19.0343.04000

FISCAL NOTE

Requested by Legislative Council
01/14/2019

Amendment to: HB 1469

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).*

The bill limits Pharmacy Benefit Managers to require step therapy in the drug treatment of metastatic cancer.

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 NDPERS pharmacy benefits do not require step therapy for any prescription drugs.

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.*

N/A

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.*

N/A

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.*

N/A

Name: Bryan Reinhardt
Agency: NDPERS
Telephone: 701-328-3919
Date Prepared: 01/17/2019

19.0343.03000

FISCAL NOTE

Requested by Legislative Council
01/14/2019

Amendment to: HB 1469

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						

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Counties			
Cities			
School Districts			
Townships			

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N/A

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.*

N/A

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.*

N/A

Name: Bryan Reinhardt
Agency: NDPERS
Telephone: 701-328-3919
Date Prepared: 01/17/2019

19.0343.02000

FISCAL NOTE

Requested by Legislative Council
01/14/2019

Amendment to: HB 1469

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						

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Counties			
Cities			
School Districts			
Townships			

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N/A

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.*

N/A

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.*

N/A

Name: Bryan Reinhardt
Agency: NDPERS
Telephone: 701-328-3919
Date Prepared: 01/17/2019

19.0343.01000

FISCAL NOTE

Requested by Legislative Council
01/14/2019

Bill/Resolution No.: HB 1469

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).*

The bill limits Pharmacy Benefit Managers to require step therapy in the drug treatment of metastatic cancer.

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 NDPERS pharmacy benefits do not require step therapy for any prescription drugs.

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N/A

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.*

N/A

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.*

N/A

Name: Bryan Reinhardt
Agency: NDPERS
Telephone: 701-328-3919
Date Prepared: 01/17/2019

2019 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1469

2019 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Peace Garden Room, State Capitol

HB 1469
1/21/2019
31108

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Ellen LeTang

Explanation or reason for introduction of bill/resolution:

Pharmacy benefits manager step therapy protocols.

Minutes: Attachment 1, 2, 3, 4

Chairman Keiser: Opens the hearing on HB 1469.

Rep Corey Mock~District 18: Attachment 1.

8:50

Rep Kasper: I'm not aware that a PBM had the power to overrule a doctor's protocol on treatment was given to a patient, whether or not it's on the payment on a formula. Did you find that the PBM's were the ones causing the problem or was there something else in the system?

Rep Mock: I looked for a truly clear answer & couldn't find one. We drafted this with legislative council's guidance because all the treatments are administered as prescriptions. It was thought this was added protection of the patient. Keeping it in title 19, we thought this at least reasonable protection, a cleaner way to start.

Rep Bosch: Do we limit it to stage 4, why wouldn't we want the best treatment regardless of the stage cancer?

Rep Mock: There are a lot of advocates that would like to see step therapy protocols never used. That is, you are diagnosed with cancer, regardless of the stage or any chronic disease, that you are not required to fail treatment based on the cost of the treatment. The most likely to succeed instead of failing many different treatments before you get to the one that would work. That would open up a much larger conversation. Many sponsors are open to that conversation. We didn't want to risk it to open it up to all.

Rep M Nelson: Section b, lines 21-23, from your testimony you were saying we want to be able to use off labeling. If the "and" was an "or", it clearly it could be used. The way I read this now, I don't think an off label use could be supported.

Rep Mock: Your correct.

Chairman Keiser: Given that this was passed in a few states, is there any data that indicates what is the impact on the cost side.

Rep Mock: We looked for it & couldn't find it. We haven't seen any cost savings.

Chairman Keiser: Anyone else here to testify in support, opposition to HB 1469?

Jack McDonald~Representing America's Health Insurance Plans (AHIP) & Prime Therapeutics: Attachment 2 & 3. Attachment 3 is from Prime Therapeutics who left their testimony with Jack McDonald because they had to testify in another hearing.

17:50

Rep Ruby: If this bill passed, would it be part of the contract with the providers or is it the wrong approach?

Jack McDonald: I suppose it would have to be in the contract. It's the cart before the horse thing.

Rep Ruby: What portion of the code is the exception.

Jack McDonald: I'll find that out.

Rep Ruby: If they already have the ability, that means that this bill wouldn't be necessary, correct?

Jack McDonald: I do believe so. There is a reason for step therapy.

Rep Kasper: We need to go to the statute & if it's silent, we need to address that.

Chairman Keiser: Following up on the questioning, there are formularies that are put into contract with the PBM. They are recommended, sometimes specific & utilized. I would bet, formularies, specifically, that they accept step therapy until all things are tried. It's possible that it is in the formulary.

Jack McDonald: A carrier that provides health benefits.

Chairman Keiser: Anyone else here to testify in opposition, a neutral position on HB 1469.

Scott Miller~Executive Director of the ND Public Employee Retirement System (NDPETRS): Attachment 4.

23:05

Chairman Keiser: What happens if a new experimental drug out that cost a million dollars? PERS couldn't be too excited about requiring by statute, that you have to use that before trying something that is significantly less?

Scott Miller: We do have people that use very expensive drugs. A million-dollar drug would impact this situation, but at the same time that is why we have over 60,000 live in our plan to help spread that out.

Chairman Keiser: Closes the hearing. Rep Schauer isn't here today & he is carrying the bill. Would anyone volunteer for this bill. Rep Adams will carry the bill.

2019 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Peace Garden Room, State Capitol

HB 1469
2/4/2019
32056

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Ellen LeTang

Explanation or reason for introduction of bill/resolution:

Pharmacy benefits manager step therapy protocols.

Minutes: Attachment 1

Chairman Keiser: Reopens the hearing on HB 1469.

Rep Adams: Moves the amendment 19.0343.01002 as distributed on HB 1469 from the Jan 21 hearing that Rep Mock submitted.

Rep P Anderson: Second.

Chairman Keiser: Further discussion?

Rep Kasper: Which amendment?

Chairman Keiser: The .01002. Who were they proposed by?

Rep Adams: Did not turn mike on.

2:00

Voice vote ~ motion carried.

Chairman Keiser: There is another amendment required. On line 8, metastatic cancer, which I don't think we need. On line 16, page 1, remove "impose" with "require". The final authority does rest with the health plan, I would suspect. The pharmacy benefit manager could recommend it but you would think that that would be part of that contract. The stage 4 element, we don't have to worry about. Line 23, add "and" with "or".

The only remaining issue is on line 16, the health plan may not "impose" & replace it with "require".

Rep M Nelson: It seem to me that we clarified it very well if we just put pharmacy benefit manager or a health care plan may not require.

Chairman Keiser: I agree with that. OK, page 1, line 16, after "manager" insert "or a health plan".

Rep M Nelson: Moves to adopt the 2nd amendment.

Rep Laning: Second.

Chairman Keiser: Further discussion?

Voice vote ~ motion carried.

Rep Kasper: Moves a Do Pass as Amended.

Rep Schauer: Second.

Chairman Keiser: Further discussion.

Roll call was taken for a Do Pass as Amended with 13 yes, 0 no, 1 absent & Rep Adams is the carrier.

Jack McDonald~Representing America's Health Insurance Plans: Attachment 1. He was in attendance, submitted testimony but did not speak at the hearing.

Prepared by the Legislative Council staff for
Representative Mock
January 21, 2019

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1469

Page 1, line 23, replace "and" with "or"

Page 1, after line 23, insert:

"3. This section does not require coverage of a nonformulary prescription drug."

Renumber accordingly

DP 2/4/19

19.0343.01003
Title.02000

Adopted by the Industry, Business and Labor Committee

February 4, 2019

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1469

Page 1, line 16, after "manager" insert "or a health plan"

Page 1, line 16, replace "impose" with "require"

Page 1, line 23, replace "and" with "or"

Page 1, after line 23, insert:

"3. This section does not require coverage of a nonformulary prescription drug."

Renumber accordingly

Date: Feb 4, 2019

Roll Call Vote #: 1

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 1469

House Industry, Business and Labor **Committee**

☐ **Subcommittee**

Amendment LC# or Description: 19.0343.01002 title 02000

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 Adams **Seconded By** Rep Anderson

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser			Rep O'Brien		
Vice Chairman Lefor			Rep Richter		
Rep Bosch			Rep D Ruby		
Rep C Johnson			Rep Schauer		
Rep Kasper			Rep Adams		
Rep Laning			Rep P Anderson		
Rep Louser			Rep M Nelson		

Total (Yes) _____ No _____

Absent _____

Floor Assignment voice vote - motion carried

Date: Feb 4, 2019

Roll Call Vote #: 2

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 1469

House Industry, Business and Labor **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 Nelson **Seconded By** Rep Laning

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser			Rep O'Brien		
Vice Chairman Lefor			Rep Richter		
Rep Bosch			Rep Ruby		
Rep C Johnson			Rep Schauer		
Rep Kasper			Rep Adams		
Rep Laning			Rep P Anderson		
Rep Louser			Rep M Nelson		

Total (Yes) _____ No _____

Absent _____

Floor Assignment voice vote - motion carried

Pg 1, line 16 after "manager" insert "or a health plan"

Date: Feb 4, 2019

Roll Call Vote #: 3

2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. 1469

House Industry, Business and Labor **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 Kasper **Seconded By** Rep Schauer

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	X		Rep O'Brien	AB	
Vice Chairman Lefor	X		Rep Richter	X	
Rep Bosch	X		Rep Ruby	X	
Rep C Johnson	X		Rep Schauer	X	
Rep Kasper	X		Rep Adams	X	
Rep Laning	X		Rep P Anderson	X	
Rep Louser	X		Rep M Nelson	X	

Total (Yes) 13 No 0

1

Absent

Floor Assignment Rep Adams

REPORT OF STANDING COMMITTEE

HB 1469: Industry, Business and Labor Committee (Rep. Keiser, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (13 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). HB 1469 was placed on the Sixth order on the calendar.

Page 1, line 16, after "manager" insert "or a health plan"

Page 1, line 16, replace "impose" with "require"

Page 1, line 23, replace "and" with "or"

Page 1, after line 23, insert:

"3. This section does not require coverage of a nonformulary prescription drug."

Renumber accordingly

2019 SENATE HUMAN SERVICES

HB 1469

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

HB 1469
3/19/2019
Job # 33932

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

Relating to pharmacy benefits manager step therapy protocols.

Minutes: Attachments #1-3

Madam Chair Lee opens the hearing on HB 1469.

(00:15-06:20) Representative Corey Mock, District 18 introduced HB 1469 and provides testimony. Please see **Attachment # 1** for written testimony.

Representative Mock: Just one quick addition, because the house did amend one thing I did catch a technical correction that I may recommend to the committee is on line 14 of the bill. On line 16 the term "or a health plan" was added. The definition of step therapy protocol on line 14 states that "before the pharmacy benefits manager allows coverage" we would recommend add the language after "manager" insert "or health plan" just to be consistent with the addition made in the house. We did this with legislative council and they agreed that was a change that was likely overlooked on the House IBL committee. The rest of the testimony has attachments regarding information on metastatic cancer and research we had done regarding staging and types of cancers that are not traditionally stage in the stage 0-4 methodology.

(07:48-10:18) Representative Mock and the committee engage in an informal discussion.

(10:00-12:50) Jack McDonald, representing American Health Insurance Plans (AHIP). Testifying in opposition to HB 1469. Please see **Attachment #2** for written testimony.

Senator Hogan: In your testimony, you said that the fiscal note had no impact on PERS but it would have a huge impact on private plans. Could you explain why?

Jack McDonald: It's because the types of drugs that are used, if you are going to mandate that these types of cancer drugs are the most expensive drugs around now so if you are going to mandate that they use these things then it is going to be without the stage 4 then it is going to be much more expensive for the private plans.

Senator Hogan: Why did PERS show no fiscal impact?

Jack McDonald: The fiscal note, PERS doesn't treat this. If you look at the fiscal note.

Madam Chair Lee: We don't have a fiscal note. There may have been one on the house side.

Senator K. Roers: I think that there are people here from PERS that could be able to answer that.

