in generic form if available. Brand-name drugs that have generic equivalents require prior authorization. There are no co-payment requirements for this program. Limited Pharmacy Services program may cover co-pays for eligible residents who are covered by insurance or Medicare Part D. Claims for vaccines must be submitted on the approved pharmacy paper claim form and mailed to ATF, PO Box 6360, Wheeling, West Virginia 26003. Certain drugs may require prior authorization and emergency supplies of these drugs may not be dispensed. Please refer to the BMS website for the Limited Pharmacy Services formulary. More information regarding Limited Pharmacy Services is available at the DHHR Office of Epidemiology and Prevention Services website or by calling the local AIDS Task Force.

518.16.2 Children with Special Health Care Needs (CSHCN)

Pharmacy services are available for certain children under 21 years of age receiving medical care under the Children with Special Health Care Needs (CSHCN) program. Services are not limited to children of families receiving public assistance grants. Coverage is established by the CSHCN program. These members do not receive a medical identification card. An identification number with a prefix of "99" is assigned. Claims may be submitted online using the pharmacy POS system or by using the approved paper claim form. Policy questions regarding this program shall be directed to CSHCN.

518.16.3 Individuals Eligible for Immunosuppressant or Antipsychotic Medications

Certain individuals who are not eligible for Medicaid services may be eligible for coverage of immunosuppressant or antipsychotic medications using all state funds. Eligibility for these services is

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determined at the individual's local county DHHR office. A six-month eligibility period is established, and it is the member's responsibility to reapply for these services. No identification card will be issued. Medicaid receives a written communication from the Division of Family Assistance defining the drug(s) that will be covered for a particular individual. A letter including the services to be covered and the individual's identification number, prefix "39", will be forwarded to the pharmacy provider and the individual. Claims for these services may be submitted online through the pharmacy POS system or on the approved paper claim form. Medicaid coverage rules apply to these claims. Some individuals may also be eligible for coverage of immunosuppressant drugs by Medicare Part B. Medicare must be billed first. This state program will pay co-insurance and deductible amounts on Medicare Part B crossover claims only. All other Medicare eligible individuals must pursue coverage of immunosuppressant drugs and antipsychotic medications through their Part D plans.

518.16.4 James "Tiger" Morton Catastrophic Illness Fund

Certain individuals who are not eligible for Medicaid services may be eligible for coverage of selected medications using state funds through the James "Tiger" Morton Catastrophic Illness Fund. These individuals will not have an identification card and coverage will be communicated to the pharmacy provider on a case-by-case basis. Claims for these services must be submitted using the approved paper claim form.

518.16.5 Emergency Medical Assistance or Other State Programs

Certain individuals who are not eligible for Medicaid services may be eligible for emergency medical assistance or other pharmacy services using state funds. These individuals will present a letter to the pharmacy provider listing particular drug(s) to be covered. A prefix of "15" or "38" along with the respective county code will be noted on the authorization letter to identify the eligible individual. Claims for these services must be submitted using the approved paper claim form with a copy of the eligibility letter attached.

518.16.6 Juvenile Services

Incarcerated minors have pharmacy services coverage through Juvenile Services. A letter of eligibility will be presented to the pharmacy which includes the individual's identification number beginning with prefix "17". Claims for these services may be submitted through the online POS system or by using the approved paper claim form. Medicaid coverage rules apply.

518.16.7 Adult Family Care and Protective Services

Children and adults receiving protective services as a result of abuse and/or neglect or other individuals in need of assistance may be provided limited eligibility for state-funded services. A Special Medical Authorization Letter is issued as needed by the DHHR field staff. This letter specifies the individual, the medical provider authorized to provide services, the services authorized and the coverage period. An identification number for use in billing the services is also provided. Pharmacy claims for these individuals may be submitted online or on the approved paper claim form. Medicaid coverage rules apply.

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518.17 DENIALS DUE TO ELIGIBILITY ISSUES

If an online denial occurs due to eligibility problems and the member presents a valid medical identification card or other proof of eligibility, the pharmacist should take the following steps:

- Dispense the prescription for valid and covered services, and
- Obtain proof of eligibility

Choose one of two options:

1. Resubmit the claim online at a later date, using the original date of service; or
2. Submit the claim on the approved paper claim form and attach a copy of the valid medical identification card or other proof of eligibility. Mail these claims to:

Gainwell Technologies
Pharmacy Claims
Post Office Box 3765
Charleston, West Virginia 25327-3709

518.18 BILLING PROCEDURES

Claims for prescribed drugs dispensed to Medicaid members may be submitted electronically using the POS system or on paper claim forms. Claims must be filed within 12 months from the date of service.

Submitting claims via electronic media offers the advantage of speed and accuracy in processing. All claims, regardless of method of submission, are subject to DUR edits, prior authorization, and other Medicaid requirements.

Medications must be dispensed at the facility from which the drug products are prepared, and the services rendered.

Claims must accurately report the National Drug Code (NDC) dispensed, the number of units dispensed, days' supply, and other required data for claims processing. Use of an incorrect NDC or inaccurate reporting of a drug quantity will cause the BMS to report false data to drug manufacturers when billed for drug rebates. The BMS will recover payments made on erroneous claims discovered during dispute resolution with drug manufacturers or during claim reviews. Pharmacies are required to submit documentation for purchases of drugs reimbursed by the BMS upon request.

518.18.1 Point-of-Sale (POS) System

Currently, online processing for Medicaid pharmacy claims is available for all pharmacies using NCPDP Version D.0. The provider must complete and submit the provider trading partner agreement prior to use of POS submission for claims.

The Pharmacy POS User Guide provides complete billing instructions for the POS system. The Pharmacy POS NCPDP Version D.0 Vendor Specification Document provides specifications and information for switch vendors. These documents and other billing information are available on the fiscal agent website.

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518.18.2 National Council on Prescription Drug Programs (NCPDP) Payer Sheet

West Virginia Medicaid accepts pharmacy POS claims submitted using NCPDP Version D.0 or Batch Version 1.1. According to the NCPDP accepted standards, some fields are required, optional, or conditional. The Pharmacy POS NCPDP Version D.0 Vendor Specification Document and the West Virginia Medicaid payer sheet are available on the BMS website.

518.18.3 Paper Claim Submission for Pharmacy Services

Pharmacies have the alternative of submitting a manual claim using a paper claim form, when necessary. The Universal Claim Form (UCF) provides a standard format for paper submission of drug claims to Medicaid. The UCF adheres to the data elements found in the NCPDP Telecommunication Standard and Data Dictionary. **Medicaid will not supply these forms to providers**.

518.18.4 Claim Reversals

Pharmacy claims submitted by POS cannot be adjusted. To correct information submitted on a POS claim, the claim must be reversed online and then resubmitted using the corrected information. There is currently no paper reversal claim form. If a paper claim submission requires corrections, the pharmacy Help Desk must be contacted.

518.18.5 Pharmacy Identification Number

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the use of the National Provider Identifier (NPI) as the standard for identifying covered healthcare providers, including pharmacies. Pharmacies must use their NPI number on electronic submissions for reimbursement of pharmacy claims. NCPDP numbers will no longer be accepted on electronic claims. The NPI or NCPDP number will continue to be used on the approved paper claim form. For additional NPI information or to complete an NPI application, visit the CMS website.

518.18.6 Prescriber Identification Number

The NPI is required for the prescriber identification information on electronic POS claims. Either the DEA number or the NPI is allowed on the manual claim form. Only prescribing NPI entities are permissible. Claims submitted with non-prescribing NPI entities will be denied, including but not limited to pharmacies, laboratories, hospitals, and dialysis centers.

518.18.7 National Drug Codes (NDC)

All pharmacy claims submitted to West Virginia Medicaid must identify the 11-digit NDC printed on the stock container in which the drug was purchased. **Using the correct NDC is extremely important in order to avoid disputes with manufacturers for rebate payments**. For example, if a drug is purchased in a 5000-count bottle and repackaged in 100-count bottles prior to dispensing, submitting the NDC for a 100-count bottle is not permitted. Most drugs distributed by repackagers are not covered by Medicaid because the repackager has not signed a rebate agreement with CMS. A pharmacy may not dispense a repackager's drug and then bill Medicaid using the original manufacturer's NDC.

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518.18.8 Decimal Units

The Medicaid pharmacy system is capable of accepting quantity amounts which contain decimal units. Pharmacy claims must be submitted using the standard units, including any decimal increments. Units must not be rounded up or down. Rounding results in over or under payments and creates inaccurate invoicing to manufacturers for the drug rebates owed to the state.

518.18.9 Days' Supply

For non-controlled substances, each Medicaid-covered prescription is limited to a maximum dispensed supply of 90 days, with some exceptions to accommodate packaging that cannot be broken.

All controlled substances are limited to a maximum supply of 34 days, with no exceptions.

If the member has coverage by a third party and is required to obtain up to a 93-day supply, coverage will be provided beyond the standard 90-day supply limit.

The pharmacist is responsible for submitting prescription claims up to the appropriate limit. Should a prescription be written for a quantity that is greater than the allowed limit, the pharmacist is responsible for notifying the prescriber of this limit and asking permission to reduce the number of units to be dispensed.

If the prescriber does not allow the prescription quantity to be reduced to the maximum Medicaid limit, the member shall be told that the cost of the prescription is his/her responsibility. The pharmacist must enter the actual day supply written on the prescription when attempting to fill a claim. Artificially adjusting the amount filled in order to meet Medicaid requirements when the prescription was written to last longer constitutes a false claim and is subject to recovery of the paid amounts.

518.18.10 Compounded Prescriptions

A compounded prescription is defined as any prescription requiring the combination of two or more substances, one of which must be a covered legend drug. The covered legend drug must be the first NDC submitted on a compounded prescription claim. The Drug Efficacy Study Implementation (DESI) drugs or non-covered drugs **not appearing as the first NDC** in a compounded product will not cause the claim to deny, but those ingredients will not be included in the reimbursement. Over-the-counter ancillary products will be reimbursed provided the drug is manufactured by a company which participates in the Federal drug rebate program. A compound may contain up to 25 ingredients.

Products such as suppository molds and other items identified as supplies included in a compounded prescription will not be reimbursed by West Virginia Medicaid.

Billing compounded prescriptions follows NCPDP Version D.0 guidelines. For a compounded prescription, an additional $6.00 will be added to the dispensing fee. Compounding is considered an integral part of the prescription services and must not be billed separately. More information can be found in the User Guide, located using the BMS link to the fiscal agent website.

518.18.11 Abuse and Inappropriate Utilization

The following practices constitute abuse and inappropriate utilization, and are subject to audit:

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- Excessive fees (commonly known as prescription splitting or incorrect or excessive dispensing fees): Billing inappropriately in order to obtain dispensing fees in excess of those allowed by:
  - Supplying medication in amounts less than necessary to cover the period of the prescription; and/or
  - Supplying multiple medications in strengths less than those prescribed to gain more than one dispensing fee.
- Excessive filling: Billing for an amount of a drug or supply greater than the prescribed quantity.
- Prescription shorting: Billing for drug or supply greater than the quantity actually dispensed.
- Substitution to achieve a higher price: Billing for a higher priced drug than prescribed even though the prescribed lower priced drug was available.
- Automated refills and automatic shipments are prohibited. Medicaid does not pay for any prescription without an explicit request from a member or the member's responsible party, such as a caregiver, for each refilling event. The pharmacy provider shall not contact the member in an effort to initiate a refill unless it is part of a good faith clinical effort to assess the member's medication regimen. The possession, by a provider, of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription. Members or providers cannot waive the explicit refill request and enroll in an electronic automatic refill program. Any prescriptions filled without a request from a member or his or her responsible party will be subject to recovery. Any pharmacy provider with a policy that includes filling prescriptions on a regular date or any type of cyclical procedure will be subject to audit, claim recovery or possible suspension or termination of the provider agreement.

518.18.12 Lost/Stolen Medications

For members who report to the pharmacy that their medications have either been lost or stolen, the following procedure applies:

- The member must supply the pharmacy with a police report for stolen controlled substances; the pharmacy must retain a copy for audit purposes.
- The prescribing practitioner must agree that the lost or stolen medication shall be replaced.
- Lost/stolen medication approvals are limited to one occurrence per drug per year.
- In cases of natural disaster, the BMS will address the situation on a case-by-case basis.

518.18.13 Wasted Medication

Members who have wasted medication due to improper use or storage may have their medication replaced. This will be determined on a case-by-case basis. Members shall be properly instructed on the storage and use of their medications and any special delivery device used to administer their medications. Requests for replacement of wasted medications due to improper storage or delivery by the pharmacy or improper handling by the administrating provider will be denied.

518.18.14 False Claims

Pharmacies are prohibited from submitting false claims to test for drug coverage, member eligibility, or for other purposes. Claims of this type result in false member drug history records and may result in the member or prescriber being included in lawsuits or reviews in error. All claims submitted for reimbursement must be the result of actual prescription requests.

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518.19 REIMBURSEMENT

Federal Medicaid regulations governing pharmacy services establish upper limits for payment; i.e., the payment shall be based on the lower of the allowable cost of the drug, plus a dispensing fee or the provider's usual and customary charge to the general public.

Reimbursement for outpatient drugs is limited to products manufactured by companies participating in the Federal Drug Rebate program.
If a provider accepts the member as a Medicaid patient, the provider must bill West Virginia Medicaid for covered services and must accept the Medicaid reimbursement amount as full payment. No charge may be billed to a Medicaid member for a covered service unless a co-payment is applicable by regulation. However, the provider may bill the member for services not covered by the West Virginia Medicaid program if the parties agree in writing to this payment arrangement before such services are rendered. Please refer to *Chapter 300, Provider Participation Requirements* for more information about billing Medicaid members.

518.19.1 Ingredient Cost

Reimbursement for covered outpatient drugs is based on the following methodology. Reimbursement for brand (single source) and generic (multiple source) drugs shall be **the lower of**:

1. **National Average Drug Acquisition Cost (NADAC) plus the professional dispensing fee.** The NADAC is based on the retail price survey of pharmacies and focuses on the average acquition cost of retail community pharmacies. The NADAC represents the average acquisition cost of pharmacies surveyed and includes independent retail community pharmacies and chain pharmacies. The prices are updated and loaded into the West Virginia Medicaid Pharmacy POS claims system on a weekly basis. To view the NADAC weekly files and the NADAC Week to Week File Comparison, please visit the Pharmacy Drug Pricing Page on the CMS website.
2. **If no NADAC is available, then Wholesale Acquistion Cost (WAC) plus 0% plus the professional dispensing fee.**
3. **The Federal Upper Limit (FUL) as supplied by CMS plus the professional dispensing fee.** The FUL is calculated at no less than 175% of the weighted average (as determined on the basis of utilization) of the most recently reported monthly Average Manufacturer's Price (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. In situations where the FUL is less than the community pharmacies' average cost, the FUL is established using a higher multiplier so the FUL amount will equal the most current average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs. This methodology is codified in 42 CFR §447.514 (b)(1) and (2).

   EXCEPTION: The FUL shall not apply in any case where a physician certifies in his/her own handwriting that, in his/her medical judgment, a specific brand is medically necessary for a particular patient. A notation like "brand medically necessary" written by the physician on the prescription above his/her signature is an acceptable certification. A procedure for checking a box on a form will not constitute an acceptable certification. All such certified prescriptions must be maintained in the pharmacy files and are subject to audit by the BMS.

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4. **The State Maximum Allowable Cost (SMAC) plus the professional dispensing fee.** The SMAC rate is applied to all brand and generic drug products in each drug group. Non-AB rated drugs recognized by national drug information suppliers as comparable to a particular brand drug are subjected to the same SMAC rate applicable to the brand and "AB" rated generic drugs of the same chemical composition, package size, dose, and drug group.

   The determination of which drugs will be part of the SMAC list will be designated by BMS. Drugs no longer available at SMAC prices are removed. New drugs will be added to the SMAC list as they are identified. The SMAC vendor on behalf of BMS will continually monitor pharmacies and industry information and make changes to the SMAC to reflect current pharmaceutical market conditions. The SMAC list may be accessed on the BMS website. Comments and questions regarding the SMAC list can be made to the vendor.

   EXCEPTION: The SMAC shall not apply in any case where a physician certifies in his/her own handwriting that, in his/her medical judgment, a specific brand is medically necessary for a particular patient. A notation like "brand medically necessary" written by the physician on the prescription above his/her signature is an acceptable certification. A procedure for checking a box on a form will not constitute an acceptable certification. All such certified prescriptions must be maintained in the pharmacy files and are subject to audit by the BMS.

5. **The submitted ingredient cost plus the professional dispensing fee.**

6. **The provider's usual and customary charges to the general public, including any sale price in effect on the date of dispensing.**

518.19.2 Application of Dispensing Fee

- For covered legend and over-the-counter drugs, a professional dispensing fee of $10.49 per prescription will be added to the NADAC (or WAC when NADAC is not available), FUL, SMAC, or submitted ingredient cost.
- Pharmacies participating in the 340B program will receive a dispensing fee of $10.49 per prescription. These pharmacies are required to submit their Actual Acquisition Costs (AAC) to Medicaid.
- For a compounded prescription, an additional $6.00 will be added to the dispensing fee. A compounded prescription is defined as any prescription requiring the combination of two or more substances, one of which must be a legend drug. Compounding is considered an integral part of the prescription services and must not be billed separately.
- The dispensing fee may only be paid once every 30 days per drug entity for members residing in ICF/IID or nursing facilities.
- Claims paid on the basis of the usual and customary charge to the general public do not include an additional dispensing fee.

518.19.3 Co-Payments

A co-payment is required for each prescription with the exception of prescriptions for members excluded by regulation and/or those items specifically excluded from the co-payment requirement. The member co-

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payment per prescription will be deducted from the allowed total charge to determine the amount payable for each prescription billed to the program. The deduction will apply as follows:

- If the allowed total charge is $5.00 or less, there is no co-payment per prescription.
- If the allowed total charge is $5.01 through $10.00, the co-payment is $.50 per prescription.
- If the allowed total charge is $10.01 through $25.00, the co-payment is $1.00 per prescription.
- If the allowed total charge is $25.01 through $50.00, the co-payment is $2.00 per prescription.
- If the allowed total charge is $50.01 or more, the co-payment is $3.00 per prescription.

