19.0277.03000

FISCAL NOTE

Requested by Legislative Council
01/14/2019

Amendment to: SB 2290

1 A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2017-2019 Biennium		2019-2021 Biennium		2021-2023 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures						
Appropriations						

1 B. **County, city, school district and township fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

	2017-2019 Biennium	2019-2021 Biennium	2021-2023 Biennium
Counties			
Cities			
School Districts			
Townships			

2 A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

SB 2290 provides authorization of a Medicaid step program based on the Medicare part B step therapy program.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

The Department does not expect a fiscal impact from SB 2290 because the department will only implement the process proposed in SB 2290 when local Medicare carriers implement step care. Also, the direction from CMS ensures that the decisions are clinically and FDA approval-based and not cost-based; therefore, we do not anticipate any fiscal impact.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation or a part of the appropriation is included in the executive budget or relates to a continuing appropriation.*

Name: Rhonda Obrigewitch
Agency: Human Services
Telephone: 325-4585
Date Prepared: 01/17/2019

19.0277.02000

FISCAL NOTE

Requested by Legislative Council
01/14/2019

Bill/Resolution No.: SB 2290

1 A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2017-2019 Biennium		2019-2021 Biennium		2021-2023 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures						
Appropriations						

1 B. **County, city, school district and township fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

	2017-2019 Biennium	2019-2021 Biennium	2021-2023 Biennium
Counties			
Cities			
School Districts			
Townships			

2 A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

SB 2290 provides authorization of a Medicaid step program based on the Medicare part B step therapy program.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

The Department does not expect a fiscal impact from SB 2290 because the department will only implement the process proposed in SB 2290 when local Medicare carriers implement step care. Also, the direction from CMS ensures that the decisions are clinically and FDA approval-based and not cost-based; therefore, we do not anticipate any fiscal impact.

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A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation or a part of the appropriation is included in the executive budget or relates to a continuing appropriation.*

Name: Rhonda Obrigewitch
Agency: Human Services
Telephone: 325-4585
Date Prepared: 01/17/2019

2019 SENATE HUMAN SERVICES

SB 2290

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2290
1/21/2019
Job # 31078

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

Relating to authorization of a Medicaid step therapy program based on Medicare part b step therapy program.

Minutes: Attachments #1-4

Madam Chair Lee: Opens the hearing for SB 2290, introduces the bill and gives a brief description.

(3:00) Senator K. Roers: Why is it called "step therapy"?

Madam Chair Lee: Let's say XYZ is the condition and maybe there is a new drug that is coming out but maybe there is one that has had very good results in that condition and so with the formularies that you and I use and the ones the Medicaid uses for the drugs that have prior authorization, they would be recommending that the first drug be the one which is proven to be effective for that condition but is not necessarily the million-dollar drug.

(6:45-11:33) Maggie Anderson, Medical Services Division, presenting testimony for **Brendan Joyce, Administrator of Pharmacy Services with the Medical Services Division for the Department of Human Services.** Offering neutral testimony for SB 2290 Please see **Attachment #1** for testimony. Also please see **Attachment #2** for proposed amendment.

(12:05-14:56) Deb Knuth, Government Relations Director for the North Dakota American Cancer Society Cancer Action Network. Testifying in opposition for SB 2290. Please see **Attachment #3** for testimony.

Madam Chair Lee: Do you have examples of situations where you think that there has been a problem with step therapy with private insurers because it's in place in a lot of different insurance policies.

Deb Knuth: The only concern that we have is in the cancer patients that we see. When they have advanced cancer we like to have the doctor to have the ability to change the medical treatment without it being reviewed.

Madam Chair Lee: Are you familiar with whether or not what's being requested here for Medicaid patients might be different or similar to what private insurance might require in a similar circumstance now?

Deb Knuth: No I can't speak to that today.

Madam Chair Lee: We will ask the other insurers

Senator Clemens: When you were going through the testimony, I just want to make sure I heard correctly. Where it says here "patients may be required to try one of more" to me it sounded like "patients must be".

Deb Knuth: It was "may be".

Madam Chair Lee: I think it's very important to note that there is a process intended to be very considerate of what the doctor's recommendation may be, as a cancer survivor myself, I think that is a big deal. I just want to make sure there isn't any misunderstanding among any of us particularly in the committee that there are comparable things in place in almost every private insurance policy also and we just need to make sure that we are trying to be as considerate of providers and patients in Medicaid as we are in the private sector.

(17:22-19:48) Courtney Koebele, representing the North Dakota Medical Association. Testifying in opposition for SB 2290. Please see **Attachment #4** for testimony.

Senator Hogan: Private insurance does step therapy primarily now don't they?

Courtney Koebele: I think they do. I suppose it depends on the type of drug.

Senator Hogan: This is a protocol that is pretty well established. Do you think there should be a difference between how Medicaid does their profile or just the time limit issue?

Courtney Koebele: That is a very good question because this is going to come up with a lot of different bills that we are going to talk about this both in IBL and here. I kind of say two wrongs don't make a right. Yeah they do that, there is no doubt about it. Whether that is right to do to anybody to have to weigh on these medications and trust that the physician knows what to prescribe for their patient. It's a policy issue.

Senator Hogan: Do you know if the 24-72-hour time frame is standard for insurance for the private sector? Is that where those hours came from, that time frame?

Courtney Koebele: Where I got that is I was looking up an article last night on step therapy that other states have done I think it was a NCSL article and the other states have used those limits. I know that's the huge complaint with some of these insurance companies that they sit and wait for thirty days and it's important to make sure its timely and I don't mean to imply that Medicaid wouldn't be timely.

Madam Chair Lee: Closes the hearing on SB 2290.

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2290
1/29/2019
Job # 31665

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

To provide an appropriation to the department of human services to implement the 1915i Medicaid state plan amendment for youth.

Minutes: No Attachments

Madam Chair Lee opens the discussion on SB 2290

(00:40) Megan Houn, Director of Government Relations with Blue Cross and Blue Shield of North Dakota: I believe I was asked about step therapy in oncology and we do not use step therapy in oncology.

Madam Chair Lee: I thought there was requirements to use a generic medication first possibly and then move to brand name, would that be accurate.

Megan Houn: That was actually in adult ADHD and ADD. We do have on occasion, generic first step and that is typically for costs reason. Other than that we typically don't do a lot of those things especially in oncology we do not use step therapy.

Senator O. Larsen: You do it on a cost basis, you don't do it on an addictive thing? I thought that there was a pain medication that was synthetic and wasn't an opioid addicting drug and it was kind of the same thing. You don't do it on that way, like the ADHD have different addictive qualities to it than its just a cost deal?

Megan Houn: The ADHD question I just asked because I was asked the question about step therapy, just generic first step in that one and we do the dispensing limitations primarily to address some of the issues you are talking about there but the doctors know, we trust the physicians on that. If you are talking about generally speaking, do we do anything with respect to watching pain medications and opioids, we have a very comprehensive special investigations unit that watches that. They watch a number of the pain medications, muscle relaxers, etc. We watch to see where they are going, if they are shopping around, what the quantity limits are, and how frequently they are going. I know prime therapeutics is our pharmacy benefit manager and they also have that type of fraud prevention in place.

Senator Anderson: Do you sell or administer Medicare part D plans?

Megan Houn: We do have Med-Sup plans, now part D I am not certain on.

Senator Anderson: My understanding from the testimony the other day that the step therapy was mostly used by Medicare and the Medicare part D plans and maybe you don't offer those.

Megan Houn: I'm not certain whether or not we do on part D, I would assume we might if we are in the Med-Sup business. I don't think it is a very strong piece of business for us but my understanding is that we would be of the same mindset. I don't think we single out certain sections of business that way. Typically, our philosophy is we are not going to get involved in step therapy and oncology that is between the physician and the patient.

Madam Chair Lee: Any further questions for Megan?

Senator O. Larsen: I just have a comment about part D. The one good thing about part D, I do sell part D supplements and the good thing about Blue Cross and Blue Shield is that it is guaranteed issue. If you have a lot of medications like cancer pills or particularly diabetic medications it is guaranteed issue so you can get on those medications as compared to like Medica or some of the other ones that you probably won't get on those.

Senator K. Roers: I just happened to notice a note that we might need an amendment to cover the gap between effective dates and that would be provided by Jonathan Alm.

Madam Chair Lee: Yes, we do have one from Maggie and Brandon which talks about the contingent effective date.