Jack McDonald: I found it here and it says; The North Dakota PERS pharmacy benefit does not require step therapy for any prescription drugs. That is why there is no fiscal impact but there would be a fiscal impact because the private plans do require that.

Madam Chair Lee: Any further questions for Mr. McDonald?

Jack McDonald: If I may add one more thing, we testified yesterday on HB 1382 and we got some solutions, they are being sent out the legal entities of the people involved so we may be able to bring those back to you by Monday.

Madam Chair Lee: We will be happy to see what solution you might come up with next week and thank you for letting us know.

(16:10-18:48) Scott Miller, Executive Director of the North Dakota Public Employee Retirement System. Offering neutral testimony on HB 1469. Please see **Attachment #3** for written testimony and memo from Deloitte Consulting.

(19:26-) LuGina Mendez-Harper, Pharmacists with Prime Therapeutics. Offering neutral testimony on HB 1469. Testimony is as follows: I stand before you in a neutral position on this legislation. Blue Cross and Blue Shield of North Dakota does not currently have any step therapy in place for cancer medications and treatments but similar to the gentleman with PERS, should there be new drugs that come out onto the market where step therapy would be not only from a cost perspective but also from a safety perspective. We would like to have that option available to us. We would support the amendment from AHIP which would just provide a guard rail, if you do have a step therapy program and you want to circumvent that, it would be limited to a stage 4 or a cancer that has metastasized to another part of the body versus stage 2 or stage 3. I am happy to hear any questions from the committee.

Senator K. Roers: I think the challenge is to actually word that. I think that Representative Mock and I have had this conversation because we do have that difficulty in that some cancers are not stage. My aunt died from extensive lung cancer because there are two types of lung cancer, one is stage 1-4 and the other is limited or extensive. My background is oncology nursing and I know that this is very difficult to define this. I'm wondering if any of the experts in the room would be willing to take a stab at, I not know that stage 4 is the right word that we want to use, is there a better word and maybe it is we may for the purposes of

this metastasized means to another area of the body. Maybe there are experts in the room that can help with the defining of that.

LuGina Mendez-Harper: If you take out lymph nodes and nearby tissue and just have other parts of the body which is on line 9, I would have to differ to you because I'm not an oncology specialist, if you just limited it to other parts of the body would that address the fact that it's not necessarily stage 4 but you are just trying to have some guard rails about where you are in the spectrum of cancer that would have this ability.

Senator K. Roers: I think that gets us closer but we would want to run it through some people to make sure we don't create unintended consequences.

Madam Chair Lee: We try to work hard to collaborate with other folks so that doesn't mean that occasionally puts onus on folks in the gallery to come up with language to help us but you might be happier in the end with and the people that you represent if we consider your expertise as well.

Senator Anderson: Perhaps because you don't have the step therapy programs, usually when someone sets something in place there is a way for the practitioner to be able to bypass and, I would like to hear about what that might be in the case where they have a patient and it looks like they have already passed the first three steps and they say this guy is going to die unless so explain that for me.

LuGina Mendez-Harper: For traditional step therapy we have exception processes in place, for step therapy it is usually the doctor or health care provider who provides us with documentation that states she is appropriate to be bumped up another step. That is typically all that we require in order to make that decision, just providing us with documentation.

Senator Anderson: What if they haven't had time to try the other steps?

LuGina Mendez-Harper: Or that there is a clinically compelling reason.

Senator Anderson: refer to recording

LuGina Mendez-Harper: Yes, there is.

(25:04-25:33) Robert Harms, CVS Health. Offering neutral testimony on HB 1469. Testimony is as follows: We just want to agree with the statements from AHIP and Prime Therapeutics and we would be happy to help get the bill to a point of where we are comfortable with the language. We support the proposed amendment from AHIP.

Madam Chair Lee: Thank you, and we appreciate your help as well. Any questions from Mr. Harms? If not, thank you. Any further testimony on HB 1469?

Madam Chair Lee closes the hearing on HB 1469.

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

HB 1469
3/26/2019
Job #34219

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

Relating to pharmacy benefits manager step therapy protocols.

Minutes: No Attachments

Madam Chair Lee opens the discussion on HB 1469.

Madam Chair Lee: Senator K. Roers, would you just repeat for the record on HB 1469.

Senator K. Roers: Yes, I have an amendment regarding the definition of metastatic cancer that came from AHIP and CVS health. I passed it by Representative Mock to ensure that he was okay with that. Representative Mock had also recommended a small technical correction in line 14, so after the word “manager” insert “or a health plan”. In the amendment that was provided by AHIP and CVS health, they had a second thing that they wanted added. I wasn’t as comfortable with that piece of the addition but also our intern ran it by legislative council and they did not feel like it would be some parts of it may be even constitutional because it would kind of be a variable when it applies type of thing so, I just want to change the definition but we can talk about the other piece separately.

(01:26-end of recording) Madam Chair Lee and the committee discuss other bills that still need to be voted on.

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

HB 1469
3/26/2019
Job #34221

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

Relating to pharmacy benefits manager step therapy protocols.

Minutes: Attachment #1

Madam Chair Lee opens the discussion on HB 1469. Please see Attachment #1 for proposed amendments from the committee.

Madam Chair Lee: So we would be removing "cancer that is spread from the primary or original". It seems to me that without being in the categories of the stage 1-4 block when not every cancer is described that way that this would be more inclusive. We do have the one that Representative Mock suggested on line 14, after "manager" inserting "health plan". Any discussion about this amendment?

Senator Hogan: Metastatic cancer means, advanced cancer that exhibits signs of secondary cancer sites. That is how it reads now?

Madam Chair Lee: Correct.

Senator K. Roers: I just want to let you know what the piece was that was originally suggested on page 1, line 23, remove "or is supported by peer review medical literature" and insert "and is preferred by the national comprehensive cancer network guidelines over the proposed plan specific step one options" and that was what our intern had checked with legislative council and they were not comfortable with that language because it is so variable.

Senator Anderson: Is this definition there suggesting it is better than the original one?

Senator K. Roers: I like it better.

Madam Chair Lee: Mr. McDonald do you have any comments? Do you find this palatable?

Jack McDonald, AHIP: Yes, we discussed this with Senator K. Roers and we agree to that and I also understand the change in that last portion where you are recommending defining different literature. The legislature has a long standing policy that you can't refer in law to

something else that is going to be changed automatically. It is better off leaving it the way that it is and we prefer the definition that is in there.

Madam Chair Lee: Any questions for Mr. McDonald? If not, thank you.

Senator K. Roers: I move the proposed **AMENDMENT**.
Seconded by Senator Hogan

Madam Chair Lee: Any further committee discussion? If not, please call the role.

ROLL CALL VOTE TAKEN

6 YEA, 0 NAY, 0 ABSENT
MOTION CARRIES TO ADOPT AMENDMENT

Madam Chair Lee: We have the amended bill before us.

Senator O. Larsen: So, is this bill going to continue that step therapy will be used at that stage 4 is that highest or is that going to relax those guidelines that they no longer need to use for step therapy?

Senator K. Roers: I think it is going to allow for the ability to ask to leave the step therapy. The first choice will be step therapy but you can kind of petition if you have that advanced cancer to jump a step. It doesn't guarantee that they will say yes but what I am understanding is it provides for the opportunity to request a jump.

Madam Chair Lee: If you look in subsection 2 it says, "a PBM or a health plan may not require a step therapy protocol for coverage of a recommended prescription drug" and then we have these categories below. It does not require coverage of a non-formulary prescription drug. Does that satisfy your question?

Senator O. Larsen: Yeah, I think it is relaxing the steps so I'm going to resist that.

Madam Chair Lee: Any other questions?

Senator K. Roers: I move a **DO PASS, AS AMENDED**
Seconded by Senator Clemens

ROLL CALL VOTE TAKEN

5 YEA, 1 NAY, 0 ABSENT
MOTION CARRIES DO PASS, AS AMENDED
Senator K. Roers will carry HB 1279 to the floor.

Madam Chair Lee closes the discussion on HB 1469.

SK
3/26
1 of 1

19.0343.02001
Title.03000

Adopted by the Senate Human Services Committee

March 26, 2019

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1469

Page 1, line 8, remove "cancer that has spread from the primary or original"

Page 1, line 9, replace "site to lymph nodes, nearby tissues, or other parts of the body" with "advanced cancer that exhibits signs of secondary cancer sites"

Page 1, line 14, after "manager" insert "or health plan"

Renumber accordingly

Date: 3/26/19
Roll Call Vote #: 1

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1469

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 19.0343.02001

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. K. Roers Seconded By Sen. Hogan

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee	X		Sen. Kathy Hogan	X	
Sen. Oley Larsen	X				
Sen. Howard C. Anderson	X				
Sen. David Clemens	X				
Sen. Kristin Roers	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment _____

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

Date: 3/26/19
Roll Call Vote #: 2

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1469

Senate 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 Sen. K. Roers Seconded By Sen. Clemens

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee	X		Sen. Kathy Hogan	X	
Sen. Oley Larsen		X			
Sen. Howard C. Anderson	X				
Sen. David Clemens	X				
Sen. Kristin Roers	X				

Total (Yes) 5 No 1

Absent 0

Floor Assignment Sen. K. Roers

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

REPORT OF STANDING COMMITTEE

HB 1469, as engrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (5 YEAS, 1 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1469 was placed on the Sixth order on the calendar.

Page 1, line 8, remove "cancer that has spread from the primary or original"

Page 1, line 9, replace "site to lymph nodes, nearby tissues, or other parts of the body" with "advanced cancer that exhibits signs of secondary cancer sites"

Page 1, line 14, after "manager" insert "or health plan"

Renumber accordingly

2019 CONFERENCE COMMITTEE

HB 1469

2019 HOUSE STANDING COMMITTEE MINUTES

Industry, Business and Labor Committee
Peace Garden Room, State Capitol

HB 1469
4/8/2019
34616

☐ Subcommittee
☒ Conference Committee

Committee Clerk: Ellen LeTang

Explanation or reason for introduction of bill/resolution:

Pharmacy benefits manager step therapy protocols.

Minutes:

Chairman Kasper: We're here to talk about the amendment the Senate added on HB 1469. Can the Senate explain what the amendment does & why it was amended?

Sen K Roers: I carried this bill & we worked together with AHAB, others & Rep Mock to come up with an amendment that they both could live with. As I read this, one of the things that they wanted an amendment of stage 4 cancer. There are not all cancers that are staged. That would be limiting. Then there are times where you have a recurrent cancer that moves but isn't necessarily at a staged 4. The intent was to have a little bit of flexibility but not have it be wide open.

AHAB & CVS brought a couple different state's version of what they had seen as qualifiers on this piece. I choose the one that I felt had the greatest breath but not a free for all. I purposed that as the amendment.

Sen H Anderson: We asked her what she was more comfortable with as a definition as she worked in the oncology area.

Chairman Kasper: Questions?

Rep Schauer: Which amendment are we looking at?

Sen K Roers: The.2001, which is the markup or the .3000. "Metastatic cancer" means cancer that has spread from the primary or original site to lymph nodes, nearby tissues or other parts of the body. The interesting thing that you can actually have a stage 2 cancer that met that definition. When there was a request to change it to stage 4, it was a too far of a jump.

So, we changed it from what I just read to "Metastatic cancer" means advanced cancer that exhibits signs of secondary cancer sites. It's a very similar definition but slightly different.

Chairman Kasper: This does not have the word stage 4, how did you jump?

Sen K Roers: There was a purposed amendment to include stage 4. It was requested by the insurance companies to include stage 4. Rather than make that change we worked with the insurance companies & Rep Mock to find language that they both could live with without using stage 4.

Rep Schauer: You also added health plan on line 15. What was your thinking?

Sen K Roers: Rep Mock requested that, it was the same language used in subsection 2. It was a technical correction.

Sen H Anderson: That needs to be in there because a lot to times the pharmacy benefit manager is not making decisions for the health plan. The health plan makes their own decisions.