The following populations and services are exempt from copays:

- Family planning services and supplies
- Members in long-term care facilities (i.e., nursing facilities or ICF/IID)
- Pregnant women including 60 days post-partum
- Native Americans and Alaska natives
- Members under age 21
- Members receiving Hospice services
- Members receiving Medicaid Waiver services, or covered through the Breast and Cervical Cancer Treatment program
- Three-day emergency supplies
- Diabetic testing supplies and syringes/needles
- BMS approved home infusion supplies
- POS-approved vaccines
- Agents for smoking cessation including nicotine replacement drugs, buproprion (Zyban) and Chantix

Please refer to *Chapter 600, Reimbursement Methodologies* regarding maximum quarterly out-of-pocket limits.

Members have been informed of co-payment requirements and the exclusions from co-payment. Federal regulations stipulate that no provider may deny services to an eligible individual in situations when the member is unable to pay co-payment charges. However, this does not preclude the member's liability for payment of the co-payment due the provider.

Providers may bill the member or refer the member to a collection agency, etc., in the same manner that the provider initiates collections from private pay customers.

Providers are prohibited from advertising or soliciting business by waiving members' co-payment responsibility. Members are responsible for applicable copays, and providers are prohibited from waiving the copay requirement to attract business from other providers.

518.19.4 Third-Party Liability (TPL) or Coordination of Benefits (COB)

Medicaid is the payer of last resort. The TPL ensures that Medicaid is the last payer to reimburse for covered Medicaid services. In particular, Medicaid participating providers must always seek reimbursement from other liable resources, including private or public insurance entities. Before submitting

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claims to Medicaid, providers must pursue all requirements of the primary insurer including, but not limited to prior authorization, brand name justifications, and DUR events.

Federal regulations require that state Medicaid administration identify any third-party resource available to meet the medical expenses of a member. The "third party" may be an individual, institution, corporation, or a public/private agency liable for all or part of the member's medical costs; e.g., private health insurance, United Mine Workers of America (UMWA) benefits, Veterans Administration benefits, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Medicare, Hospice, etc. Additionally, no Medicaid reimbursement may be made if the service is the responsibility of a public or private Workers Compensation Plan.

Medicaid covered drugs which currently require a prior authorization from BMS will continue to require a prior authorization if a primary insurer approves that service, and Medicaid reimburses any part of the cost.

Medicaid co-payment is still required, if applicable, for claims considered by third party payers and reimbursed by the BMS.
Chapter 600, Reimbursement Methodologies, of the BMS Provider Manual provides more detailed information regarding Third Party Liability.

More information regarding the billing of COB for NCPDP Version D.0 can be found on the fiscal agent website.

518.19.5 Medicare-Covered Drugs and Supplies, Part B

Pharmacies are required to verify and pursue members' Medicare coverage and to submit pharmacy claims to Medicare for those pharmacy services covered by Medicare. Pharmacies can submit claims to Medicare Part B either on the acceptable paper claim form (CMS 1500) or electronically. Once the Medicare claim has been approved and processed, Medicare will automatically submit the balance of the claim as a "crossover" to Medicaid electronically, if the provider's Medicare number is on file with Medicaid. These claims should not be submitted to Medicaid separately if the claim crossed over from Medicare.

For Dually Eligible members and Qualified Medicare Beneficiary (QMB), if the service is covered by Medicare and Medicaid, Medicaid will pay the lesser of:

- The full coinsurance and deductible amounts due, based upon the Medicare allowed amount, or
- Medicaid's maximum allowable fee for that service minus the amount paid by Medicare.

For QMB, if the service is not covered or is denied by Medicare, Medicaid will not reimburse.

Drugs that are not covered by Medicare Part B may be covered by Medicare Part D. Medicaid does not reimburse for Part D co-payments.

518.19.6 Medicare-Covered Drugs, Part D

Dual eligible members have prescription drug coverage through Medicare Part D. Medicaid is not responsible for covering pharmacy benefits for these individuals, except for drugs in the Medicare excluded categories. Dual eligible members are limited to coverage of Medicare Part D excluded drugs. Coverage is limited to drugs that are covered for other Medicaid eligible members in the following classes:

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- Barbiturates (if not for treatment of epilepsy, cancer, or mental health disorder, as Medicare Part D covers these conditions)
- OTC medications
- Agents for the symptomatic relief of cough and cold symptoms
- Prescription vitamins and minerals

Medicaid does not reimburse for Medicare Part D co-payments. Medicaid does not pay as the secondary payer on Medicare Part D covered drugs.

518.19.7 In-Home Parenteral Therapy (IHPT) Billing and Reimbursement Via Point-of-Sale

Billing for IHPT claims is accomplished through NCPDP Version D.0 electronic or 1.1 batch (paper claim) system. Instructions for the processing of claims are found in the general pharmacy manual information.

The active ingredient(s) for each prescription is/are to be billed using the NDC and its respective unit of use. The drug portion of IHPT will be reimbursed online according to the current reimbursement policy. The codes used for the reimbursement of compounding services are inclusive of, but not limited to, diluents for reconstitution, IV fluids, and other supplies used in the compounding process.
Billing shall correspond to those items and fees reflecting therapy for a duration of a maximum of 34 days as prior authorized by the Pharmacy prior authorization vendor. If the order is discontinued, any billing for agents that have not been delivered to the member must be reversed.

- **Pre-mixed Solutions or products requiring no compounding:** After receiving prior authorization, prescriptions for items which are dispensed with no compounding requirements shall be submitted for payment via POS or approved paper claim form using the NDC number of the product and the quantity dispensed. Reimbursement will be made using the established retail reimbursement policy. Do not use the NCPDP compound indicator.
- **IV Drugs Requiring Compounding:** Products for IHPT requiring compounding involve billing in multiple parts. Drug components shall be submitted online or on the approved paper claim form using the actual NDC's that were used and quantity of each drug component, as approved by the Pharmacy prior authorization vendor. Use the NCPDP compound indicator when the product includes multiple agents. **Please note:** reimbursement for the diluting agent is included in the compounding fee and shall not be billed as a component of the compounded IHPT product if reimbursement for a compounding fee is requested.
- **Compounding Fee:** The compounding fee which includes all components of the prescription compounding, such as sterile water, alcohol swabs, IV fluids, needles/syringes, etc., and professional services shall be submitted online or on the approved paper claim form. The authorization for reimbursement of the compounding fee will be issued from the Pharmacy prior authorization vendor upon receipt of a copy of the signed order from the prescribing physician. Do not use the NCPDP compound indicator.
- **Units Dispensed:** Units are defined by First Data Bank product classification. In general, if a drug requires reconstitution, the units submitted will be the number of vials. For example, a 2-gm vial of cephazolin is submitted as a quantity of "1" for each vial. If the drug or component is available in solution, the units are submitted in milliliters. For example, a 2ml vial of gentamicin injection (80mg/vial) is submitted as "2" for each vial. The actual amount used in compounding shall be

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submitted. Wastage shall be kept to a minimum. The units dispensed must match the amount prior authorized by the pharmacy prior authorization vendor.

The pharmacy prior authorization vendor Help Desk is available to assist providers with questions regarding proper unit billing. In all cases, the amount and duration of therapy for which the BMS is billed must match those ordered by the physician and delivered to the member.

- **Brand Name Justification:** If a drug being dispensed is a product for which a generic equivalent exists, the generic must be dispensed. The use of brand name products must be justified, as referenced in the general pharmacy instructions.
- **Supplies:** Please refer to *Chapter 506, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)* for coverage policy and billing instructions for supplies associated with IHPT.

REFERENCES

West Virginia State Plan references pharmacy services at sections 3.1-A(12)(a), 3.1-B(12)(a), supplement 2 to attachments 3.1-A and 3.1-B(12)(a) and reimbursement at 4.19-B(12)(a). The Plan also references vaccine administration by a pharmacist (other licensed practitioner) at supplement 2 to attachments 3.1-A and 3.1-B(6)(d)(3) and reimbursement at 4.19-B(6)(d)(3), 4.18-A outlines required copayments.

GLOSSARY

Definitions in *Chapter 200, Definitions and Acronyms* apply to all West Virginia Medicaid services, including those covered by this chapter. Definitions in this glossary are specific to this chapter.

340B Program: A Federal program administered by the Health Resources and Services Administration (HRSA) whereby certain designated facilities purchase prescription medications at deep discounts, allowing these facilities to offer some medications to their patients at greatly reduced prices.

Dispense As Written (DAW): A numerical value used by providers to explain the dispensing of a brand-name product instead of a generic one.

Drug Efficacy Study and Implementation Program (DESI): Drugs determined by the Food and Drug Administration as lacking substantial evidence of effectiveness.

End Stage Renal Disease (ESRD): The stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

First Data Bank (FDB): A database company for drug pricing and drug utilization review (DUR) edits.

Federal Drug Rebates: Payments made by pharmaceutical manufacturers to the states for drugs dispensed to Medicaid members.

Federal Upper Limit (FUL): Maximum allowable cost established by CMS for certain prescribed drugs.

Home IV: Intravenous medications administered in the home, provided by specialized pharmacies, which require the services of a nurse or trained caregiver.

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In-Home Parenteral Therapy (IHPT): The parenteral administration of fluids, drugs, chemical agents, or nutritional substances to members in the home setting.

Lock-In: Program administered through the retrospective DUR process to limit members to the use of one pharmacy provider.

Multi-Source Drugs: Drugs that are marketed or sold by two or more manufacturers or labelers.

National Provider Identifier (NPI): A standard unique healthcare provider identification number mandated by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Parenteral: All routes of administration of substances other than gastrointestinal.

Pharmaceutical and Therapeutics Committee (P&T Committee): An advisory body that recommends drugs to West Virginia Medicaid for inclusion or exclusion relating to the PDL.

Pharmacy Prior Authorization Vendor: Agency designated by the BMS for prior authorizing prescription drugs.

Qualified Medicare Beneficiary (QMB): A Medicaid program for beneficiaries who need help in paying for Medicare services. The beneficiary must have Medicare Part A and limited income and resources. For those who qualify, the Medicaid program pays Medicare Part A premiums, Part B premiums, and Medicare deductibles and coinsurance amounts for Medicare services.

Retrospective Drug Utilization Review (DUR): Review of member drug history records against predetermined standards to improve quality of healthcare and to educate physicians and pharmacists on common drug therapy issues.

Single-Source Drug: A drug that is available from only one manufacturer.

State MAC (SMAC): Maximum allowable cost for drug products or supplies established by the state Medicaid agency.

Supplemental Drug Rebate: A payment from a pharmaceutical manufacturer, negotiated by the state, in addition to the Federal rebate.

CHANGE LOG

REPLACE	TITLE	EFFECTIVE DATE
Entire Chapter	Pharmacy Services	October 1, 2015

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CHAPTER 518 PHARMACY SERVICES

Entire Chapter	Changes were made to: 518.1.9 Brand Name versus Generic Drugs 518.1.10 Pharmacies Participating in the 340B Program 518.15.2 Medicaid Members Enrolled in Managed Care Organizations 518.19.1 Ingredient Cost 518.19.2 Application of Dispensing Fee	July 20, 2018
Entire Chapter	Changes were made to: 518.1.6 Tobacco Cessation Program 518.1.7 Buprenorphine-Naloxone (Suboxone®) / Buprenorphine (Subutex®) Coverage (PA and Lock-In requirements were removed 518.3 Non-Covered Services 518.10 Pharmacies Participating in the 340B Program 518.12 Reporting of Cash Payments (also renamed to "Cash Payments")	December 1, 2020
Entire Chapter	Changes were made to: 518.15.3 Medicaid Members With End Stage Renal Disease (ESRD)	February 4, 2021
Entire Chapter	518.16.1 Limited Pharmacy Services or Ryan White Program claims updated.	July 28, 2021

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- Prior authorization for a non-preferred agent in any class will be given only if there has been a trial of the preferred brand/generic equivalent or preferred formulation of the active ingredient, at a therapeutic dose, that resulted in a partial response with a documented intolerance.
- Prior authorization of a non-preferred isomer, pro-drug, or metabolite will be considered with a trial of a preferred parent drug of the same chemical entity, at a therapeutic dose, that resulted in a partial response with documented intolerance or a previous trial and therapy failure, at a therapeutic dose, with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis. The required trial may be overridden when documented evidence is provided that the use of these preferred agent(s) would be medically contraindicated.
- Unless otherwise specified, the listing of a particular brand or generic name includes all legend forms of that drug. OTC drugs are not covered unless specified.
- PA criteria for non-preferred agents apply in addition to general Drug Utilization Review policy that is in effect for the entire pharmacy program, including, but not limited to, appropriate dosing, duplication of therapy, etc.
- The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization.
- Quantity limits may apply. Refer to the Limits List on the BMS Website by clicking the hyperlink.
- Unless otherwise indicated, non-preferred combination products require medical reasoning beyond convenience or enhanced compliance as to why the clinical need cannot be met with a preferred agent or combination of preferred single-ingredient agents.
- Acronyms
  - CL - Requires clinical PA. For detailed clinical criteria, please go to the PA criteria page by clicking the hyperlink.
  - NR – Denotes a new drug which has not yet been reviewed by the P & T Committee. **These agents are available only on appeal to the BMS Medical Director.**
  - AP - Non-preferred and selected preferred drugs, where indicated, are subject to auto-PA criteria. See PA criteria column.

Exhibit
FL 11

EXHIBIT
6

BUREAU FOR MEDICAL SERVICES
WEST VIRGINIA MEDICAID
PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA
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CLASSES CHANGING	Status Changes	PA Criteria Changes	New Drugs
ANTIHEMOPHILIA FACTOR AGENTS			XXX
ANTIPARKINSONS AGENTS			XXX
GLUCOCORTICOIDS, INHALED			XXX
GUANYLATE CYCLASE STIMULATORS			XXX
HYPOGLYCEMICS, INSULIN AND RELATED AGENTS	XXX		XXX
IMMUNOSUPPRESSIVES, ORAL			XXX
LAXATIVES AND CATHARTICS			XXX
MULTIPLE SCLEROSIS AGENTS			XXX
OPHTHALMICS, ANTI-INFLAMMATORIES- IMMUNOMODULATORS			XXX
PAH AGENTS, PROSTACYCLINS			XXX
STEROIDS, TOPICAL			XXX
SPINAL MUSCULAR ATROPHY AGENTS		XXX	XXX

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THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
ACNE AGENTS, TOPICAL[AP]		
CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of one (1) preferred retinoid and two (2) unique chemical entities in two (2) other subclasses, including the generic version of the requested non-preferred product, before they will be approved, unless one (1) of the exceptions on the PA form is present. In cases of pregnancy, a trial of retinoids will *not* be required. For members eighteen (18) years of age or older, a trial of retinoids will *not* be required. Acne kits are non-preferred. **Specific Criteria for sub-class will be listed below.** NOTE: Non-preferred agents in the Rosacea sub-class are available only on appeal and require at least a 30-day trial of all preferred agents in that sub-class.		
	ANTI-INFECTIVE	
CLINDAGEL (clindamycin) clindamycin lotion, medicated swab, solution erythromycin gel, solution	AMZEEQ FOAM (minocycline) CLEOCIN-T (clindamycin) CLINDACIN ETZ kit, medicated swab (clindamycin) CLINDACIN P (clindamycin) CLINDACIN PAC (clindamycin) clindamycin gel, foam dapsone ERYGEL (erythromycin) erythromycin medicated swab EVOCLIN (clindamycin) FABIOR (tazarotene) KLARON (sulfacetamide) OVACE/PLUS (sulfacetamide) sodium sulfacetamide 10% cleansing gel sulfacetamide	
	RETINOIDS	
DIFFERIN (adapalene) RETIN-A (tretinoin) RETIN-A MICRO (tretinoin)	adapalene AKLIEF CREAM (trifarotene) ALTRENO LOTION (tretinoin) ARAZLO (tazarotene) ATRALIN (tretinoin) AVITA (tretinoin) tazarotene cream tretinoin cream, gel tretinoin gel micro	**In addition to the Class Criteria:** PA required for members eighteen (18) years of age or older.
	KERATOLYTICS	

benzoyl peroxide cleanser Rx & OTC, 10% cream OTC, gel Rx & OTC, lotion OTC, wash OTC PANOXYL-4 OTC (benzoyl peroxide)	BENZEFOAM benzoyl peroxide) BP 10-1 (benzoyl peroxide) BPO (benzoyl peroxide)	
COMBINATION AGENTS		
ACANYA (clindamycin phosphate/benzoyl peroxide) BENZAMYCIN PAK (benzoyl peroxide/ erythromycin) benzoyl peroxide/clindamycin gel (generic DUAC only) EPIDUO (adapalene/benzoyl peroxide)* EPIDUO FORTE (adapalene/benzoyl peroxide)* ONEXTON (clindamycin phosphate/benzoyl peroxide) sulfacetamide sodium/sulfur suspension ZIANA (clindamycin/tretinoin)*	adapalene-benzoyl peroxide* AVAR/-E/LS (sulfur/sulfacetamide) BENZACLIN GEL (benzoyl peroxide/ clindamycin) benzoyl peroxide/clindamycin gel (all generics other than DUAC) benzoyl peroxide/urea clindamycin phosphate/benzoyl peroxide (generic Acanya) clindamycin-tretinoin gel* erythromycin/benzoyl peroxide NEUAC (clindamycin phosphate/benzoyl peroxide) SSS 10-4 (sulfacetamide /sulfur) SSS 10-5 foam (sulfacetamide /sulfur) sulfacetamide sodium/sulfur cloths, lotion, pads sulfacetamide/sulfur wash/cleanser sulfacetamide/sulfur wash kit sulfacetamide sodium/sulfur/ urea SUMADAN/XLT (sulfacetamide/sulfur) SUMAXIN/TS (sulfacetamide sodium/sulfur)	**In addition to the Class Criteria:** Non-preferred combination agents require thirty (30) day trials of the corresponding preferred single agents before they will be approved. *PA required for combination agents with Retinoid products for members eighteen (18) years of age or older.
ROSACEA AGENTS		
FINACEA GEL (azelaic acid) MIRVASO GEL (brimonidine) metronidazole cream metronidazole gel 0.75% (NDCs 00115-1474-46, 00168-0275-45, 51672-4116-06, 66993-0962-45 only)	azelaic acid gel FINACEA FOAM (azelaic acid) ivermectin METROCREAM (metronidazole) METROGEL GEL (metronidazole) metronidazole lotion metronidazole gel (all other NDCs) NORITATE CREAM (metronidazole) RHOFADE (oxymetazoline) ROSADAN (metronidazole) SOOLANTRA CREAM (ivermectin) ZILXI (minocycline) foam	**Subclass criteria**: Non-preferred agents are available only on appeal and require evidence of 30-day trials of all chemically-unique preferred agents in the sub-class.

