

2019 DRAFTING REQUEST**Senate Substitute Amendment (SSA-SB26)**For: **Alberta Darling (608) 266-5830**Drafter: **tdodge**By: **Rachel**Secondary Drafters: **swalkenh**Date: **3/5/2019**

May Contact:

Same as LRB:

Submit via email: **YES**Requester's email: **Sen.Darling@legis.wisconsin.gov**Carbon copy (CC) to: **tamara.dodge@legis.wisconsin.gov**
sarah.walkenhorstbarber@legis.wisconsin.gov

Pre Topic:

No specific pre topic given

Topic:

Changes to step therapy

Instructions:

See attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	tdodge 3/7/2019	aernsttr 3/7/2019			
/P1	tdodge 3/18/2019	kfollett 3/18/2019	mbarman 3/7/2019		
/P2	tdodge 3/21/2019	kfollett 3/21/2019	dwalker 3/18/2019		
/P3	swalkenh 3/25/2019		lparisi 3/21/2019		
/1		kfollett	dwalker	dwalker	

Vers. Drafted

Reviewed
3/25/2019

Submitted
3/25/2019

Jacketed
3/25/2019

Required

FE Sent For:

<END>

Dodge, Tamara

From: Keith, Rachel
Sent: Wednesday, March 06, 2019 7:41 AM
To: Dodge, Tamara
Subject: RE: Step Therapy Draft Request

Hi Tammy,

I actually just heard back from a stakeholder on the line regarding the biosimilars on page 7 of the draft. It currently references a federal code, but WI passed a biosimilar law in the past few years, and we would like it to reflect that instead.

So, on page "7" can the line read: "or a biological product that is an interchangeable biological product pursuant to section 450.135 of the Wisconsin Statutes prior to providing coverage for the equivalent branded prescription drug."

Let me know if this makes sense or if you feel it needs to be altered.

Again, thank you so much. I really appreciate it!

Rachel Keith

From: Keith, Rachel
Sent: Tuesday, March 05, 2019 5:57 PM
To: Dodge, Tamara <Tamara.Dodge@legis.wisconsin.gov>
Subject: RE: Step Therapy Draft Request

Thank you so much. I really appreciate it!

From: Dodge, Tamara <Tamara.Dodge@legis.wisconsin.gov>
Sent: Tuesday, March 05, 2019 3:53 PM
To: Keith, Rachel <Rachel.Keith@legis.wisconsin.gov>
Subject: RE: Step Therapy Draft Request

Rachel,

If you would like a substitute amendment, that is no problem for me. I can do either. And, I should be able to get that to you sometime Thursday. I have to run to an appointment now, but I'll let you know tomorrow if I run into any issues.

Tami

Tamara J. Dodge
Senior Legislative Attorney
Wisconsin Legislative Reference Bureau
P.O. Box 2037
Madison, WI 53701-2037
(608) 504 - 5808
tamara.dodge@legis.wisconsin.gov

Please note my new direct phone number (as of June 13, 2018).

From: Keith, Rachel <Rachel.Keith@legis.wisconsin.gov>
Sent: Tuesday, March 05, 2019 3:46 PM
To: Dodge, Tamara <Tamara.Dodge@legis.wisconsin.gov>
Subject: Step Therapy Draft Request

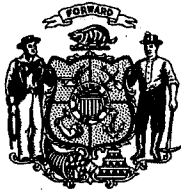
Hi Tammy,

We are requesting some pretty substantive changes to the Step Therapy bill.

- 1) Do you think a sub amendment is appropriate?
- 2) Can we please have the attached changes drafted as soon as you are able?

Thank you,

Rachel Keith
Office of State Senator Alberta Darling
608-266-5830



State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-0350/1
TJD:ahe&kjf

2019 BILL

1 AN ACT *to create* 632.866 of the statutes; **relating to:** step therapy protocols for
2 prescription drug coverage and requiring the exercise of rule-making
3 authority.

Analysis by the Legislative Reference Bureau

~~This bill sets specifications on the development and use of and exceptions to step therapy protocols for prescription drug coverage. A step therapy protocol, as defined in the bill, is a protocol that establishes the specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a particular patient are covered by a policy or plan. When establishing a step therapy protocol, an insurer, pharmacy benefit manager, or utilization review organization must use clinical review criteria based on clinical practice guidelines that meet certain criteria specified in the bill, including development and endorsement of the guidelines either by a multidisciplinary panel of experts that manages conflicts of interest among its members or, in the absence of a multidisciplinary panel, based on peer reviewed publications. The bill requires the insurer, pharmacy benefit manager, or utilization review organization to consider the needs of atypical patient populations and diagnoses when establishing the clinical review criteria.~~

~~If an insurer, pharmacy benefit manager, or utilization review organization restricts the coverage of a prescription drug through a step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must provide access to a process to request an exception to the step therapy protocol, though an~~

~~existing medical exceptions process may be used to satisfy this requirement. The insurer, pharmacy benefit manager, or utilization review organization must expeditiously grant an exception to the step therapy protocol under certain circumstances specified in the bill, including when the drug is contraindicated for the patient or will likely cause an adverse reaction for the patient; the drug is expected to be ineffective; the patient tried the drug previously and discontinued its use due to adverse event or ineffectiveness; use of the drug is not in the patient's best interest; or the patient is stable on a different drug under this or a previous policy or plan. Upon granting an exception to the step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must authorize coverage for the drug prescribed by the patient's treating health care provider. An insured may appeal a denied request for an exception to the step therapy protocol. An insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for an exception within 72 hours of receipt, or within 24 hours in exigent circumstances. If this deadline is not met, the exception is considered granted.~~

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 632.866 of the statutes is created to read:

2 **632.866 Step therapy protocols. (1) DEFINITIONS.** In this section:

3 (a) "Clinical practice guideline" means a systematically developed statement
4 to assist decision making by health care providers and patients about appropriate
5 health care for specific clinical circumstances and conditions.

6 (b) "Clinical review criteria" means written screening procedures, decision
7 abstracts, clinical protocols, and clinical practice guidelines used by an insurer,
8 pharmacy benefit manager, or utilization review organization to determine whether
9 health care services are medically necessary and appropriate.

10 (c) "Exigent circumstances" means when a patient is suffering from a health
11 condition that may seriously jeopardize the patient's life, health, or ability to regain
12 maximum function.