Senator Hogan: Would you like to move that amendment? I move to **ADOPT AMENDMENT. Seconded by Senator O. Larsen**

ROLL CALL VOTE TAKEN
6 YEA, 0 NAY, 0 ABSENT
MOTION CARRIES TO ADOPTED AMENDMENT

Madam Chair Lee: If I haven't heard from Sanford Health by this afternoon then we are just going to move this out. We can't just sit on it and wait.

Madam Chair Lee closes the discussion on SB 2290.

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

SB 2290
1/29/2019
Job # 31712

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

Relating to authorization of a Medicaid step therapy program based on Medicare part b step therapy program.

Minutes: No Attachments

Madam Chair Lee opens the discussion on SB 2290.

Madam Chair Lee: We voted on the amendment but not on the bill.

Senator Anderson: We just heard a few minutes ago from Blue Cross and Blue Shield that said they don't do step therapy for oncology. So I asked the question if the sold any Medicare part D plans that would have the step therapy that Medicare adopted, could you talk a little about that?

Dr. Brendan Joyce, Pharmacy Administrator for DHS, Medical Services: What the department sees for this one is Medicare Part B not Part D. The step care that is being proposed by the Trump Administration, previously they did not allow any step care in Medicare Part B. They changed their policies, CMS sent out the notification and I believe that was included in an attachment in the testimony on this. That is where we are concerned. If the Medicare Part B carriers in the state, if they choose to do step care for what is not allowed by the feds and the Trump Administration, then we would just mirror exactly what they are doing. We wouldn't do it if they don't so if Blue Cross and the other carriers in the state do not do it for Medicare Part B, we wouldn't do it. This would be an allowance to copy what is going on in the exact commercial role.

Senator Anderson: Could you explain for us what the difference is between part B and part D?

Dr. Joyce: Medicare Part B is the medical side of things, not you going to the pharmacy to get a prescription typically. There are some medications like those products administered with durable medical equipment like nebulization solutions or diabetic testing supplies that you happen to get at a pharmacy, those happen to be covered under part B. Medicare Part D is the outpatient drugs, flipping back to prior 2006 all the Medicare recipients they would

get all their hospitalization covered under part A and part B for the clinic and office visits, but then they would be stuck with their prescriptions. So as the anger continued to increase as more and more people became Medicare aged and not having drug coverage, that is where congress was pushed to finally get Medicare Part D.

Senator Anderson: With the risk of antagonizing those who work for hospitals, what you are talking about is the part B section applies to what is billed through the medical clinics or the hospitals typically.

Dr. Joyce: Correct, so the oncology offices, years ago there was a push to peel the drugs out of the Medicare part B side of things and have them all done under part D but there was resistance for the clinics and health systems. They were pretty used to the process and used to the CMS 1,500 form and they are used to all of that and didn't want to change so you will have oncology offices for instance giving out 60 pills which it's not administered in the office but it is dispensed by that office, so they will be dispensing a month's supply of oncology meds but its billed under part B. Just because they started doing it and it's hard to stop doing it.

Madam Chair Lee: If you look in the testimony, which Brendan has provided for us where CMS is rescinding the 2012 memo about prohibition on mandatory step therapy for access to part B drugs and services and it says at the bottom "in addition CMS will consider rule making relating to step therapy that might be appropriate for 2020 and future years", "CMS intends to treat step therapy as part B drugs similar to out other requirements around prior authorization on part C benefits and services". Thank you for reminding us about that because it is spelled out in Mrs. Verma's letter.

Senator Hogan: Is this really enabling legislation to allow Medicare to follow the new Medicare Part B and the efforts of private insurers its enabling legislation in some ways?

Dr. Joyce: Yes, it is not a requirement. Just for efficiency purposes because we don't have a fiscal note on this, it is not a cost saving thing. If the carriers for part B do it, would like to piggy back on what all the providers know, right now in the private sector if they do things, these oncology drugs will cost 60,000 dollars or whatever it may cost and we discussed this in previous sessions where they contact us saying that we want to get a prior authorization from you because we don't want to give it out unless you tell us that you are going to pay for it. We couldn't do prior authorization on it then or currently, we had asked to at least do prior authorization to where we can just roll it in to the whole thing and then it would have the process, right now when they contact us we don't have a letter saying that we are going to cover it, we don't have the process. If it was within the prior authorization, it goes to the vendor and they see it has been approved then the letter goes out and gets faxed right back to the fax number where they faxed it from. It gives everybody that feeling of a guarantee because they don't want to give out the 60,000 dollars, they don't want to order it in unless they know they are going to get paid. We want to make it as simple for everyone we are not trying to complicate things, and again if the carriers won't do it than we won't do it. If the carriers do it then we will do the exact same thing.

Madam Chair Lee: Further questions for Dr. Joyce?

Senator Anderson: I move a **DO PASS, AS AMENDED.**
Seconded by Senator O. Larsen

ROLL CALL VOTE TAKEN
6 YEA, 0 NAY, 0 ABSENT
MOTION CARRIES DO PASS, AS AMENDED
Senator Anderson will carry SB 2290 to the floor.

Madam Chair Lee closes the discussion on SB 2290

19.0277.02001
Title.03000

Adopted by the Human Services Committee

January 29, 2019

PROPOSED AMENDMENTS TO SENATE BILL NO. 2290

Page 1, line 3, after "program" insert "; and to provide a contingent effective date"

Page 4, after line 10, insert:

"**SECTION 2. CONTINGENT EFFECTIVE DATE.** Section 1 of this Act becomes effective on the date the executive director of the department of human services certifies to the legislative council a Medicare advantage plan operating in the state has implemented a prior authorization step therapy program protocol for Medicare part B."

Renumber accordingly

Date: 1/29/19
Roll Call Vote #: 1

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2290

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 19.6277.02001

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Sen. Hogan Seconded By Sen. O. Larsen

Senators	Yes	No	Senators	Yes	No
Chair Lee	✓		Senator Hogan	✓	
Vice Chair Larsen	✓				
Senator Anderson	✓				
Senator Clemens	✓				
Senator Roers	✓				

Total (Yes) 6 No 0

Absent 0

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date: 1/29/19
Roll Call Vote #: 2

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2290

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 19.0277.02001

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☒ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Sen. Anderson Seconded By Sen. O. Larsen

Senators	Yes	No	Senators	Yes	No
Chair Lee	X		Senator Hogan	X	
Vice Chair Larsen	X				
Senator Anderson	X				
Senator Clemens	X				
Senator Roers	X				

Total (Yes) 6 No 6

Absent 0

Floor Assignment Sen. Anderson

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2290: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2290 was placed on the Sixth order on the calendar.

Page 1, line 3, after "program" insert "; and to provide a contingent effective date"

Page 4, after line 10, insert:

"**SECTION 2. CONTINGENT EFFECTIVE DATE.** Section 1 of this Act becomes effective on the date the executive director of the department of human services certifies to the legislative council a Medicare advantage plan operating in the state has implemented a prior authorization step therapy program protocol for Medicare part B."

Renumber accordingly

2019 HOUSE HUMAN SERVICES

SB 2290

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Fort Union Room, State Capitol

SB 2290
3/4/2019
33129

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Nicole Klaman

Explanation or reason for introduction of bill/resolution:

Relating to authorization of a Medic aid step therapy program based on the Medicare part B step therapy program and to provide a contingent effective date.

Minutes: 2

Senator Judy Lee: Introduced SB 2290.
This bill would allow the Department to have step therapy for the Medicaid program for new prescriptions for cancer medications.
An important thing to note regarding insurance coverage is to know we are prior authorized in our health coverage. Whether we have private insurance or state coverage. There are formulary restrictions and prior authorizations based on what is appropriate. If you want to pay out of pocket for this you can have whatever you want. If someone else is paying, often there will be recommendations what to do.

Brendan Joyce, Administrator of Pharm Services with the Medical Services Division for the Dept. of Human Services: In support, see **attachment 1**.
This bill would allow the Department to have step therapy for the Medicaid program for new prescriptions for cancer medications. This step therapy would be modeled completely on Medicare Part B. The Department would not implement any step therapy protocol that is not already being used by Medicare Part B Plans.

Chairman Weisz: Further Support? Seeing none. Is there opposition?

Opposition:

Courtney Koebele, ND Medical Association, opposition, written testimony provided see **attachment 2.**
North Dakota Medical Association find the growing trend towards the use of restrictive and burdensome utilization management tactics by payers concerning. Step therapy protocols requiring a patient to try and fail certain treatments before allowing access to other, potentially more appropriate treatments can both harm patients and undercut the physician-patient decision making process. Step therapy also places a high burden on physicians and staff.