ALZHEIMER'S AGENTS[AP]

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

Prior authorization is required for members up to forty-five (45) years of age if there is no diagnosis of Alzheimer's disease.

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CHOLINESTERASE INHIBITORS		
donepezil 5 and 10 mg donepezil ODT	ARICEPT (donepezil) donepezil 23 mg* EXELON PATCH (rivastigmine) galantamine galantamine ER RAZADYNE ER (galantamine) Rivastigmine	*Donepezil 23 mg tablets will be authorized if the following criteria are met: 1. There is a diagnosis of moderate-to-severe Alzheimer's Disease **and** 2. There has been a trial of donepezil 10 mg daily for at least three (3) months and donepezil 20 mg daily for an additional one (1) month.
NMDA RECEPTOR ANTAGONIST		
memantine	memantine ER memantine solution NAMENDA (memantine) NAMENDA XR (memantine)*	*Namenda XR requires ninety (90) days of compliant therapy with Namenda.
CHOLINESTERASE INHIBITOR/NMDA RECEPTOR ANTAGONIST COMBINATIONS		
	NAMZARIC (donepezil/memantine)	Combination agents require thirty (30) day trials of each corresponding preferred single agent.

ANALGESICS, NARCOTIC LONG ACTING (Non-parenteral)[AP]

CLASS PA CRITERIA: Non-preferred agents require six (6) day trials of three (3) chemically distinct preferred agents **AND** a six (6) day trial of the generic form of the requested non-preferred agent (if available) before they will be approved, unless one (1) of the exceptions on the PA form is present. If no generic form is available for the requested non-preferred brand agent, then another generic non-preferred agent must be trialed instead. **NOTE: All long-acting opioid agents require a prior authorization for children under 18 years of age.** Requests must be for an FDA approved age and indication and specify previous opioid and non-opioid therapies attempted.

BUTRANS (buprenorphine) fentanyl transdermal 12, 25, 50, 75, 100 mcg/hr morphine ER tablets tramadol ER tablets (generic Ultram ER) XTAMPZA ER (oxycodone)	ARYMO ER (morphine sulfate) BELBUCA (buprenorphine buccal film)* buprenorphine patch (all labelers including 00093) CONZIP ER (tramadol) fentanyl transdermal 37.5, 62.5, 87.5 mcg/hr hydromorphone ER HYSINGLA ER (hydrocodone) hydrocodone ER capsule and tablet KADIAN (morphine) methadone** MORPHABOND ER (morphine sulfate) morphine ER capsules (generic for Avinza) morphine ER capsules (generic for Kadian) MS CONTIN (morphine) NUCYNTA ER (tapentadol)**** oxycodone ER OXYCONTIN (oxycodone) oxymorphone ER tramadol ER (generic Conzip ER)*** ULTRAM ER (tramadol) ZOHYDRO ER (hydrocodone)	*Belbuca prior authorization requires manual review. Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. **Methadone will be authorized without a trial of the preferred agents if a diagnosis of cancer is submitted. ***Tramadol ER (generic Conzip) requires a manual review and may be authorized for ninety (90) days with submission of a detailed treatment plan including anticipated duration of treatment and scheduled follow-ups with the prescriber. ****Nucynta requires six (6) day trials of three (3) chemically distinct preferred agents

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ANALGESICS, NARCOTIC SHORT ACTING (Non-parenteral)[AP]

CLASS PA CRITERIA: Non-preferred agents require six (6) day trials of at least four (4) chemically distinct preferred agents (based on the narcotic ingredient only), including the generic formulation of the requested non-preferred agent, before they will be approved, unless one (1) of the exceptions on the PA form is present.
NOTE: All tramadol and codeine products require a prior authorization for children under 18 years of age. Requests must be for an FDA approved age and indication and specify non-opioid therapies attempted.

APAP/codeine butalbital/APAP/caffeine/codeine codeine hydrocodone/APAP 2.5/325 mg, 5/325 mg, 7.5/325 mg,10/325 mg hydrocodone/APAP solution hydrocodone/ibuprofen hydromorphone tablets LORTAB SOLUTION (hydrocodone/acetaminophen) morphine oxycodone tablets, concentrate, solution oxycodone/APAP oxycodone/ASA pentazocine/naloxone tramadol tramadol/APAP	ABSTRAL (fentanyl) ACTIQ (fentanyl) butalbital/ASA/caffeine/codeine butorphanol DEMEROL (meperidine) dihydrocodeine/ APAP/caffeine DILAUDID (hydromorphone) fentanyl FENTORA (fentanyl) FIORICET W/ CODEINE (butalbital/APAP/caffeine/codeine) FIORINAL W/ CODEINE (butalbital/ASA/caffeine/codeine) hydrocodone/APAP 5/300 mg, 7.5/300 mg, 10/300 mg hydromorphone liquid, suppositories levorphanol LORCET (hydrocodone/APAP) LORTAB (hydrocodone/APAP) meperidine NORCO (hydrocodone/APAP) NUCYNTA (tapentadol) oxycodone capsules oxycodone/ibuprofen oxymorphone PERCOCET (oxycodone/APAP) ROXICODONE (oxycodone) ULTRACET (tramadol/APAP) VICOPROFEN (hydrocodone/ibuprofen)	Fentanyl buccal, nasal and sublingual products will only be authorized for a diagnosis of cancer and as an adjunct to a long-acting agent. These dosage forms will not be authorized for monotherapy. **Limits:** Unless the patient has escalating cancer pain or another diagnosis supporting increased quantities of short-acting opioids, all short acting solid forms of the narcotic analgesics are limited to 120 tablets per thirty (30) days. Longer-acting medications should be maximized to prevent unnecessary breakthrough pain in chronic pain therapy. Immediate-release tramadol is limited to 240 tablets per thirty (30) days.

ANDROGENIC AGENTS

CLASS PA CRITERIA: A non-preferred agent will only be authorized if one (1) of the exceptions on the PA form is present.

ANDRODERM (testosterone) ANDROGEL (testosterone) METHITEST (methyltestosterone) testosterone cypionate vial[CL] testosterone enanthate vial[CL]	ANDROID (methyltestosterone) FORTESTA (testosterone) JATENZO (testosterone undecanoate) methyltestosterone capsule NATESTO (testosterone) TESTIM (testosterone) TESTRED (methyltestosterone) testosterone gel VOGELXO (testosterone) XYOSTED (testosterone enanthate)

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ANESTHETICS, TOPICAL[AP]

CLASS PA CRITERIA: Non-preferred agents require ten (10) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

lidocaine	lidocaine/hydrocortisone	
lidocaine/prilocaine	LIDOTRAL CREAM (lidocaine)	
xylocaine	LIDOZION LOTION (lidocaine)	
	SYNERA (lidocaine/tetracaine)	

ANGIOTENSIN MODULATORS[AP]

CLASS PA CRITERIA: Non-preferred agents require fourteen (14) day trials of each preferred agent in the same sub-class, with the exception of the Direct Renin Inhibitors, before they will be approved, unless one (1) of the exceptions on the PA form is present.

ACE INHIBITORS

benazepril	ACCUPRIL (quinapril)	*Epaned will be authorized with a diagnosis of hypertension, symptomatic heart failure or asymptomatic left ventricular dysfunction provided that the patient is less than seven (7) years of age **OR** is unable to ingest a solid dosage form due to documented oral-motor difficulties or dysphagia.
captopril	ALTACE (ramipril)	
enalapril	EPANED (enalapril)*	
fosinopril	LOTENSIN (benazepril)	
lisinopril	moexipril	
quinapril	perindopril	
ramipril	PRINIVIL (lisinopril)	**Qbrelis solution may be authorized for children ages 6-10 who are unable to tolerate a solid dosage form. Qbrelis may also be authorized for older patients with clinical documentation indicating oral-motor difficulties or dysphagia.
	QBRELIS SOLUTION (lisinopril)**	
	trandolapril	
	VASOTEC (enalapril)	
	ZESTRIL (lisinopril)	

ACE INHIBITOR COMBINATION DRUGS

benazepril/amlodipine	ACCURETIC (quinapril/HCTZ)
benazepril/HCTZ	LOTENSIN HCT (benazepril/HCTZ)
captopril/HCTZ	LOTREL (benazepril/amlodipine)
enalapril/HCTZ	TARKA (trandolapril/verapamil)
fosinopril/HCTZ	trandolapril/verapamil
lisinopril/HCTZ	VASERETIC (enalapril/HCTZ)
quinapril/HCTZ	ZESTORETIC (lisinopril/HCTZ)

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs)

irbesartan	ATACAND (candesartan)
losartan	AVAPRO (irbesartan)
valsartan	BENICAR (olmesartan)
olmesartan	candesartan
	COZAAR (losartan)
	DIOVAN (valsartan)
	EDARBI (azilsartan)
	MICARDIS (telmisartan)
	telmisartan

ARB COMBINATIONS

ENTRESTO (valsartan/sacubitril)[AP]*	ATACAND-HCT (candesartan/HCTZ)	*Entresto will only be authorized for patients 18 years of age or older who are diagnosed with chronic heart-failure.
irbesartan/HCTZ	AVALIDE (irbesartan/HCTZ)	
losartan/HCTZ	AZOR (olmesartan/amlodipine)	
olmesartan/amlodipine	BENICAR-HCT (olmesartan/HCTZ)	

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olmesartan/HCTZ TRIBENZOR (olmesartan/amlodipine/HCTZ) valsartan/amlodipine valsartan/amlodipine/HCTZ valsartan/HCTZ	candesartan/HCTZ DIOVAN-HCT (valsartan/HCTZ) EDARBYCLOR (azilsartan/chlorthalidone) EXFORGE (valsartan/amlodipine) EXFORGE HCT (valsartan/amlodipine/HCTZ) HYZAAR (losartan/HCTZ) MICARDIS-HCT (telmisartan/HCTZ) olmesartan/amlodipine/HCTZ telmisartan/amlodipine telmisartan HCTZ	
	DIRECT RENIN INHIBITORS	
	aliskiren TEKTURNA (aliskiren) TEKTURNA HCT (aliskiren/HCTZ)	**Substitute for Class Criteria**: Tekturna requires a thirty (30) day trial of one (1) preferred ACE, ARB, or combination agent, at the maximum tolerable dose, before it will be authorized unless one (1) of the exceptions on the PA form is present. Amturnide, Tekamlo, Tekturna HCT or Valturna will be authorized if the criteria for Tekturna are met and the patient also needs the other agents in the combination.
ANTIANGINAL & ANTI-ISCHEMIC		
CLASS PA CRITERIA: Agents in this class may only be authorized for patients with angina who are also taking a calcium channel blocker, a beta blocker, or a nitrite as single agents or a combination agent containing one (1) of these ingredients.		
ranolazine[AP]	RANEXA	
ANTIBIOTICS, GI & RELATED AGENTS		
CLASS PA CRITERIA: Non-preferred agents require a fourteen (14) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
FIRVANQ (vancomycin) metronidazole tablet neomycin tinidazole	DIFICID (fidaxomicin)* FLAGYL (metronidazole) metronidazole capsule paromomycin VANCOCIN (vancomycin) vancomycin XIFAXAN (rifaximin)*	*Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.
ANTIBIOTICS, INHALED		
CLASS PA CRITERIA: Non-preferred agents require a twenty-eight (28) day trial of a preferred agent and documentation of therapeutic failure before they will be approved, unless one (1) of the exceptions on the PA form is present.		
BETHKIS (tobramycin) KITABIS PAK (tobramycin)	CAYSTON (aztreonam) TOBI (tobramycin) TOBI PODHALER (tobramycin) tobramycin	
ANTIBIOTICS, TOPICAL		
CLASS PA CRITERIA: Non-preferred agents require ten (10) day trials of at least one preferred agent, including the generic formulation of the requested non-preferred agent, before they will be approved, unless one (1) of the exceptions on the PA form is present.		

bacitracin (Rx, OTC)	CENTANY (mupirocin)
gentamicin sulfate	CORTISPORIN (bacitracin/neomycin/polymyxin/HC)
mupirocin ointment	mupirocin cream
	neomycin/polymyxin/pramoxine
	XEPI CREAM (ozenoxacin)

ANTIBIOTICS, VAGINAL

CLASS PA CRITERIA: Non-preferred agents require trials of each chemically unique preferred agent at the manufacturer's recommended duration, before they will be approved, unless one (1) of the exceptions on the PA form is present.

CLEOCIN OVULE (clindamycin)	CLEOCIN CREAM (clindamycin)
CLINDESSE (clindamycin)	clindamycin cream
metronidazole gel	METROGEL (metronidazole)
NUVESSA (metronidazole)	SOLOSEC (secnidazole)
	VANDAZOLE (metronidazole)

ANTICOAGULANTS

CLASS PA CRITERIA: Non-preferred agents require a trial of each preferred agent in the same sub-class, unless one (1) of the exceptions on the PA form is present.

INJECTABLE[CL]

enoxaparin	ARIXTRA (fondaparinux)
	fondaparinux
	FRAGMIN (dalteparin)
	LOVENOX (enoxaparin)

ORAL

ELIQUIS (apixaban)	SAVAYSA (edoxaban)
PRADAXA (dabigatran)	
warfarin	
XARELTO (rivaroxaban)	

ANTICONVULSANTS

CLASS PA CRITERIA: For a diagnosis of seizure disorder, non-preferred agents require a fourteen (14) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present; patients currently on established therapies shall be grandfathered.

For all other diagnoses, non-preferred agents require a thirty (30) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

In situations where AB-rated generic equivalent products are available, "Brand Medically Necessary" must be hand-written by the prescriber on the prescription for the brand name product to be reimbursed.

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ADJUVANTS		
carbamazepine carbamazepine ER divalproex divalproex ER divalproex sprinkle EPITOL (carbamazepine) GABITRIL (tiagabine) lamotrigine levetiracetam IR levetiracetam ER levetiracetam IR suspension oxcarbazepine suspension and tablets TEGRETOL SUSPENSION (carbamazepine) topiramate IR topiramate ER* valproic acid VIMPAT (lacosamide) zonisamide	APTIOM (eslicarbazepine) BANZEL (rufinamide) BRIVIACT (brivaracetam) carbamazepine oral suspension CARBATROL (carbamazepine) DEPAKOTE (divalproex) DEPAKOTE ER (divalproex) DEPAKOTE SPRINKLE (divalproex) DIACOMIT CAPSULE/POWDER PACK (stripentol)** EQUETRO (carbamazepine) felbamate FELBATOL (felbamate) FINTEPLA (fenfluramine) SOLUTION**** FYCOMPA (perampanel) KEPPRA (levetiracetam) KEPPRA SOLUTION (levetiracetam) KEPPRA XR (levetiracetam) LAMICTAL (lamotrigine) LAMICTAL CHEWABLE (lamotrigine) LAMICTAL ODT (lamotrigine) LAMICTAL XR (lamotrigine) lamotrigine dose pack lamotrigine ER lamotrigine ODT OXTELLAR XR (oxcarbazepine) QUDEXY XR (topiramate ER)*** rufinamide oral suspension SABRIL (vigabatrin) SPRITAM (levetiracetam) TEGRETOL TABLETS (carbamazepine) TEGRETOL XR (carbamazepine) tiagabine TOPAMAX (topiramate) TRILEPTAL SUSPENSION and TABLETS (oxcarbazepine) TROKENDI XR (topiramate)*** vigabatrin tablet/powder pack XCOPRI (cenobamate)	*Topiramate ER will be authorized after a thirty (30) day trial of topiramate IR. **Diacomit may only be approved as adjunctive therapy for diagnosis of Dravet Syndrome when prescribed by, or in consultation with, a neurologist AND requires a thirty (30) day trial of valproate and clobazam unless one (1) of the exceptions on the PA form is present. Diacomit must be used concurrently with clobazam. ***Qudexy XR and Trokendi XR are only approvable on appeal. ****Full PA criteria for Fintepla may be found on the PA Criteria page by clicking the hyperlink.
BARBITURATES[AP]		
phenobarbital primidone	MYSOLINE (primidone)	
BENZODIAZEPINES[AP]		
clonazepam diazepam rectal gel diazepam tablets	clobazam* clonazepam ODT DIASTAT (diazepam rectal)	*Onfi shall be authorized as adjunctive therapy for treatment of Lennox-Gastaut Syndrome and Dravet Syndrome without further restrictions. All other indications require an appeal to

NAYZILAM NASAL SPRAY (midazolam) VALTOCO NASAL SPRAY (diazepam)	KLONOPIN (clonazepam) ONFI (clobazam)* ONFI SUSPENSION (clobazam)* SYMPAZAN (clobazam film)*	the Medical Director. NOTE: generic clobazam is preferred over brand ONFI.
	CANNABINOIDS	
	EPIDIOLEX SOLUTION (cannabidiol)*	* Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.
	HYDANTOINS[AP]	
DILANTIN (phenytoin sodium, extended) PEGANONE (ethotoin) phenytoin capsules, chewable tablets, suspension	DILANTIN INFATABS (phenytoin) PHENYTEK (phenytoin)	
	SUCCINIMIDES	
CELONTIN (methsuximide) ethosuximide capsules ethosuximide syrup	ZARONTIN (ethosuximide) capsules ZARONTIN (ethosuximide) syrup	
ANTIDEPRESSANTS, OTHER		
CLASS PA CRITERIA: See below for individual sub-class criteria.		
	MAOIs[AP]	
	MARPLAN (isocarboxazid) NARDIL (phenelzine) phenelzine tranylcypromine	Patients stabilized on MAOI agents will be grandfathered.
	SNRIS[AP]	
duloxetine capulses venlafaxine ER capsules	CYMBALTA (duloxetine) desvenlafaxine ER desvenlafaxine fumarate ER EFFEXOR XR (venlafaxine) FETZIMA (levomilnacipran) PRISTIQ (desvenlafaxine) venlafaxine IR venlafaxine ER tablets (venlafaxine)	Non-preferred agents require separate thirty (30) day trials of a preferred agent in this sub-class **AND** an SSRI before they will be approved, unless one (1) of the exceptions on the PA form is present.
	SECOND GENERATION NON-SSRI, OTHER[AP]	
bupropion IR bupropion SR bupropion XL mirtazapine trazodone	APLENZIN (bupropion hbr) EMSAM (selegiline) FORFIVO XL (bupropion) nefazodone REMERON (mirtazapine) TRINTELLIX (vortioxetine) VIIBRYD (vilazodone HCl) WELLBUTRIN SR (bupropion) WELLBUTRIN XL (bupropion)	Non-preferred agents require separate thirty (30) day trials of a preferred agent in this sub-class **AND** an SSRI before they will be approved, unless one (1) of the exceptions on the PA form is present.
	SELECTED TCAs	

imipramine HCl	imipramine pamoate	Non-preferred agents require a twelve (12) week trial of imipramine HCl before they will be approved, unless one (1) of the exceptions on the PA form is present.
ANTIDEPRESSANTS, SSRIs[AP]		
CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of at least two (2) preferred agents before they will be approved, unless one (1) of the exceptions on the PA form is present. Upon hospital discharge, patients admitted with a primary mental health diagnosis who have been stabilized on a non-preferred SSRI will receive an authorization to continue that drug.		
citalopram escitalopram tablets fluoxetine capsules, solution fluvoxamine paroxetine sertraline	BRISDELLE (paroxetine) CELEXA (citalopram) escitalopram solution fluoxetine tablets fluvoxamine ER LEXAPRO (escitalopram) paroxetine 7.5 mg capsules paroxetine ER PAXIL (paroxetine) PAXIL CR (paroxetine) PEXEVA (paroxetine) PROZAC (fluoxetine) SARAFEM (fluoxetine) ZOLOFT (sertraline)	
ANTIEMETICS[AP]		
CLASS PA CRITERIA: See below for sub-class criteria.		
	5HT3 RECEPTOR BLOCKERS	
granisetron ondansetron ODT, solution, tablets	ondansetron vials SANCUSO (granisetron) SUSTOL (granisetron) ZOFRAN (ondansetron) ZUPLENZ (ondansetron)	Non-preferred agents require a three (3) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.
	CANNABINOIDS	
	dronabinol* MARINOL (dronabinol)*	*Dronabinol will only be authorized for: 1. The treatment of anorexia associated with weight loss in patients with AIDS or cancer and unresponsive to megestrol **or** 2. The prophylaxis of chemotherapy induced nausea and vomiting unresponsive to three (3) day trials of ondansetron or promethazine for patients from eighteen (18) up to sixty-five (65) years of age.