Chairman Kasper: I'm still not understanding what was wrong on the House language. When you read what you struck, cancer that has spread from the primary or original site to lymph nodes, tissues or other parts of the body. So that's moving from the primary site to someplace else. What was wrong with that definition?

Sen K Roers: There wasn't anything wrong with that, there was a request for a more clarified definition. My specialty in blood cancers, so blood cancers are everywhere in the body, so it's not necessarily about other tissues or parts of the body. It's a secondary cancer site, it's a slight technical difference. It's where you are talking about switching forms.

Chairman Kasper: The new language stipulates advanced cancer, what is the potential negative to someone who might have a cancer that has moved from one part of the body to the other? It's not labeled advances by a physician or an oncologist, but there are no drugs that can help it that on the formulary. But the specialty drugs that have not been normalized, yet are there. What does the words "advanced cancer" do the ability for that patient?

Sen K Roers: I don't have the expertise in that area. My understanding is if there isn't a drug on the formulary, if you failed drugs, you already get to petition for other drugs. This is allowing to skip a step, not have to fail drug to go to the next drug. This is what it's allowing, for that ability to skip that step.

Sen H Anderson: That's truly what the bill is about, to allow the practitioner to skip that step & go to the next drug.

Chairman Kasper: What was wrong with the definition the House had on line 8?

Sen H Anderson: I didn't see anything particularly wrong with that, we left that to Sen K Roers to come up with a different definition that they were happy with.

Chairman Kasper: My concern is that the words "advanced cancer" is limiting.

Sen K Roers: I'm wondering if that definition would be able to talk about what your concerns were with the original that was solved by the amended. If we went back to the original, what would be the down side?

Chairman Kasper: I want to know what's wrong with the original definition? We didn't talk in the House about the stage 4. I thought it was self-explanatory.

Jack McDonald: My understanding was the feeling of the groups were on the first bill that there needed some definition for stage 4. As we worked through that, we decided this was better & that not all cancers are the same. We wanted more definition than what was in the first one.

Chairman Kasper: I think the second definition is less descriptive. I don't know what the consequences of the step protocol not being required by the words "advanced cancer" that's limiting certain types of cancer. I don't know what the word "advanced cancer" is?

Rep Schauer: When you say exhibits signs of secondary cancer sites, might that be an opportunity when it says signs, to include language to be specific?

Sen K Roers: I don't have a problem with the original definition. I understand that Rep Mock didn't want it to say stage 4. I'm trying middle ground. I understand your point.

Chairman Kasper: The words "advanced cancer" is a little frightening to me of the limitations.

Rep Adams: There was an amendment when we heard it in committee that was brought forward, they wanted to say "stage 4 advanced" & we did not take part of that amendment. I agree with the "advanced" part, we need to think big not just little. Little can spread too. The word "advanced" should be removed.

Chairman Kasper: We can do two things, we can continue & mull over my concern or we can adjourn & try to find some type of wording or the Senate can recede.

Sen K Roers: If we were to recede but want to keep that "or health plan" correction?

Chairman Kasper: We can further amend.

Rep Adams: We added on line 17, a health care plan. It's technical.

Sen K Roers: Moves the Senate recede from the Senate amendments & amend as follows that on page 1, line 14, after "manager" insert "or health plan".

Sen Larsen: Second.

Chairman Kasper: Further discussion.

Roll call was taken on HB 1469 for the Senate to recede from the Senate Amendments & amends with 6 yes, 0 o, 0 absent & Chairman Kasper & Sen H Anderson are the carriers.

19.0343.02002
Title.04000

Adopted by the Conference Committee

April 8, 2019

1 of 1
4/8/19

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1469

That the Senate recede from its amendments as printed on page 1376 of the House Journal and page 1096 of the Senate Journal and that Engrossed House Bill No. 1469 be amended as follows:

Page 1, line 14, after "manager" insert "or health plan"

Renumber accordingly

Date: 4/8/2019

Roll Call Vote: 1

2019 HOUSE CONFERENCE COMMITTEE
ROLL CALL VOTES

BILL/RESOLUTION NO. HB 1469 as (re) engrossed

House Industry, Business & Labor Committee

Action Taken
- ☐ **HOUSE accede to Senate Amendments**
- ☐ **HOUSE accede to Senate Amendments and further amend**
- ☐ **SENATE recede from Senate amendments**
- ☒ **SENATE recede from Senate amendments and amend as follows**

☐ **Unable to agree**, recommends that the committee be discharged and a new committee be appointed

Motion Made by: Sen K Roers Seconded by: Sen Larsen

Representatives	4/8			Yes	No	Senators	4/8			Yes	No
Chairman Kasper	X			X		Sen H Anderson	X			X	
Rep Schauer	X			X		Sen K Roers	X			X	
Rep Adams	X			X		Sen Larsen	X			X	
Total Rep. Vote						Total Senate Vote					

Vote Count Yes: 6 No: 0 Absent: 0

House Carrier Chairman Kasper Senate Carrier Sen H Anderson

LC Number 19.0343 . 02002 of amendment

Title . 04000 of engrossment

Emergency clause added or deleted

Statement of purpose of amendment

Page 1, line 14, after "manager" insert "or health plan"

Insert LC: 19.0343.02002
House Carrier: Kasper
Senate Carrier: Anderson

REPORT OF CONFERENCE COMMITTEE

HB 1469, as engrossed: Your conference committee (Sens. Anderson, K. Roers, O. Larsen and Reps. Kasper, Schauer, Adams) recommends that the **SENATE RECEDE** from the Senate amendments as printed on HJ page 1376, adopt amendments as follows, and place HB 1469 on the Seventh order:

That the Senate recede from its amendments as printed on page 1376 of the House Journal and page 1096 of the Senate Journal and that Engrossed House Bill No. 1469 be amended as follows:

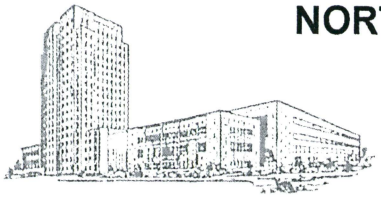
Page 1, line 14, after "manager" insert "or health plan"

Renumber accordingly

Engrossed HB 1469 was placed on the Seventh order of business on the calendar.

2019 TESTIMONY

HB 1469



NORTH DAKOTA HOUSE OF REPRESENTATIVES

STATE CAPITOL
600 EAST BOULEVARD
BISMARCK, ND 58505-0360

Representative Corey Mock
District 18
P.O. Box 12542
Grand Forks, ND 58208-2542
C: 701-732-0085
crmock@nd.gov

HB 1469

COMMITTEES:
Appropriations

Attachment 1
Jan 21, 2019
Page 1

To: Chairman George Keiser and Members of the House Industry, Business and Labor Committee

Date: January 21, 2019

Support Testimony for HB 1469 -- Eliot Glassheim Act

Good morning, Mr. Chairman and members of the committee. My name is Corey Mock, representative for District 18 in Grand Forks, ND, and I am here today as one of the sponsors of HB 1469.

This proposed legislation was modeled after policies enacted in several states known as the "Jimmy Carter Act." Originating in Georgia, the Jimmy Carter Act passed with near unanimous support and was signed into law by Governor Nathan Deal in 2016. The legislation was inspired by former President Jimmy Carter who, in August 2015, announced he was diagnosed with skin cancer that had spread to his brain and liver. His recommended treatment was Keytruda, an immunotherapy drug that allows the body's immune system to destroy cancer cells.

By early December of 2015, President Carter announced that medical scans revealed no signs of cancer. Now 94 years of age, he has remained in remission for a little more than three years.

My reasoning for bringing HB 1469 before you today is slightly more personal. Many of you remember one of our jovial colleagues from Grand Forks who retired in 2016 after serving 13 sessions in the North Dakota House of Representatives. Rep. Eliot Glassheim has been a dear friend and a respected statesman to so many who've served in our chambers. Which made his final session in 2015 especially difficult for all serving at the time.

Eliot had been diagnosed with lung cancer that had metastasized and spread throughout lymphatic system prior the 2015 legislative session. Like so many cancer patients he was prescribed a variety of

HB 1469

Attachment 1
Jan 21, 2019
Page 2

treatments -- most of them showing few if any promising results. Eventually Eliot was able to receive immunotherapy treatments and soon claimed the upper-hand in his fight against his cancer.

I am pleased to inform you that the poet of many legislative assemblies remains in remission today, spending quality time with his family, reading, writing, and sharing his vastly researched opinions with anyone who'll offer a moment of their time.

The treatment process Eliot experience is often referred to as "step therapy protocol," which requires a patient to fail less expensive treatment options before being allowed to use more advanced methods of treatment recommended by their oncologist.

While there are efforts to reform or prohibit step therapy protocols for all cancer and chronic disease patients, this legislation was specifically written to apply only to metastatic cancer patients -- often referred as stage IV or multi-system cancers. Sponsors are open to amendments that may expand the scope of the legislation, but ultimately, we want to ensure cancer patients with the most advanced stages of cancer are never required to fail treatments before they can receive the medication recommended by their medical team.

Because all health insurers in North Dakota utilize services of pharmacy benefit managers (PBMs), the cleanest way to draft the legislation was to place it in Title 19 for food, drugs, oils, and compounds, instead of Title 26.1 for insurance.

To be clear, this legislation does not require any insurance provider or PBM to provide treatment that is not already on their formulary -- an important distinction that has led to overwhelming, bipartisan support in numerous states across the country.

On behalf of the thousands of North Dakotans diagnosed with cancer each year, including my legislative colleague and District 18 predecessor, I want to thank you for your consideration of the Eliot Glassheim Act and hope to work with the committee to ensure a favorable outcome.

HB 1469

Attachment 1
Jan 21, 2019
Page 3

An Act

HOUSE BILL 18-1148

BY REPRESENTATIVE(S) Michaelson Jenet, Becker K., Benavidez, Bridges, Buckner, Coleman, Danielson, Esgar, Gray, Hansen, Herod, Hooton, Jackson, Kennedy, Kraft-Tharp, Landgraf, Liston, Lontine, McLachlan, Pabon, Pettersen, Roberts, Rosenthal, Valdez, Weissman, Winter, Young, Duran;
also SENATOR(S) Crowder, Aguilar, Baumgardner, Coram, Court, Fenberg, Fields, Garcia, Jahn, Jones, Kagan, Kefalas, Kerr, Martinez Humenik, Merrifield, Moreno, Priola, Scott, Sonnenberg, Tate, Todd, Williams A., Zenzinger.

CONCERNING THE PROHIBITION AGAINST A CARRIER REQUIRING STEP THERAPY FOR COVERED PERSONS WITH STAGE FOUR ADVANCED METASTATIC CANCER.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, 10-16-145, **amend** (1) as follows:

10-16-145. Step therapy - prohibited - definitions. (1) For the purposes of this section AND SECTION 10-16-145.5, "step therapy" means a protocol that requires a covered person to use a prescription drug or sequence of prescription drugs, other than the drug that the covered person's

health care provider recommends for the covered person's treatment, before the carrier provides coverage for the recommended prescription drug.

SECTION 2. In Colorado Revised Statutes, **add** 10-16-145.5 as follows:

10-16-145.5. Step therapy prohibited - stage four advanced metastatic cancer - definition. (1) NOTWITHSTANDING SECTION 10-16-145, A CARRIER THAT PROVIDES COVERAGE UNDER A HEALTH BENEFIT PLAN FOR THE TREATMENT OF STAGE FOUR ADVANCED METASTATIC CANCER SHALL NOT LIMIT OR EXCLUDE COVERAGE UNDER THE HEALTH BENEFIT PLAN FOR A DRUG APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND THAT IS ON THE CARRIER'S PRESCRIPTION DRUG FORMULARY BY MANDATING THAT A COVERED PERSON WITH STAGE FOUR ADVANCED METASTATIC CANCER UNDERGO STEP THERAPY IF THE USE OF THE APPROVED DRUG IS CONSISTENT WITH:

(a) THE UNITED STATES FOOD AND DRUG ADMINISTRATION-APPROVED INDICATION OR THE NATIONAL COMPREHENSIVE CANCER NETWORK DRUGS AND BIOLOGICS COMPENDIUM INDICATION FOR THE TREATMENT OF STAGE FOUR ADVANCED METASTATIC CANCER; OR

(b) PEER-REVIEWED MEDICAL LITERATURE.