BILL

1 (d) “Medically necessary” means, as related to health care services and
2 supplies, provided under the applicable standard of care and appropriate to do any
3 of the following:

(a) Required to prevent, identify or treat a recipient's illness, injury or disability; and

(b) Meets the following standards:

1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;

2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider and the setting in which the service is provided;

3. Is appropriate with regard to generally accepted standards of medical practice;

4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;

5. Is of proven medical value or usefulness and is not experimental in nature;

6. Is not duplicative with respect to other services being provided to the recipient;

7. Is not solely for the convenience of the recipient, the recipient's family or a provider;

8 (e) “Pharmacy benefit manager” has the meaning given in s. 632.865 (1) (c).

9 (f) “Step therapy protocol” means a protocol or program that establishes the
10 specific sequence in which prescription drugs for a specified medical condition,
11 whether self-administered or physician-administered, that are medically
12 appropriate for a particular patient are covered under a policy or plan.

13 (g) “Utilization review organization” means an entity that conducts utilization
14 review, other than an insurer or pharmacy benefit manager performing utilization
15 review for its own policy or plan.

16 **(2) CLINICAL REVIEW CRITERIA.** (a) When establishing a step therapy protocol,
17 an insurer, pharmacy benefit manager, or utilization review organization shall use clinical review
criteria that are based on clinical practice guidelines derived from peer-reviewed publications,
evidence-based research, and widely-accepted medical practice. If such guidelines are unavailable, clinical
review criteria shall be derived from peer-reviewed publications, evidence-based research, and
widely-accepted medical practice.

(b) The individuals establishing such step therapy protocol shall be required to disclose any
potential conflict of interest due to any financial or other relationship or payment from pharmaceutical
manufacturers, and to recuse themselves from voting if they have a conflict of interest.

(c) The insurer, pharmacy benefit manager or utilization review organization shall describe the

BILL**SECTION 1**

process used for selecting and evaluating the clinical practice guidelines used to develop step therapy protocols on its website. Such a description shall highlight any differences in the process or criteria used by the insurer, pharmacy benefit manager, or utilization review organization by benefit plan or formulary class.

9 d. The guidelines are continually updated through a review of new evidence
10 and research and newly developed treatments.

23 (e) Nothing in this subsection shall be construed to require insurers,
24 pharmacy benefit managers, or the state to create a new entity to develop clinical
review criteria used for step therapy protocols.

BILL

1 **(3) TRANSPARENCY OF EXCEPTIONS PROCESS.** (a) When coverage of a prescription
2 drug for the treatment of any medical condition is restricted for use by an insurer,
3 pharmacy benefit manager, or utilization review organization through the use of a
4 step therapy protocol, the insurer, pharmacy benefit manager, or utilization review
5 organization shall provide access to a clear, readily accessible and convenient process
6 to request an exception to the step therapy protocol. An insurer, pharmacy benefit
7 manager, or utilization review organization may use any existing medical exceptions
8 process to satisfy the requirement under this paragraph. The exception process shall
9 be made easily accessible on the Internet site of the insurer, pharmacy benefit
10 manager, or utilization review organization.

11 (b) An insurer, PBM, or utilization review organization shall grant an exception to
the step therapy protocol if the prescribing provider submits relevant written
documentation and clinical rationale supporting a step therapy exception request and any of
the following are satisfied:

14 1. The prescription drug required under the step therapy protocol is
contraindicated or, due to a documented adverse event with a previous use or a documented
medical condition, including a comorbid condition, is likely to do any of the following:

a) cause an adverse reaction to the enrollee

b) decrease the ability to achieve or maintain reasonable functional ability in
performing daily activities, or

c) cause physical or mental harm to the enrollee

17 2. The prescription drug required under the step therapy protocol is expected
to be ineffective based on:

a. sound clinical evidence or medical and scientific evidence;

b. the known clinical characteristics of the patient; and

**c. the known characteristics of the prescription drug regimen as described in
peer-reviewed literature or the manufacturer's prescribing
information for the drug.**

20 3. The patient has tried the prescription drug required under the step therapy
protocol, or another prescription drug in the same pharmacologic class or with the same
mechanism of action, under the policy or a previous policy or plan, was adherent during

such a trial to allow for a positive treatment outcome, and the patient's use of the prescription drug was discontinued by the patient's healthcare provider due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

BILL

SECTION 1

1 4. Based on an evaluation of medically necessary drugs for the patient's
2 condition, the prescription drug required under the step therapy protocol is not in the
3 best interest of the patient.

4 5. The patient is stable on a prescription drug selected by his or her health care
5 provider for the medical condition under consideration while covered under the
6 policy or plan or a previous policy or plan.

a) This subparagraph shall not be construed to encourage the use of a pharmaceutical
sample for the sole purpose of meeting the requirements for a step therapy override
exception.

7 (c) Upon granting an exception to the step therapy protocol under par. (b), the
8 insurer, pharmacy benefit manager, or utilization review organization shall
9 authorize coverage for the prescription drug prescribed by the patient's treating
10 health care provider, to the extent the prescribed drug is a covered drug under
the covered person's policy or contract.

11 (d) An insured may appeal any request for an exception to the step therapy
12 protocol that is denied.

13 (e) An insurer, pharmacy benefit manager, or utilization review organization shall
grant or deny a request for any exception to the step therapy protocol within 72 hours of receipt
of the relevant written documentation and clinical rationale supporting a step therapy exception
or receipt of an appeal of the previous decision with relevant written documentation and clinical
rationale supporting a step therapy exception request. In exigent circumstances, an insurer,
pharmacy benefit manager, or utilization review organization shall grant or deny a request for
an exception to the step therapy protocol within 24 hours of receipt of the relevant written
documentation and clinical rationale supporting a step therapy exception request. If the
insurer, pharmacy benefit manager, or utilization review organization does not grant or deny a
request or an appeal under the time specified under this paragraph, the exception is considered
granted.

22 (f) Nothing in this subsection shall be construed to prevent any of the following:

23 1. An insurer, pharmacy benefit manager, or utilization review organization
24 from requiring a patient to try an A-rated generic equivalent prescription drug, as

BILL

1 designated by the federal food and drug administration, or a biosimilar, as defined under
2 42 USC 262(i)(2), before providing coverage for the equivalent brand name prescription drug.

3 2. A health care provider from prescribing a prescription drug that is
4 determined to be medically appropriate

5 (4) RULES. The commissioner shall promulgate any rules necessary to

6 implement or enforce this section.