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SUBSTANCE P ANTAGONISTS		
EMEND (aprepitant)	aprepitant VARUBI (rolapitant)	Non-preferred agents require a three (3) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.
COMBINATIONS		
	AKYNZEO (netupitant/palonosetron) BONJESTA (doxylamine/pyridoxine) DICLEGIS (doxylamine/pyridoxine) doxylamine/pyridoxine (generic Diclegis)	Non-preferred agents will only be approved on appeal.
ANTIFUNGALS, ORAL		
CLASS PA CRITERIA: Non-preferred agents will only be authorized if one (1) of the exceptions on the PA form is present.		
clotrimazole fluconazole* nystatin terbinafine[CL]	ANCOBON (flucytosine) CRESEMBA (isovuconazonium)[CL]** DIFLUCAN (fluconazole) flucytosine griseofulvin*** itraconazole ketoconazole**** MYCELEX (clotrimazole) NOXAFIL (posaconazole) ORAVIG (miconazole) posaconazole tablet SPORANOX (itraconazole) TOLSURA (itraconazole) VFEND (voriconazole) voriconazole suspension voriconazole tablets	*PA is required when limits are exceeded. **Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. ***PA is not required for griseofulvin suspension for children up to eighteen (18) years of age for the treatment of tinea capitis. ****Ketoconazole will be authorized if the following criteria are met: 1. Diagnosis of one of the following fungal infections: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis **and** 2. Documented failure or intolerance of all other diagnosis-appropriate antifungal therapies, i.e. itraconazole, fluconazole, flucytosine, etc **and** 3. Baseline assessment of the liver status including alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, alkaline phosphatase, prothrombin time, and international normalized ratio (INR) before starting treatment **and** 4. Weekly monitoring of serum ALT for the duration of treatment (If ALT values increase to a level above the upper limit of normal or 30% above baseline, or if the patient develops symptoms of abnormal liver function, treatment should be interrupted and a full set of liver tests be obtained. Liver tests should be repeated to ensure normalization of values.) **and** 5. Assessment of all concomitant medications for potential adverse drug interactions with ketoconazole. **Ketoconazole will not be authorized for treatment for fungal infections of the skin and nails.**

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ANTIFUNGALS, TOPICAL[AP]

CLASS PA CRITERIA: Non-preferred agents require fourteen (14) day trials of two (2) preferred agents before they will be approved, unless one (1) of the exceptions on the PA form is present. If a non-preferred shampoo is requested, a fourteen (14) day trial of one (1) preferred product (i.e. ketoconazole shampoo) is required.

ANTIFUNGALS		
econazole ketoconazole cream, shampoo MENTAX (butenafine) miconazole (OTC) nystatin	CICLODAN (ciclopirox) ciclopirox ERTACZO (sertaconazole) EXELDERM (sulconazole) EXTINA (ketoconazole) GYNAZOLE 1 CREAM (butoconazole) JUBLIA (efinaconazole) ketoconazole foam KERYDIN (tavaborole) KETODAN (ketoconazole) LOPROX (ciclopirox) LUZU (luliconazole) miconazole/petrolatum/zinc oxide NAFTIN GEL (naftifine) OXISTAT (oxiconazole)* tavaborole 5% topical solution VUSION (miconazole/petrolatum/zinc oxide)	*Oxistat cream will be authorized for children up to thirteen (13) years of age for tinea corporis, tinea cruris, tinea pedis, and tinea (pityriasis) versicolor.
ANTIFUNGAL/STEROID COMBINATIONS		
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion nystatin/triamcinolone	

ANTIHEMOPHILIA FACTOR AGENTS[CL]

CLASS PA CRITERIA: All agents will require prior-authorization, and non-preferred agents require medical reasoning explaining why the need cannot be met using a preferred product.

All currently established regimens shall be grandfathered with documentation of adherence to therapy.

FACTOR VIII	
ADVATE AFSTYLA ALPHANATE HEMOFIL M HUMATE-P KOATE KOGENATE FS NOVOEIGHT NUWIQ WILATE XYNTHA XYNTHA SOLOFUSE	ADYNOVATE ELOCTATE ESPEROCT JIVI KOVALTRY RECOMBINATE VONVENDI
FACTOR VII	

	NOVOSEVEN[NR] SEVENFACT[NR]	
	FACTOR IX	
ALPHANINE SD ALPROLIX BENEFIX IXINITY MONONINE PROFILNINE RIXUBIS	IDELVION REBINYN	
	FACTOR IXa/IX	
	HEMLIBRA (emicizumab-kxwh)*	*Hemlibra shall be approved without further restriction for patients with Hemophilia A with documented presence of Factor VIII inhibitors.
ANTIHYPERTENSIVES, SYMPATHOLYTICS		
CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each preferred unique chemical entity in the corresponding formulation before they will be approved, unless one (1) of the exceptions on the PA form is present.		
CATAPRES-TTS (clonidine) clonidine patch clonidine tablets	CATAPRES TABLETS (clonidine)	
ANTIHYPERURICEMICS		
CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of one (1) of the preferred agents for the prevention of gouty arthritis attacks (colchicine/probenecid, probenecid, or allopurinol) before they will be approved, unless one (1) of the exceptions on the PA form is present.		
	ANTIMITOTICS	
COLCRYS (colchicine) tablets	colchicine capsules colchicine tablets MITIGARE (colchicine) GLOPERBA (colchicine)*	In the case of acute gouty attacks, a ten (10) day supply (twenty (20) units) of the preferred agent(s) in this subclass will be authorized per ninety (90) days. *Gloperba may only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia.
	ANTIMITOTIC-URICOSURIC COMBINATION	
colchicine/probenecid		
	URICOSURIC	
probenecid		
	XANTHINE OXIDASE INHIBITORS	
allopurinol	febuxostat tablets ULORIC (febuxostat) ZYLOPRIM (allopurinol)	

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ANTIMIGRAINE AGENTS, PROPHYLAXIS[CL]

CLASS PA CRITERIA: All agents require a prior authorization. Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. Non-preferred agents require a 90-day trial of all preferred agents. All currently established regimens may be grandfathered with documentation of efficacy and adherence to therapy.

AIMOVIG (erenumab)	EMGALITY (galcanezumab) 120mg/mL	*Emgality 300 mg/3 mL requires review by the Medical Director and is available only on appeal.
AJOVY (fremanezumab)	EMGALITY (galcanezumab) 300mg/3 mL*	

ANTIMIGRAINE AGENTS, ACUTE[AP]

CLASS PA CRITERIA: Non-preferred agents require three (3) day trials of each preferred unique chemical entity as well as a three (3) day trial using the same route of administration as the requested agent (if available), before they will be approved, unless one (1) of the exceptions on the PA form is present.

	TRIPTANS	
naratriptan rizatriptan ODT rizatriptan tablet sumatriptan injection[CL] sumatriptan nasal spray sumatriptan tablets	almotriptan AMERGE (naratriptan) eletriptan FROVA (frovatriptan) frovatriptan IMITREX NASAL SPRAY (sumatriptan) IMITREX tablets (sumatriptan) MAXALT MLT (rizatriptan) MAXALT (rizatriptan) ONZETRA XSAIL (sumatriptan)* RELPAX (eletriptan) TOSYMRA NASAL SPRAY (sumatriptan)* ZEMBRACE SYMTOUCH (sumatriptan) zolmitriptan zolmitriptan ODT ZOMIG (zolmitriptan) ZOMIG ZMT (zolmitriptan)	***In addition to the Class Criteria**: Onzetra Xsail and Tosymra require three (3) day trials of each preferred oral, nasal and injectable forms of sumatriptan.
	TRIPTAN COMBINATIONS	
	TREXIMET (sumatriptan/naproxen sodium)	
	OTHER	
NURTEC ODT (rimegepant)*	CAMBIA (diclofenac) UBRELVY (ubrogepant)** REYVOW (lasmiditan)**	*Nurtec ODT requires three (3) day trials of two (2) preferred chemically distinct triptans before it may be approved, unless one (1) of the exceptions on the PA form is present. **Ubrelvy and Reyvow require three (3) day trials of two (2) preferred chemically distinct triptans as well as a three (3) day trial of Nurtec ODT before they may be approved, unless one (1) of the exceptions on the PA form is present.

ANTIPARASITICS, TOPICAL[AP]

CLASS PA CRITERIA: Non-preferred agents require trials of each preferred agent (which are age and weight appropriate) before they will be approved, unless one (1) of the exceptions on the PA form is present.

NATROBA (spinosad) permethrin 5% cream pyrethrins-piperonyl butoxide OTC	ELIMITE CREAM (permethrin) EURAX (crotamiton) ivermectin 0.5% lotion LICE EGG REMOVER OTC (benzalkonium chloride) lindane malathion OVIDE (malathion) SKLICE (ivermectin) spinosad VANALICE (piperonyl/pyrethin)	
ANTIPARKINSON'S AGENTS		
CLASS PA CRITERIA: Patients starting therapy on drugs in this class must show a documented allergy to all preferred agents in the corresponding sub-class, before a non-preferred agent will be authorized.		
	ANTICHOLINERGICS	
benztropine trihexyphenidyl		
	COMT INHIBITORS	
entacapone	COMTAN (entacapone) ONGENTYS (opicapone) TASMAR (tolcapone) tolcapone	COMT Inhibitor agents will only be approved as add-on therapy to a levodopa-containing regimen for treatment of documented motor complications.
	DOPAMINE AGONISTS	
APOKYN (apomorphine) PEN bromocriptine pramipexole ropinirole	KYNMOBI (apomorphine) FILM MIRAPEX ER (pramipexole)* NEUPRO (rotigotine) pramipexole ER ropinirole ER	*Mirapex ER will be authorized for a diagnosis of Parkinsonism without a trial of preferred agents.
	OTHER ANTIPARKINSON'S AGENTS	
amantadine*AP carbidopa/levodopa levodopa/carbidopa/entacapone selegiline	AZILECT (rasagiline) carbidopa GOCOVRI ER (amantadine) INBRIJA (levodopa) levodopa/carbidopa ODT LODOSYN (carbidopa) NOURIANZ (istradefylline) OSMOLEX ER (amantadine) PARLODEL (bromocriptine) rasagiline RYTARY (levodopa/carbidopa) SINEMET (levodopa/carbidopa) STALEVO (levodopa/carbidopa/entacapone) XADAGO (safinamide) ZELAPAR (selegiline)	*Amantadine will not be authorized for the treatment or prophylaxis of influenza.

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ANTIPSORIATICS, TOPICAL

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of two (2) preferred unique chemical entities before they will be approved, unless one (1) of the exceptions on the PA form is present.

TACLONEX (calcipotriene/ betamethasone) VECTICAL (calcitriol)	calcipotriene cream calcipotriene ointment calcipotriene solution calcipotriene/betamethasone ointment, suspension calcitriol DOVONEX (calcipotriene) ENSTILAR (calcipotriene/betamethasone) SORILUX (calcipotriene) tazarotene cream	

ANTIPSYCHOTICS, ATYPICAL

CLASS PA CRITERIA: All antipsychotic agents require prior authorization for children up to eighteen (18) years of age. All PA requests for antipsychotics for children 6 years of age and younger will be reviewed by Medicaid's consultant psychiatrist.

Non-preferred agents require thirty (30) day trials of two (2) preferred agents, including the generic formulation of the requested agent (if available), before they will be approved unless one (1) of the exceptions on the PA form is present. All trials must be at the maximum recommended dose for the diagnosis provided before they would be considered a failure unless an adverse reaction is documented necessitating a change in therapy.

Patients shall be grandfathered onto their existing therapy, provided the requested agent is being used according to the manufacturer label. Continuation of therapy for an off-label indication or non-standard dosage may be granted a thirty (30) day prior-authorization while the Medical Director reviews the request.

SINGLE INGREDIENT

ABILIFY MAINTENA (aripiprazole)[CL] aripiprazole tablets ARISTADA (aripiprazole)[CL] ARISTADA INITIO (aripiprazole)[CL] clozapine INVEGA SUSTENNA (paliperidone)[CL] INVEGA TRINZA (paliperidone)* [CL] olanzapine olanzapine ODT PERSERIS (risperidone)[CL] quetiapine ER	ABILIFY MYCITE (aripiprazole) ABILIFY TABLETS (aripiprazole) ADASUVE (loxapine) aripiprazole solution asenapine sublingual tablets CAPLYTA (lumateperone) clozapine ODT CLOZARIL (clozapine) FANAPT (iloperidone) GEODON (ziprasidone) GEODON IM (ziprasidone)	**The following criteria exceptions apply to the specified products:** *Invega Trinza will be authorized after four months' treatment with Invega Sustenna **Quetiapine 25 mg will be authorized: 1. For a diagnosis of schizophrenia **or** 2. For a diagnosis of bipolar disorder **or** 3. When prescribed concurrently with other strengths of Seroquel in order to achieve therapeutic treatment levels.

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quetiapine** AP for the 25 mg Tablet Only RISPERDAL CONSTA (risperidone)CL risperidone ODT risperidone solution, tablet ziprasidone ZYPREXA RELPREVV (olanzapine)	INVEGA ER (paliperidone) LATUDA (lurasidone)*** NUPLAZID (pimavanserin) **** olanzapine IMCL paliperidone ER REXULTI (brexipiprazole) RISPERDAL (risperidone) SAPHRIS (asenapine) SECUADO (asenapine) SEROQUEL (quetiapine) SEROQUEL XR (quetiapine) VERSACLOZ (clozapine) VRAYLAR (cariprazine)***** VRAYLAR DOSE PAK (cariprazine)***** ZYPREXA (olanzapine) ZYPREXA IM (olanzapine)CL	**Quetiapine 25 mg will not be authorized for use as a sedative hypnotic.** *** Latuda will be be authorized for the indication of Bipolar Depression with documentation of the diagnosis. All other indications require class criteria to be followed. ****Nuplazid may only be authorized for the treatment of Parkinson Disease Induced Psychosis after documented treatment failure with quetiapine. ***** Vraylar may be authorized for the indication of Bipolar Depression only after failure of a 30-day trial of Latuda and a 30-day trial of either quetiapine OR a combination of olanzapine + fluoxetine. All other indications require class criteria to be followed.
	ATYPICAL ANTIPSYCHOTIC/SSRI COMBINATIONS	
	olanzapine/fluoxetine	
ANTIRETROVIRALSAP		
CLASS PA CRITERIA: Non-preferred drugs require medical reasoning beyond convenience or enhanced compliance as to why the clinical need cannot be met with a preferred agent or combination of preferred agents. NOTE: Regimens consisting of preferred agents will result in no more than one additional unit per day over equivalent regimens composed of non-preferred agents. Patients already on a non-preferred regimen shall be grandfathered.		
	SINGLE TABLET REGIMENS	
BIKTARVY (bictegravir/emtricitabine/ tenofovir alafenamide) COMPLERA (emtricitabine/rilpivirine/tenofovir) DELSTRIGO (doravirine/lamivudine/ tenofovir df) GENVOYA (elvitegravir/cobicistat/ emtricitabine/tenofovir) ODEFSEY (emtricitabine/rilpivirine/tenofovir) SYMFI (efavirenz/lamivudine/tenofovir) SYMFI LO (efavirenz/lamivudine/tenofovir)	ATRIPLA (efavirenz/emtricitabine/tenofovir) DOVATO (dolutegravir/lamivudine) efavirenz/emtricitabine/tenofovir JULUCA (dolutegravir/rilpivirine) SYMTUZA (darunavir/cobicistat/ emtricitabine/tenofovir alafenamide) STRIBILD (elvitegravir/cobicistat/ emtricitabine/tenofovir)* TRIUMEQ (abacavir/lamivudine/ dolutegravir)**	*Stribild requires medical reasoning beyond convenience or enhanced compliance as to why the medical need cannot be met with the the preferred agent Genvoya. **Triumeq requires medical reasoning beyond convenience or enhanced compliance as to why the medical need cannot be met with the preferred agents Epzicom and Tivicay.
	INTEGRASE STRAND TRANSFER INHIBITORS	
ISENTRESS (raltegravir potassium) TIVICAY (dolutegravir sodium) TIVICAY PD (dolutegravir sodium)	ISENTRESS HD (raltegravir potassium)	
	NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTI)	
abacavir sulfate tablet EMTRIVA (emtricitabine) EPIVIR SOLUTION (lamivudine) lamivudine	abacavir sulfate solution didanosine DR capsule emtricitabine capsule EPIVIR TABLET (lamivudine)	