(2) FOR THE PURPOSES OF THIS SECTION, "STAGE FOUR ADVANCED METASTATIC CANCER" MEANS CANCER THAT HAS SPREAD FROM THE PRIMARY OR ORIGINAL SITE OF THE CANCER TO NEARBY TISSUES, LYMPH NODES, OR OTHER PARTS OF THE BODY.

SECTION 3. Act subject to petition - effective date - applicability. (1) This act takes effect January 1, 2019; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within the ninety-day period after final adjournment of the general assembly, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2018 and, in such case, will take effect on January 1, 2019, or on the date of the official declaration of the vote thereon by the governor, whichever is later.

HB 1469

Attachment 1
Jan 21, 2019
Page 5

(2) This act applies to health benefit plans issued, amended, or renewed on or after the applicable effective date of this act.

Crisanta Duran
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Kevin J. Grantham
PRESIDENT OF
THE SENATE

Marilyn Eddins
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

Effie Ameen
SECRETARY OF
THE SENATE

APPROVED 1:50 PM 4/9/18

John W. Hickenlooper
GOVERNOR OF THE STATE OF COLORADO

HB 1469

Attachment 1
Jan 21, 2019

Bill inspired by Jimmy Carter's cancer treatment passes in Georgia

Page 6

Updated March 14, 2016
By Kristina Torres, The Atlanta Journal-Constitution

• • •

More cancer patients in Georgia would be able to receive the same treatment that former President Jimmy Carter says eliminated signs of his disease under a bill given final passage Monday by the state Senate.

House Bill 965 — dubbed the Honorable Jimmy Carter Cancer Treatment Access Act — now goes to Gov. Nathan Deal for his signature to become law.

The bill aims to prevent insurance companies from limiting coverage of drugs for Stage 4 cancer patients. Its sponsor, state Rep. Mike Cheokas, R-Americus, counts Carter as a constituent and has said the former president's cancer battle inspired him to try to help others get access to the same drugs that helped Carter.

Carter, 91, announced in August that doctors found four small melanoma lesions on his brain, and that he would undergo treatment at Winship Cancer Institute of Emory University using the drug pembrolizumab as well as radiation therapy. In early December, Carter announced that tests showed no sign of the cancer in his body.

The bill says any insurance company that offers health care plans in Georgia cannot force patients to first fail to respond to other treatments before trying more advanced treatment programs such as those that helped Carter. The bill would only apply to health plans that cover the treatment of advanced, metastatic cancer, which typically involves Stage 4 patients in which cancer has spread to other parts of the body.

The state House unanimously passed the bill last month. The Senate vote was 53-1, with state Sen. Bill Heath, R-Bremen, the lone no.

HB 1469 Attachment 1

19.0343.01002
Title.

Prepared by the Legislative Council staff for
Representative Mock
January 21, 2019

Jan 21, 2019
Page 7

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1469

Page 1, line 23, replace "and" with "or"

Page 1, after line 23, insert:

"3. This section does not require coverage of a nonformulary prescription drug."

Renumber accordingly

Attachment 1
Jan 21, 2019
Page 8

PROPOSED AMENDMENTS TO HB 1469

From Robert W. Harms, on behalf of CVS Health

January 21, 2019

1. At line 8, insert "Stage four advanced" before "Metastatic Cancer"
   (to be more specific and consistent with other states)

2. At line 16, remove "A pharmacy benefits manager may not impose" and insert "A health plan may not require"
   (because the employer, or health plan ask the PBM to utilize a step-therapy program as part of the service of administering the plan)

3. At line 20, after "of" insert "stage four advanced"
   (to be more specific and consistent with other states).

4. At the end of line 23 add "and" and new subsection c "the prescribed drug is covered on the health plan's formulary".

Attachment 2

Monday, January 21, 2019

House Industry, Business & Labor Committee
HB 1469

CHAIRMAN KEISER AND COMMITTEE MEMBERS:

My name is Jack McDonald. I'm appearing on behalf of America's Health Insurance Plans or, as it is commonly known, AHIP.

AHIP is the national trade association representing the health insurance industry. AHIP members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual and small group insurance markets, and public programs such as Medicare and Medicaid.

AHIP is opposed to HB 1469 as presented to you for several reasons. First, it is directed toward pharmacy benefit managers (PBMs). PBMs do not deny or make coverage decisions – those are made by our members, health insurance plans. Note that the Colorado Act the sponsor included with his written testimony aimed its provisions at insurance carriers and not PBMs.

Step therapy protocols are utilized by many insurers to ensure that patients begin drug therapy for a medical condition with the most cost-effective and safest drug before progressing to other costlier or riskier therapy. Step therapy protocols are often developed using U.S. Food and Drug Administration (FDA) guidelines, clinical evidence and research. Bills such as HB 1469 that impose other criteria on step therapy protocols would hinder the use of this important tool and limit its effectiveness.

Step therapy protocols encourage physicians and patients to undertake a more evidence-based and measured approach to treatment that is tailored to the individual by gauging a patient's response to less harmful medications before graduating to the more potent and high-risk drugs. Step therapy protocols already work to ensure patient safety using scientifically appropriate guidelines.

Legislation such as HB 1469 that limits step therapy protocols as suggested starting on line 16 is potentially dangerous. An exception to an

established step therapy protocol should only be considered at the request of a health care provider, not the patient.

Important clinical decisions should not be made at the behest of patients who may not fully understand the scientific ramifications behind a physician's decision or are partial due to direct-to-consumer drug advertising.

An exception to an established step therapy protocol should not be granted only because a patient is stable on a prescription drug. This would potentially allow patients to receive exemptions as a result of using sampled drugs, and would eliminate one of the key functions of a step therapy protocol: the use of cost-effective alternative treatments in the place of more expensive or higher risk medications.

This bill, dealing specifically with cancer where the drugs are almost always brand and massively expensive, could have a very large fiscal note for any plan forced to adopt them. The fiscal note for this bill shows no fiscal impact to PERS but it would have a huge fiscal impact on private plans.

The use of step therapy protocols should be encouraged rather than prohibited. They are important cost containment measures. Expenditures on prescription drugs are rising every year and contribute significantly to rising health care costs. Step therapy protocols ensure that insurers can continue to provide affordable coverage of prescription drugs.

Therefore, we respectfully as for a **DO NOT PASS** on HB 1469.

Thank you for your time and consideration. I'd be happy to answer any questions.

Attachment 3
Page 1

2900 Ames Crossing Road
Eagan, Minnesota 55121

Oppose House Bill 1469
January 21, 2019
Submitted by LuGina Mendez-Harper, Pharm.D., R.Ph.
Government Affairs Principal
Prime Therapeutics
House Industry, Business, and Labor Committee

Chairman Keiser, Vice Chair Lefor, and Committee Members:

Thank you for the opportunity to submit testimony in opposition of House Bill 1469.

Prime Therapeutics is a non-profit pharmacy benefit manager (PBM) owned by 17 Blue Cross Blue Shield plans including Blue Cross Blue Shield of North Dakota (BCBS-ND). We improve health outcomes by making the use of prescription drugs safer and more affordable.

Prime does not administer any step therapy programs for Blue Cross Blue Shield of North Dakota for metastatic cancer medicines.

We respectfully oppose House Bill 1469 because it will limit the use of a tool we use to effectively keep the overall cost of medicines down for members, health plans, employers, and state governments.

It is important to mention that step therapy programs are designed or chosen by health plans to meet their own needs. Prime does not require health plans to implement step therapy programs. Payers choose to use step therapy programs because they provide high quality health care that employers and consumers can afford.

Step therapy programs are clinically-based, cost-effective programs used by insurers to have members use existing, highly effective and safer medications before "stepping up" to new high-cost medicines, unless special circumstance exist. Prime's independent Pharmacy and Therapeutics Committee (P&T), a group of several independent physicians and pharmacists from active community and academic practices representing a broad range of medical specialties, review and approve step therapy programs. These health care professionals, who are not employed by Prime, are selected based on their contributions to medical and pharmacy literature, their specialty, involvement in clinical practice, and previous experience with P&T committees. When developing step therapy programs, only drugs with similar safety and effectiveness are considered. The P&T committee reviews clinical trials, medical guidelines, and peer reviewed journals to determine medicines that would be good candidates for step therapy. Only after a drug is determined safe and effective to treat the condition are costs considered.

Step Therapy encourages prescribers and patients to undertake a more evidence-based measured approach to treatment by gauging a patient's response to less harmful medications before graduating to more potent or high-risk high-cost drugs. The use of step therapy increases the use of FDA approved, lower cost alternative brand and generic medicines.

Prime has an override or exception process to allow patients to receive their medicines when a physician believes there are clinically valid reasons to bypass the step one medicine.

Step therapy programs have an accepted place in our health care system and are a critical tool used to ensure North Dakota citizens have access to sustainable, affordable health care benefits.

Prime respectfully opposes this bill.

Attachment 4
Jan 21, 2019

TESTIMONY OF SCOTT MILLER

House 1469 Bill – Pharmacy Benefits Manager Step Therapy Protocols

Good Morning, my name is Scott Miller. I am the Executive Director of the North Dakota Public Employee Retirement System (NDPERS). I appear before you today to provide neutral testimony regarding House Bill 1469. We have not had the opportunity to discuss this bill with the NDPERS Board, but will review it with them on Thursday. We have also not had the opportunity to provide the actuarial and technical analysis to the Employee Benefits Programs Committee.

House Bill 1469 prohibits a pharmacy benefit manager (PBM) from imposing a step therapy protocol for patients with metastatic cancer. Sanford Health Plan has advised us that there would currently be no actuarial impact to the NDPERS health insurance plan as their PBM does not require step-therapy for oncology drugs today. Express Scripts, Inc. (ESI), the PBM for the NDPERS Medicare Part D prescription drug plan, does use step therapy as a way to control costs. ESI has indicated that this bill is not anticipated to have any impact on the NDPERS Part D plan. However, our actuary, Deloitte, has indicated that if a new, high-cost drug became available, the health plan could be subject to added financial risk, especially if the situation would have warranted a step therapy protocol.

Deloitte has also advised us of proposed federal legislation specific to Medicare Part D prescription drug plans, that would allow step therapy protocols to be implemented on protected class drugs. Deloitte has indicated that House Bill 1469 appears to contradict that proposed federal legislation, were it to be passed. Therefore, the committee may want to clarify whether this bill should apply to the NDPERS Medicare Part D prescription drug plan.

Mr. Chairman, that concludes my testimony.

Attachment 1
Page 1
Feb 4, 2019

Wednesday, January 30, 2019

House Industry, Business & Labor Committee
HB 1469

CHAIRMAN KEISER AND COMMITTEE MEMBERS:

My name is Jack McDonald. I'm appearing on behalf of America's Health Insurance Plans or, as it is commonly known, AHIP.

AHIP opposed the step therapy bill – HB 1469 – at the hearing January 21 and still opposes it. You have my written testimony on this.

However, should you decide to give it a do pass, AHIP respectfully requests you consider the following amendments to make the bill more workable.

Thank you for your time and consideration. I'd be happy to answer any questions.

PROPOSED AMENDMENTS TO HB 1469

Page 1, line 8, after "means" insert "stage four advanced"

Page 1, line 20, after "diagnosis of" insert "stage four advanced"

Page 1, line 23, replace "supported by peer-reviewed medical literature" with "preferred by the national comprehensive cancer network (NCCN) guidelines over the proposed plan-specific step one options(s)"

Renumber accordingly

NORTH DAKOTA HOUSE OF REPRESENTATIVES

STATE CAPITOL
600 EAST BOULEVARD
BISMARCK, ND 58505-0360

Representative Corey Mock
District 18
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COMMITTEES:
Appropriations

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To: Chairwoman Judy Lee and Members of the Senate Human Services Committee
Date: March 19, 2019
Support Testimony for HB 1469 -- Eliot Glassheim / Jimmy Carter Act

Good morning, Madam Chair and members of the committee. My name is Corey Mock, representative for District 18 in Grand Forks, ND, and I am here today as one of the sponsors of HB 1469.