7 **SECTION 2. Initial applicability.**

8 (1) For policies and plans containing provisions inconsistent with this act, the
9 act first applies to policy or plan years beginning on January 1 of the year following
10 the year in which this subsection takes effect.

11 **SECTION 3. Effective date.**

12 (1) This act takes effect on the first day of the 4th month beginning after
13 publication.

(END)



In: 317 (Due ASAP Today)

State of Wisconsin
2019 - 2020 LEGISLATURE

50016/P1

LRB-1748/1

TJD:ah&kjf

2019 SENATE BILL 26

Sal

February 8, 2019 - Introduced by Senators DARLING, JACQUE, ROTH, JOHNSON, FEYEN, MARKLEIN, NASS, OLSEN, RINGHAND, WANGGAARD, TESTIN, COWLES, LEMAHIEU, CARPENTER and WIRCH, cosponsored by Representatives NYGREN, OLDENBURG, SCHRAA, KOLSTE, SUBECK, RODRIGUEZ, BALLWEG, DITTRICH, PETERSEN, HORLACHER, VORPAGEL, MURSAU, KUGLITSCH, SPIROS, EDMING, GUNDRUM, FELZKOWSKI, KULP, SKOWRONSKI, THIESFELDT, BROOKS, RAMTHUN, TITTL, SWEARINGEN, NOVAK, JAGLER, VANDERMEER, ZIMMERMAN, KRUG, QUINN, ROHRKASTE, DUCHOW, MAGNAFICI, BORN, KURTZ, BRANDTJEN, PLUMER, SUMMERFIELD, LOUDENBECK, OTT and KNODL. Referred to Committee on Health and Human Services.

1 AN ACT to create 632.866 of the statutes; relating to: step therapy protocols for
2 prescription drug coverage and requiring the exercise of rule-making
3 authority.

Analysis by the Legislative Reference Bureau

This bill sets specifications on the development and use of and exceptions to step therapy protocols for prescription drug coverage. A step therapy protocol, as defined in the bill, is a protocol that establishes the specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a particular patient are covered by a policy or plan. When establishing a step therapy protocol, an insurer, pharmacy benefit manager, or utilization review organization must use clinical review criteria based on clinical practice guidelines that meet certain criteria specified in the bill, including development and endorsement of the guidelines either by a multidisciplinary panel of experts that manages conflicts of interest among its members or, in the absence of a multidisciplinary panel, based on peer reviewed publications. The bill requires the insurer, pharmacy benefit manager, or utilization review organization to consider the needs of atypical patient populations and diagnoses when establishing the clinical review criteria.

If an insurer, pharmacy benefit manager, or utilization review organization restricts the coverage of a prescription drug through a step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must provide access to a process to request an exception to the step therapy protocol, though an

SENATE BILL 26

Insert Analysis

existing medical exceptions process may be used to satisfy this requirement. The insurer, pharmacy benefit manager, or utilization review organization must expeditiously grant an exception to the step therapy protocol under certain circumstances specified in the bill, including when the drug is contraindicated for the patient or will likely cause an adverse reaction for the patient; the drug is expected to be ineffective; the patient tried the drug previously and discontinued its use due to adverse event or ineffectiveness; use of the drug is not in the patient's best interest; or the patient is stable on a different drug under this or a previous policy or plan.

Upon granting an exception to the step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must authorize coverage for the drug prescribed by the patient's treating health care provider. An insured may appeal a denied request for an exception to the step therapy protocol. An insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for an exception within 72 hours of receipt, or within 24 hours in exigent circumstances. If this deadline is not met, the exception is considered granted.

of receipt of supporting documentation

to the extent the drug is covered under the patient's policy or plan

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

- 1 **SECTION 1.** 632.866 of the statutes is created to read:
- 2 **632.866 Step therapy protocols. (1) DEFINITIONS.** In this section:
- 3 (a) "Clinical practice guideline" means a systematically developed statement
- 4 to assist decision making by health care providers and patients about appropriate
- 5 health care for specific clinical circumstances and conditions.
- 6 (b) "Clinical review criteria" means written screening procedures, decision
- 7 abstracts, clinical protocols, and clinical practice guidelines used by an insurer,
- 8 pharmacy benefit manager, or utilization review organization to determine whether
- 9 health care services are medically necessary and appropriate.
- 10 (c) "Exigent circumstances" means when a patient is suffering from a health
- 11 condition that may seriously jeopardize the patient's life, health, or ability to regain
- 12 maximum function.

SENATE BILL 26

1 (d) "Medically necessary" means, as related to health care services and
2 supplies, provided under the applicable standard of care and appropriate to do any
3 of the following: *satisfies all*

- 4 1. Improve or preserve health, life, or function.
- 5 2. Slow the deterioration of health, life, or function.
- 6 3. Provide for the early screening, prevention, evaluation, diagnosis, or
7 treatment of a disease, condition, illness, or injury.

8 (e) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

9 (f) "Step therapy protocol" means a protocol or program that establishes the
10 specific sequence in which prescription drugs for a specified medical condition,
11 whether self-administered or physician-administered, that are medically
12 appropriate for a particular patient are covered under a policy or plan.

13 (g) "Utilization review organization" means an entity that conducts utilization
14 review, other than an insurer or pharmacy benefit manager performing utilization
15 review for its own policy or plan.

16 (2) CLINICAL REVIEW CRITERIA. (a) When establishing a step therapy protocol,
17 an insurer, pharmacy benefit manager, or utilization review organization shall use
18 clinical review criteria that are based on clinical practice guidelines that satisfy all
19 of the following:

- 20 1. The guidelines recommend that the prescription drugs be taken in the
21 specific sequence required by the step therapy protocol.
- 22 2. The guidelines are developed and endorsed by a multidisciplinary panel of
23 experts that manages conflicts of interest among its members in accordance with par.
24 (b) or, if such guidelines are unavailable, are developed based on peer-reviewed
25 publications.

*Insert
3-4*

Insert 3-18

SENATE BILL 26**SECTION 1**

1 3. The guidelines are based on evidence-based, high quality studies, research,
2 and medical practice.

3 4. The guidelines are created in an explicit and transparent process that does
4 all of the following:

- 5 a. Minimizes biases and conflicts of interest.
- 6 b. Explains the relationship between treatment options and outcomes.
- 7 c. Rates the quality of evidence supporting recommendations.
- 8 d. Considers relevant patient subgroups and preferences.