Chairman Weisz: Closes hearing

2019 HOUSE STANDING COMMITTEE MINUTES

Human Service Committee
Fort Union Room, State Capitol

SB 2290
3/12/2019
33600

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Risa Bergquist by Donna Whetham

Minutes:

Chairman Weisz: Called the meeting to order for SB 2290. Does everyone understand what we mean about step therapy?

Brendan Joyce, Administrator of Pharmacy Services: Step therapy is making sure the prescriber uses treatment that goes through the steps that are supposed to be used. For the cancer medications if Medicare does this for Part B they would have step care where a certain medication would be first line and another second line for the guidelines. They would just ensure that the prescribers would be following the guidelines when those steps are appropriate. If is making sure that

Chairman Weisz: Some people believe that the step therapy is that you have to use the cheaper drug first and can't use the other one unless the first one doesn't' work, is that so?

Brendan Joyce: That is if you are using this as a cost savings method, we wouldn't be looking at this as cost saving we would simply be looking at guidelines. Only again if Medicare in the state in Part B would pick up this same process.

Chairman Weisz: Any other questions?

Rep. Rohr: If you don't follow the guidelines then you wouldn't get reimbursed?

Brendan Joyce: You would get a denial saying this isn't following the guidelines and they would have the right to appeal that and say why they weren't following the guidelines. Then they would get a result from that and 9 times out of 10 is okay that makes sense. Thank you for letting us know and it is good. They just need to give us a reason.

Rep. Rohr: How long does that process take?

Brendan Joyce: We are required to respond within 24 hours.

Rep. Schneider: We've have gotten requests to kill this because of the interference with patient doctor relationships and the delays between the steps. It seems that there are some real concerns.

Brendan Joyce: This bill is specific to the oncology medications. I think the providers look at everything that would take more paperwork as troublesome. If Medicare does this we would do this.

Rep. Skroch: In the testimony provided by American Society of Clinical Oncology (ASCO) they opposed this and they made a lengthy explanation as to why they oppose this. In this paragraph as an alternative to step therapy ASCO recommend the use of clinical pathways to achieve high value care. Clinical treatment pathways select a preferred evidence based therapeutic option based upon the efficiency and toxicity and considers costs etc. So if that mechanism could be used versus this step therapy, how difficult would that be and would it be as effective? I would consider that a better option personally.

Brendan Joyce: I think it is just a matter of definition, what they propose is what we are saying. It would be having them follow the steps that are in those guidelines. Just as they have a preferred product that is first line. Okay we agree, we are using the same guidelines. We aren't looking at the cost we are looking at safety to follow the guidelines. I think it is just a terminology problem.

11:00

Rep. Skroch: Is that why we are seeing the delays? Because you are saying hold on a minute, is that is what is causing the delay of getting medications approved? Is that why they don't want to do this?

Brendan Joyce: I believe it has to do with the fact that all of the insurance companies throughout the nation do this. We don't have a single payer system so they are having to contact 14 different companies for 14 different patients. It's an administrative burden but if everybody was infallible none of this would have to be done. We have prioritization not for prescribers who are prescribing on point through the guidelines but for those who are not. We have actually decreased our prioritization numbers over the years by probably over half. Just because we have had better messaging going on and with supplemental rebates that you have approved a couple sessions ago we were able to decrease the number of products that required prior approval. We don't want it to fail, we to help the recipients. We want to be there to help protect the patients. If it's not by the guidelines they just need to explain why that's it. Yes, there's a delay and it's a burden to the providers but if everyone did what they should this wouldn't be necessary.

Rep. Anderson: Who is determining what drugs you should be taking and does the patient have any input into it?

Brendan Joyce: It is up to the prescriber what is being used, patients may have the conversation about other drugs. The prescribers have the final decision and to agree with the experts and they want to work with their patients.

Rep. Anderson: If you are dying you are willing to try anything.

Brendan Joyce: Yes and that is understandable.

Chairman Weisz: Any other questions? Seeing none. What are your wishes?

Rep. Devlin: I would move a Do Not Pass on SB 2290.

Rep. M. Ruby: Seconded.

Rep. Devlin: It is really hard for me to think that the Doctor and his patient could sit here and find a treatment and then someone that hasn't ever seen this patient can change their treatment. I think it's up to the patient and the doctor.

Roll Call Vote: Yes: 12 **No:** 2 **Absent**: 0.

Motion carries on a Do Not Pass on SB 2290.

Rep. Devlin: Will carry the bill.

Hearing closed.

Date: 3/12/2019
Roll Call Vote #: 1

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2290

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description:

Recommendation: ☐ Adopt Amendment
☐ Do Pass ☒ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐

Motion Made By Rep. Devlin Seconded By Rep. M. Ruby

Representatives	Yes	No	Representatives	Yes	No
Robin Weisz - Chairman		X	Gretchen Dobervich	X	
Karen M. Rohr – Vice Chairman		X	Mary Schneider	X	
Dick Anderson	X				
Chuck Damschen	X				
Bill Devlin	X				
Clayton Fegley	X				
Dwight Kiefert	X				
Todd Porter	X				
Matthew Ruby	X				
Bill Tveit	X				
Greg Westlind	X				
Kathy Skroch	X				

Total (Yes) 12 No 2

Absent 0

Floor Assignment Rep. Devlin

If the vote is on an amendment, briefly indicate intent:

Motion Carries.

REPORT OF STANDING COMMITTEE

SB 2290, as engrossed: Human Services Committee (Rep. Weisz, Chairman) recommends **DO NOT PASS** (12 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). Engrossed SB 2290 was placed on the Fourteenth order on the calendar.

2019 TESTIMONY

SB 2290

SB 2290
1/21/19
#1 pg. 1

Testimony
Senate Bill 2290 - Department of Human Services
Senate Human Services Committee
Senator Judy Lee, Chairman

January 21, 2019

Chairman Lee and members of the Senate Human Services Committee, I am Brendan Joyce, Administrator of Pharmacy Services with the Medical Services Division for the Department of Human Services (Department). I appear today to provide testimony on Senate Bill 2290.

Senate Bill 2290 would allow the Department to have step therapy for the Medicaid program for new prescriptions for cancer medications. For instance, Cabometyx® was approved by the Food and Drug Administration on January 14, 2019 for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. If step therapy was implemented for this medication, it would simply ensure that any HCC patient receiving a prescription order for Cabometyx® was previously treated with sorafenib.

The step therapy would be completely modeled on Medicare Part B. Please reference the August 7, 2018 memorandum from the Centers for Medicare and Medicaid Services (CMS) outlining guidance allowing Medicare Advantage plans to utilize step therapy for Part B drugs (Attachment A).

The Department would not implement any step therapy protocol that is not already being used by Medicare Part B plans. Also, as required by section 50-24.6-04 of the North Dakota Century Code, the Drug Use Review (DUR) Board would review any step therapy protocols prior to implementation. Since step therapy is based on clinical protocols and Food and Drug Administration approvals, the Department does not anticipate any fiscal impact. Also, given requirements for DUR Board review and approval, and the timeframes surrounding such, no step therapy would be

implemented prior to calendar year 2020, and only then if Medicare Part B has approved the specific step therapy protocol.

While preparing the fiscal note and testimony for Senate Bill 2290, the Department recognized that it may be appropriate for the bill to have a contingent effective date. Without a contingent effective date, the proposed changes on Page 2, Lines 14 and 28 would become effective August 1, 2019, while the changes proposed on Page 3, Lines 11 through 25 would not become effective until on or after January 1, 2020. If the committee concurs, the Department would be happy to draft an amendment for consideration.

This concludes my testimony, and I am happy to answer any questions you may have.

SB 2290
1/21/19
#1 pg. 3

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244

DATE: August 7, 2018

TO: Medicare Advantage Organizations

FROM: Seema Verma
Administrator

SUBJECT: Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage

CMS is hereby rescinding our September 17, 2012 HPMS memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services," and issuing new guidance that recognizes Medicare Advantage (MA) plans may use step therapy for Part B drugs, beginning January 1, 2019, as part of a patient-centered care coordination program.

In the September 17, 2012 guidance, CMS stated that plans were precluded from imposing additional requirements for access to certain Part B drugs or services, such as step therapy requirements. That 2012 guidance did not affect other methods of prior authorization, which has been and continues to be allowed for Part B drugs. Section 1852 of the Social Security Act expressly anticipates a plan's application of utilization management tools, like prior authorization, and other "procedures used by the organization to control utilization of services and expenditures."[1] In this guidance, CMS is acknowledging that the use of step therapy is a recognized utilization management tool. The allowance of step therapy practices for Part B drugs will help achieve the goal of lower drug prices while maintaining access to covered services and drugs for beneficiaries.