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tenofovir disoproxil fumarate VIREAD ORAL POWDER (tenofovir disoproxil fumarate) ZIAGEN SOLUTION (abacavir sulfate) zidovudine	RETROVIR (zidovudine) stavudine VIDEX EC (didanosine) VIDEX SOLUTION (didanosine) VIREAD TABLETS (tenofovir disoproxil fumarate) ZIAGEN TABLET (abacavir sulfate)	
NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NNRTI)		
SUSTIVA (efavirenz)	EDURANT (rilpivirine) efavirenz etravirine INTELENCE (etravirine) nevirapine nevirapine ER PIFELTRO (doravirine) VIRAMUNE ER 24H (nevirapine) VIRAMUNE SUSPENSION (nevirapine)	
PHARMACOENHANCER – CYTOCHROME P450 INHIBITOR		
TYBOST (cobicistat)		
PROTEASE INHIBITORS (PEPTIDIC)		
atazanavir EVOTAZ (atazanavir/cobicistat) NORVIR (ritonavir) REYATAZ POWDER PACK (atazanavir)	fosamprenavir LEXIVA (fosamprenavir) REYATAZ CAPSULE (atazanavir) ritonavir tablet VIRACEPT (nelfinavir mesylate)	
PROTEASE INHIBITORS (NON-PEPTIDIC)		
PREZCOBIX (darunavir/cobicistat) PREZISTA (darunavir ethanolate)	APTIVUS (tipranavir)	
ENTRY INHIBITORS – CCR5 CO-RECEPTOR ANTAGONISTS		
	SELZENTRY (maraviroc)	
ENTRY INHIBITORS – FUSION INHIBITORS		
	FUZEON (enfuvirtide)	
COMBINATION PRODUCTS – NRTIs		
abacavir/lamivudine CIMDUO (lamivudine/tenofovir) lamivudine/zidovudine	abacavir/lamivudine/zidovudine COMBIVIR (lamivudine/zidovudine) EPZICOM (abacavir/lamivudine) TEMIXYS (lamivudine/tenofovir) TRIZIVIR (abacavir/lamivudine/zidovudine)	
COMBINATION PRODUCTS – NUCLEOSIDE & NUCLEOTIDE ANALOG RTIs		
DESCOVY (emtricitabine/tenofovir)	TRUVADA (emtricitabine/tenofovir)* emtricitabine/tenofovir	*Truvada shall be treated as preferred when prescribed for PrEP in members assigned female at birth. Truvada may also be approved over Descovy where guidelines clearly indicate superiority over Descovy (documentation may be required to support the request for PA).
COMBINATION PRODUCTS – PROTEASE INHIBITORS		
KALETRA (lopinavir/ritonavir)	lopinavir/ritonavir	

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GP 120 DIRECTED ATTACHMENT INHIBITORS		
RUKOBIA (fostemsavir tromethamine) TABLETS		
ANTIVIRALS, ORAL		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of each preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.		
ANTI HERPES		
acyclovir valacyclovir	famciclovir SITAVIG (acyclovir) VALTREX (valacyclovir) ZOVIRAX (acyclovir)	
ANTI-INFLUENZA		
oseltamivir RELENZA (zanamivir) TAMIFLU (oseltamivir)	FLUMADINE (rimantadine) rimantadine XOFLUZA (baloxavir)	**In addition to the Class Criteria**: The anti-influenza agents will be authorized only for a diagnosis of influenza.
ANTIVIRALS, TOPICAL[AP]		
CLASS PA CRITERIA: Non-preferred agents require a five (5) day trial of the preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
ZOVIRAX CREAM (acyclovir) ZOVIRAX OINTMENT (acyclovir)	acyclovir ointment docosanol cream DENAVIR (penciclovir)	
BETA BLOCKERS[AP]		
CLASS PA CRITERIA: Non-preferred agents require fourteen (14) day trials of three (3) chemically distinct preferred agents, including the generic formulation of the requested non-preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
BETA BLOCKERS		
acebutolol atenolol betaxolol bisoprolol CORGARD (nadolol) metoprolol metoprolol ER pindolol propranolol SORINE (sotalol) sotalol timolol	BETAPACE (sotalol) BYSTOLIC (nebivolol) HEMANGEOL (propranolol)* INDERAL LA (propranolol) INDERAL XL (propranolol) INNOPRAN XL (propranolol) KAPSPARGO SPRINKLE (metoprolol) LOPRESSOR (metoprolol) nadolol propranolol ER** TENORMIN (atenolol) TOPROL XL (metoprolol)	*Hemangeol will be authorized for the treatment of proliferating infantile hemangioma requiring systemic therapy. **Propranolol ER shall be authorized for patients with a diagnosis of migraines. Existing users will be grandfathered for use in migraine prophylaxis.
BETA BLOCKER/DIURETIC COMBINATION DRUGS		
atenolol/chlorthalidone bisoprolol/HCTZ metoprolol/HCTZ propranolol/HCTZ	nadolol/bendroflumethiazide TENORETIC (atenolol/chlorthalidone) ZIAC (bisoprolol/HCTZ)	
BETA- AND ALPHA-BLOCKERS		

carvedilol labetalol	COREG (carvedilol) COREG CR (carvedilol)	

BLADDER RELAXANT PREPARATIONS[AP]

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each chemically distinct preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present

GELNIQUE (oxybutynin) oxybutynin IR oxybutynin ER solifenacin TOVIAZ (fesoterodine)	darifenacin ER tablet DETROL (tolterodine) DITROPAN XL (oxybutynin) ENABLEX (darifenacin) flavoxate GEMTESA (vibegron)[NR] MYRBETRIQ (mirabegron) OXYTROL (oxybutynin) tolterodine tolterodine ER trospium trospium ER VESICARE (solifenacin)	

BONE RESORPTION SUPPRESSION AND RELATED AGENTS

CLASS PA CRITERIA: See below for class criteria.

BISPHOSPHONATES

alendronate tablets ibandronate	ACTONEL (risedronate) alendronate solution ATELVIA (risedronate) BINOSTO (alendronate) BONIVA (ibandronate) FOSAMAX TABLETS (alendronate) FOSAMAX PLUS D (alendronate/vitamin D) Risedronate	Non-preferred agents require thirty (30) day trials of **each** preferred Bisphosphonate agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

OTHER BONE RESORPTION SUPPRESSION AND RELATED AGENTS

	calcitonin EVISTA (raloxifene)* FORTEO (teriparatide) MIACALCIN (calcitonin) raloxifene* teriparatide TYMLOS (abaloparatide)	Non-preferred agents require a thirty (30) day trial of a preferred Bisphosphonate agent before they will be approved, unless one (1) of the exceptions on the PA form is present. *Raloxifene will be authorized for postmenopausal women with osteoporosis who are at high risk for invasive breast cancer.

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BPH TREATMENTS

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of at least two (2) chemically distinct preferred agents, including the generic formulation of the requested non-preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

	5-ALPHA-REDUCTASE (5AR) INHIBITORS AND PDE-5 AGENTS	
finasteride	AVODART (dutasteride) CIALIS 5 mg (tadalafil) dutasteride PROSCAR (finasteride)	
	ALPHA BLOCKERS	
alfuzosin doxazosin tamsulosin terazosin	CARDURA (doxazosin) CARDURA XL (doxazosin) FLOMAX (tamsulosin) RAPAFLO (silodosin) silodosin	
	5-ALPHA-REDUCTASE (5AR) INHIBITORS/ALPHA BLOCKER COMBINATION	
	dutasteride/tamsulosin JALYN (dutasteride/tamsulosin)	**Substitute for Class Criteria**: Concurrent thirty (30) day trials of dutasteride and tamsulosin are required before the non-preferred agent will be authorized.

BRONCHODILATORS, BETA AGONIST[AP]

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each chemically distinct preferred agent in their corresponding sub-class unless one (1) of the exceptions on the PA form is present.

	INHALATION SOLUTION	
albuterol	BROVANA (arformoterol) levalbuterol metaproterenol PERFOROMIST (formoterol) XOPENEX (levalbuterol)*	*Xopenex Inhalation Solution will be authorized for twelve (12) months for a diagnosis of asthma or COPD for patients on concurrent asthma controller therapy (either oral or inhaled) with documentation of failure on a trial of albuterol or documented intolerance of albuterol, or for concurrent diagnosis of heart disease.
	INHALERS, LONG-ACTING	
SEREVENT (salmeterol)	STRIVERDI RESPIMAT (olodaterol)	
	INHALERS, SHORT-ACTING	
PROAIR HFA (albuterol) PROAIR RESPICLICK (albuterol) VENTOLIN HFA (albuterol)	albuterol HFA PROAIR DIGIHALER (albuterol) PROVENTIL HFA (albuterol) XOPENEX HFA (levalbuterol)	
	ORAL	
	albuterol ER albuterol IR metaproterenol terbutaline	

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CALCIUM CHANNEL BLOCKERS[AP]

CLASS PA CRITERIA: Non-preferred agents require fourteen (14) day trials of each preferred agent within the corresponding sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

LONG-ACTING		
amlodipine diltiazem ER felodipine ER nifedipine ER verapamil ER	ADALAT CC (nifedipine) CALAN SR (verapamil) CARDIZEM CD, LA (diltiazem) diltiazem LA KATERZIA SUSPENSION (amlodipine)* MATZIM LA (diltiazem) nisoldipine NORVASC (amlodipine) PROCARDIA XL (nifedipine) SULAR (nisoldipine) TIAZAC (diltiazem) verapamil ER PM VERELAN/VERELAN PM (verapamil)	*Katerzia will be authorized for children who are 6-10 years of age who are unable to ingest solid dosage forms. Katerzia may also be authorized for older patients with clinical documentation indicating oral-motor difficulties or dysphagia.
SHORT-ACTING		
diltiazem verapamil	CARDIZEM (diltiazem) isradipine nicardipine nifedipine nimodipine NYMALIZE SOLUTION (nimodipine) PROCARDIA (nifedipine)	

CEPHALOSPORINS AND RELATED ANTIBIOTICS

CLASS PA CRITERIA: Non-preferred agents require a five (5) day trial of a preferred agent within the corresponding sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

BETA LACTAMS AND BETA LACTAM/BETA-LACTAMASE INHIBITOR COMBINATIONS		
amoxicillin/clavulanate IR	amoxicillin/clavulanate ER AUGMENTIN (amoxicillin/clavulanate)	
CEPHALOSPORINS		
cefaclor capsule cefadroxil capsule, tablet cefdinir cefuroxime tablet cephalexin capsule, suspension	cefaclor suspension cefaclor ER tablet cefadroxil suspension cefixime cefpodoxime cefprozil cefuroxime suspension cephalexin tablet KEFLEX (cephalexin) SUPRAX (cefixime)	

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COPD AGENTS

CLASS PA CRITERIA: Non-preferred agents require a sixty (60) day trial of one preferred agent from the corresponding sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

ANTICHOLINERGIC[AP]		
ATROVENT HFA (ipratropium) ipratropium nebulizer solution SPIRIVA (tiotropium) SPIRIVA RESPIMAT (tiotropium) TUDORZA (aclidinium)	INCRUSE ELLIPTA (umeclidinium) LONHALA MAGNAIR (glycopyrrolate) YUPELRI SOLUTION (revefenacin)	
ANTICHOLINERGIC-BETA AGONIST COMBINATIONS[AP]		
ANORO ELLIPTA (umeclidinium/vilanterol) albuterol/ipratropium nebulizer solution BEVESPI (glycopyrrolate/formoterol) COMBIVENT RESPIMAT (albuterol/ipratropium)	DUAKLIR PRESSAIR (aclidinium/formoterol)* STIOLTO RESPIMAT (tiotropium/olodaterol)**	*In addition to the Class PA criteria, Duaklir Pressair requires sixty (60) day trials of each long acting preferred agent, as well as a 60-day trial of Stiolto Respimat. **In addition to the Class PA criteria, Stiolto Respimat requires a sixty (60) day trial of a long acting preferred agent.
ANTICHOLINERGIC-BETA AGONIST-GLUCOCORTICOID COMBINATIONS		
	TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)* BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)**	* Trelegy Ellipta may be prior authorized for patients currently established on the individual components for at least 30 days. **Breztri may be prior authorized for patients currently established on the individual components for at least 30 days.
PDE4 INHIBITOR		
	DALIRESP (roflumilast)*	*Daliresp will be authorized if the following criteria are met: 1. Patient is forty (40) years of age or older **and** 2. Diagnosis of severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis and multiple exacerbations requiring systemic glucocorticoids in the preceding six (6) months **and** 3. Concurrent therapy with an inhaled corticosteroid and long-acting bronchodilator and evidence of compliance **and** 4. No evidence of moderate to severe liver impairment (Child-Pugh Class B or C) **and** 5. No concurrent use with strong cytochrome P450 inducers (rifampicin, phenobarbital, carbamazepine or phenytoin)

CROHNS DISEASE ORAL STEROIDS

ORAL		
budesonide ER capsule (generic Entocort EC)	ENTOCORT EC (budesonide)* ORTIKOS (budesonide)*	*Please see the following PDL classes for PDL status of additional agents used for induction and remission (Cytokine and CAM Antagonists/ Immunosuppressives, Oral/ Ulcerative Colitis Agents)

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		*Entocort EC and Ortikos may only be authorized if the patient has a documented allergy or intolerance to the generic budesonide 3mg 24-hour capsules.

CYTOKINE & CAM ANTAGONISTS[CL]

CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of all preferred agents which are indicated for the diagnosis, unless one (1) of the exceptions on the PA form is present. *Patients stabilized for at least 6-months on their existing non-preferred regimen shall be grandfathered (provided the current therapy is for a labeled indication). All off-label requests require review by the Medical Director.*

	ANTI-TNFs	
ENBREL (etanercept)* HUMIRA (adalimumab)*	CIMZIA (certolizumab pegol) REMICADE (infliximab) RENFLEXIS (infliximab) SIMPONI subcutaneous (golimumab)	*Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.
	OTHERS	
TALTZ (ixekizumab)* XELJANZ (tofacitinib)**	ACTEMRA subcutaneous (tocilizumab) COSENTYX (secukinumab) ENTYVIO (vedolizumab) ILARIS (canakinumab) ILUMYA (tildrakizumab) KEVZARA (sarilumab) KINERET (anakinra) OLUMIANT (baricitinib) ORENCIA subcutaneous (abatacept) OTEZLA (apremilast) RINVOQ ER (upadacitinib) SILIQ (brodalumab) SKYRIZI (risankizumab) STELARA subcutaneous (ustekinumab) TREMFYA (guselkumab) XELJANZ XR (tofacitinib)	*Taltz will be authorized for treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis only after inadequate response to a ninety (90) day trial of one preferred agent. **Xeljanz will only be preferred for the treatment of rheumatoid arthritis and ulcerative colitis. For all other indications it is non preferred. Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.

EPINEPHRINE, SELF-INJECTED

CLASS PA CRITERIA: A non-preferred agent may be authorized with documentation showing the patient's inability to follow the instructions, or the patient's failure to understand the training for the preferred agent(s).

epinephrine (labeler 49502 only)	epinephrine (all labelers except 49502) EPIPEN (epinephrine) EPIPEN JR (epinephrine) SYMJEPI (epinephrine)

ERYTHROPOIESIS STIMULATING PROTEINS[CL]

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

EPOGEN (rHuEPO) RETACRIT (epoetin alfa)	ARANESP (darbepoetin) MIRCERA (methoxy PEG-epoetin) PROCRIT (rHuEPO)	Erythropoiesis agents will be authorized if the following criteria are met: 1. Hemoglobin or Hematocrit less than 10/30 respectively. For renewal, hemoglobin or hematocrit levels greater than 12/36 will require dosage reduction or discontinuation. Exceptions will be considered on an individual basis after medical documentation is reviewed. (Lab oratory values must be dated within six (6) weeks of request.) **and** 2. Transferrin saturation ≥ 20%, ferritin levels ≥100 mg/ml, or on concurrent therapeutic iron therapy. (Laboratory values must be dated within three (3) weeks of request. For re-authorization, transferrin saturation or ferritin levels are not required if the patient has been responsive to the erythropoietin agent **and** 3. For HIV-infected patients, endogenous serum erythropoietin level must be ≤ 500mU/ml to initiate therapy **and** 4. No evidence of untreated GI bleeding, hemolysis, or Vitamin B-12, iron or folate deficiency.

FLUOROQUINOLONES (Oral)[AP]

CLASS PA CRITERIA: Non-preferred agents require a five (5) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

CIPRO SUSPENSION (ciprofloxacin) ciprofloxacin levofloxacin tablet	BAXDELA (delafloxacin) CIPRO TABLETS (ciprofloxacin) ciprofloxacin suspension levofloxacin solution moxifloxacin ofloxacin

GLUCOCORTICOIDS, INHALED[AP]

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each chemically unique preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

GLUCOCORTICOIDS

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ASMANEX TWISTHALER (mometasone) budesonide nebulizer 0.5 mg/2 ml & 0.25 mg/2 ml solution* FLOVENT DISKUS (fluticasone) FLOVENT HFA (fluticasone) PULMICORT FLEXHALER (budesonide)	ARMONAIR DIGIHALER (fluticasone) ALVESCO (ciclesonide) ARNUITY ELLIPTA (fluticasone) ASMANEX HFA (mometasone) budesonide nebulizer 1 mg/2ml solution PULMICORT NEBULIZER SOLUTION (budesonide) QVAR REDIHALER (beclomethasone)	*Budesonide Respules are only preferred for children up to nine (9) years of age. For patients nine (9) and older, prior authorization is required and will be approved only for a diagnosis of severe nasal polyps.
	GLUCOCORTICOID/BRONCHODILATOR COMBINATIONS	
ADVAIR DISKUS (fluticasone/salmeterol) ADVAIR HFA (fluticasone/salmeterol) DULERA (mometasone/formoterol) SYMBICORT(budesonide/formoterol)	AIRDUO DIGIHALER (fluticasone/salmeterol) AIRDUO RESPICLICK (fluticasone/salmeterol) budesonide/formoterol BREO ELLIPTA (fluticasone/vilanterol) fluticasone/salmeterol WIXELA (fluticasone/salmeterol)	
GUANYLATE CYCLASE STIMULATORS[CL]		
	ADEMPAS (riociguat)* VERQUVO (vericiguat)**	*Adempas requires a thirty (30) day trial of a preferred agent from any other PAH Class before it may be approved, unless one (1) of the exceptions on the PA form is present. **Full PA criteria for Verquvo may be found on the PA Criteria page by clicking the hyperlink.
GROWTH HORMONE[CL]		
CLASS PA CRITERIA: Non-preferred agents require three (3) month trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
GENOTROPIN (somatropin) NORDITROPIN (somatropin)	INCRELEX (mecasermin) NUTROPIN AQ (somatropin) OMNITROPE (somatropin) SAIZEN (somatropin) SEROSTIM (somatropin) ZOMACTON (somatropin) ZORBTIVE (somatropin)	Patients already on a non-preferred agent will receive authorization to continue therapy on that agent for the duration of the existing PA.
***H. PYLORI* TREATMENT**		
CLASS PA CRITERIA: Non-preferred agents require a trial of the combination of individual preferred components of the requested non-preferred agent and must be used at the recommended dosages, frequencies and duration of the non-preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		

Please use individual components: preferred PPI (omeprazole or pantoprazole) amoxicillin tetracycline metronidazole clarithromycin bismuth PYLERA (bismuth/metronidazole/tetracycline)	HELIDAC (bismuth/metronidazole/tetracycline) lansoprazole/amoxicillin/clarithromycin OMECLAMOX-PAK (omeprazole/amoxicillin/clarithromycin) TALICIA (omeprazole/amoxicillin/rifabutin)	

HEPATITIS B TREATMENTS

CLASS PA CRITERIA: Non-preferred agents require ninety (90) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

BARACLUDE SOLUTION (entecavir) * entecavir lamivudine HBV	adefovir BARACLUDE TABLET (entecavir) EPIVIR HBV (lamivudine) HEPSERA (adefovir) VEMLIDY (tenofovir alafenamide fumarate)	*Baraclude solution will be authorized only for patients with documentation of dysphagia.