9 5. The guidelines are continually updated through a review of new evidence
10 and research and newly developed treatments.

11 (b) To satisfy par. (a) 2., the multidisciplinary panel of experts shall manage
12 conflicts of interest among its members by doing all of the following:

13 1. Requiring members to disclose any potential conflict of interest to specific
14 entities, including insurers, pharmacy benefit managers, and pharmaceutical
15 manufacturers, and to recuse themselves from voting if they have a conflict of
16 interest.

17 2. Using a methodology to provide objectivity in data analysis and ranking of
18 evidence through the preparation of evidence tables and facilitating consensus.

19 3. Offering opportunities for public review and comments.

20 (c) An insurer, pharmacy benefit manager, or utilization review organization
21 shall consider the needs of atypical patient populations and diagnoses when
22 establishing clinical review criteria for the establishment of a step therapy protocol.

23 (d) Nothing in this subsection shall be construed to require insurers, pharmacy
24 benefit managers, or the state to create a new entity to develop clinical review
25 criteria used for step therapy protocols.

SENATE BILL 26 *the prescribing provider submits relevant written documentation and clinical rationale supporting a step therapy exception request and*

1 (3) TRANSPARENCY OF EXCEPTIONS PROCESS. (a) When coverage of a prescription
2 drug for the treatment of any medical condition is restricted for use by an insurer,
3 pharmacy benefit manager, or utilization review organization through the use of a
4 step therapy protocol, the insurer, pharmacy benefit manager, or utilization review
5 organization shall provide access to a clear, readily accessible and convenient process
6 to request an exception to the step therapy protocol. An insurer, pharmacy benefit
7 manager, or utilization review organization may use any existing medical exceptions
8 process to satisfy the requirement under this paragraph. The exception process shall
9 be made easily accessible on the Internet site of the insurer, pharmacy benefit
10 manager, or utilization review organization.

11 (b) An insurer, pharmacy benefit manager, or utilization review organization
12 shall expeditiously grant an exception to the step therapy protocol if any of the
13 following are satisfied:

Insert 5-15

14 1. The prescription drug required under the step therapy protocol is
15 contraindicated or will likely cause an adverse reaction by or physical or mental
16 harm to the patient.

all of the following:

17 2. The prescription drug required under the step therapy protocol is expected
18 to be ineffective based on the known clinical characteristics of the patient and the
19 known characteristics of the prescription drug regimen.

Insert 5-20

20 3. The patient has tried the prescription drug required under the step therapy
21 protocol, or another prescription drug in the same pharmacologic class or with the
22 same mechanism of action, under the policy or plan or a previous policy or plan and
23 the patient's use of the prescription drug was discontinued due to lack of efficacy or
24 effectiveness, diminished effect, or an adverse event.

Insert 5-22

SENATE BILL 26

SECTION 1

1 4. Based on an evaluation of medically necessary drugs for the patient's
2 condition, the prescription drug required under the step therapy protocol is not in the
3 best interest of the patient.

4 5. The patient is stable on a prescription drug selected by his or her health care
5 provider for the medical condition under consideration while covered under the
6 policy or plan or a previous policy or plan.

Insert 6-7

7 (d) (c) Upon granting an exception to the step therapy protocol under par. (b), the
8 insurer, pharmacy benefit manager, or utilization review organization shall
9 authorize coverage for the prescription drug prescribed by the patient's treating
10 health care provider.

to the extent the prescribed drug is covered under the patient's policy or plan

11 (d) An insured may appeal any request for an exception to the step therapy
12 protocol that is denied.

Insert 6-15

13 (e) An insurer, pharmacy benefit manager, or utilization review organization
14 shall grant or deny a request for any exception to the step therapy protocol within
15 72 hours of receipt of the request or the request to appeal the previous decision. In

16 exigent circumstances, an insurer, pharmacy benefit manager, or utilization review
17 organization shall grant or deny a request for an exception to the step therapy
18 protocol within 24 hours of receipt of the request. If the insurer, pharmacy benefit

Insert 6-18

19 manager, or utilization review organization does not grant or deny a request or an
20 appeal under the time specified under this paragraph, the exception is considered
21 granted.

22 (f) Nothing in this subsection shall be construed to prevent any of the following:

23 1. An insurer, pharmacy benefit manager, or utilization review organization
24 from requiring a patient to try an AB-rated generic equivalent prescription drug, as

Handwritten mark at the bottom of the page.

SENATE BILL 26

Insert 7-1

1 designated by the federal food and drug administration, before providing coverage
2 for the equivalent brand name prescription drug.

3 2. A health care provider from prescribing a prescription drug that is
4 determined to be medically appropriate.

5 (4) RULES. The commissioner shall promulgate any rules necessary to
6 implement or enforce this section.

7 **SECTION 2. Initial applicability.**

8 (1) For policies and plans containing provisions inconsistent with this act, the
9 act first applies to policy or plan years beginning on January 1 of the year following
10 the year in which this subsection takes effect.

11 **SECTION 3. Effective date.**

12 (1) This act takes effect on the first day of the 4th month beginning after
13 publication.

14 (END)

1

2

INSERT ANALYSIS

if the prescribing provider submits relevant written documentation and clinical rationale supporting the request and any of the circumstances specified in the bill apply, including when the drug is contraindicated for the patient or will likely cause an adverse event for the patient; the drug is expected to be ineffective based on certain evidence and the known characteristics of the patient and the drug regimen; the patient previously tried the drug or a similar drug and its use by the patient was discontinued under circumstances described in the bill; the use of the drug is not in the patient's best interest; or the patient is stable on a different drug under this or a previous policy or plan.

previously

✓

3

END INSERT ANALYSIS

4

INSERT 3-4 ✓

5

1. Is required to prevent, identify, or treat a patient's illness, injury, or

6

disability.

7

2. Is consistent with the patient's symptoms or with prevention, diagnosis or

8

treatment of the patient's illness, injury, or disability.

9

3. Is provided consistent with standards of acceptable quality of care applicable

10

to the type of service, the type of provider, and the setting in which the service is

11

provided.

12

4. Is appropriate with regard to generally accepted standards of medical

13

practice.

14

5. Is not medically contraindicated with regard to the patient's diagnosis, the

15

patient's symptoms, or other services being provided to the patient.