Step therapy is a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions. This new guidance recognizes that MA plans may apply step therapy to control the utilization of services in a manner that does not create an undue access barrier for beneficiaries.[2] Specifically, CMS believes that appropriate patient engagement and care coordination services support appropriate pathways to access to Part B drugs such as step therapy.

In addition, CMS will consider rulemaking related to step therapy that might be appropriate for 2020 and future years. We remind MA organizations that the regulatory requirement to properly disclose policies and procedures to enrollees in accordance with 42 CFR § 422.111 remains. We also remind MA organizations of their statutory obligations to furnish and provide access to benefits that are available under Parts A and B. As such, CMS intends to treat step therapy for

[1] *See* section 1852(c)(1)(G), (c)(2)(B).
[2] Prior authorization cannot be required for emergency services. *See* section 1852(d)(1)(E) of the Act and 42 CFR 422.111(b)(5)(ii).

Part B drugs in a manner similar to our other requirements around prior authorization of Part C benefits and services.

Accordingly, MA organizations remain subject to regulations at 42 CFR § 422.101(b) to comply with national and, in some cases, local coverage determinations. An MA plan may implement its own step therapy policies and procedures as part of utilization management where an applicable national and/or local coverage determination is silent on the matter. However, an MA plan remains subject to FFS Medicare's step therapy policies and procedures when they are specified in a national and/or local coverage determination.

CMS strongly encourages that MAPD plans use their qualified Part D pharmacy and therapeutics (P&T) committees to determine when it is medically appropriate to use step therapy for selected drugs in Part B. In addition to requiring one Part B drug be used before a different Part B drug, MA plans that also offer prescription drug coverage (also known as "MAPD plans") may use step therapy to require a Part D drug therapy prior to allowing a Part B drug therapy. MAPD plans may also apply step therapy to require a Part B drug therapy prior to allowing a Part D drug therapy. However, in these latter cases, MAPD plans must ensure that these requirements are clearly outlined in the Part D prior authorization criteria for the affected Part D drugs. For the 2019 annual election period, CMS will provide a special 8/17-8/21 window for MA submissions of Part B step therapy PA. The Part D drug must have a prior authorization edit submitted to CMS during this formulary update window. If the MAPD plan's P&T committee is unable to develop and approve PA criteria prior to this formulary submission window, placeholder PA criteria may be submitted with the submission by indicating "Criteria Pending" in the required PA submission fields. The standard Part D utilization management criteria review processes will provide MAPD plans an opportunity to finalize the criteria for the affected Part D drugs. If an MAPD plan chooses to implement criteria during the 2019 plan year, the addition of PA to a Part D drug can be requested as a negative change via the standard negative formulary change request timeframes.

If an MA plan decides to adopt and apply step therapy to Part B drugs, the MA plan must disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents. In the ANOC, this information must be included under the Changes to Benefits and Costs for Medical Services. In the EOC, this information must be included in the Medical Benefits Chart under "Medicare Part B prescription drugs." If these documents are already in production, plans may send out an addendum to the ANOC and EOC to appropriately inform enrollees of the change. MA plans must provide benefits consistent with the coverage rules and benefits listed in these documents. For MA plans that choose to apply step therapy to Part B drugs in 2019, including this information in the ANOC and EOC prior to this year's annual election period satisfies that obligation. No changes to 2019 Plan Benefit Packages in the Bid Pricing Tool are needed in conjunction with adding a step therapy program for Part B drugs in 2019 based on this memo.

CMS believes that in order to maintain access to necessary drugs, step therapy should be coupled with drug management care coordination services and, importantly, rewards that incentivize beneficiary participation. In other words, under CMS's interpretation of its regulations, it is necessary for an MA plan opting to apply step therapy to Part B drugs to offer beneficiaries an

opportunity to participate in drug management care coordination activities. Patient-centered care coordination is an essential element to improved health outcomes, lower costs and providing access to drugs in the context of step therapy. It is an integral part of MA plans to coordinate and manage care in order to achieve quality care outcomes for enrollees. *See* 42 CFR §§ 422.112(b) and 422.152. Care coordination activities are truly effective when they reflect an enrollee's individual needs. In this context, CMS understands drug management care coordination activities to include, at a minimum:

- Interactive medication review and associated consultations for enrollees to discuss all current medications and perform medication reconciliation and follow-up when necessary;
- Providing educational materials and information to enrollees about drugs within the drug management care coordination program; and
- Implementing medication adherence strategies to help enrollees with their medication regimen.

Patient engagement is essential to a successful care coordination program. To ensure adequate access to Part B drugs, it is necessary, under CMS's interpretation of its regulations, that MA plans opting to apply step therapy encourage enrollees to participate in such a drug management care coordination program by offering rewards in exchange for enrollee participation. Rewarding drug management care coordination helps encourage participation in a program that works to ensure that enrollees get safe and clinically appropriate medication to treat their condition, and will enable plans to pass on the cost savings generated from more active management of the drug benefit. Consistent with 42 CFR §422.134, plan rewards cannot be offered in the form of cash or monetary rebate, but may be offered as gift cards or other items of value to all eligible enrollees. MA plans should make sure any rewards or incentives comply with all rules at 42 CFR § 422.134 and Chapter 4 of the Medicare Managed Care Manual. Under these rules, the value of the rewards or incentives must be reasonable and appropriate. In this particular context, CMS will presume that the reward or incentive is reasonable and appropriate if it is equivalent to more than half the amount saved on average per participant by a more efficient use of health care resources, promotion of improved health, or prevention of injuries and illness. Also, pursuant to the requirement that information must be made available to CMS about the form and manner of rewards or incentives programs, MA plans offering this particular reward or incentive must include the value of the offered reward or incentive on a per member basis in comparison to the average planned per participant savings in the annual Part C Reporting Requirements submission.

For those plans that did not previously consider initial costs associated with rewards and incentives, these costs need not be separately included in the bid as a non-benefit expense. This is only for rewards and incentives offered in connection with step therapy driven drug management care coordination activities for 2019.

While step therapy requirements may reduce costs to both the enrollee and the MA plan, due to variances in cost-sharing for Part B and Part D drugs, there may be occasions when enrollees could experience higher out-of-pocket costs for the "stepped" Part D drug. CMS reminds MA plans that benefits must be provided consistent with the 2019 benefit packages submitted and

approved by CMS and it is our expectation that step therapy for Part B drugs, and other utilization management practices, should not result in increased costs to enrollees.

Additionally, it is critical that MA plans continue to comply with the statutory requirement that they provide access to all Part A and Part B benefits that would be available in Original Medicare. Step therapy or other utilization management policies may not be used as an unreasonable means to deny coverage of medically necessary services or to eliminate access to a Part B covered benefit, which is why CMS believes it is important to pair step therapy with a beneficiary engagement program. Furthermore, enrollees must be able to request an exception from the plan's step therapy requirement in order to access a Part B covered drug. The ability to request such an exception is consistent with current Part D rules involving exceptions related to the application of utilization management tools, such as step therapy requirements.[3] CMS recommends that MA plans follow the rules governing Part D exceptions in 42 CFR § 423.578(b) and grant an exception whenever it determines that the drug is medically necessary and is a covered Part B drug.

CMS considers plan decisions involving requests for exceptions to be pre-service organization determinations because they involve an MA plan's refusal to provide or pay for services that the enrollee believes should be furnished or arranged by the MA plan.[4] As a result, exception requests are subject to applicable adjudication timeframes and notice requirements in 42 CFR §§ 422.568 and 422.572. Organization determination timeframes require that MA plans make determinations as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days (72 hours for expedited requests) after the date the organization receives the request. CMS strongly encourages that MA plans expedite requests for exceptions in Part B, to align with the 72-hour adjudication timeframe for requests in Part D.

Finally, MA plans should ensure that new step therapy requirements do not disrupt ongoing Part B drug therapies for enrollees. Step therapy may only be applied to new prescriptions or administrations of Part B drugs for enrollees that are not actively receiving the affected medication. Also, Part D transition requirements will continue to apply to Part D drugs that are subject to step therapy where the first "step" is a Part B drug. With these additional tools and enrollee protections in place, MA plans will be able to provide more coordinated and cost-effective care.

Questions related to the information in this memorandum, may be submitted at: https://dpap.lmi.org/dpapmailbox/.