HEPATITIS C TREATMENTS[CL]

CLASS PA CRITERIA: For patients starting therapy in this class, preferred regimens may be found on the PA Criteria page. Requests for non-preferred regimens require medical reasoning why a preferred regimen cannot be used.

MAVYRET (pibrentasvir/glecaprevir)* ribavirin sofosbuvir/velpatasvir (labeler 72626)* ZEPATIER (elbasvir/grazoprevir)*	EPCLUSA (sofosbuvir/velpatasvir)* HARVONI (ledipasvir/sofosbuvir)* ledipasvir/sofosbuvir* PEGASYS (pegylated interferon) PEG-INTRON (pegylated interferon) RIBASPHERE RIBAPAK (ribavirin) RIBASPHERE 400 mg, 600 mg (ribavirin) SOVALDI (sofosbuvir)* VIEKIRA XR (dasabuvir/ombitasvir/ paritaprevir/ritonavir)* VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	*Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.

HYPERPARATHYROID AGENTS[AP]

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

paricalcitol capsule	cinacalcet doxercalciferol HECTOROL (doxercalciferol) paricalcitol injection RAYALDEE (calcifediol) SENSIPAR (cinacalcet) ZEMPLAR (paricalcitol)	

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HYPOGLYCEMICS, BIGUANIDES

CLASS PA CRITERIA: Non-preferred agents require a ninety (90) day trial of a preferred agent of similar duration before they will be approved, unless one (1) of the exceptions on the PA form is present.

metformin metformin ER (generic Glucophage XR)	FORTAMET (metformin ER) GLUCOPHAGE XR (metformin ER) GLUMETZA (metformin ER)* metformin solution (generic Riomet) metformin ER (generic Glumetza & Fortamet) RIOMET (metformin)	*Glumetza will be approved only after a 30-day trial of Fortamet.

HYPOGLYCEMICS, DPP-4 INHIBITORS

CLASS PA CRITERIA: Non-preferred agents are available only on appeal.

NOTE: DPP-4 inhibitors will NOT be approved in combination with a GLP-1 agonist.

JANUMET (sitagliptin/metformin) JANUMET XR (sitagliptin/metformin) JANUVIA (sitagliptin) JENTADUETO (linagliptin/metformin) TRADJENTA (linagliptin)	alogliptin alogliptin/metformin alogliptin/pioglitazone JENTADUETO XR (linagliptin/metformin) KAZANO (alogliptin/metformin) KOMBIGLYZE XR (saxagliptin/metformin) NESINA (alogliptin) ONGLYZA (saxagliptin) OSENI (alogliptin/pioglitazone)	

HYPOGLYCEMICS, GLP-1 AGONISTS[CL]

CLASS PA CRITERIA: Non-preferred agents will only be approved (in 6-month intervals) if ALL of the following criteria has been met:

1) Current A1C must be submitted. Agents in this class will not be approved for patients with a starting A1C of less than (<) 7%.
2) Documentation demonstrating 90 days of compliance on all current diabetic therapies is provided.
3) Documentation demonstrating treatment failure with all unique preferred agents in the same class.

Re-authorizations will require documentation of continued compliance on all diabetic therapies and A1C levels must reach goal, (either an A1C of ≤8%, or demonstrated continued improvement).

NOTE: GLP-1 agents will NOT be approved in combination with a DPP-4 inhibitor.

OZEMPIC (semaglutide) TRULICITY (dulaglutide) VICTOZA (liraglutide)	ADLYXIN (lixisenatide) BYETTA (exenatide) BYDUREON BCISE (exenatide) RYBELSUS (semaglutide)	

HYPOGLYCEMICS, INSULIN AND RELATED AGENTS

CLASS PA CRITERIA: Non-preferred agents require a ninety (90) day trial of a pharmacokinetically similar agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

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APIDRA (insulin gluisine)[AP]* FIASP (insulin aspart) HUMALOG (insulin lispro) HUMALOG JR KWIKPEN (insulin lispro) HUMALOG KWIKPEN U-100 (insulin lispro) HUMALOG MIX PENS (insulin lispro/lispro protamine) HUMALOG MIX VIALS (insulin lispro/lispro protamine) HUMULIN N VIAL (insulin) HUMULIN R U-500 VIAL (insulin) HUMULIN R U-500 KWIKPEN (insulin) LANTUS (insulin glargine) LEVEMIR (insulin detemir) NOVOLOG (insulin aspart) NOVOLOG MIX (insulin aspart/aspart protamine) TOUJEO SOLOSTAR (insulin glargine) TOUJEO MAX SOLOSTAR (insulin glargine	ADMELOG (insulin lispro) AFREZZA (insulin)[CL] BASAGLAR (insulin glargine) HUMALOG KWIKPEN U-200 (insulin lispro) HUMULIN PENS (insulin) HUMULIN R VIAL (insulin) HUMULIN 70/30 (insulin) insulin aspart insulin aspart/aspart protamine insulin lispro LYUMJEV (insulin lispro) NOVOLIN (insulin) SEMGLEE (insulin glargine) SOLIQUA (insulin glargine/lixisenatide)** TRESIBA (insulin degludec)*** TRESIBA FLEXTOUCH (insulin degludec)*** XULTOPHY (insulin degludec/liraglutide)**	*Apidra will be authorized if the following criteria are met: 1. Patient is four (4) years of age or older; **and** 2. Patient is currently on a regimen including a longer acting or basal insulin, **and** 3. Patient has had a trial of a similar preferred agent, Novolog or Humalog, with documentation that the desired results were not achieved.. ** Non-preferred insulin combination products require that the patient must already be established on the individual agents at doses not exceeding the maximum dose achievable with the combination product, and require medical reasoning beyond convenience or enhanced compliance as to why the clinical need cannot be met with a combination of preferred single-ingredient agents. ***Patients stabilized on Tresiba may be grandfathered at the request of the prescriber, if the prescriber considers the preferred products to be clinically inappropriate. ***Tresiba U-100 may be approved only for: Patients who have demonstrated at least a 6-month history of compliance on a preferred long-acting insulin and who continue to have regular incidents of hypoglycemia. ***Tresiba U-200 may be approved only for: Patients who require once-daily doses of at least 60 units of long-acting insulin and have demonstrated at least a 6-month history of compliance on preferred long-acting insulin and who continue to have regular incidents of hypoglycemia.

HYPOGLYCEMICS, MEGLITINIDES

CLASS PA CRITERIA: Non-preferred agents are available only on appeal.

MEGLITINIDES

nateglinide repaglinide	PRANDIN (repaglinide) STARLIX (nateglinide)

MEGLITINIDE COMBINATIONS

repaglinide/metformin

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HYPOGLYCEMICS, MISCELLANEOUS AGENTS

CLASS PA CRITERIA: Welchol will be authorized for add-on therapy for type 2 diabetes when there is a previous history of a thirty (30) day trial of an oral diabetic agent.

WELCHOL (colesevelam)[AP]	colesevelam SYMLIN (pramlintide)*	*Symlin will be authorized with a history of bolus insulin utilization in the past ninety (90) days with no gaps in insulin therapy greater than thirty (30) days.

HYPOGLYCEMICS, SGLT2 INHIBITORS

CLASS PA CRITERIA: Non-preferred agents will only be approved (in 6-month intervals) if ALL of the following criteria has been met:

1) Current A1C must be submitted. Agents in this class will not be approved for patients with a starting A1C of less than (<) 7%.
2) Documentation demonstrating 90 days of compliance on all current diabetic therapies is provided.
3) Documentation demonstrating treatment failure with all unique preferred agents in the same class.

Re-authorizations will require documentation of continued compliance on all diabetic therapies and A1C levels must reach goal, (either an A1C of ≤8%, or demonstrated continued improvement).

*Preferred SGLT2 inhibitors and combinations may be approved for a diagnosis of Heart Failure with Reduced Ejection Fraction (HFrEF) with or without Type II DM, Chronic Kidney Disease (CKD) with or without Type II DM, or Atherosclerotic Cardiovascular Disease (ASCVD) with Type II DM without further restrictions.

SGLT2 INHIBITORS	
FARXIGA (dapagliflozin)* INVOKANA (canagliflozin)* JARDIANCE (empagliflozin)*	STEGLATRO (ertugliflozin)
SGLT2 COMBINATIONS	
INVOKAMET (canagliflozin/metformin)* SYNJARDY (empagliflozin/metformin)*	GLYXAMBI (empagliflozin/linagliptin) INVOKAMET XR (canagliflozin/metformin) SEGLUROMET (ertugliflozin/metformin STEGLUJAN (ertugliflozin/sitagliptin) SYNJARDY XR (empagliflozin/metformin) TRIJARDY XR (empagliflozin/linagliptin/metformin) QTERN (dapagliflozin/saxagliptin) XIGDUO XR (dapagliflozin/metformin)

HYPOGLYCEMICS, TZD

CLASS PA CRITERIA: Non-preferred agents are available only on appeal.

THIAZOLIDINEDIONES	
pioglitazone	ACTOS (pioglitazone) AVANDIA (rosiglitazone)
TZD COMBINATIONS	

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	ACTOPLUS MET (pioglitazone/ metformin) DUETACT (pioglitazone/glimepiride) pioglitazone/glimepiride pioglitazone/ metformin	Patients are required to use the components of Actoplus Met and Duetact separately. Exceptions will be handled on a case-by-case basis.

IMMUNOMODULATORS, ATOPIC DERMATITIS

CLASS PA CRITERIA: Non-preferred agents require 30-day trial of a medium to high potency topical corticosteroid **AND** all preferred agents in this class unless one (1) of the exceptions on the PA form is present. Requirement for topical corticosteroids may be excluded with involvement of sensitive areas such as the face and skin folds.

ELIDEL (pimecrolimus) PROTOPIC (tacrolimus)	DUPIXENT (dupilumab)* EUCRISA (crisaborole)[AP]** pimecrolimus cream tacrolimus ointment	*Full PA criteria for Dupixent may be found on the PA Criteria page by clicking the hyperlink **Eucrisa requires a 30-day trial of Elidel **OR** a medium to high potency corticosteroid unless contraindicated.

IMMUNOMODULATORS, GENITAL WARTS & ACTINIC KERATOSIS AGENTS

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

CONDYLOX GEL (podofilox) EFUDEX (fluorouracil) imiquimod	ALDARA (imiquimod) CARAC (fluorouracil) diclofenac 3% gel fluorouracil 0.5% cream fluorouracil 5% cream podofilox TOLAK (fluorouracil 4% cream) VEREGEN (sinecatechins) ZYCLARA (imiquimod)*	*Zyclara will be authorized for a diagnosis of actinic keratosis.

IMMUNOSUPPRESSIVES, ORAL

CLASS PA CRITERIA: Non-preferred agents require a fourteen (14) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

azathioprine cyclosporine cyclosporine, modified mycophenolate mofetil sirolimus tacrolimus capsule	ASTAGRAF XL (tacrolimus) AZASAN (azathioprine) CELLCEPT (mycophenolate mofetil) ENVARSUS XR (tacrolimus) IMURAN (azathioprine) LUPKYNIS (voclosporin)* mycophenolic acid mycophenolic mofetil suspension MYFORTIC (mycophenolic acid) NEORAL (cyclosporine, modified) PROGRAF (tacrolimus) RAPAMUNE (sirolimus) SANDIMMUNE (cyclosporine)	*Lupkynis requires a ninety (90) day trial of Benlysta prior to approval. Full PA criteria for Lupkynis may be found on the PA Criteria page by clicking the hyperlink.

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	ZORTRESS (everolimus)	
INTRANASAL RHINITIS AGENTS[AP]		
CLASS PA CRITERIA: See below for individual sub-class criteria.		
	ANTICHOLINERGICS	
ipratropium	ATROVENT (ipratropium)	Non-preferred agents require thirty (30) day trials of one (1) preferred nasal anti-cholinergic agent, **AND** one (1) preferred antihistamine **AND** one (1) preferred intranasal corticosteroid agent before they will be approved, unless one (1) of the exceptions on the PA form is present.
	ANTIHISTAMINES	
azelastine	olopatadine PATANASE (olopatadine)	Non-preferred agents require thirty (30) day trials of one (1) preferred antihistamine **AND** one (1) preferred intranasal corticosteroid before they will be approved, unless one (1) of the exceptions on the PA form is present.
	COMBINATIONS	
	azelastine/fluticasone DYMISTA (azelastine / fluticasone)	Dymista requires a concurrent thirty (30) day trial of each preferred component before it will be approved, unless one (1) of the exceptions on the PA form is present.
	CORTICOSTEROIDS	
fluticasone propionate OMNARIS (ciclesonide) QNASL HFA (beclomethasone) ZETONNA (ciclesonide)	BECONASE AQ (beclomethasone) flunisolide mometasone NASONEX (mometasone)	Non-preferred agents require thirty (30) day trials of each preferred agent in this sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present
IRRITABLE BOWEL SYNDROME/SHORT BOWEL SYNDROME/SELECTED GI AGENTS [CL]		
CLASS PA CRITERIA: All agents are approvable only for patients age eighteen (18) and older. **See below for additional sub-class criteria.**		
	CONSTIPATION	
AMITIZA (lubiprostone) MOVANTIK (naloxegol) LINZESS (linaclotide)	LINZESS 72 mcg (linaclotide) lubiprostone capsule MOTEGRITY (prucalopride) RELISTOR INJECTION (methylnaltrexone) RELISTOR TABLET (methylnaltrexone) SYMPROIC (naldemedine) TRULANCE (plecanatide) ZELNORM (tegaserod maleate)	All agents in this subclass require documentation of the current diagnosis and evidence that the patient has failed to find relief with dietary modification and a fourteen (14) day trial of an osmotic laxative. No agent shall be approved to treat opioid induced constipation (OIC) without evidence of at least 90-days of opioid use preceding the request. Continuation of coverage shall be granted with evidence of continuous and concurrent opioid use. **Agents may be authorized only for their FDA-approved labeled indication. The following agent-specific criteria**

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		shall also apply, unless one (1) of the exceptions on the PA form is present: **Motegrity** requires a 30-day trial of both Amitiza and Linzess. **Relistor** and **Symproic** are indicated for OIC and require thirty (30) day trials of both Movantik and Amitiza. **Trulance** requires thirty (30) day trials of both Amitiza and Linzess, however for the indication of IBS-C in males, a trial of Amitiza is not required. **Linzess 72mcg** may only be approved for a diagnosis of chronic idiopathic constipation (CIC) AND for those who cannot tolerate the 145mcg dose. **Zelnorm** is indicated for females < 65 years of age diagnosed with irritable bowel syndrome with constipation (IBS-C) AND requires thirty (30) day trials of Amitiza and Linzess. **Lubiprostone** may only be authorized with a documented allergy or intolerance to Amitiza.
	DIARRHEA	
	Alosetron MYTESI (crofelemer) LOTRONEX (alosetron) VIBERZI (eluxadoline)	Full PA criteria may be found on the PA Criteria page by clicking the hyperlink
LAXATIVES AND CATHARTICS		
CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present		
COLYTE GOLYTELY NULYTELY peg 3350	CLENPIQ (sodium picosulfate, magnesium oxide, citric acid) MOVIPREP OSMOPREP SUPREP SUTAB (magnesium sulfate, potassium sulfate, sodium sulfate)	
LEUKOTRIENE MODIFIERS		
CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
montelukast zafirlukast	ACCOLATE (zafirlukast) SINGULAIR (montelukast) zileuton ZYFLO (zileuton)	

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LIPOTROPICS, OTHER (Non-statins)

CLASS PA CRITERIA: Non-preferred agents require a twelve (12) week trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

BILE ACID SEQUESTRANTS[AP]		
cholestyramine colestipol tablets	COLESTID (colestipol) colesevelam colestipol granules QUESTRAN (cholestyramine) WELCHOL (colesevelam)*	*Welchol will be authorized for add-on therapy for type 2 diabetes when there is a previous history of a thirty (30) day trial of an oral agent (metformin, sulfonylurea or thiazolidinedione (TZD)). See HYPOGLYCEMICS, MISCELLANEOUS.
CHOLESTEROL ABSORPTION INHIBITORS		
ezetimibe	ZETIA (ezetimibe)	
FATTY ACIDS[CL]		
omega-3 acid ethyl esters VASCEPA (icosapent ethyl)*	icosapent ethyl capsules LOVAZA (omega-3-acid ethyl esters)	[CL]All agents in this subclass require a prior authorization and an initial triglyceride level ≥ 500 mg/dL. *Additionally, Vascepa may be approved if the following criteria is met: 1. The patient has an initial triglyceride level of ≥ 150 mg/dL prior to start of therapy; AND 2. The patient has established cardiovascular disease or diabetes; AND 3. The patient is concomitantly receiving a statin.
FIBRIC ACID DERIVATIVES[AP]		
fenofibrate 54 and 160 mg fenofibrate micronized 67mg, 134mg & 200mg fenofibrate nanocrystallized 48 mg, 145 mg gemfibrozil	ANTARA (fenofibrate) FENOGLIDE (fenofibrate) FIBRICOR (fenofibric acid) fenofibrate 40 mg tablet fenofibrate 150 mg capsules fenofibrate 43, 50, 120 and 130 mg fenofibric acid LIPOFEN (fenofibrate) LOPID (gemfibrozil) TRICOR (fenofibrate nanocrystallized) TRILIPIX (fenofibric acid)	
MTP INHIBITORS		
	JUXTAPID (lomitapide)*	*Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.
NIACIN		
niacin niacin ER (OTC) NIASPAN (niacin)	niacin ER (Rx)	
PCSK-9 INHIBITORS/BEMPEDOIC ACID		