16

6. Is of proven medical value or usefulness and is not experimental in nature.

17

7. Is not duplicative with respect to other services being provided to the patient.

1 8. Is not provided solely for the convenience of the patient, the patient's family,
2 or a provider.

3 END INSERT 3-4

4 INSERT 3-18 ✓

5 that are derived from peer-review publications, evidence-based research, and
6 widely accepted medical practice. If such clinical practice guidelines are
7 unavailable, the insurer, pharmacy benefit manager, or utilization review
8 organization shall derive clinical review criteria from peer-reviewed publications,
9 evidence-based research, and widely accepted medical practice. The insurer,
10 pharmacy benefit manager, or utilization review organization shall continually
11 update the clinical review criteria based on an update to the clinical practice
12 guidelines or a review of new evidence and research and newly developed
13 treatments.

14 (b) Any individual involved in establishing a step therapy protocol under this
15 subsection shall disclose to the insurer, pharmacy benefit manager, or utilization
16 review organization any potential conflict of interest due to a financial or other
17 relationship or payment from a pharmaceutical manufacturer and shall recuse
18 himself or herself from voting on a decision regarding the step therapy protocol if he
19 or she has a conflict of interest.

20 (c) An insurer, pharmacy benefit manager, or utilization review organization
21 shall describe on its Internet site the process and criteria used for selecting and
22 evaluating clinical practice guidelines used under par. (a) to develop step therapy
23 protocols. The description shall include any differences in the process or criteria
24 among benefit plans or formulary classes.

25 END INSERT 3-18

1 INSERT 5-15 ✓

2 , due to a documented adverse event with a previous use or a documented
3 medical condition, including a comorbid condition, is likely to do any of the following:

4 a. Cause an adverse reaction to the patient.

5 b. Decrease the ability to achieve or maintain reasonable functional ability in
6 performing daily activities.

7 c. Cause physical or mental harm to the patient.

8 END INSERT 5-15 ✓

9 INSERT 5-20

10 a. Sound clinical evidence or medical and scientific evidence.

11 b. The known clinical characteristics of the patient.

12 c. The known characteristics of the prescription drug regimen as described in
13 peer-reviewed literature or the manufacturer's prescribing information for the
14 prescription drug.

15 END INSERT 5-20

16 INSERT 5-22 ✓

17 , the patient was adherent to the prescription drug regimen during the trial to
18 sufficiently observe any treatment outcomes, and the patient's use of the prescription
19 drug was discontinued by the patient's provider due to lack of efficacy or effectiveness,
20 diminished effect, or adverse event.

21 END INSERT 5-22

22 INSERT 6-7 ✓

23 (c) Nothing in this subsection shall be construed to encourage the use of a
24 pharmaceutical sample for the sole purpose of satisfying a criterion for an exception
25 to a step therapy protocol.

1 END INSERT 6-7

2 INSERT 6-15 ✓

3 *exception*
④ of the written documentation and clinical rationale to support a step therapy
④ exemption request under par. (b) or the receipt of a request to appeal a previous
5 decision that includes the written documentation and clinical rationale supporting
6 a step therapy exception request.

7 END INSERT 6-15

8 INSERT 6-18 ✓

9 written documentation and clinical rationale *rationale* supporting a step therapy
10 exception

11 END INSERT 6-18

12 INSERT 7-1

13 or an interchangeable biological product under s. 450.135 ✓

14 END INSERT 7-1

Dodge, Tamara

From: Keith, Rachel
Sent: Friday, March 15, 2019 4:59 PM
To: Dodge, Tamara
Subject: Step Therapy Sub Amendment P2
Attachments: SUB Compromise Language.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Important reminder

Hi Tami,

We need to change a few things on LRB s0016/P1. I attached the changes to this email. Please let me know if you have any questions.

Best,

Rachel Keith
Office of State Senator Alberta Darling
608-266-5830

Senate Substitute Amendment to Senate Bill 26 (LRBs-0016/P1)

Compromise Language

Citation

<p>Section (1)(d): Definition of “Medically Necessary” <i>Page 3, Lines 1-18</i></p>	<p><u>Delete definition.</u></p>
<p>Section (2)(c): Clinical Review Criteria <i>Page 4, Lines 21-25</i></p>	<p>“An insurer, pharmacy benefit manager, or utilization review organization shall describe on its Internet site the process and criteria used for selecting and evaluating clinical practice guidelines used under par. (a) to develop step therapy protocols.”</p>
<p>Section (3)(b): Exceptions Process <i>Page 5, Lines 14-17</i></p>	<p>“An insurer, pharmacy benefit manager or utilization review organization shall grant an exception to the step therapy protocol if the prescribing provider submits <u>complete clinically relevant written documentation supporting a step therapy exception request and any of the following are satisfied:</u>”</p>
<p>Section (3)(b)(1): Exception for Adverse Reactions or Physical or Mental Harm <i>Page 5, Lines 18-25</i></p>	<p>The prescription drug required under the step therapy protocol is contraindicated or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:</p> <ol style="list-style-type: none"> a. <u>Cause a serious adverse reaction in the patient.</u> b. <u>Decrease the ability to achieve or maintain reasonable functional ability in performing daily activities.</u> c. <u>Cause physical or psychiatric harm to the patient.</u>
<p>Section (3)(b)(3): Exception for a Previous Trial of Drug <i>Page 6, Lines 8-14</i></p>	<p>The patient has tried the prescription drug required under the step therapy protocol, or another prescription drug in the same pharmacologic class or with the same mechanism of action, under the policy or plan or a previous policy or plan, the patient was adherent to the prescription drug regimen for a period of time to allow for a positive treatment outcome, and the patient's use of the prescription drug was discontinued by the patient's provider due to lack of efficacy or effectiveness, diminished effect, or adverse event. <u>This clause does not prohibit an insurer, pharmacy benefit manager, or utilization review organization from requiring a patient to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by the clinical review criteria developed in accordance with sub. (2).</u></p>
<p>Section (3)(b)(4): Exception for “The Best Interest of the Patient” <i>Page 6, Lines 15-17</i></p>	<p><u>Delete exception.</u></p>