This proposed legislation was modeled after policies enacted in several states known as the "Jimmy Carter Act." Originating in Georgia, the Jimmy Carter Act passed with near unanimous support and was signed into law by Governor Nathan Deal in 2016. The legislation was inspired by former President Jimmy Carter who, in August 2015, announced he was diagnosed with skin cancer that had spread to his brain and liver. His recommended treatment was Keytruda, an immunotherapy drug that allows the body's immune system to destroy cancer cells.

By early December of 2015, President Carter announced that medical scans revealed no signs of cancer. Now 94 years of age, he has remained in remission for a little more than three years.

My inspiration for bringing HB 1469 before you today is slightly more personal. Many of you remember one of our jovial colleagues from Grand Forks who retired in 2016 after serving 13 sessions in the North Dakota House of Representatives. Rep. Eliot Glassheim has been a dear friend and a respected statesman to so many who've served with him in our chambers, on the Grand Forks City Council, or in any number of his civic leadership roles.

Eliot had been diagnosed with lung cancer that had metastasized and spread throughout his lymphatic system prior the 2015 legislative session. Like so many cancer patients he was prescribed a variety of

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treatments -- most of them showing few if any promising results. Eventually Eliot was able to receive immunotherapy treatments and soon claimed the upper-hand in his fight against his cancer.

I am pleased to inform you that our former colleague and the legislature's unofficial poet laureate remains in remission today, spending quality time with his family, reading, writing, and sharing his vastly researched opinions with anyone who'll offer a moment of their time.

Eliot's treatment was part of a "step therapy protocol," which requires a patient to fail less expensive treatments before receiving more advanced methods of treatment recommended by their oncologist.

This legislation was specifically written to apply only to metastatic cancer patients -- often referred as stage IV or multi-system cancers. Sponsors and industry worked carefully on language and definitions to preserve our original intent. For example: we considered "stage four metastatic cancer" as the operative term, however not all cancers are staged using the traditional TNM system.

According to the American Joint Committee on Cancer, "...it continues to be the recommendation of the CNS (central nervous system) Tumor Task Force that a formal classification and staging system not be attempted." Brain and CNS cancers are among the types of cancers that do not receive a formal classification and therefore may not be covered if this legislation were limited only to "stage IV metastatic cancer." We have yet to identify alternative language that would accommodate the uniqueness of these types of cancers.

Moreover, once cancer patients are diagnosed with a type and class of cancer, any recurrence remains based on the original classification. An example: if a patient is diagnosed with stage II breast cancer and the cancer is successfully treated, only to return later and spread to the bones, this would be classified as stage II breast cancer with bone metastasis.

Sponsors wanted to be clear that a patient presenting with an advanced form of cancer that is either not staged or is a metastasized recurrence would not be treated differently than a patient originally presenting with a type of the disease traditionally categorized as stage IV metastatic cancer.

Before we move to questions and additional testimony, I would like to walk through the bill briefly:

Subsection 1 *(lines 7-15)* contains definitions, including the definition of "metastatic cancer", "pharmacy benefit manager", and "step therapy protocol."

Subsection 2 *(lines 16-23)* is where the proposed limitation regarding step therapy protocols exists. As drafted and later amended by the House, a "pharmacy benefit manager or a health plan may not require a step therapy protocol for coverage of a recommended prescription drug, or sequence of prescription drugs, approved by the United States food and drug administration if:"

- The drug or series of drugs is prescribed to treat a patient's metastatic cancer; and
- The use of the drug or series of drugs is consistent with FDA-approved indications or is supported by peer-reviewed medical literature.

Subsection 3 *(line 24)* was added to ensure it was emphatically clear that HB 1469 does not require coverage of drugs not otherwise on the provider's formulary -- an important distinction that has allowed similar legislation to receive overwhelming, bipartisan support in numerous states across the country.

Madam Chair and members of the Senate Human Services committee, HB 1469 was approved by the Employee Benefits committee and showed no fiscal impact. It was amended at the request of sponsors and industry to arrive in it's current form and was ultimately adopted by the House of Representatives with an unanimous 93-0 vote.

On behalf of the thousands of North Dakotans diagnosed with cancer each year, including my legislative colleague and District 18 predecessor, I want to thank you for your consideration of the Eliot Glassheim Act and hope to work with the committee to ensure a favorable outcome.

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NIH NATIONAL CANCER INSTITUTE

[redacted]etastatic Cancer

What Is Metastatic Cancer?

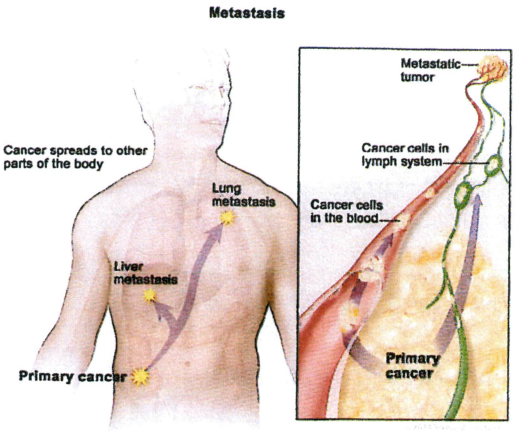
The main reason that cancer is so serious is its ability to spread in the body. Cancer cells can spread locally by moving into nearby normal tissue. Cancer can also spread regionally, to nearby lymph nodes, tissues, or organs. And it can spread to distant parts of the body. When this happens, it is called metastatic cancer. For many types of cancer, it is also called stage IV (four) cancer. The process by which cancer cells spread to other parts of the body is called metastasis.

When observed under a microscope and tested in other ways, metastatic cancer cells have features like that of the primary cancer and not like the cells in the place where the cancer is found. This is how doctors can tell that it is cancer that has spread from another part of the body.

Metastatic cancer has the same name as the primary cancer. For example, breast cancer that spreads to the lung is called metastatic breast cancer, not lung cancer. It is treated as stage IV breast cancer, not as lung cancer.

Sometimes when people are diagnosed with metastatic cancer, doctors cannot tell where it started. This type of cancer is called cancer of unknown primary origin, or CUP. See the Carcinoma of Unknown Primary page for more information.

When a new primary cancer occurs in a person with a history of cancer, it is known as a second primary cancer. Second primary cancers are rare. Most of the time, when someone who has had cancer has cancer again, it means the first primary [redacted]cer has returned.



In metastasis, cancer cells break away from where they first formed (primary cancer), travel through the blood or lymph system, and form new tumors (metastatic tumors) in other parts of the body. The metastatic tumor is the same type of cancer as the primary tumor.

How Cancer Spreads

Metastasis: How Cancer Spreads

During metastasis, cancer cells spread from the place in the body where they first formed to other parts of the body.

[redacted]ncer cells spread through the body in a series of steps. These steps include:

1. Growing into, or invading, nearby normal tissue
2. Moving through the walls of nearby lymph nodes or blood vessels

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3. Traveling through the lymphatic system and bloodstream to other parts of the body
4. Stopping in small blood vessels at a distant location, invading the blood vessel walls, and moving into the surrounding tissue
5. Growing in this tissue until a tiny tumor forms
6. Causing new blood vessels to grow, which creates a blood supply that allows the tumor to continue growing

Most of the time, spreading cancer cells die at some point in this process. But, as long as conditions are favorable for the cancer cells at every step, some of them are able to form new tumors in other parts of the body. Metastatic cancer cells can also remain inactive at a distant site for many years before they begin to grow again, if at all.

Where Cancer Spreads

Cancer can spread to most any part of the body, although different types of cancer are more likely to spread to certain areas than others. The most common sites where cancer spreads are the bone, liver, and lung. The following list shows the most common sites of metastasis, not including the lymph nodes, for some common cancers:

Common Sites of Metastasis

Cancer Type	Main Sites of Metastasis
Bladder	Bone, liver, lung
Breast	Bone, brain, liver, lung
Colon	Liver, lung, peritoneum
Kidney	Adrenal gland, bone, brain, liver, lung
Lung	Adrenal gland, bone, brain, liver, other lung
Melanoma	Bone, brain, liver, lung, skin, muscle
Ovary	Liver, lung, peritoneum
Pancreas	Liver, lung, peritoneum
Prostate	Adrenal gland, bone, liver, lung
Rectal	Liver, lung, peritoneum
Stomach	Liver, lung, peritoneum
Thyroid	Bone, liver, lung
Uterus	Bone, liver, lung, peritoneum, vagina

Symptoms of Metastatic Cancer

Metastatic cancer does not always cause symptoms. When symptoms do occur, their nature and frequency will depend on the size and location of the metastatic tumors. Some common signs of metastatic cancer include:

- Pain and fractures, when cancer has spread to the bone
- Headache, seizures, or dizziness, when cancer has spread to the brain
- Shortness of breath, when cancer has spread to the lung
- Jaundice or swelling in the belly, when cancer has spread to the liver

Treatment for Metastatic Cancer

Once cancer spreads, it can be hard to control. Although some types of metastatic cancer can be cured with current treatments, most cannot. Even so, there are treatments for all patients with metastatic cancer. The goal of these treatments is to stop or slow the growth of the cancer or to relieve symptoms caused by it. In some cases, treatments for metastatic cancer may help prolong life.

The treatment that you may have depends on your type of primary cancer, where it has spread, treatments you've had in the past, and your general health. To learn about treatment options, including clinical trials, find your type of cancer among the PDQ® Cancer Information Summaries for Adult Treatment and Pediatric Treatment.

When Metastatic Cancer Can No Longer Be Controlled

If you have been told you have metastatic cancer that can no longer be controlled, you and your loved ones may want to discuss end-of-life care. Even if you choose to continue receiving treatment to try to shrink the cancer or control its growth, you can always receive palliative care to control the symptoms of cancer and the side effects of treatment. Information on coping with and planning for end-of-life care is available in the Advanced Cancer section.

Ongoing Research

Researchers are studying new ways to kill or stop the growth of primary and metastatic cancer cells. This research includes finding ways to help your immune system fight cancer. Researchers are also trying to find ways to disrupt the steps in the process that allow cancer cells to spread. Visit the Metastatic Cancer Research page to stay informed of ongoing research funded by NCI.

[redacted]lated Resources

Advanced Cancer

Coping with Advanced Cancer

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Cancer Staging

Staging is the process of finding out how much cancer is in a person's body and where it's located. It's how the doctor determines the *stage* of a person's cancer.

For most types of cancer, doctors use staging information to help plan treatment and to predict a person's outlook (prognosis). Although each person's situation is different, cancers with the same stage tend to have similar outlooks and are often treated the same way. The cancer stage is also a way for doctors to describe the extent of the cancer when they talk with each other about a person's cancer.

Why is staging needed?

Doctors need to know the amount of cancer and where it is in the body to be able to choose the best treatment options. For example, the treatment for an early-stage cancer may be surgery (/treatment/treatments-and-side-effects/treatment-types/surgery.html) or radiation (/treatment/treatments-and-side-effects/treatment-types/radiation/radiation-therapy-guide.html), while a more advanced-stage cancer may need to be treated with chemotherapy (/treatment/treatments-and-side-effects/treatment-types/chemotherapy.html). Doctors also use a cancer's stage to help predict the course it will likely take.

In a larger sense, doctors use staging information when they're studying cancer treatments. It allows researchers to make sure study groups are actually similar when they test cancer treatments against one another, measure outcomes, and more.

Not all cancers are staged. For example, leukemias (/cancer/leukemia.html) are cancers of the blood cells and therefore spread throughout the body. Most types of leukemias aren't staged the way cancers that form tumors are.

What is the doctor looking for when staging cancer?

When trying to determine the extent of the cancer in the body, doctors first look at the primary (main) tumor for its size, location, and whether it has grown into nearby areas. Doctors also check for other nearby tumors.