	PRALUENT (alirocumab)* REPATHA (evolocumab)* NEXLETOL (bempedoic acid)* NEXLIZET (bempedoic acid/ezetimibe)*	*Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.
LIPOTROPICS, STATINS[AP]		
CLASS PA CRITERIA: See below for individual sub-class criteria.		
	STATINS	
atorvastatin lovastatin pravastatin rosuvastatin simvastatin*	ALTOPREV (lovastatin) CRESTOR (rosuvastatin) EZALLOR (rosuvastatin)[NR] EZALLOR SPRINKLE (rosuvastatin)* fluvastatin fluvastatin ER LESCOL XL (fluvastatin) LIPITOR (atorvastatin) LIVALO (pitavastatin) PRAVACHOL (pravastatin) ZOCOR (simvastatin)** ZYPITAMAG (pitavastatin)	Non-preferred agents require twelve (12) week trials of two (2) preferred agents, including the generic formulation of the requested non-preferred agent, before they will be approved, unless one (1) of the exceptions on the PA form is present. *Ezallor SPRINKLE will only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia. **Zocor/simvastatin 80mg tablets will require a clinical PA.
	STATIN COMBINATIONS	
	amlodipine/atorvastatin CADUET (atorvastatin/amlodipine) ezetimibe/simvastatin VYTORIN (simvastatin/ezetimibe)*	Non-preferred agents require thirty (30) day concurrent trials of the corresponding preferred single agents before they will be approved, unless one (1) of the exceptions on the PA form is present. *Vytorin will be authorized only after an insufficient response to a twelve (12) week trial of the maximum tolerable dose of atorvastatin or rosuvastatin, unless one (1) of the exceptions on the PA form is present. Vytorin 80/10mg tablets will require a clinical PA.
MABS, ANTI-IL/IgE		
CLASS PA CRITERIA: For FDA-approved indications, non-preferred agents require a ninety (90) day trial of Xolair. **Full PA Criteria may be found on the PA Criteria page by clicking the hyperlink.**		
XOLAIR (omalizumab)	DUPIXENT (dupilumab) FASENRA (benralizumab) FASENRA PEN (benralizumab) NUCALA SYRINGE/VIAL (mepolizumab) NUCALA AUTO INJECTOR (mepolizumab)	

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MACROLIDES

CLASS PA CRITERIA: Non-preferred agents require a five (5) day trial of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

MACROLIDES		
azithromycin erythromycin base	clarithromycin tablets clarithromycin ER clarithromycin suspension E.E.S. (erythromycin ethylsuccinate) ERYPED (erythromycin ethylsuccinate) ERY-TAB (erythromycin) ERYTHROCIN (erythromycin stearate) erythromycin estolate ZITHROMAX (azithromycin)	

MULTIPLE SCLEROSIS AGENTS[CL]

CLASS PA CRITERIA: All agents require a prior authorization and documented diagnosis of multiple sclerosis. Preferred oral agents require a ninety (90) day trial of any preferred injectable agent. Non-preferred agents require ninety (90) day trials of two (2) chemically unique preferred agents (in the same sub-class) before they will be approved, unless one (1) of the exceptions on the PA form is present.

INTERFERONS[AP]		
AVONEX (interferon beta-1a) AVONEX PEN (interferon beta-1a) BETASERON (interferon beta-1b) REBIF (interferon beta-1a) REBIF REBIDOSE (interferon beta-1a)	EXTAVIA KIT (interferon beta-1b) EXTAVIA VIAL (interferon beta-1b) PLEGRIDY (peginterferon beta-1a)	

NON-INTERFERONS		
AUBAGIO (teriflunomide)* dalfampridine ER** COPAXONE 20 mg (glatiramer) GILENYA (fingolimod) TECFIDERA (dimethyl fumarate)***	AMPYRA (dalfampridine)** BAFIERTAM CAPSULES (monomethyl fumarate) COPAXONE 40 mg (glatiramer)**** dimethyl fumerate*** glatiramer GLATOPA (glatiramer) KESIMPTA INJECTION (ofatumumab) MAYZENT (siponimod)***** MAVENCLAD (cladribine) VUMERITY (diroximel) ZEPOSIA (ozanimod)	**In addition to class PA criteria, the following conditions and criteria may also apply:** *Aubagio requires the following additional criteria to be met: 1. Diagnosis of relapsing multiple sclerosis **and** 2. Measurement of transaminase and bilirubin levels within the (6) months before initiation of therapy and ALT levels at least monthly for six (6) months after initiation of therapy **and** 3. Complete blood cell count (CBC) within six (6) months before initiation of therapy **and** 4. Female patients must have a negative pregnancy test before initiation of therapy and be established on a reliable method of contraception if appropriate **and** 5. Patient is between eighteen (18) up to sixty-five (65) years of age **and** 6. Negative tuberculin skin test before initiation of therapy

**Dalfampridine ER and Ampyra require the following additional criteria to be met:
1. Diagnosis of multiple sclerosis **and**
2. No history of seizures **and**
3. No evidence of moderate or severe renal impairment.

***Dimethyl fumerate and Tecfidera require the following additional criteria to be met:
1. Diagnosis of relapsing multiple sclerosis **and**
2. Complete blood count (CBC) within six (6) months of initiation of therapy and six (6) months after initiation **and**
3. Complete blood count (CBC) annually during therapy.

****Copaxone 40mg will only be authorized for documented injection site issues.

*****Mayzent may be authorized with no additional requirement beyond the diagnosis for patients with documented secondary progressive MS.

NEUROPATHIC PAIN

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent in the corresponding dosage form (oral or topical) before they will be approved, unless one (1) of the exceptions on the PA form is present.

capsaicin OTC
duloxetine
gabapentin
lidocaine patch 5%
pregabalin capsule
ZTLIDO PATCH (lidocaine)

CYMBALTA (duloxetine)
DRIZALMA SPRINKLE (duloxetine)*
GRALISE (gabapentin)**
HORIZANT (gabapentin)
lidocaine patch 4%
LIDODERM (lidocaine)
LYRICA CR (pregabalin)***
LYRICA SOLUTION (pregabalin)***
NEURONTIN (gabapentin)[AP]
pregabalin ER tablet (generic Lyrica CR)
QUTENZA (capsaicin)
SAVELLA (milnacipran)****
LYRICA CAPSULE (pregabalin)

*Drizalma SPRINKLE will only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia.

**Gralise will be authorized only if the following criteria are met:
1. Diagnosis of post herpetic neuralgia **and**
2. Trial of a tricyclic antidepressant for a least thirty (30) days **and**
3. 90-day trial of gabapentin immediate release formulation (positive response without adequate duration) **and**
4. Request is for once daily dosing with 1800 mg maximum daily dosage.

***Lyrica CR and Lyrica Solution require medical reasoning beyond convenience as to why the need cannot be met using preferred pregabalin capsules.

****Savella will be authorized for a diagnosis of fibromyalgia only after a 90-day trial of one preferred agent

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NSAIDS[AP]		
CLASS PA CRITERIA: See below for sub-class PA criteria.		
	NON-SELECTIVE	
diclofenac (IR, SR) flurbiprofen ibuprofen (Rx and OTC) INDOCIN SUSPENSION (indomethacin) indomethacin ketoprofen ketorolac meloxicam tablet nabumetone naproxen sodium tablet naproxen sodium DS tablet naproxen suspension EC-naproxen DR tablet piroxicam sulindac	DAYPRO (oxaprozin) diflunisal DUEXIS (famotidine/ibuprofen) etodolac IR etodolac SR FELDENE (piroxicam) fenoprofen INDOCIN SUPPOSITORIES (indomethacin) indomethacin ER ketoprofen ER meclofenamate mefenamic acid meloxicam submicronized capsule (generic Vivlodex) meloxicam suspension MOBIC TABLET (meloxicam) NALFON (fenoprofen) NAPRELAN (naproxen) naproxen CR oxaprozin RELAFEN DS (nabumetone) SPRIX (ketorolac) TIVORBEX (indomethacin) tolmetin VIVLODEX (meloxicam) VOLTAREN (diclofenac) ZIPSOR (diclofenac potassium) ZORVOLEX (diclofenac)	Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.
	NSAID/GI PROTECTANT COMBINATIONS	
	ARTHROTEC (diclofenac/misoprostol) diclofenac/misoprostol naproxen/esomeprazole VIMOVO (naproxen/esomeprazole)	Non-preferred agents are only available on appeal and require medical reasoning beyond convenience as to why the need cannot be met with the combination of preferred single agents.
	COX-II SELECTIVE	
	CELEBREX (celecoxib) celecoxib	COX-II Selective agents require thirty (30) day trials of each preferred Non-Selective Oral NSAID, **UNLESS** the following criteria are met: Patient has a history or risk of a serious GI complication; **OR**

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		Agent is requested for treatment of a chronic condition **and** 1. Patient is seventy (70) years of age or older, **or** 2. Patient is currently on anticoagulation therapy.
	TOPICAL	
FLECTOR PATCH (diclofenac)* diclofenac gel (RX)**	diclofenac patch diclofenac solution LICART PATCH (diclofenac) PENNSAID (diclofenac)	*Flector patches are limited to two per day. **diclofenac gel will be limited to 100 grams per month. Non-preferred agents require a thirty (30) day trial of the preferred Topical agent and thirty (30) day trials of each preferred oral NSAID before they will be approved, unless one(1) of the exceptions on the PA form is present.
OPHTHALMIC ANTIBIOTICS[AP]		
CLASS PA CRITERIA: Non-preferred agents require three (3) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
bacitracin/polymyxin ointment ciprofloxacin* erythromycin gentamicin levofloxacin* MOXEZA (moxifloxacin) neomycin/bacitracin/polymyxin ofloxacin* polymyxin/trimethoprim tobramycin TOBREX OINT (tobramycin)	AZASITE (azithromycin) bacitracin BLEPH-10 (sulfacetamide) BESIVANCE (besifloxacin)* CILOXAN (ciprofloxacin) gatifloxacin moxifloxacin** NATACYN (natamycin) neomycin/polymyxin/gramicidin OCUFLOX (ofloxacin) POLYTRIM (polymyxin/trimethoprim) sulfacetamide drops sulfacetamide ointment TOBREX (tobramycin) VIGAMOX (moxifloxacin) ZYMAXID (gatifloxacin)	*Prior authorization of any fluoroquinolone agent requires three (3) day trials of all other preferred agents unless definitive laboratory cultures exist indicating the need to use a fluoroquinolone.
OPHTHALMIC ANTIBIOTIC/STEROID COMBINATIONS[AP]		
CLASS PA CRITERIA: Non-preferred agents require three (3) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
neomycin/polymyxin/dexamethasone sulfacetamide/prednisolone TOBRADEX OINTMENT (tobramycin/ dexamethasone) TOBRADEX SUSPENSION (tobramycin/ dexamethasone) ZYLET (loteprednol/tobramycin)	BLEPHAMIDE (prednisolone/sulfacetamide) MAXITROL ointment (neomycin/polymyxin/ dexamethasone) MAXITROL suspension (neomycin/polymyxin/ dexamethasone) neomycin/bacitracin/polymyxin/ hydrocortisone neomycin/polymyxin/hydrocortisone PRED-G (prednisolone/gentamicin) TOBRADEX ST (tobramycin/ dexamethasone) tobramycin/dexamethasone suspension	

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OPHTHALMICS FOR ALLERGIC CONJUNCTIVITIS[AP]

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of three (3) preferred chemically unique agents before they will be approved, unless one (1) of the exceptions on the PA form is present.

ALAWAY (ketotifen)	ALOCRIL (nedocromil)	
ALREX (loteprednol)	ALOMIDE (lodoxamide)	
BEPREVE (bepotastine)	azelastine	
cromolyn	Epinastine	
ketotifen	LUMIFY (brimonidine)	
LASTACAFT (alcaftadine)	olopatadine 0.1% (all formulations except Generic PATANOL labeler 61314)	
olopatadine 0.1% (Generic PATANOL labeler 61314 only)	olopatadine 0.2% (all labelers)	
ZADITOR OTC (ketotifen)	PATANOL (olopatadine)	
	ZERVIATE (cetirizine)	

OPHTHALMICS, ANTI-INFLAMMATORIES- IMMUNOMODULATORS[CL]

CLASS PA CRITERIA: All agents require a prior authorization. Non-preferred agents require a 60-day trial of the preferred agent(s).

RESTASIS (cyclosporine)	CEQUA (cyclosporine)	***Restasis Multidose** is approvable only on appeal and requires medical reasoning as to why the clinical need cannot be met with the preferred product (Restasis).
	EYSUVIS (loteprednol)	**All agents must meet the following prior-authorization criteria:** 1.) Patient must be sixteen (16) years of age or greater; **AND** 2.) Prior Authorization must be requested by an ophthalmologist or optometrist; **AND** 3.) Clinically diagnosed tear deficiency due to ocular inflammation in patients with keratoconjunctivitis sicca or dry eye syndrome (also known as dry eye); **AND** 4.) Patient must have a functioning lacrimal gland; **AND** 5.) Patient using artificial tears at least four (4) times a day over the last thirty (30) days; **AND** Patient must not have an active ocular infection
	RESTASIS MULTIDOSE (cyclosporine)*	
	XIIDRA (lifitegrast)	

OPHTHALMICS, ANTI-INFLAMMATORIES

CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of at least two (2) preferred agents before they will be approved, unless one (1) of the exceptions on the PA form is present. Trials must include at least one agent with the same mechanism of action as the requested non-preferred agent.

dexamethasone	ACULAR (ketorolac)	
diclofenac	ACULAR LS (ketorolac)	
DUREZOL (difluprednate)	ACUVAIL (ketorolac tromethamine)	
fluorometholone	bromfenac	
FML FORTE (fluorometholone)	BROMSITE (bromfenac)	
FML S.O.P. (fluorometholone)	FLAREX (fluorometholone)	

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ketorolac LOTEMAX DROPS, OINTMENT (loteprednol) MAXIDEX (dexamethasone) NEVANAC (nepafenac) PRED MILD (prednisolone) prednisolone acetate prednisolone sodium phosphate	flurbiprofen FML (fluorometholone) ILEVRO (nepafenac) INVELTYS (loteprednol) LOTEMAX GEL (loteprednol) loteprednol drops, gel OMNIPRED (prednisolone) OZURDEX (dexamethasone) PRED FORTE (prednisolone) PROLENSA (bromfenac) RETISERT (fluocinolone) TRIESENCE (triamcinolone)	

OPHTHALMICS, GLAUCOMA AGENTS

CLASS PA CRITERIA: Non-preferred agents will only be authorized if there is an allergy to all preferred agents in the corresponding sub-class.

COMBINATION AGENTS		
COMBIGAN (brimonidine/timolol) dorzolamide/timolol SIMBRINZA (brinzolamide/brimonidine)	COSOPT PF (dorzolamide/timolol)	
BETA BLOCKERS		
BETOPTIC S (betaxolol) carteolol levobunolol timolol drops	betaxolol ISTALOL (timolol) timolol gel TIMOPTIC (timolol)	
CARBONIC ANHYDRASE INHIBITORS		
AZOPT (brinzolamide) dorzolamide	brinzolamide TRUSOPT (dorzolamide)	
PARASYMPATHOMIMETICS		
PHOSPHOLINE IODIDE (echothiophate iodide)	pilocarpine	
PROSTAGLANDIN ANALOGS		
latanoprost TRAVATAN-Z (travoprost)	bimatoprost LUMIGAN (bimatoprost) travoprost VYZULTA (latanoprostene)* XALATAN (latanoprost) XELPROS (latanoprost) ZIOPTAN (tafluprost)	*Vyzulta – prior authorization requires failure on a 3-month trial of at least one preferred prostaglandin eye drop used in combination with an agent from another subclass.
RHO-KINASE INHIBITORS		
RHOPRESSA (netarsudil) ROCKLATAN (netarsudil/latanoprost)		
SYMPATHOMIMETICS		
brimonidine 0.2%	ALPHAGAN P 0.1% Solution (brimonidine) ALPHAGAN P 0.15% Solution (brimonidine) apraclonidine	

	IOPIDINE (apraclonidine)	

OPIATE DEPENDENCE TREATMENTS

CLASS PA CRITERIA: Bunavail and Zubsolv may only be approved with a documented intolerance or allergy to Suboxone strips AND buprenorphine/naloxone tablets.