[3] 42 CFR § 423.578(b)
[4] *See* 42 CFR § 422.566(b)(3)

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PROPOSED AMENDMENTS TO SENATE BILL NO. 2290

Page 1, line 3, after "program" add "; and to provide an effective date"

Page 4, after line 10, insert:

"**SECTION 2. CONTINGENT EFECTIVE DATE.** Section 1 of this Act becomes effective on the date the department implements a prior authorization step therapy program. The department shall certify to the legislative council the effective date."

Renumber accordingly

SB 2290
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American Cancer Society
Cancer Action Network
2401 46th Ave SE, Ste. 102, Mandan, ND
701.471.2859
Deb.knuth@cancer.org

North Dakota SB 2290
Red River Room
January 21, 2019
Senate Human Service Committee
Senator Judy Lee, Chairman

My name is Deb Knuth and I am the Government Relations Director for the North Dakota American Cancer Society Cancer Action Network.

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, non-partisan advocacy affiliate of the American Cancer Society advocates for public policies that reduce death and suffering from cancer. ACS CAN opposes SB 2290, a bill relating to authorization of a Medicaid step therapy program because the exception process described in the bill is insufficient to protect cancer patients. As such, we urge you to strengthen Section 4(b) of the bill to include prompt timeframes within which exception requests must be decided such as 5 days for non-urgent requests and 24 hours for urgent requests. We also recommend that specific criteria be added to delineate the situations in which a step therapy exception must be granted.

ACS CAN supports legislation that balances protecting patients when a step therapy protocol would produce an adverse health outcome, with allowing for the use of step therapy when it is appropriate for controlling costs.

Step therapy is a tool insurers use to limit how much they spend covering patients' medications. Under a step therapy protocol, a patient must try one or more drugs chosen by their insurer—usually based on financial, not medical, considerations—before coverage is granted for the drug prescribed by the patient's health care provider.

Patients may be required to try one or more alternative prescription drugs that are of lower cost to the insurer but may not be the best therapy for some patients.

Scientific breakthroughs mean that, in many cases, a cancer diagnosis now can be managed and treated. Patients need the ability to quickly assess their condition with their doctors and find the best course of treatment for their individual medical needs. Delays in access to the best treatment available, that could be experienced as a result of patients having to go through a step therapy protocol, can pose significant risk to the treatment of disease.

Step therapy can undermine physicians' ability to effectively treat patients, can lower quality of care, and lead to set backs and disease progression for patients.

Exemptions from step therapy do not prohibit insurers from using step therapy but seek to balance cost containment with patient needs.

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The American Cancer Society Cancer Action Network urges this Committee to oppose this legislation or consider amending it to include the exceptions I've discussed.

Thank you for allowing me to testify. Are there any questions?

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NDMA
Est. 1887 NORTH DAKOTA MEDICAL ASSOCIATION

Senate Human Services Committee
SB 2290
January 21, 2019

Chair Lee and Committee Members, I am Courtney Koebele and represent the North Dakota Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students. NDMA does not support SB 2290.

Part of NDMA's mission is to advance the health and promote the well-being of the people of North Dakota. SB 2290 does not help promote the health of Medicaid patients.

We find the growing trend towards the use of restrictive and burdensome utilization management tactics by payors concerning and urge the state to reconsider its stance on this critical patient care issue. Step therapy protocols that require patients to try and fail certain treatments before allowing access to other, potentially more appropriate treatments can both harm patients and undercut the physician-patient decision-making process. The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation and the care plan developed by the physician in close consultation with that patient.

We appreciate that biologic medicines are expensive and that the upfront cost is more than Medicaid normally spends on older medications. However, the biologic medicines have a much higher chance of getting the patient into remission so that you can avoid the complications, the emergency room visits, the hospitalizations, and the need for surgery.

One suggestion that we have seen in other states, is that the expedition exception should be time limited. Medicaid should be required to respond to exception requests expeditiously, which typically ranges from 24 to 72 hours, after a request is submitted.

Thank you for the opportunity to testify today. I would be happy to answer any questions.

NDLA, S HMS - Velez, Justin

From: Judy Lee <judylee1822@gmail.com>
Sent: Tuesday, January 29, 2019 10:08 PM
To: -Grp-NDLA Senate Human Services; NDLA, S HMS - Velez, Justin; NDLA, Intern 02 - Carthew, Alexandra
Subject: FW: [EXTERNAL] SB 2290

***** CAUTION: This email originated from an outside source. Do not click links or open attachments unless you know they are safe. *****

-----Original Message-----
From: Carlson,Lisa M (DIR- Health Plan) <Lisa.M.Carlson@sanfordhealth.org>
Sent: Tuesday, January 29, 2019 8:50 AM
To: 'Judy Lee' <judylee1822@gmail.com>
Cc: Walth,Marnie <Marnie.Walth@SanfordHealth.org>; Carmody,Molly <Molly.Carmody@SanfordHealth.org>
Subject: RE: [EXTERNAL] SB 2290

Good morning Senator Lee, we are neutral on SB2290 because we do not utilize step therapy for the drugs outlined in this bill. Instead, we rely on a medical management tool called Eviti (a program that is operated by oncologists and oncology nurses). The tool has built-in (and regularly updated) clinical guidelines and research to ensure our members are getting the best oncology care no matter where they reside and receive their treatment. In oncology care, it is very rare that a case exists where generic medications can approximate the efficacy and safety of the newer treatments. While older therapies were effective, they often cause the toxic side effects associated with chemotherapy. In modern therapies that are more targeted toward select markers on tumors, the medications are more effective and better tolerated. For this reason, we have little reason to require step-therapy in this space. Our pharmacy director, Danny Weiss is not surprised that Medicare and Medicaid is moving to allow step therapy in the oncology space so that they can leverage equivalent brands for rebates, and then maximize those through step-therapy. But in the private sector, we accomplish the same through formulary management using tools described above, which is not always available in areas like Medicare/Medicaid.

I hope that helps, if not, I'd be happy to arrange a call with our pharmacy director as he can explain in more detail.

Respectfully,

Lisa M. Carlson
Senior Director, Market Strategy
(605) 328-6859 | Lisa.M.Carlson@sanfordhealth.org

-----Original Message-----
From: Judy Lee <judylee1822@gmail.com>
Sent: Monday, January 28, 2019 1:36 PM
To: Carlson,Lisa M (DIR- Health Plan) <Lisa.M.Carlson@sanfordhealth.org>

Subject: [EXTERNAL] SB 2290

The bill would permit Medicaid to follow Medicare, if Medicare changes its policy about step therapy for oncology drugs. I'm just checking with private carriers to see if such prior authorization or formulary rules are in place for their coverage.

Judy Lee
1822 Brentwood Court
West Fargo, ND 58078
Phone: 701-282-6512
Cell: 701-238-1531
e-mail: judylee1822@gmail.com

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Testimony
Engrossed Senate Bill 2290 - Department of Human Services
House Human Services Committee
Representative Robin Weisz, Chairman

March 4, 2019

Chairman Weisz and members of the House Human Services Committee, I am Brendan Joyce, Administrator of Pharmacy Services with the Medical Services Division for the Department of Human Services (Department). I appear today to provide testimony on Engrossed Senate Bill 2290.

Engrossed Senate Bill 2290 would allow the Department to have step therapy for the Medicaid program for new prescriptions for cancer medications. For instance, Cabometyx® was approved by the Food and Drug Administration (FDA) on January 14, 2019 for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. If step therapy was implemented for this medication, it would simply ensure that any HCC patient receiving a prescription order for Cabometyx® was previously treated with sorafenib. For further examples and to show how FDA approvals are done, you will see all of the 2018 FDA approvals and safety notifications for hematology/oncology (cancer) medications in Attachment A with all of the similar situations highlighted. Blue highlight shows drugs approved to be used as first line, and yellow shows those whose approval specifically is not for first line use.

The step therapy would be completely modeled on Medicare Part B. Please reference the August 7, 2018 memorandum from the Centers for Medicare and Medicaid Services (CMS) outlining guidance allowing Medicare Advantage plans to utilize step therapy for Part B drugs (Attachment B).

The Department would not implement any step therapy protocol that is not already being used by Medicare Part B plans. Also, as required by section 50-24.6-04 of the

North Dakota Century Code, the Drug Use Review (DUR) Board would review any step therapy protocols prior to implementation. Since step therapy is based on clinical protocols and Food and Drug Administration approvals, the Department does not anticipate any fiscal impact. Also, given requirements for DUR Board review and approval, and the timeframes surrounding such, no step therapy would be implemented prior to calendar year 2020, and only then if Medicare Part B has approved the specific step therapy protocol.