Doctors might also look at nearby lymph nodes (/cancer/cancer-basics/lymph-nodes-and-cancer.html) to find out if cancer has spread into them. Lymph nodes are small, bean-shaped collections of immune cells. Many types of cancer often spread to nearby lymph nodes before they reach other parts of the body.

Doctors might also look at other parts of the body to see if the cancer has spread there. When cancer spreads to parts of the body far from the primary tumor, it is known as *metastasis*.

In some kinds of cancer, other factors are also used to help determine the stage, such as the cancer cell type and grade (how abnormal the cancer cells look under a microscope), or the results of certain blood tests.

How are cancers staged?

Doctors use different types of exams and tests to figure out a cancer's stage. Depending on where the cancer is located, the physical exam may give some clue as to how much cancer there is. Imaging tests (/treatment/understanding-your-diagnosis/tests.html) like x-rays, CT scans, MRIs, ultrasound, and PET scans may also give information about how much and where cancer is in the body.

A biopsy often is needed to confirm a cancer diagnosis. Biopsies might also be needed to find out if an abnormal spot seen on an imaging test is really cancer spread. During a biopsy, the doctor removes a tumor or pieces of a tumor to be looked at under a microscope. Some biopsies are done during surgery. But with many types of biopsies, the doctor removes small pieces of tumor through a thin needle or through a flexible lighted tube called an *endoscope*. The different kinds of biopsies used to check for cancer are described in Cancer Surgery (/treatment/treatments-and-side-effects/treatment-types/surgery.html).

Types of staging

Staging is done when a person is first diagnosed, before any treatment is given. The main types of staging are:

Clinical staging

This is an estimate of the extent of the cancer based on results of physical exams, imaging tests (x-rays, CT scans, etc.), and tumor biopsies. For some cancers, the results of other tests, such as blood tests, are also used in staging.

The clinical stage is a key part of deciding the best treatment to use. It's also the baseline used for comparison when looking at how the cancer responds to treatment.

Pathologic staging

If surgery is being done, doctors can also determine the pathologic stage (also called the surgical stage) of the cancer. The pathologic stage relies on the results of the exams and tests mentioned before, as well as what is learned about the cancer during surgery. Often this is surgery to remove the cancer and nearby lymph nodes, but sometimes surgery may be done to just look at how much cancer is in the body and take out tissue samples.

Sometimes, the pathologic stage is different from the clinical stage (for instance, if the surgery shows the cancer has spread more than was thought). The pathologic stage gives the health care team more precise information that can be used to predict treatment response and outcomes (prognosis).

Staging systems

There are different types of staging systems, but the most common and useful staging system for most types of cancers is the TNM system.

The TNM system

The American Joint Committee on Cancer (AJCC) and the International Union for Cancer Control (UICC) maintain the *TNM classification system* as a tool for doctors to stage different types of cancer based on certain standards. It's updated every 6 to 8 years to include advances in our understanding of cancer.

In the TNM system, each cancer is assigned a letter or number to describe the tumor, node, and metastases.

- **T** stands for the original (primary) **tumor**.
- **N** stands for **nodes**. It tells whether the cancer has spread to the nearby lymph nodes
- **M** stands for **metastasis**. It tells whether the cancer has spread to distant parts of the body

  The **T** category gives information about aspects of the original (primary) tumor, such as its size, how deeply it has grown into the organ it started in, and whether it has grown into nearby tissues.

- **TX** means the tumor can't be measured.
- **T0** means there is no evidence of a primary tumor (it cannot be found).
- **Tis** means that the cancer cells are only growing in the most superficial layer of tissue, without growing into deeper tissues. This may also be called *in situ* cancer or *pre-cancer.*
- Numbers after the T (such as **T1, T2, T3, and T4**) might describe the tumor size and/or amount of spread into nearby structures. The higher the T number, the larger the tumor and/or the more it has grown into nearby tissues.

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The **N** category describes whether the cancer has spread into nearby lymph nodes.

- **NX** means the nearby lymph nodes cannot be evaluated.
- **N0** means nearby lymph nodes do not contain cancer.
- Numbers after the N (such as **N1, N2, and N3**) might describe the size, location, and/or the number of nearby lymph nodes affected by cancer. The higher the N number, the greater the cancer spread to nearby lymph nodes.

The **M** category tells whether the cancer has spread (metastasized) to distant parts of body).

- **M0** means that no distant cancer spread was found.
- **M1** means that the cancer has spread to distant organs or tissues (distant metastases were found).

Most cancer types have their own version of this classification system, so letters and numbers don't always mean the same thing for every kind of cancer. For example, in some types of cancer, the T categories describe the size of the main tumor, while in others they describe how deeply the tumor has grown in to the organ it started in, or whether the tumor has grown into nearby structures (regardless of its size).

Some cancer types also have special groupings that are different from other cancer types. For instance, for some cancers, classifications may have subcategories, such as T3a and T3b, while others may not have an N3 category.

Stage grouping

Once the values for T, N, and M have been determined, they are combined to assign an overall stage. For most cancers, the stage is a Roman numeral from I to IV, where stage IV (4) is the highest and means the cancer is more advanced than in the lower stages. Sometimes stages are subdivided as well, using letters such as A and B.

Stage 0 is *carcinoma in situ* for most cancers. This means the cancer is at a very early stage, is only in the area where it first developed, and has not spread. Not all cancers have a stage 0.

Stage I cancers are the next least advanced and often have a good prognosis (outlook). The outlook is usually not as good for higher stages.

Other factors that can affect the stage

For some cancers, the values for T, N, and M aren't the only things that determine the stage. Some other factors that may be taken into account include:

Grade: For most cancers, the grade is a measure of how abnormal the cancer cells look under the microscope. This is called *differentiation*. Grade can be important because cancers with more abnormal-looking cells tend to grow and spread faster.

The grade is usually assigned a number. In low-grade (well-differentiated) cancers, the cancer cells look a lot like cells from normal tissue. In general, these cancers tend to grow slowly. In high-grade (poorly differentiated) cancers, the cancer cells look very different from normal cells. High-grade cancers often tend to grow quickly and have a worse outlook, so they may need different treatments than low-grade cancers. Even when the grade doesn't affect a cancer's stage, it may still affect the outlook and/or treatment.

Cell type: Some cancers can be made up of different types of cells. Because the type of cancer cell can affect treatment and outlook, it can be a factor in staging. For example, cancers of the esophagus (/cancer/esophagus-cancer.html) are mainly either squamous cell cancers or adenocarcinomas. Squamous cell esophageal cancers are staged differently from esophageal adenocarcinomas.

Tumor location: For some cancers, the tumor's location affects outlook and is taken into account in staging. The stage of cancer of the esophagus, for example, depends on whether the cancer is in the upper, middle, or lower third of the esophagus.

Tumor marker levels: For some cancers, the blood levels of certain substances (called *tumor markers*) can affect the stage of the cancer. For example, in prostate cancer (/cancer/prostate-cancer.html), the level of prostate-specific antigen (PSA) in the blood is taken into account in assigning a stage.

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Other staging systems

Not all cancers are staged using the TNM system. Some cancers grow and spread in a different way. For example, many cancers in or around the brain are not staged using the TNM system, since these cancers tend to spread to other parts of the brain and not to lymph nodes or other parts of the body. Staging systems other than the TNM system are often used for Hodgkin disease and other lymphomas, too, as well as for some childhood cancers.

The International Federation of Gynecologists and Obstetricians (FIGO) has a staging system for cancers of the female reproductive organs. The TNM stages closely match the FIGO stages, which makes it fairly easy to convert stages between these 2 systems.

Other, older staging systems (such as the Dukes system for colorectal cancer) may still be used by some doctors. If your doctor uses another staging system, you may want to find out if the stage can be translated into the TNM system. This will often help if you want to read more about your cancer and its treatment, since the TNM system is more widely used.

A cancer's stage does not change

An important point some people have trouble understanding is that the stage of a cancer is determined only when (or soon after) the cancer is diagnosed. This stage does not change over time, even if the cancer shrinks, grows, spreads, or comes back after treatment. The cancer is still referred to by the stage it was given when it was first found and diagnosed, although information about the current extent of the cancer is added (and of course, the treatment is adjusted as needed).

For example, let's say a woman is first diagnosed with stage II breast cancer. The cancer goes away with treatment, but then it comes back and has spread to the bones. The cancer is still called a stage II breast cancer, now with recurrent disease in the bones.

If the breast cancer did not go away with the original treatment and spread to the bones it would be called a stage II breast cancer with bone metastasis. In either case, the original stage does not change and it's *not* called a stage IV breast cancer. Stage IV breast cancer refers to a cancer that has already spread to a distant part of the body when it's first diagnosed.

This is important to understand because survival statistics and information on treatment by stage for specific cancer types refer to the stage when the cancer was first diagnosed. The survival statistics related to stage II breast cancer that has recurred in the bones may not be the same as the survival statistics for stage IV breast cancer.

At some point you may hear the term "restaging." Restaging is a term sometimes used to describe doing tests to find the extent of the cancer after treatment. This is rarely done, but it may be used to measure the cancer's response to treatment or to assess cancer that has come back (recurred) and will need more treatment. Often the same tests that were done when the cancer was first diagnosed (such as physical exams, imaging tests, biopsies, and maybe surgery) will be done again. After these tests a new stage may be assigned. It's written with a lower-case "r" before the new stage to note that it's different from the stage at diagnosis. The originally diagnosed stage always stays the same. While testing to see the extent of cancer is common during and after treatment, actually assigning a new stage is rarely done, except in clinical trials.

Finding out more about your type of cancer

For details on staging or grading for a certain type of cancer, see our information on specific cancer types. You can find this information on our website, or call our toll-free number.

Written by Additional resources References

The American Cancer Society medical and editorial content team (/cancer/acs-medical-content-and-news-staff.html)

Our team is made up of doctors and oncology certified nurses with deep knowledge of cancer care as well as journalists, editors, and translators with extensive experience in medical writing.

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Brain and Spinal Cord

At-A-Glance

SUMMARY OF CHANGES

- Central nervous system tumors continue to have no TNM designation

ANATOMIC STAGE/PROGNOSTIC GROUP

No stage grouping applies

ICD-O-3 TOPOGRAPHY CODES

C70.0	Cerebral meninges
C70.1	Spinal meninges
C70.9	Meninges, NOS
C71.0	Cerebrum
C71.1	Frontal lobe
C71.2	Temporal lobe
C71.3	Parietal lobe
C71.4	Occipital lobe
C71.5	Ventricle NOS
C71.6	Cerebellum NOS
C71.7	Brain stem
C71.8	Overlapping lesion of brain
C71.9	Brain NOS
C72.0	Spinal cord
C72.1	Cauda equina
C72.2	Olfactory nerve
C72.3	Optic nerve
C72.4	Acoustic/vestibular nerve
C72.5	Cranial nerve, NOS
C72.8	Overlapping lesion of brain and central nervous system
C72.9	Nervous system, NOS
C75.1	Pituitary gland
C75.2	Craniopharyngeal duct
C75.3	Pineal gland

ICD-O-3 HISTOLOGY CODE RANGES

8000, 8680–9136, 9141–9582

INTRODUCTION

Attempts at developing a TNM-based classification and staging system for tumors of the central nervous system (CNS) have not been successful. Previous editions of this manual had proposed a system that was used with poor compliance and proved not to be particularly useful as a predictor of outcome in clinical trials for the management of patients with primary CNS tumors. The reasons for this are several. (1) Tumor size is significantly less relevant than tumor histology and location of the tumor, so the T classification is less pertinent than the biologic nature of the tumor itself. (2) Because the brain and spinal cord have no lymphatics, the N classification does not apply, as there are no lymph nodes that can be identified in either classification or staging. (3) An M classification is not pertinent to the majority of neoplasms that affect the central nervous system, because of the inherent biology favoring local recurrence, and the fact that most patients with tumors of the central nervous system do not live long enough to develop metastatic disease (except for some pediatric tumors that tend to "seed" through the cerebrospinal fluid spaces).