<p>Section (3)(b)(5): Exception When a Patient is “Stable” on a Drug <i>Page 6, Lines 18-20</i></p>	<p><u>Retain original language. Add:</u> Nothing in this subsection shall be construed to allow the use of a pharmaceutical sample to satisfy a criterion for an exception to a step therapy protocol.</p>
<p>Section (3)(f): Requirements for Responding to Exceptions Requests <i>Page 7, Lines 6-17</i></p>	<p>An insurer, pharmacy benefit manager, or utilization review organization shall grant or deny a request for any exception to the step therapy protocol within <u>3 business days</u> of receipt of the <u>complete clinically relevant written documentation</u> to support a step therapy exception request under par. (b) or the receipt of a request to appeal a previous decision that includes the <u>complete clinically relevant written documentation</u> supporting a step therapy exception request. In exigent circumstances, an insurer, pharmacy benefit manager, or utilization review organization shall grant or deny a request for an exception to the step therapy protocol <u>by the end of the next business day</u> after receipt of the <u>complete clinically relevant written documentation</u> supporting a step therapy exception request. If the insurer, pharmacy benefit manager, or utilization review organization does not grant or deny a request or an appeal under the time specified under this paragraph, the exception is considered granted.</p>
<p>Section (3)(g)(1): Generics and Interchangeable Biological Products <i>Page 7, Lines 19-23</i></p>	<p>An insurer, pharmacy benefit manager, or utilization review organization from requiring a patient to try an <u>A-rated generic equivalent</u> prescription drug, as designated by the federal food and drug administration, <u>or a biosimilar</u>, as defined under <u>42 USC 262(i)(2)</u>, before providing coverage for the equivalent brand name prescription drug.</p>



State of Wisconsin
2019 - 2020 LEGISLATURE

LRBs0016/P1
TJD:ah&kjf

In: 3118

Due
Today

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION
SENATE SUBSTITUTE AMENDMENT,
TO SENATE BILL 26

1 **AN ACT to create** 632.866 of the statutes; **relating to:** step therapy protocols for
2 prescription drug coverage and requiring the exercise of rule-making
3 authority.

Analysis by the Legislative Reference Bureau

This bill sets specifications on the development and use of and exceptions to step therapy protocols for prescription drug coverage. A step therapy protocol, as defined in the bill, is a protocol that establishes the specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a particular patient are covered by a policy or plan. When establishing a step therapy protocol, an insurer, pharmacy benefit manager, or utilization review organization must use clinical review criteria based on clinical practice guidelines that meet certain criteria specified in the bill.

If an insurer, pharmacy benefit manager, or utilization review organization restricts the coverage of a prescription drug through a step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must provide access to a process to request an exception to the step therapy protocol, though an existing medical exceptions process may be used to satisfy this requirement. The insurer, pharmacy benefit manager, or utilization review organization must grant an

a serious

complete and clinically

exception to the step therapy protocol if the prescribing provider submits relevant written documentation and clinical rationale supporting the request and any of the circumstances specified in the bill apply, including when the drug is contraindicated for the patient or will likely cause an adverse event for the patient; the drug is expected to be ineffective based on certain evidence and the known characteristics of the patient and the drug regimen; the patient previously tried the drug or a similar drug and its use by the patient was discontinued under circumstances described in the bill; ~~the use of the drug is not in the patient's best interest;~~ or the patient is stable on a different drug under this or a previous policy or plan. Upon granting an exception to the step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must authorize coverage for the drug prescribed by the patient's treating health care provider to the extent the drug is covered under the patient's policy or plan. An insured may appeal a denied request for an exception to the step therapy protocol. An insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for an exception within 72 hours, or within 24 hours in exigent circumstances, of receipt of supporting documentation. If this deadline is not met, the exception is considered granted.

file
3 business days

by the end of the next business day

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

- 1 **SECTION 1.** 632.866 of the statutes is created to read:
- 2 **632.866 Step therapy protocols. (1) DEFINITIONS.** In this section:
- 3 (a) "Clinical practice guideline" means a systematically developed statement
- 4 to assist decision making by health care providers and patients about appropriate
- 5 health care for specific clinical circumstances and conditions.
- 6 (b) "Clinical review criteria" means written screening procedures, decision
- 7 abstracts, clinical protocols, and clinical practice guidelines used by an insurer,
- 8 pharmacy benefit manager, or utilization review organization to determine whether
- 9 health care services are medically necessary and appropriate.
- 10 (c) "Exigent circumstances" means when a patient is suffering from a health
- 11 condition that may seriously jeopardize the patient's life, health, or ability to regain
- 12 maximum function.

1 (d) "Medically necessary" means, as related to health care services and
2 supplies, provided under the applicable standard of care and satisfies all of the
3 following:

4 1. Is required to prevent, identify, or treat a patient's illness, injury, or
5 disability.

6 2. Is consistent with the patient's symptoms or with prevention, diagnosis, or
7 treatment of the patient's illness, injury, or disability.

8 3. Is provided consistent with standards of acceptable quality of care applicable
9 to the type of service, the type of provider, and the setting in which the service is
10 provided.

11 4. Is appropriate with regard to generally accepted standards of medical
12 practice.

13 5. Is not medically contraindicated with regard to the patient's diagnosis, the
14 patient's symptoms, or other services being provided to the patient.

15 6. Is of proven medical value or usefulness and is not experimental in nature.

16 7. Is not duplicative with respect to other services being provided to the patient.

17 8. Is not provided solely for the convenience of the patient, the patient's family,
18 or a provider.

19 (d) ~~(d)~~ (e) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

20 (e) ~~(e)~~ (f) "Step therapy protocol" means a protocol or program that establishes the
21 specific sequence in which prescription drugs for a specified medical condition,
22 whether self-administered or physician-administered, that are medically
23 appropriate for a particular patient are covered under a policy or plan.

1 (g) "Utilization review organization" means an entity that conducts utilization
2 review, other than an insurer or pharmacy benefit manager performing utilization
3 review for its own policy or plan.

4 (2) CLINICAL REVIEW CRITERIA. (a) When establishing a step therapy protocol,
5 an insurer, pharmacy benefit manager, or utilization review organization shall use
6 clinical review criteria that are based on clinical practice guidelines that are derived
7 from peer-review publications, evidence-based research, and widely accepted
8 medical practice. If such clinical practice guidelines are unavailable, the insurer,
9 pharmacy benefit manager, or utilization review organization shall derive clinical
10 review criteria from peer-reviewed publications, evidence-based research, and
11 widely accepted medical practice. The insurer, pharmacy benefit manager, or
12 utilization review organization shall continually update the clinical review criteria
13 based on an update to the clinical practice guidelines or a review of new evidence and
14 research and newly developed treatments.