This concludes my testimony, and I am happy to answer any questions you may have.

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- FDA approved tagraxofusp-erzs (ELZONRIS™, Stemline Therapeutics), a CD123-directed cytotoxin, for blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older. More information. December 21, 2019
- FDA approved ravulizumab-cwvz (ULTOMIRIS™, Alexion Pharmaceuticals, Inc.) for adult patients with paroxysmal nocturnal hemoglobinuria (PNH). More information. December 21, 2018
- FDA approved calaspargase pegol-mknl (ASPARLAS, Servier Pharmaceuticals LLC), an asparagine specific enzyme, as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years. This new product provides for a longer interval between doses compared to other available pegaspargase products. More Information. December 20, 2018
- FDA approved olaparib (LYNPARZA, AstraZeneca Pharmaceuticals LP) for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. More Information. December 19, 2018
- FDA granted accelerated approval to pembrolizumab (KEYTRUDA, Merck & Co. Inc.) for adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC). More Information. December 19, 2018.
- FDA approved Herzuma (trastuzumab-pkrb, Celltrion Inc.) as a biosimilar to Herceptin (trastuzumab, Genentech Inc.) for patients with HER2-overexpressing breast cancer. More Information. December 14, 2018
- FDA approved romiplostim (NPLATE, Amgen Inc.) for pediatric patients 1 year of age and older with immune thrombocytopenia (ITP) for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. More Information. December 14, 2018
- FDA approved atezolizumab (TECENTRIQ, Genentech, Inc.), in combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of patients with metastatic non-squamous, non-small cell lung cancer (NSq NSCLC) with no EGFR or ALK genomic tumor aberrations. More Information. December 6, 2018
- FDA approved gilteritinib (XOSPATA, Astellas Pharma US Inc.) for treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. More Information. November 28, 2018
- FDA approved Truxima (rituximab-abbs, Celltrion Inc.) as the first biosimilar to Rituxan (rituximab, Genentech Inc.) for patients with CD20-positive, B-cell non-Hodgkin's lymphoma (NHL) to be used as a single agent or in combination with chemotherapy. More Information. November 28, 2018
- FDA granted accelerated approval to larotrectinib (VITRAKVI, Loxo Oncology Inc. and Bayer) for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or whose cancer has progressed following treatment. More Information. November 26, 2018
- FDA granted accelerated approval to venetoclax (VENCLEXTA, AbbVie Inc. and Genentech Inc.) in combination with azacitidine or decitabine or lo w-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. More Information. November 21, 2018
- FDA approved glasdegib (DAURISMO, Pfizer Labs) in combination with low-dose cytarabine (LDAC), for newly-diagnosed acute myeloid leukemia (AML) in patients who are 75 years old

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or older or who have comorbidities that preclude intensive induction chemotherapy. More Information. November 21, 2018

- FDA approved emapalumab (GAMIFANT, Novimmune SA), a monoclonal antibody that binds and neutralizes interferon gamma, for adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy. More Information November 20, 2018
- FDA approved brentuximab vedotin (ADCETRIS, Seattle Genetics Inc.) in combination with chemotherapy for previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas. More information. November 16, 2018
- FDA granted accelerated approval to pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. More Information. November 9, 2018
- FDA granted accelerated approval to lorlatinib (LORBRENA, Pfizer, Inc.) for patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease or whose disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease. More Information. November 2, 2018
- FDA approved pembrolizumab (KEYTRUDA, Merck & Co. Inc.) in combination with carboplatin and either paclitaxel or nab-paclitaxel as first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC)..More Information. October 30, 2018
- FDA approved talazoparib (TALZENNA, Pfizer Inc.), a poly (ADP-ribose) polymerase (PARP) inhibitor, for patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2 negative locally advanced or metastatic breast cancer. Patients must be selected for therapy based on an FDA-approved companion diagnostic for talazoparib. More Information. October 16, 2018.
- FDA approved emicizumab-kxwh injection (HEMLIBRA, Genentech, Inc.) for prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients (ages newborn and older) with hemophilia A (congenital factor VIII deficiency) with or without factor VIII (FVIII) inhibitors. More Information. October 4, 2018
- FDA approved cemiplimab-rwlc (LIBTAYO, Regeneron Pharmaceuticals Inc.) for patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. More Information. September 28, 2018.
- FDA approved dacomitinib tablets (VIZIMPRO, Pfizer Pharmaceutical Company) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. More Information. September 27, 2018
- FDA granted regular approval to duvelisib (COPIKTRA, Verastem, Inc.) for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies. In addition, duvelisib received accelerated approval for adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. More Information. September 24, 2018
- FDA approved moxetumomab pasudotox-tdfk (LUMOXITI, AstraZeneca Pharmaceuticals LP), a CD22-directed cytotoxin indicated for adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA). More Information. September 13, 2018

- FDA approved pembrolizumab (KEYTRUDA, Merck & Co., Inc.) in combination with pemetrexed and platinum as first-line treatment of patients with metastatic, non-squamous non-small cell lung cancer (NSqNSCLC), with no EGFR or ALK genomic tumor aberrations. More Information. August 20, 2018.
- FDA updated the prescribing information for Keytruda (pembrolizumab) and Tecentriq (atezolizumab) to require the use of an FDA-approved companion diagnostic test to determine PD-L1 levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible. FDA approved two different companion diagnostic tests, one for use with Keytruda and one for use with Tecentriq, More Information. August 16, 2018.
- FDA granted accelerated approval to nivolumab (Opdivo, Bristol-Myers Squibb Company Inc.) for patients with metastatic small cell lung cancer (SCLC) with progression after platinum-based chemotherapy and at least one other line of therapy. More Information. August 16, 2018
- FDA approved lenvatinib capsules (Lenvima, Eisai Inc.) for first-line treatment of patients with unresectable hepatocellular carcinoma (HCC). More Information. August 16, 2018
- FDA approved mogamulizumab-kpkc (Poteligeo, Kyowa Kirin, Inc.) for adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. More Information. August 8, 2018
- FDA approved lusutrombopag (Mulpleta, Shionogi Inc.) for thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure. More Information. July 31, 2018.
- FDA approved iobenguane I 131 (AZEDRA, Progenics Pharmaceuticals, Inc.) for adult and pediatric patients (12 years and older) with iobenguane scan-positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (PPGL) who require systemic anticancer therapy. More Information. July 30, 2018.
- FDA approved ivosidenib (Tibsovo, Agios Pharmaceuticals, Inc.) for adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test. More Information. July 20, 2018
- FDA expanded the indication for ribociclib (Kisqali, Novartis Pharmaceuticals Corporation) in combination with an aromatase inhibitor for pre/perimenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. More Information. July 18, 2018
- FDA approved enzalutamide (XTANDI, Astellas Pharma US, Inc.), for patients with castration-resistant prostate cancer (CRPC). More Information. July 13, 2018
- FDA granted accelerated approval to ipilimumab (YERVOY, Bristol-Myers Squibb Company Inc.) for use in combination with nivolumab for the treatment of patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. More Information. July 10, 2018
- FDA has limited the use of Tecentriq and Keytruda for patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing therapy. More Information. June 19, 2018
- FDA approved encorafenib and binimetinib (BRAFTOVI and MEKTOVI, Array BioPharma Inc.) in combination for patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. More Information. June 27, 2018