Many important studies have been done regarding the most common tumors affecting the brain and spinal cord, and a variety of prognostic factors have been identified. Unfortunately, these factors do not easily fall into the usual categories that have traditionally been part of the American Joint Committee on Cancer (AJCC) TNM system.

For those reasons, it continues to be the recommendation of the CNS Tumor Task Force that a formal classification and staging system not be attempted. This chapter, however, attempts to highlight what is known about prognostic factors in tumors of the central nervous system (Table 56.1).

PROGNOSTIC FEATURES

Tumor Histology. The histology of tumors that affect the brain and spinal cord is by far the most important variable affecting prognosis, and in many cases it determines the treatment modalities that are employed. The latest World Health Organization (WHO) classification system has combined tumor nomenclature with an associated grading system,

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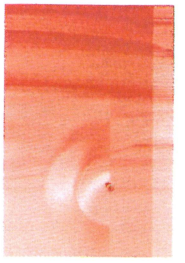

PART XII
Lymphoid Neoplasms

INTRODUCTION

Lymphoid malignancies are a diverse group of disorders. These malignancies share derivation from B-cells, T-cells, and NK-cells, but they have a wide range of presentations, clinical course, and response to therapy. The incidence of lymphoid malignancies is significant and increasing. Non-Hodgkin lymphomas occur in more than 63,000 new individuals each year and have been increasing in incidence over the past several decades. Hodgkin lymphoma occurs in approximately 8,000 new individuals each year in the USA and seems stable in incidence. Approximately 20,000 new cases of multiple myeloma and more than 20,000 new cases of lymphoid leukemias occur annually in the USA (Figure 1).

PATHOLOGY

Lymphoid neoplasms are malignancies of B-cells, T-cells, and NK (natural killer) cells. They include Hodgkin lymphoma (Hodgkin disease), non-Hodgkin lymphoma, multiple myeloma, and lymphoid leukemias. Traditionally, classifications have distinguished between "lymphomas" – i.e., neoplasms that typically present with an obvious tumor or mass of lymph nodes or extranodal sites – and "leukemias" – i.e., neoplasms that typically involve the bone marrow and peripheral blood, without tumor masses. However, we now know that many B- and T/NK-cell neoplasms may have both tissue masses *and* circulating cells. Thus, it is artificial to call them different diseases, when in fact they are just different presentations of the same disease. For this reason, we now refer to these diseases as lymphoid neoplasms rather than as lymphomas or leukemias, reserving the latter terms for the specific clinical presentation. In the current classification of lymphoid neoplasms, diseases that typically produce tumor masses are called lymphomas, those that typically have only circulating cells are called leukemias, and those that often have both solid and circulating phases are designated lymphoma/leukemia. Finally, plasma cell neoplasms, including multiple myeloma and plasmacytoma, have typically not been considered "lymphomas," but plasma cells are part of the B-cell lineage, and, thus, these tumors are B-cell neoplasms, which are now included in the classification of lymphoid neoplasms.

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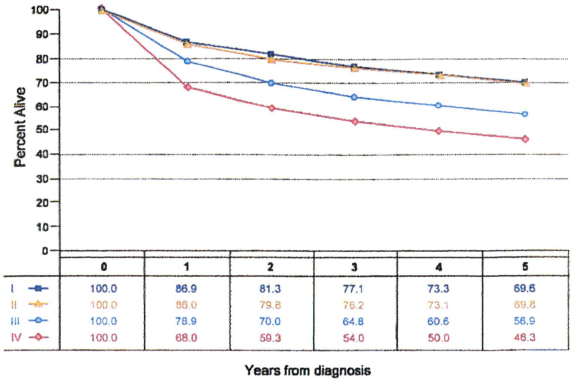
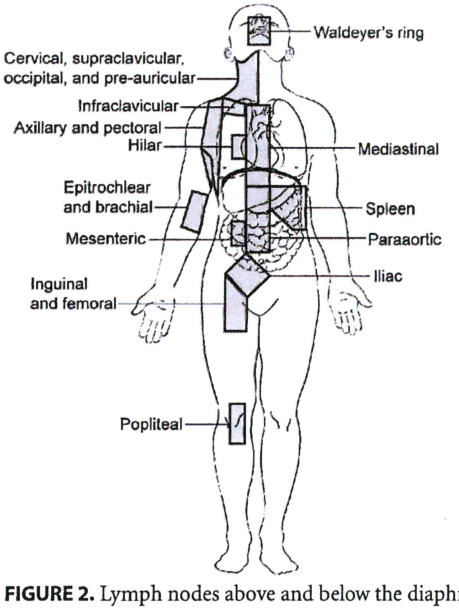


	0	1	2	3	4	5
I	100.0	86.9	81.3	77.1	73.3	69.6
II	100.0	86.0	79.8	76.2	73.1	69.8
III	100.0	78.9	70.0	64.8	60.6	56.9
IV	100.0	68.0	59.3	54.0	50.0	46.3

FIGURE 1. Observed survival rates for 57,596 patients with lymphomas classified by the current AJCC staging classification. Cases represent all lymphoma types and are not predictive of outcome for any particular lymphoma type. Data taken from the National Cancer Data Base (Commission of Cancer of the American College of Surgeons and the American Cancer Society) for the years 2001–2002. Stage I includes 17,674 patients; Stage II, 12,523; Stage III, 9,257; and Stage IV, 18,142.

Lymphoid neoplasms are malignancies of lymphoid cells. Lymphoid cells include lymphoblasts, lymphocytes, follicle center cells (centrocytes and centroblasts), immunoblasts, and plasma cells. These cells are responsible for immune responses to infections. Immune responses involve recognition by lymphocytes of foreign molecules, followed by proliferation and differentiation to generate either specific cytotoxic cells (T or NK – natural killer – cells) or antibodies (B-cells and plasma cells). Lymphoid cells are normally found in greatest numbers in lymph nodes and in other lymphoid tissues such as Waldeyer's ring (which includes the palatine and lingual tonsils and adenoids), the thymus, Peyer's patches of the small intestine, the spleen, and the bone marrow (Figure 2). Lymphocytes also circulate in the peripheral blood and are found in small



Lymph nodes above the diaphragm

1. Waldeyer's ring
2. Cervical, supraclavicular, occipital, and pre-auricular
3. Infraclavicular
4. Axillary and pectoral
5. Mediastinal
6. Hilar
7. Epitrochlear and brachial

Lymph nodes below the diaphragm

8. Spleen
9. Mesenteric
10. Paraaortic
11. Iliac
12. Inguinal and femoral
13. Popliteal

FIGURE 2. Lymph nodes above and below the diaphragm.

numbers in almost every organ of the body, where they either wait to encounter antigens or carry out specific immune reactions. Lymphoid neoplasms may occur in any site to which lymphocytes normally travel. Because lymphocytes normally circulate through the blood as well as the lymphatics – in contrast to epithelial cells, for example – it is often impossible to determine the "primary site" of a lymphoid neoplasm or to use a staging scheme that was developed for epithelial cancers, such as the TNM scheme.

RULES FOR CLASSIFICATION

Many different classification schemes have been proposed for lymphoid neoplasms, which has led to confusion on the part of both pathologists and oncologists. Between 1982 and 1994, in the USA, a classification called the Working Formulation was used. This scheme had the advantage of being simple, with only ten categories, and it did not require any special studies such as immunophenotyping or genetic studies. In addition, it provided simple clinical groupings for determining the approach to treatment (low, intermediate, and high clinical grades). Since its introduction, advances in understanding of the immune system and lymphoid neoplasms led to the recognition of many new categories of lymphoid neoplasms. The fact that several subtypes were in an incorrect category based on clinical behavior, and the development of better methods for diagnosis and classification – as well as for treatment – have caused the Working Formulation to become obsolete. In 1994 the International Lymphoma Study Group (ILSG) introduced a new classification, called the Revised European American Classification of Lymphoid Neoplasms (REAL), which incorporated not only morphology, but new information such as immunophenotype and genetic features, as well as clinical features, to define over 25 different categories of lymphoid neoplasms, including Hodgkin lymphoma.[1] More recently, the World Health Organization (WHO)[2] updated its Classification of Diseases of the Hematopoietic and Lymphoid Systems and adopted the REAL classification for lymphoid neoplasms with some modifications (the WHO classification also includes myeloid and histiocytic neoplasms). The WHO classification is now the standard for clinical trials in lymphoma (Table 1).

The WHO classification is a list of distinct disease entities, which are defined by a combination of morphology, immunophenotypic, and genetic features and which have distinct clinical features.[3–6] The relative importance of each of these features varies among diseases, and there is no one gold standard. Morphology remains the first and most basic approach and is sufficient for both diagnosis and classification in many typical cases of lymphoma. Immunophenotyping and – particularly – molecular genetic studies are not needed in all cases, but they are very important in some diseases, are useful in difficult cases, and improve interobserver reproducibility. As mentioned previously, the WHO classification includes all lymphoid neoplasms: Hodgkin lymphoma, non-Hodgkin lymphomas, lymphoid leukemias, and plasma cell neoplasms. Both lymphomas and lymphoid leukemias are included, because both solid and circulating phases are present in many lymphoid neoplasms, and drawing a distinction between them is arbitrary. Thus, B-cell chronic lymphocytic leukemia and B-cell small lymphocytic lymphoma are simply different manifestations of the same neoplasm, as are lymphoblastic lymphomas and acute lymphoblastic leukemias. In addition, Hodgkin lymphoma and plasma cell myeloma are now recognized as lymphoid neoplasms of B-lineage and, therefore, belong in a compilation of lymphoid neoplasms.

The ability to study patterns of gene expression is providing new insights into these disorders. It is likely to change classification and might eventually supersede staging in the ability to predict outcome and the response to specific therapies.

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TABLE 1. WHO Classification of lymphoid neoplasms, 4th edition

B-cell neoplasms

Precursor B-cell neoplasm

- B-lymphoblastic leukemia/lymphoma (B-cell acute lymphoblastic leukemia)

Mature (peripheral) B-cell neoplasms

- Chronic lymphocytic leukemia/small lymphocytic lymphoma
- B-cell prolymphocytic leukemia
- Lymphoplasmacytic lymphoma
- Splenic marginal zone B-cell lymphoma (with or without villous lymphocytes)
- Hairy cell leukemia
- Splenic lymphoma/leukemia, unclassifiable
- Plasma cell myeloma/plasmacytoma
- Heavy chain diseases
- Extranodal marginal zone B-cell lymphoma of MALT type
- Nodal marginal zone B-cell lymphoma (with or without monocytoid B cells)
- Follicular lymphoma
- Primary cutaneous follicle center lymphoma
- Mantle cell lymphoma
- Diffuse large B-cell lymphoma (DLBCL)
  - Diffuse large B-cell lymphoma, not otherwise specified
  - T-cell/histiocyte rich large B-cell lymphoma
  - DLBCL associated with chronic inflammation
  - EBV positive DLBCL of the elderly
  - Lymphomatoid granulomatosis
  - Primary mediastinal (thymic) large B-cell lymphoma
  - Intravascular large B-cell lymphoma
  - Primary cutaneous DLBCL, leg type
  - ALK positive DLBCL
  - Plasmablastic lymphoma
  - Primary effusion lymphoma
  - Large B-cell lymphoma arising in HHV8-associated multicentric Castleman disease
- Burkitt lymphoma/Burkitt cell leukemia
- B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and Burkitt lymphoma
- B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and classical Hodgkin lymphoma

T-cell and NK-cell neoplasms

Precursor T-cell neoplasm

- T-lymphoblastic lymphoma/leukemia (T-cell acute lymphoblastic leukemia)

Mature (peripheral) T/NK-cell neoplasms

- T-cell prolymphocytic leukemia
- T-cell large granular lymphocytic leukemia
- Aggressive NK-cell leukemia
- Systemic EBV positive T-cell lymphoproliferative disease of childhood (associated with chronic active EBV infection)
- Hydra vacciniforme-like lymphoma
- Adult T-cell lymphoma/leukemia (HTLV 1 +)
- Extranodal NK/T-cell lymphoma, nasal type
- Enteropathy-type T-cell lymphoma
- Hepatosplenic T-cell lymphoma
- Subcutaneous panniculitis-like T-cell lymphoma
- *Mycosis fungoides*/Sézary syndrome
- Primary cutaneous anaplastic large cell lymphoma
- Primary cutaneous aggressive epidermotropic CD8 positive cytotoxic T-cell lymphoma
- Primary cutaneous gamma-delta T-cell lymphoma
- Primary cutaneous small/medium CD4 positive T-cell lymphoma
- Peripheral T-cell lymphoma, not otherwise characterized
- Angioimmunoblastic T-cell lymphoma
- Anaplastic large cell lymphoma, ALK-positive
- Anaplastic large cell lymphoma, ALK-negative

From Swerdlow SH, Campo E, Harris NL, et al. WHO classification of Tumours of Haematopoietic and Lymphoid Tissues, 4th edition. Lyon: IARC, 2008, with permission.