15 (b) Any individual involved in establishing a step therapy protocol under this
16 subsection shall disclose to the insurer, pharmacy benefit manager, or utilization
17 review organization any potential conflict of interest due to a financial or other
18 relationship or payment from a pharmaceutical manufacturer and shall recuse
19 himself or herself from voting on a decision regarding the step therapy protocol if he
20 or she has a conflict of interest.

21 (c) An insurer, pharmacy benefit manager, or utilization review organization
22 shall describe on its Internet site the process and criteria used for selecting and
23 evaluating clinical practice guidelines used under par. (a) to develop step therapy
24 protocols. The description shall include any differences in the process or criteria
25 among benefit plans or formulary classes.

1 (d) Nothing in this subsection shall be construed to require insurers, pharmacy
2 benefit managers, or the state to create a new entity to develop clinical review
3 criteria used for step therapy protocols.

4 (3) TRANSPARENCY OF EXCEPTIONS PROCESS. (a) When coverage of a prescription
5 drug for the treatment of any medical condition is restricted for use by an insurer,
6 pharmacy benefit manager, or utilization review organization through the use of a
7 step therapy protocol, the insurer, pharmacy benefit manager, or utilization review
8 organization shall provide access to a clear, readily accessible and convenient process
9 to request an exception to the step therapy protocol. An insurer, pharmacy benefit
10 manager, or utilization review organization may use any existing medical exceptions
11 process to satisfy the requirement under this paragraph. The exception process shall
12 be made easily accessible on the Internet site of the insurer, pharmacy benefit
13 manager, or utilization review organization.

14 (b) An insurer, pharmacy benefit manager, or utilization review organization
15 shall grant an exception to the step therapy protocol if the prescribing provider
16 submits ^{complete and clinically} relevant written documentation and clinical rationale supporting a step
17 therapy exception request and any of the following are satisfied:

18 1. The prescription drug required under the step therapy protocol is
19 contraindicated or, due to a documented adverse event with a previous use or a
20 documented medical condition, including a comorbid condition, is likely to do any of
21 the following:

- 22 a. Cause ^{a serious} an adverse reaction in the patient.
- 23 b. Decrease the ability to achieve or maintain reasonable functional ability in
24 performing daily activities.
- 25 c. Cause physical or mental ^{psychiatric} harm to the patient.

**2019-2020 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRBs0016/P2ins
TJD:...

1 INSERT 6-14

2 Nothing in this subdivision prohibits an insurer, pharmacy benefit manager, or

3 utilization review organization from requiring a patient to try another drug in the

4 same pharmacologic class or with the same mechanism of action if that therapy

5 sequence is supported by clinical review criteria under sub. (2) (a).

6 END INSERT 6-14

1 2. The prescription drug required under the step therapy protocol is expected
2 to be ineffective based on all of the following:

3 a. Sound clinical evidence or medical and scientific evidence.

4 b. The known clinical characteristics of the patient.

5 c. The known characteristics of the prescription drug regimen as described in
6 peer-reviewed literature or the manufacturer's prescribing information for the
7 prescription drug. *for a time that allows for a positive treatment outcome*

8 3. The patient has tried the prescription drug required under the step therapy
9 protocol, or another prescription drug in the same pharmacologic class or with the
10 same mechanism of action, under the policy or plan or a previous policy or plan, the
11 patient was adherent to the prescription drug regimen *during the trial to sufficiently*

12 *observe any treatment outcomes*, and the patient's use of the prescription drug was
13 discontinued by the patient's provider due to lack of efficacy or effectiveness,
14 diminished effect, or adverse event. *Insert 6-14*

15 4. Based on an evaluation of medically necessary drugs for the patient's
16 condition, the prescription drug required under the step therapy protocol is not in the
17 best interest of the patient.

18 *4* ~~5~~. The patient is stable on a prescription drug selected by his or her health care
19 provider for the medical condition under consideration while covered under the
20 policy or plan or a previous policy or plan.

21 (c) Nothing in this subsection shall be construed to *allow* ~~encourage~~ the use of a
22 pharmaceutical sample *to satisfy* ~~for the sole purpose of satisfying~~ a criterion for an exception
23 to a step therapy protocol.

24 (d) Upon granting an exception to the step therapy protocol under par. (b), the
25 insurer, pharmacy benefit manager, or utilization review organization shall

1 authorize coverage for the prescription drug prescribed by the patient's treating
2 health care provider to the extent the prescribed drug is covered under the patient's
3 policy or plan.

4 (e) An insured may appeal any request for an exception to the step therapy
5 protocol that is denied.

6 (f) An insurer, pharmacy benefit manager, or utilization review organization
7 shall grant or deny a request for any exception to the step therapy protocol within
8 72 hours of receipt of the ^{complete and clinically relevant} written documentation and clinical rationale ^{required under par. (b)} to support a
9 step therapy exception request under par. (b) or the receipt of a request to appeal a
10 previous decision that includes the ^{complete and clinically relevant} written documentation and clinical rationale
11 supporting a step therapy exception request. In exigent circumstances, an insurer,

12 pharmacy benefit manager, or utilization review organization shall grant or deny a
13 request for an exception to the step therapy protocol within 24 hours of receipt of the
14 ^{complete and clinically relevant} written documentation and clinical rationale supporting a step therapy exception
15 request. ^{under par. (b)} If the insurer, pharmacy benefit manager, or utilization review
16 organization does not grant or deny a request or an appeal under the time specified
17 under this paragraph, the exception is considered granted. ^{by the end of the next business day after}

18 (g) Nothing in this subsection shall be construed to prevent any of the following:

19 1. An insurer, pharmacy benefit manager, or utilization review organization
20 from requiring a patient to try an A-rated generic equivalent prescription drug, as
21 designated by the federal food and drug administration, or an interchangeable
22 biological product under s. 450.135 before providing coverage for the equivalent
23 brand name prescription drug. ^{a biosimilar, as defined under 42 USC 262 (i) (2)}

24 2. A health care provider from prescribing a prescription drug that is
25 determined to be medically appropriate.

Dodge, Tamara

From: Keith, Rachel
Sent: Wednesday, March 20, 2019 3:12 PM
To: Dodge, Tamara
Subject: P3 Please
Attachments: 19s0016_P2.pdf

Follow Up Flag: FollowUp
Flag Status: Flagged

Hi Tami,

Just two modifications to step therapy draft this time.