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- FDA granted accelerated approval to pembrolizumab (Keytruda, Merck) for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy. More Information. June 13, 2018
- FDA approved bevacizumab (Avastin, Genentech, Inc.) for patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, followed by single-agent bevacizumab, for stage III or IV disease after initial surgical resection. More Information. June 13, 2018
- FDA approved pembrolizumab (Keytruda, Merck and Co. Inc.) for patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. More Information. June 12, 2018
- FDA granted regular approval to venetoclax (VENCLEXTA, AbbVie Inc. and Genentech Inc.) for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. More Information. June 8, 2018
- FDA approved methoxy polyethylene glycol-epoetin beta (Mircera, Vifor Pharma Inc.) for the treatment of pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA. More Information. June 7, 2018
- FDA approved Fulphila (pegfilgrastim-jmdb, Mylan GmbH) as a biosimilar to Neulasta (pegfilgrastim, Amgen, Inc.) to decrease the chance of infection as suggested by febrile neutropenia in patients with non-myeloid cancer who are receiving myelosuppressive chemotherapy that has a clinically significant incidence of febrile neutropenia. More Information. June 4, 2018
- FDA approved avatrombopag (Doptelet, AkaRx Inc.) for thrombocytopenia in adults with chronic liver disease scheduled to undergo a procedure. More Information. May 21, 2018
- FDA approved Retacrit (epoetin alfa-epbx, Hospira Inc., a subsidiary of Pfizer Inc.) as a biosimilar to Epogen/Procrit (epoetin alfa, Amgen Inc.) for the treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and not on dialysis, use of zidovudine in patients with HIV infection, and the effects of concomitant myelosuppressive chemotherapy. It is also approved for the reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery. More Information. May 15, 2018
- FDA approves dabrafenib plus trametinib for anaplastic thyroid cancer with BRAF V600E mutation. More Information. May 4, 2018.
- FDA approved tisagenlecleucel (KYMRIAH, Novartis Pharmaceuticals Corp.) a CD19-directed genetically modified autologous T-cell immunotherapy, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. More Information. May 1, 2018.
- FDA granted regular approval to dabrafenib (TAFINLAR, Novartis Pharmaceuticals Corp.) and trametinib (MEKINIST, Novartis Pharmaceuticals Corp.) in combination for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. More Information. April 30, 2018
- FDA approved osimertinib (Tagrisso, AstraZeneca Pharmaceuticals LP) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have

epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. More Information. April 19, 2018

- FDA approved fostamatinib disodium hexahydrate tablets (TAVALISSE, Rigel Pharmaceuticals, Inc.) for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. More Information. April 17, 2018
- FDA granted approvals to nivolumab and ipilimumab (Opdivo and Yervoy, Bristol-Myers Squibb Co.) in combination for the treatment of intermediate or poor risk, previously untreated advanced renal cell carcinoma. More Information. April 16, 2018
- FDA approved everolimus tablets for oral suspension (Afinitor Disperz, Novartis Pharmaceuticals Corp.) for the adjunctive treatment of adult and pediatric patients aged 2 years and older with tuberous sclerosis complex (TSC)-associated partial-onset seizures. Everolimus is also approved for two other manifestations of TSC: TSC-associated subependymal giant cell astrocytoma (SEGA) and TSC-associated renal angiomyolipoma. More Information. April 10, 2018
- FDA approved rucaparib for maintenance treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer. More Information. April 6, 2018
- FDA granted accelerated approval to blinatumomab (Blincyto, Amgen Inc.) for the treatment of adult and pediatric patients with B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. More Information. March 29, 2018
- FDA approved nilotinib (TASIGNA, Novartis Pharmaceuticals Corporation) for pediatric patients 1 year of age or older with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. More Information. March 22, 2018
- FDA approved brentuximab vedotin (Adcetris, Seattle Genetics, Inc.) to treat adult patients with previously untreated stage III or IV classical Hodgkin lymphoma (cHL) in combination with chemotherapy. More Information. March 20, 2018
- FDA approved abemaciclib (VERZENIO, Eli Lilly and Company) in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. More Information. February 26, 2018
- FDA approved durvalumab (Imfinzi, AstraZeneca Inc.) for patients with unresectable stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. More Information. February 16, 2018
- FDA approves apalutamide for non-metastatic castration-resistant prostate cancer. More Information. February 14, 2018
- FDA approved abiraterone acetate (Zytiga, Janssen Biotech Inc.) tablets in combination with prednisone for metastatic high-risk castration-sensitive prostate cancer (CSPC). More Information. February 7, 2018
- FDA approved lutetium Lu 177 dotatate (LUTATHERA, Advanced Accelerator Applications USA, Inc.) a radiolabeled somatostatin analog, for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. More Information. January 26, 2018
- FDA granted approval to afatinib (Gilotrif, Boehringer Ingelheim Pharmaceutical, Inc.) for a broadened indication in first-line treatment of patients with metastatic non-small cell lung

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cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. More Information. January 12, 2018

- FDA granted regular approval to olaparib tablets (Lynparza, AstraZeneca Pharmaceuticals LP), a poly (ADP-ribose) polymerase (PARP) inhibitor, for the treatment of patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2-negative metastatic breast cancer who have been treated with chemotherapy either in the neoadjuvant, adjuvant, or metastatic setting. More Information. January 12, 2018

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

DATE: August 7, 2018

TO: Medicare Advantage Organizations

FROM: Seema Verma
Administrator

SUBJECT: Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage

CMS is hereby rescinding our September 17, 2012 HPMS memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services," and issuing new guidance that recognizes Medicare Advantage (MA) plans may use step therapy for Part B drugs, beginning January 1, 2019, as part of a patient-centered care coordination program.

In the September 17, 2012 guidance, CMS stated that plans were precluded from imposing additional requirements for access to certain Part B drugs or services, such as step therapy requirements. That 2012 guidance did not affect other methods of prior authorization, which has been and continues to be allowed for Part B drugs. Section 1852 of the Social Security Act expressly anticipates a plan's application of utilization management tools, like prior authorization, and other "procedures used by the organization to control utilization of services and expenditures."[1] In this guidance, CMS is acknowledging that the use of step therapy is a recognized utilization management tool. The allowance of step therapy practices for Part B drugs will help achieve the goal of lower drug prices while maintaining access to covered services and drugs for beneficiaries.

Step therapy is a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions. This new guidance recognizes that MA plans may apply step therapy to control the utilization of services in a manner that does not create an undue access barrier for beneficiaries.[2] Specifically, CMS believes that appropriate patient engagement and care coordination services support appropriate pathways to access to Part B drugs such as step therapy.

In addition, CMS will consider rulemaking related to step therapy that might be appropriate for 2020 and future years. We remind MA organizations that the regulatory requirement to properly disclose policies and procedures to enrollees in accordance with 42 CFR § 422.111 remains. We also remind MA organizations of their statutory obligations to furnish and provide access to benefits that are available under Parts A and B. As such, CMS intends to treat step therapy for

[1] *See* section 1852(c)(1)(G), (c)(2)(B).
[2] Prior authorization cannot be required for emergency services. *See* section 1852(d)(1)(E) of the Act and 42 CFR 422.111(b)(5)(ii).

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Part B drugs in a manner similar to our other requirements around prior authorization of Part C benefits and services.

Accordingly, MA organizations remain subject to regulations at 42 CFR § 422.101(b) to comply with national and, in some cases, local coverage determinations. An MA plan may implement its own step therapy policies and procedures as part of utilization management where an applicable national and/or local coverage determination is silent on the matter. However, an MA plan remains subject to FFS Medicare's step therapy policies and procedures when they are specified in a national and/or local coverage determination.

CMS strongly encourages that MAPD plans use their qualified Part D pharmacy and therapeutics (P&T) committees to determine when it is medically appropriate to use step therapy for selected drugs in Part B. In addition to requiring one Part B drug be used before a different Part B drug, MA plans that also offer prescription drug coverage (also known as "MAPD plans") may use step therapy to require a Part D drug therapy prior to allowing a Part B drug therapy. MAPD plans may also apply step therapy to require a Part B drug therapy prior to allowing a Part D drug therapy. However, in these latter cases, MAPD plans must ensure that these requirements are clearly outlined in the Part D prior authorization criteria for the affected Part D drugs. For the 2019 annual election period, CMS will provide a special 8/17-8/21 window for MA submissions of Part B step therapy PA. The Part D drug must have a prior authorization edit submitted to CMS during this formulary update window. If the MAPD plan's P&T committee is unable to develop and approve PA criteria prior to this formulary submission window, placeholder PA criteria may be submitted with the submission by indicating "Criteria Pending" in the required PA submission fields. The standard Part D utilization management criteria review processes will provide MAPD plans an opportunity to finalize the criteria for the affected Part D drugs. If an MAPD plan chooses to implement criteria during the 2019 plan year, the addition of PA to a Part D drug can be requested as a negative change via the standard negative formulary change request timeframes.

If an MA plan decides to adopt and apply step therapy to Part B drugs, the MA plan must disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents. In the ANOC, this information must be included under the Changes to Benefits and Costs for Medical Services. In the EOC, this information must be included in the Medical Benefits Chart under "Medicare Part B prescription drugs." If these documents are already in production, plans may send out an addendum to the ANOC and EOC to appropriately inform enrollees of the change. MA plans must provide benefits consistent with the coverage rules and benefits listed in these documents. For MA plans that choose to apply step therapy to Part B drugs in 2019, including this information in the ANOC and EOC prior to this year's annual election period satisfies that obligation. No changes to 2019 Plan Benefit Packages in the Bid Pricing Tool are needed in conjunction with adding a step therapy program for Part B drugs in 2019 based on this memo.