Retreatment Classification. The retreatment classification (rTNM) is assigned when further treatment is planned for a cancer that recurs after a disease-free interval. The original stage assigned at the time of initial diagnosis and treatment does not change when the cancer recurs or progresses. The use of this staging for retreatment or recurrence is denoted using the r prefix (rTNM). All information available at the time of retreatment should be used in determining the rTNM stage. Biopsy confirmation of recurrent cancer is important if clinically feasible. However, this may not be appropriate for each component, so clinical evidence for the T, N, or M component by clinical, endoscopic, radiologic, or related methods may be used.

Autopsy Classification. TNM classification of a cancer may be performed by postmortem examination for a patient where cancer was not evident prior to death. This autopsy classification (aTNM) is denoted using the a prefix (aTNM) and should include all clinical and pathologic information obtained at the time of death and autopsy.

Stage Groupings. Cases of cancers with similar prognosis are grouped based on the assigned cT, cN, and cM and/or pT, pN and c/pM categories, and disease-specific groups of T, N, and M are defined. In select disease sites nonanatomic factors are required to supplement T, N, and M to define these groups. Termed *anatomic stage/prognostic groups*, and commonly referred to as stage groups, these form a reproducible and easily communicated summary of staging information (Table 1.8).

Groups are assigned increasing values that correlate with worsening prognosis. Stage I is usually assigned to tumors confined to the primary site with a better prognosis, stages II and III for tumors with increasing local and regional nodal involvement, and stage IV to cases with distant metastatic disease. In addition, a group termed stage 0 is assigned to cases of carcinoma in situ (CIS). Groupings may be expanded into subsets (e.g., stage II can become stage IIA, stage IIB) for more refined prognostic information.

TABLE 1.8. Anatomic stage/prognostic grouping rules

Define separate clinical and pathologic group for each case
May combine clinical and pathologic information as a "working stage" in either the pathologic or clinical classification when only partial information is available – this may be necessary for clinical care
Minimize use of TX and NX
Use of "X" for any component makes case unstageable
Case will not be usable in comparison analyses (exception: any combination of T and N including TX or NX with M1 is stage IV)
For groupings that require a nonanatomic factor, if factor is missing, stage using lowest category for that factor
Case with pT and pN and cM0 or cM1 staged as pathologic stage group
Case with cT and cN and pM1 staged as clinical and pathologic stage group
Carcinoma in situ, stage pTis cN0 cM0 as both clinical and pathologic stage 0

Generally, a pure clinical group and pure pathologic group are defined for each case, using the classifications discussed earlier. In the clinical setting, it is appropriate to combine clinical and pathologic data when only partial information is available in either the pathologic or clinical classification, and this may be referred to as the *working* stage.

Carcinoma in situ (CIS) is an exception to the stage grouping guidelines. By definition, CIS has not involved any structures in the primary organ that would allow tumor cells to spread to regional nodes or distant sites. Therefore, pTis cN0 cM0 should be reported as both clinical and pathologic stage 0.

The clinical, pathologic, and if applicable, posttherapy and retreatment, groups are recorded in the medical record. Once assigned according to the appropriate rules and timing, the stage group recorded in the medical record does not change. The rule applied to T, N, or M that in cases with uncertainty about the classification the cases are assigned the lower (less advanced) category also applies to grouping. One specific circumstance requires special comment. When there has been a complete pathologic response and the ypTNM is ypT0 ypN0 cM0, this is not a "stage 0" case as this would denote in situ disease, and as in every case, the stage for comparison of cases is the pretreatment clinical stage.

Multiple Tumors. When there are multiple simultaneous tumors of the same histology in one organ, the tumor with the highest T category is the one selected for classification and staging, and the multiplicity or the number of tumors is indicated in parentheses: for example, T2(m) or T2(5). For simultaneous bilateral cancers in paired organs, the tumors are classified separately as independent tumors in different organs. For tumors of the thyroid, liver, and ovary, multiplicity is a criterion of the T classification. Most registry software systems have a mechanism to record the m descriptor.

Metachronous Primaries. Second or subsequent primary cancers occurring in the same organ or in different organs are staged as a new cancer using the TNM system described in this manual. Second cancers are not staged using the y prefix unless the treatment of the second cancer warrants this use.

Unknown Primary. In cases where there is no evidence of a primary tumor or the site of the primary tumor is unknown, staging may be based on the clinical suspicion of the primary tumor with the T category classified as T0. For example, a case with metastatic adenocarcinoma in axillary lymph nodes that is pathologically consistent with breast cancer, but in which there is no apparent primary breast tumor may be classified as breast cancer – T0 N1 M0 (Table 1.9).

HISTOPATHOLOGIC TYPE, GRADE, AND OTHER DESCRIPTORS

Histopathologic Type. The histopathologic type is a *qualitative* assessment whereby a tumor is categorized according to the normal tissue type or cell type it most closely resembles

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Tuesday, March 19, 2019

Senate Human Services Committee
HB 1469

SENATOR LEE AND COMMITTEE MEMBERS:

My name is Jack McDonald. I'm appearing on behalf of America's Health Insurance Plans or, as it is commonly known, AHIP.

AHIP is the national trade association representing the health insurance industry. AHIP members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual and small group insurance markets, and public programs such as Medicare and Medicaid.

AHIP is opposed to engrossed HB 1469 unless it is amended as suggested at the end of my testimony.

Step therapy protocols are utilized by many insurers to ensure that patients begin drug therapy for a medical condition with the most cost-effective and safest drug before progressing to other costlier or riskier therapy. Step therapy protocols are often developed using U.S. Food and Drug Administration (FDA) guidelines, clinical evidence and research. Bills such as HB 1469 that impose other criteria on step therapy protocols would hinder the use of this important tool and limit its effectiveness.

Step therapy protocols encourage physicians and patients to undertake a more evidence-based and measured approach to treatment that is tailored to the individual by gauging a patient's response to less harmful medications before graduating to the more potent and high-risk drugs. Step therapy protocols already work to ensure patient safety using scientifically appropriate guidelines.

Legislation such as HB 1469 that limits step therapy protocols as suggested starting on line 16 is potentially dangerous. An exception to an established step therapy protocol should only be considered at the request of a health care provider, not the patient.

Important clinical decisions should not be made at the behest of patients who may not fully understand the scientific ramifications behind a

physician's decision or are partially due to direct-to-consumer drug advertising.

An exception to an established step therapy protocol should not be granted only because a patient is stable on a prescription drug. This would potentially allow patients to receive exemptions as a result of using sampled drugs, and would eliminate one of the key functions of a step therapy protocol: the use of cost-effective alternative treatments in the place of more expensive or higher risk medications.

This bill, dealing specifically with cancer where the drugs are almost always brand and massively expensive, could have a very large fiscal note for any plan forced to adopt them. The fiscal note for this bill shows no fiscal impact to PERS but it would have a huge fiscal impact on private plans.

The use of step therapy protocols should be encouraged rather than prohibited. They are important cost containment measures. Expenditures on prescription drugs are rising every year and contribute significantly to rising health care costs. Step therapy protocols ensure that insurers can continue to provide affordable coverage of prescription drugs.

Therefore, we respectfully ask for a **DO NOT PASS** on HB 1469 unless the amendments below are adopted. Thank you for your time and consideration. I'd be happy to answer any questions.

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL 1469

Page 1, line 8, after "means" insert "stage four advanced"

Page 1, line 20, after "of" insert "stage four advanced"

Page 1, line 23, delete the remainder of the sentence after "indications" and insert in lieu thereof "and is preferred by the national comprehensive cancer network guidelines over the proposed plan–specific step one option(s)."

Renumber accordingly

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TESTIMONY OF SCOTT MILLER

Engrossed House Bill 1469 – Pharmacy Benefits Manager Step Therapy Protocols

Good Morning, my name is Scott Miller. I am the Executive Director of the North Dakota Public Employee Retirement System (NDPERS). I appear before you today to provide neutral testimony regarding House Bill 1469. The Employee Benefits Programs Committee gave this bill a favorable recommendation.

House Bill 1469 prohibits a pharmacy benefit manager (PBM) or a health plan from imposing a step therapy protocol for patients with metastatic cancer. Sanford Health Plan has advised us that there would currently be no actuarial impact to the NDPERS health insurance plan as their PBM does not require step-therapy for oncology drugs today. Express Scripts, Inc. (ESI), the PBM for the NDPERS Medicare Part D prescription drug plan, does use step therapy as a way to control costs. ESI has indicated that this bill is not anticipated to have any impact on the NDPERS Part D plan. However, our actuary, Deloitte, has indicated that if a new, high-cost drug became available, the health plan could be subject to added financial risk, especially if the situation would have warranted a step therapy protocol.

Deloitte has also advised us of proposed federal legislation specific to Medicare Part D prescription drug plans, that would allow step therapy protocols to be implemented on protected class drugs. Deloitte has indicated that House Bill 1469 appears to contradict that proposed federal legislation, were it to be passed. Therefore, the committee may want to clarify whether this bill should apply to the NDPERS Medicare Part D prescription drug plan. I have attached an amendment that would remove the applicability of this bill to Medicare Part D plans.

Ms. Chairman, that concludes my testimony.

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PROPOSED AMENDMENT TO ENGROSSED HOUSE BILL NO. 1469

Page 1, after line 24, insert, " 4. This section does not apply to Medicare Part D prescription drug plans."

Renumber accordingly

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Memo

Date: January 23, 2019

To: Rep. Mike Lefor, Chairman
Legislative Employee Benefits Programs Committee

From: Josh Johnson and Jon Herschbach, Deloitte Consulting LLP

Subject: **ACTUARIAL REVIEW OF PROPOSED BILL 19.0343.01000**

The following summarizes our review of the proposed legislation as it relates to actuarial impact to the Group Insurance Program.

OVERVIEW OF PROPOSED BILL

The following is a summary of the relevant proposed amendments:

1) Disallows the requirement of step therapy protocols for FDA-approved drugs used to treat metastatic cancer

ESTIMATED ACTUARIAL IMPACTS

Sanford Health Plan has analyzed the bill and reported no actuarial impact at this time based on the current drugs on the market. This legislation would add financial risk to insurers, pharmacy benefits managers and employer groups due to the possibility of a new, high-cost drug becoming available which would have otherwise been a candidate for a step therapy protocol to be implemented.

Express Scripts Incorporated was asked to comment on the impact to the NDPERS Medicare Part D Employer Group Waiver Plan (EGWP) and generally stated that it is not anticipated that the legislation would have any impact on the NDPERS EGWP plan.

Currently there is proposed federal legislation*, specific to Part D plans, which would allow step therapy protocols to be implemented on protected class drugs, which includes antineoplastics. So, 19.0343.01000 appears to be contradictory to this proposed federal legislation.

* https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses

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DRAFT PROPOSED AMENDMENT TO HB NO. 1469

Page 1, line 8, remove "cancer that has spread from the primary or original"

Page 1, line 8, after "means" insert "advanced cancer that exhibits signs of secondary cancer sites."

Page 1, remove line 9

Page 1, line 14, after "manager" insert "or a health plan"