WV Medicaid's buprenorphine coverage policy may be viewed by clicking on the following hyperlink: Buprenorphine Coverage Policy and Related Forms

buprenorphine/naloxone tablets*	BUNAVAIL (buprenorphine/naloxone)	* Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.
naloxone	buprenorphine tablets	
NARCAN NASAL SPRAY (naloxone)	buprenorphine/naloxone film	
SUBOXONE FILM (buprenorphine/naloxone)*	LUCEMYRA (lofexidine)	**Sublocade is approvable only on appeal and requires medical reasoning as to why the clinical need cannot be met with a preferred product.
VIVITROL (naltrexone)	SUBLOCADE (buprenorphine soln)**	
	ZUBSOLV (buprenorphine/naloxone)	

OTIC ANTIBIOTICS[AP]

CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

CIPRO HC (ciprofloxacin/hydrocortisone)	ciprofloxacin
CIPRODEX (ciprofloxacin/dexamethasone)	ciprofloxacin/dexamethasone)
ofloxacin	ciprofloxacin/fluocinolone
CORTISPORIN-TC (colistin/hydrocortisone/ neomycin)	neomycin/polymyxin/HC solution/suspension
	OTOVEL (ciprofloxacin/fluocinolone)

PAH AGENTS – ENDOTHELIN RECEPTOR ANTAGONISTS[CL]

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

LETAIRIS (ambrisentan)	ambrisentan
TRACLEER TABLET (bosentan)	bosentan
	OPSUMIT (macitentan)
	TRACLEER SUSP (bosentan)

PAH AGENTS – PDE5s[CL]

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.
Patients stabilized on non-preferred agents will be grandfathered.

sildenafil tablets	ADCIRCA (tadalafil)
	REVATIO IV (sildenafil)
	REVATIO SUSPENSION (sildenafil)
	REVATIO TABLETS (sildenafil)
	sildenafil suspension (generic Revatio)

PAH AGENTS – PROSTACYCLINS[CL]

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CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent, including the preferred generic form of the non-preferred agent (if available), before they will be approved, unless one (1) of the exceptions on the PA form is present.

epoprostenol (generic Flolan) VENTAVIS (iloprost)*	epoprostenol (generic Veletri) FLOLAN (epoprostenol) ORENITRAM ER (treprostinil) REMODULIN (treprostinil sodium) TYVASO (treprostinil) UPTRAVI (selexipag) VELETRI (epoprostenol)	*Ventavis will only be authorized for the treatment of pulmonary artery hypertension (WHO Group 1) in patients with NYHA Class III or IV symptoms.

PANCREATIC ENZYMES[AP]

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.
For members with cystic fibrosis, a trial of a preferred agent will not be required.

CREON ZENPEP	PANCREAZE PERTZYE VIOKACE

PHOSPHATE BINDERS[AP]

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of at least two (2) preferred agents before they will be approved, unless one (1) of the exceptions on the PA form is present.

calcium acetate CALPHRON (calcium acetate) MAGNEBIND RX (calcium carbonate, folic acid, magnesium carbonate) PHOSLYRA (calcium acetate) sevelamer carbonate	AURYXIA (ferric citrate) FOSRENOL (lanthanum) lanthanum chewable RENAGEL (sevelamer) RENVELA (sevelamer carbonate) VELPHORO (sucroferric oxyhydroxide)

PITUITARY SUPPRESSIVE AGENTS, LHRH[CL]

CLASS PA CRITERIA: Unless otherwise noted, non-preferred agents are available only on appeal.

LUPANETA (leuprolide) LUPRON DEPOT KIT (leuprolide) LUPRON DEPOT-PED KIT (leuprolide) SYNAREL (nafarelin) TRELSTAR (triptorelin) TRIPTODUR (triptorelin) VANTAS (histrelin) ZOLADEX (goserelin)	leuprolide ORILISSA (elagolix)* ORIAHNN (elagolix-estradiol-norethindrone)* SUPPRELIN LA KIT (histrelin)	* Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.

PLATELET AGGREGATION INHIBITORS

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

BRILINTA (ticagrelor) clopidogrel	clopidogrel kit dipyridamole/aspirin

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dipyridamole prasugrel	EFFIENT (prasugrel) PLAVIX (clopidogrel) ZONTIVITY (vorapaxar)	

PROGESTATIONAL AGENTS

CLASS PA CRITERIA: Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.

MAKENA (hydroxyprogesterone caproate) AUTO INJECTOR MAKENA (hydroxyprogesterone caproate) VIAL	hydroxyprogesterone caproate	

PROGESTINS FOR CACHEXIA

CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

Megestrol

PROTON PUMP INHIBITORS[AP]

CLASS PA CRITERIA: Non-preferred agents require sixty (60) day trials of both omeprazole (Rx) and pantoprazole at the maximum recommended dose*, inclusive of a concurrent thirty (30) day trial at the maximum dose of an H_2 antagonist before they will be approved, unless one (1) of the exceptions on the PA form is present.

NEXIUM PACKETS (esomeprazole)** omeprazole (Rx) pantoprazole PROTONIX GRANULES (pantoprazole)**	ACIPHEX (rabeprazole) ACIPHEX SPRINKLE (rabeprazole) DEXILANT (dexlansoprazole) esomeprazole magnesium lansoprazole Rx NEXIUM (esomeprazole) omeprazole/sodium bicarbonate (Rx) PREVACID CAPSULES (lansoprazole) PREVACID SOLUTABS (lansoprazole)** PRILOSEC Rx (omeprazole) PROTONIX DR TABLETS (pantoprazole) rabeprazole ZEGERID Rx (omeprazole/sodium bicarbonate)	*Maximum recommended doses of the PPIs and H2-receptor antagonists may be located at the BMS Pharmacy PA criteria page titled "Max PPI and H2RA" by clicking on the hyperlink. **Prior authorization is required for members nine (9) years of age or older for these agents.

SEDATIVE HYPNOTICS[AP]

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of all preferred agents in **BOTH** sub-classes before they will be approved, unless one (1) of the exceptions on the PA form is present. All agents except melatonin will be limited to fifteen (15) tablets in a thirty (30) day period. NOTE: WV Medicaid covers melatonin up to a maximum dose of 9 mg/day without a PA. Melatonin labeler code 51645 is preferred if available, however all NDCs are payable.

BENZODIAZEPINES

temazepam 15, 30 mg	estazolam flurazepam HALCION (triazolam) RESTORIL (temazepam) temazepam 7.5, 22.5 mg triazolam	

OTHERS		
melatonin ROZEREM (ramelteon) zolpidem 5, 10 mg	AMBIEN (zolpidem) AMBIEN CR (zolpidem) BELSOMRA (suvorexant) DAYVIGO (lemborexant) EDLUAR (zolpidem) eszopiclone HETLIOZ (tasimelteon)[CL]* LUNESTA (eszopiclone) ramelteon SILENOR (doxepin) zaleplon zolpidem ER 6.25, 12.5 mg	Strengths of zolpidem that are non-preferred (6.25 and 12.5 mg) must be created by combining or splitting the preferred doses (5 and 10 mg) of zolpidem, if appropriate. For treatment naïve female patients, zolpidem and zolpidem ER maximum dosages will be limited to 5 mg and 6.25 mg respectively per day. *Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.
SKELETAL MUSCLE RELAXANTS[AP]		
CLASS PA CRITERIA: See below for individual sub-class criteria.		
ACUTE MUSCULOSKELETAL RELAXANT AGENTS		
chlorzoxazone (generic PARAFON FORTE) cyclobenzaprine IR 5, 10 mg methocarbamol	AMRIX (cyclobenzaprine) carisoprodol* carisoprodol/ASA* carisoprodol/ASA/codeine* chlorzoxazone (generic LORZONE) cyclobenzaprine ER cyclobenzaprine IR 7.5 mg FEXMID (cyclobenzaprine) LORZONE (chlorzoxazone) metaxalone orphenadrine orphenadrine ER ROBAXIN (methocarbamol) SKELAXIN (metaxalone) SOMA (carisoprodol)	Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present, with the exception of carisoprodol. *Carisoprodol requires thirty (30) day trials of each of the preferred acute musculoskeletal relaxants and Skelaxin before it will be approved.
MUSCULOSKELETAL RELAXANT AGENTS USED FOR SPASTICITY		
baclofen tizanidine tablets	DANTRIUM (dantrolene) dantrolene tizanidine capsules ZANAFLEX (tizanidine)	Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.
STEROIDS, TOPICAL		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of **EACH** preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.		

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VERY HIGH & HIGH POTENCY		
betamethasone dipropionate cream betamethasone valerate cream betamethasone valerate lotion betamethasone valerate oint clobetasol propionatecream, gel, ointment, solution clobetasol emollient clobetasol propionate shampoo fluocinonide gel triamcinolone acetonide cream, ointment triamcinolone acetonide lotion	amcinonide APEXICON E (diflorasone diacetate) betamethasone dipropionate gel, lotion, ointment BRYHALI LOTION (halobetasol) clobetasol lotion clobetasol propionate foam CLOBEX (clobetasol propionate) CLODAN KIT (clobetasol propionate) CLODAN SHAMPOO (clobetasol propionate) desoximetasone cream/gel/ointment diflorasone diacetate DIPROLENE (betamethasone dipropionate/propylene glycol) fluocinonide cream fluocinonide ointment fluocinonide solution fluocinonide/emollient halcinonide cream halobetasol propionate HALOG (halcinonide) IMPEKLO LOTION (clobetasol propionate) KENALOG (triamcinolone acetonide) LEXETTE FOAM (halobetasol) OLUX (clobetasol propionate) OLUX-E (clobetasol propionate/emollient) PSORCON (diflorasone diacetate) TEMOVATE (clobetasol propionate) TOPICORT CREAM, GEL, OINTMENT (desoximetasone) TOPICORT SPRAY (desoximetasone) TOVET FOAM (clobetasol) ULTRAVATE (halobetasol propionate) ULTRAVATE PAC cream VANOS (fluocinonide)	
MEDIUM POTENCY		
fluticasone propionate cream, ointment mometasone furoate triamcinolone acetonide 0.025% and 0.1% cream	BESER LOTION (fluticasone) betamethasone valerate foam CLODERM (clocortolone pivalate) clocortolone cream CORDRAN (flurandrenolide) CUTIVATE (fluticasone propionate) fluocinolone acetonide cream, ointment, solution fluticasone propionate lotion hydrocortisone butyrate cream hydrocortisone butyrate ointment, solution hydrocortisone valerate	

	LOCOID (hydrocortisone butyrate) LOCOID LIPOCREAM (hydrocortisone butyrate/emollient) LUXIQ (betamethasone valerate) PANDEL (hydrocortisone probutate) prednicarbate	
	LOW POTENCY	
DERMA-SMOOTHE FS (fluocinolone acetonide) hydrocortisone acetate (Rx, OTC) hydrocortisone cream (Rx, OTC) hydrocortisone lotion OTC hydrocortisone ointment (Rx, OTC) hydrocortisone solution OTC hydrocortisone-aloe cream OTC hydrocortisone-aloe ointment OTC	alclometasone dipropionate AQUA GLYCOLIC HC (hydrocortisone) CAPEX (fluocinolone acetonide) DESONATE (desonide) desonide cream, ointment desonide lotion fluocinolone oil hydrocortisone/mineral oil/petrolatum hydrocortisone acetate/urea hydrocortisone lotion hydrocortisone/aloe gel SCALPICIN OTC (hydrocortisone) SYNALAR (fluocinolone) TEXACORT (hydrocortisone)	

STIMULANTS AND RELATED AGENTS

CLASS PA CRITERIA: A PA is required for adults eighteen (18) years of age or older.

Non-preferred agents require a thirty (30) day trial of at least one preferred agent in the same subclass and with a similar duration of effect and mechanism of action, unless one (1) of the exceptions on the PA form is present. **NOTE**: Non-preferred agents will NOT be "grandfathered" for adults. Children under the age of 18 may continue their current therapy until the end of the school year after which they will be required to switch to a preferred agent.

	AMPHETAMINES	
amphetamine salt combination ER amphetamine salt combination IR dextroamphetamine ER dextroamphetamine IR VYVANSE CHEWABLE (lisdexamfetamine) VYVANSE CAPSULE (lisdexamfetamine)	ADDERALL (amphetamine salt combination) ADDERALL XR (amphetamine salt combination) ADZENYS XR ODT (amphetamine) ADZENYS ER SUSP (amphetamine) amphetamine tablets DESOXYN (methamphetamine) DEXEDRINE ER (dextroamphetamine) dextroamphetamine solution DYANAVEL XR SUSP (amphetamine) EVEKEO (amphetamine) EVEKEO ODT (amphetamine) methamphetamine MYDAYIS (dextroamphetamine/amphetamine salt)* PROCENTRA solution (dextroamphetamine) ZENZEDI (dextroamphetamine)	**In addition to the Class Criteria**: Thirty (30) day trials of at least three (3) antidepressants are required before amphetamines will be authorized for depression. *Mydayis requires a 30-day trial of at least one long-acting preferred agent in this subclass and a trial of Adderall XR.

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NON-AMPHETAMINE		
atomoxetine CONCERTA (methylphenidate) clonidine IR dexmethylphenidate IR FOCALIN XR (dexmethylphenidate) guanfacine ER guanfacine IR methylphenidate IR methylphenidate ER tablet (generic RITALIN SR) methylphenidate solution QUILLICHEW ER (methylphenidate) QUILLIVANT XR (methylphenidate)	ADHANSIA XR (methylphenidate) APTENSIO XR (methylphenidate) clonidine ER COTEMPLA XR ODT (methylphenidate) DAYTRANA (methylphenidate) dexmethylphenidate XR FOCALIN IR (dexmethylphenidate) INTUNIV (guanfacine extended-release) JORNAY PM (methylphenidate) METHYLIN SOLUTION (methylphenidate) methylphenidate CD methylphenidate chewable tablets methylphenidate ER 24 tablet (generic CONCERTA) methylphenidate ER capsule methylphenidate LA capsule RITALIN (methylphenidate) RITALIN LA (methylphenidate) STRATTERA (atomoxetine)*	* Strattera is limited to a maximum of 100 mg per day.
NARCOLEPTIC AGENTS		
armodafinil[CL] modafinil[CL]	NUVIGIL (armodafinil) PROVIGIL (modafinil) SUNOSI (solriamfetol)* WAKIX (pitolisant)**	* Sunosi is approvable only with documentation of treatment failure after 30-day trials of both armodafinil and modafinil. **Wakix is approvable only with documentation of treatment failure after 30-day trials of armodafinil, modafinil and Sunosi.

TETRACYCLINES

CLASS PA CRITERIA: Non-preferred agents require ten (10) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

doxycycline hyclate capsules doxycycline hyclate 100 mg tablets doxycycline monohydrate 50, 100 mg capsules minocycline capsules	demeclocycline* DORYX (doxycycline hyclate) doxycycline hyclate 75, 150 mg tablets doxycycline hyclate tablet DR 75, 100, 150, 200 mg doxycycline hyclate tablet DR 50 mg doxycycline monohydrate 40, 75, 150 mg capsule doxycycline monohydrate tablet doxycycline monohydrate suspension MINOCIN (minocycline) minocycline ER capsules minocycline tablets MINOLIRA ER (minocycline) MORGIDOX KIT (doxycycline) ORACEA (doxycycline monohydrate)	*Demeclocycline will be authorized for conditions caused by susceptible strains of organisms designated in the product information supplied by the manufacturer. A C&S report must accompany this request. Demeclocycline will also be authorized for SIADH.

BUREAU FOR MEDICAL SERVICES
WEST VIRGINIA MEDICAID
PREFERRED DRUG LIST WITH PRIOR AUTHORIZATION CRITERIA
This is not an all-inclusive list of available covered drugs and includes only managed categories. Refer to cover page for complete list of rules governing this PDL.

EFFECTIVE
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	SOLODYN (minocycline) tetracycline VIBRAMYCIN CAPSULES, SUSPENSION, SYRUP (doxycycline) XIMINO (minocycline)	

ULCERATIVE COLITIS AGENTS[AP]

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each preferred dosage form or chemical entity before the corresponding non-preferred agent of that dosage form or chemical entity will be approved, unless one (1) of the exceptions on the PA form is present.

ORAL

APRISO (mesalamine) ASACOL HD (mesalamine) balsalazide PENTASA (mesalamine) 250 mg PENTASA (mesalamine) 500 mg sulfasalazine	AZULFIDINE (sulfasalazine) COLAZAL (balsalazide) DELZICOL (mesalamine) DIPENTUM (olsalazine) LIALDA (mesalamine) mesalamine UCERIS (budesonide) ZEPOSIA (ozanimod)	

RECTAL

mesalamine	DELZICOL DR (mesalamine) mesalamine kit ROWASA (mesalamine) SF ROWASA (mesalamine) UCERIS (budesonide)	

VASODILATORS, CORONARY

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each preferred dosage form before they will be approved, unless one (1) of the exceptions on the PA form is present.

SUBLINGUAL NITROGLYCERIN

nitroglycerin spray (generic NITROLINGUAL) nitroglycerin sublingual NITROSTAT SUBLINGUAL (nitroglycerin)	GONITRO SPRAY POWDER (nitroglycerin) nitroglycerin spray (generic NITROMIST) NITROLINGUAL SPRAY (nitroglycerin) NITROMIST (nitroglycerin)	

MISCELLANEOUS COVERED AGENTS

This category contains covered agents which either did not easily fit into a single PDL category or had criteria that was too lengthy to cite within the PDL itself. Full criteria for the agents listed below may be found by following this hyperlink: (https://dhhr.wv.gov/bms/BMS%20Pharmacy/Pages/PA-Criteria.aspx). Please note that some agents may be available only by billing the appropriate HCPCS code noted in the criteria.

Afinitor
Albenza and Emverm
Ampyra
Antifungal Agents
Austedo

Belbuca
Benlysta
Botox
Carbaglu
CGRP Receptor Antagonists
Continuous Glucose Monitors
Corlanor
Cresemba
Cuvposa
Cytokine & CAM Antagonists
Diclegis
Dificid
Dojolvi
Droxidopa
Duavee
Dupixent
Epidiolex
Emflaza
Enspryng
Esbriet
Evrysdi
ExJade
Exondys 51
Fasenra
Ferriprox
Firazyr
Fuzeon
Gattex
Gralise
Growth Hormone for Adults
Growth Hormone for Children
Hepatitis C PA Criteria
Hereditary Angioedema Agents
Hetlioz
Home Infusion Drugs and Supplies
Horizant
HP Acthar
HyQvia
Increlex
Ingrezza
Jublia
Juxtapid
Kalydeco
Ketoconazole
Korlym
Kuvan

Kymriah
Kynamro
Lucemyra
Lutathera
Lupkynis
Luxturna
Makena
Max PPI an H2RA
Mozobil
Myalept
Mytesi
Natpara
Nexletol and Nexlizet
Non-Sedating Antihistamines
Nuvigil
Nucala
OFEV
Oforta
Omnipod
Orilissa
Oralair
Oriahnn
Orkambi
Osphena
Oxlumo
Palforzia
Palynziq
PCSK9 Inhibitor
Provigil
Qbrexza
Rectiv
Regranex
Remicade
Restasis
Rilutek
Riluzole
Risperdal Consta
Ruconest
Sirturo
Spinraza
Spravato
Sprycel
Suboxone Policy
Symdeko
Synagis
Testosterone
Thalomid

Tobacco Cessation Policy
Trikafta
V-Go
Viberzi and Lotronex
Verquvo
Vyondys 53
Xanax XR
Xenazine
Xhance
Xifaxan
Xolair
Xyrem and Xywav
Yescarta
Zolgensma
Zulresso
Zurampic
Zyvox