CMS believes that in order to maintain access to necessary drugs, step therapy should be coupled with drug management care coordination services and, importantly, rewards that incentivize beneficiary participation. In other words, under CMS's interpretation of its regulations, it is necessary for an MA plan opting to apply step therapy to Part B drugs to offer beneficiaries an

opportunity to participate in drug management care coordination activities. Patient-centered care coordination is an essential element to improved health outcomes, lower costs and providing access to drugs in the context of step therapy. It is an integral part of MA plans to coordinate and manage care in order to achieve quality care outcomes for enrollees. *See* 42 CFR §§ 422.112(b) and 422.152. Care coordination activities are truly effective when they reflect an enrollee's individual needs. In this context, CMS understands drug management care coordination activities to include, at a minimum:

- Interactive medication review and associated consultations for enrollees to discuss all current medications and perform medication reconciliation and follow-up when necessary;
- Providing educational materials and information to enrollees about drugs within the drug management care coordination program; and
- Implementing medication adherence strategies to help enrollees with their medication regimen.

Patient engagement is essential to a successful care coordination program. To ensure adequate access to Part B drugs, it is necessary, under CMS's interpretation of its regulations, that MA plans opting to apply step therapy encourage enrollees to participate in such a drug management care coordination program by offering rewards in exchange for enrollee participation. Rewarding drug management care coordination helps encourage participation in a program that works to ensure that enrollees get safe and clinically appropriate medication to treat their condition, and will enable plans to pass on the cost savings generated from more active management of the drug benefit. Consistent with 42 CFR §422.134, plan rewards cannot be offered in the form of cash or monetary rebate, but may be offered as gift cards or other items of value to all eligible enrollees. MA plans should make sure any rewards or incentives comply with all rules at 42 CFR § 422.134 and Chapter 4 of the Medicare Managed Care Manual. Under these rules, the value of the rewards or incentives must be reasonable and appropriate. In this particular context, CMS will presume that the reward or incentive is reasonable and appropriate if it is equivalent to more than half the amount saved on average per participant by a more efficient use of health care resources, promotion of improved health, or prevention of injuries and illness. Also, pursuant to the requirement that information must be made available to CMS about the form and manner of rewards or incentives programs, MA plans offering this particular reward or incentive must include the value of the offered reward or incentive on a per member basis in comparison to the average planned per participant savings in the annual Part C Reporting Requirements submission.

For those plans that did not previously consider initial costs associated with rewards and incentives, these costs need not be separately included in the bid as a non-benefit expense. This is only for rewards and incentives offered in connection with step therapy driven drug management care coordination activities for 2019.

While step therapy requirements may reduce costs to both the enrollee and the MA plan, due to variances in cost-sharing for Part B and Part D drugs, there may be occasions when enrollees could experience higher out-of-pocket costs for the "stepped" Part D drug. CMS reminds MA plans that benefits must be provided consistent with the 2019 benefit packages submitted and

approved by CMS and it is our expectation that step therapy for Part B drugs, and other utilization management practices, should not result in increased costs to enrollees.

Additionally, it is critical that MA plans continue to comply with the statutory requirement that they provide access to all Part A and Part B benefits that would be available in Original Medicare. Step therapy or other utilization management policies may not be used as an unreasonable means to deny coverage of medically necessary services or to eliminate access to a Part B covered benefit, which is why CMS believes it is important to pair step therapy with a beneficiary engagement program. Furthermore, enrollees must be able to request an exception from the plan's step therapy requirement in order to access a Part B covered drug. The ability to request such an exception is consistent with current Part D rules involving exceptions related to the application of utilization management tools, such as step therapy requirements.[3] CMS recommends that MA plans follow the rules governing Part D exceptions in 42 CFR § 423.578(b) and grant an exception whenever it determines that the drug is medically necessary and is a covered Part B drug.

CMS considers plan decisions involving requests for exceptions to be pre-service organization determinations because they involve an MA plan's refusal to provide or pay for services that the enrollee believes should be furnished or arranged by the MA plan.[4] As a result, exception requests are subject to applicable adjudication timeframes and notice requirements in 42 CFR §§ 422.568 and 422.572. Organization determination timeframes require that MA plans make determinations as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days (72 hours for expedited requests) after the date the organization receives the request. CMS strongly encourages that MA plans expedite requests for exceptions in Part B, to align with the 72-hour adjudication timeframe for requests in Part D.

Finally, MA plans should ensure that new step therapy requirements do not disrupt ongoing Part B drug therapies for enrollees. Step therapy may only be applied to new prescriptions or administrations of Part B drugs for enrollees that are not actively receiving the affected medication. Also, Part D transition requirements will continue to apply to Part D drugs that are subject to step therapy where the first "step" is a Part B drug. With these additional tools and enrollee protections in place, MA plans will be able to provide more coordinated and cost-effective care.

Questions related to the information in this memorandum, may be submitted at: https://dpap.lmi.org/dpapmailbox/.

[3] 42 CFR § 423.578(b)
[4] *See* 42 CFR § 422.566(b)(3)

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NDMA
Est.1887 NORTH DAKOTA MEDICAL ASSOCIATION

House Human Services Committee
SB 2290
March 4, 2019

Chairman Weisz and Committee Members, I am Courtney Koebele and represent the North Dakota Medical Association. The North Dakota Medical Association is the professional membership organization for North Dakota physicians, residents, and medical students. NDMA does not support SB 2290.

Part of NDMA's mission is to advance the health and promote the well-being of the people of North Dakota. SB 2290 does not help promote the health of Medicaid patients.

We find the growing trend towards the use of restrictive and burdensome utilization management tactics by payors concerning and urge the state to reconsider its stance on this critical patient care issue. Step therapy protocols that require patients to try and fail certain treatments before allowing access to other, potentially more appropriate treatments can both harm patients and undercut the physician-patient decision-making process. The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation and the care plan developed by the physician in close consultation with that patient.

We appreciate that biologic medicines are expensive and that the upfront cost is more than Medicaid normally spends on older medications. However, that medicine has a much higher chance of getting the patient into remission so that you can avoid the complications, the emergency room visits, the hospitalizations, and the need for surgery.

Thank you for the opportunity to testify today. I would be happy to answer any questions.

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ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

1 March 2019

Representative Robin Weisz
2639 First Street SE
Hurdsfield, ND 58451-9029

Dear Chairman Weisz,

Thank you for the opportunity to provide feedback on Senate Bill 2290, currently pending in the Assembly Human Services Committee. SB 2290 seeks authorization to deploy a Medicaid step-therapy program, a utilization management tool also permitted in the Medicare Advantage program. ASCO is concerned that this legislation is based solely on costs and is not in the best interests of North Dakota Medicaid recipients. The American Society of Clinical Oncology (ASCO) opposes SB 2290—and the Centers for Medicare and Medicaid Services (CMS) decision to allow its use in Medicare Advantage plans.

ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

Senate bill 2290 would remove "antineoplastic agents, for the treatment of cancer" currently exempt from prior authorization, allowing use of step therapy in the North Dakota Medicaid Program. Step therapy requires patients to try and fail on a lower cost medication before they can access medication or treatment recommended by their physician. Step therapy can: delay patient access to appropriate care, lead to irreversible disease progression, alter the ability of preferred treatments to achieve their desired effect, and may introduce a range of other significant patient health risks.

As an alternative to step therapy, ASCO recommends use of clinical pathways to achieve high-value care. Clinical treatment pathways select a preferred, evidence-based therapeutic option based upon efficacy and toxicity and consider costs only if two or more drugs are equally acceptable in the clinical situation. In this way, the North Dakota Medicaid program can ensure its beneficiaries with cancer receive high quality care, while also working to remove costs associated with unwarranted variation in treatment.

2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571-483-1300
F: 571-366-9530
www.asco.org

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We ask that the North Dakota Assembly Human Services Committee oppose SB 2290 and work with stakeholders such as ASCO to develop an alternative option for cancer drugs in the Medicaid program. Our goal is to ensure all patients with cancer have access to the treatment best suited to their disease. If you have questions or would like assistance on any issue involving the care of individuals with cancer, please contact Kate Flannigan at ASCO at katherine.flannigan@asco.org.

Sincerely,

Monica Bertagnolli, MD

Monica Bertagnolli, MD, FACS, FASCO
President, American Society of Clinical Oncology