1. Change "complete and clinically relevant written documentation and clinical rationale" to "complete, clinically relevant written documentation"
 - a. Locations:
 - i. Page 4, lines 20-21
 - ii. Page 6, lines 16-17
 - iii. Page 6, lines 18-19
 - iv. Page 6, lines 23-24
- 2) Change "Nothing in this subdivision prohibits an insurer, pharmacy benefit manager, or utilization review organization from requiring a patient to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by clinical review criteria under sub (2) (a)." to "This clause does not prohibit an insurer, pharmacy benefit manager, or utilization review organization from requiring a patient to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by the clinical review criteria developed in accordance with sub (2)."
 - a. Location: P5, Lines 20-24

Thank you so much.

Rachel Keith
Office of State Senator Alberta Darling
608-266-5830



State of Wisconsin
2019 - 2020 LEGISLATURE

LRBs0016/P2
TJD:ah&kjf P3

Due Today

In: 3/21

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION
SENATE SUBSTITUTE AMENDMENT ,
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If an insurer, pharmacy benefit manager, or utilization review organization restricts the coverage of a prescription drug through a step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must provide access to a process to request an exception to the step therapy protocol, though an existing medical exceptions process may be used to satisfy this requirement. The insurer, pharmacy benefit manager, or utilization review organization must grant an

exception to the step therapy protocol if the prescribing provider submits complete, and clinically relevant written documentation and clinical rationale supporting the request and any of the circumstances specified in the bill apply, including when the drug is contraindicated for the patient or will likely cause a serious adverse event for the patient; the drug is expected to be ineffective based on certain evidence and the known characteristics of the patient and the drug regimen; the patient previously tried the drug or a similar drug and its use by the patient was discontinued under circumstances described in the bill; or the patient is stable on a different drug under this or a previous policy or plan. Upon granting an exception to the step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must authorize coverage for the drug prescribed by the patient's treating health care provider to the extent the drug is covered under the patient's policy or plan. An insured may appeal a denied request for an exception to the step therapy protocol. An insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for an exception within three business days, or by the end of the next business day in exigent circumstances, of receipt of supporting documentation. If this deadline is not met, the exception is considered granted.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 632.866 of the statutes is created to read:

2 **632.866 Step therapy protocols. (1) DEFINITIONS.** In this section:

3 (a) "Clinical practice guideline" means a systematically developed statement
4 to assist decision making by health care providers and patients about appropriate
5 health care for specific clinical circumstances and conditions.

6 (b) "Clinical review criteria" means written screening procedures, decision
7 abstracts, clinical protocols, and clinical practice guidelines used by an insurer,
8 pharmacy benefit manager, or utilization review organization to determine whether
9 health care services are medically necessary and appropriate.

10 (c) "Exigent circumstances" means when a patient is suffering from a health
11 condition that may seriously jeopardize the patient's life, health, or ability to regain
12 maximum function.

13 (d) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

1 (e) "Step therapy protocol" means a protocol or program that establishes the
2 specific sequence in which prescription drugs for a specified medical condition,
3 whether self-administered or physician-administered, that are medically
4 appropriate for a particular patient are covered under a policy or plan.

5 (f) "Utilization review organization" means an entity that conducts utilization
6 review, other than an insurer or pharmacy benefit manager performing utilization
7 review for its own policy or plan.

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12 medical practice. If such clinical practice guidelines are unavailable, the insurer,
13 pharmacy benefit manager, or utilization review organization shall derive clinical
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16 utilization review organization shall continually update the clinical review criteria
17 based on an update to the clinical practice guidelines or a review of new evidence and
18 research and newly developed treatments.

19 (b) Any individual involved in establishing a step therapy protocol under this
20 subsection shall disclose to the insurer, pharmacy benefit manager, or utilization
21 review organization any potential conflict of interest due to a financial or other
22 relationship or payment from a pharmaceutical manufacturer and shall recuse
23 himself or herself from voting on a decision regarding the step therapy protocol if he
24 or she has a conflict of interest.

1 (c) An insurer, pharmacy benefit manager, or utilization review organization
2 shall describe on its Internet site the process and criteria used for selecting and
3 evaluating clinical practice guidelines used under par. (a) to develop step therapy
4 protocols.

5 (d) Nothing in this subsection shall be construed to require insurers, pharmacy
6 benefit managers, or the state to create a new entity to develop clinical review
7 criteria used for step therapy protocols.

8 **(3) TRANSPARENCY OF EXCEPTIONS PROCESS.** (a) When coverage of a prescription
9 drug for the treatment of any medical condition is restricted for use by an insurer,
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11 step therapy protocol, the insurer, pharmacy benefit manager, or utilization review
12 organization shall provide access to a clear, readily accessible and convenient process
13 to request an exception to the step therapy protocol. An insurer, pharmacy benefit
14 manager, or utilization review organization may use any existing medical exceptions
15 process to satisfy the requirement under this paragraph. The exception process shall
16 be made easily accessible on the Internet site of the insurer, pharmacy benefit
17 manager, or utilization review organization.

18 (b) An insurer, pharmacy benefit manager, or utilization review organization
19 shall grant an exception to the step therapy protocol if the prescribing provider
20 submits complete, [↑] (and) clinically relevant written documentation (and clinical
21 rationale) supporting a step therapy exception request and any of the following are
22 satisfied:

23 1. The prescription drug required under the step therapy protocol is
24 contraindicated or, due to a documented adverse event with a previous use or a

1 documented medical condition, including a comorbid condition, is likely to do any of
2 the following:

3 a. Cause a serious adverse reaction in the patient.

4 b. Decrease the ability to achieve or maintain reasonable functional ability in
5 performing daily activities.

6 c. Cause physical or psychiatric harm to the patient.

7 2. The prescription drug required under the step therapy protocol is expected
8 to be ineffective based on all of the following:

9 a. Sound clinical evidence or medical and scientific evidence.

10 b. The known clinical characteristics of the patient.

11 c. The known characteristics of the prescription drug regimen as described in
12 peer-reviewed literature or the manufacturer's prescribing information for the
13 prescription drug.

14 3. The patient has tried the prescription drug required under the step therapy
15 protocol, or another prescription drug in the same pharmacologic class or with the
16 same mechanism of action, under the policy or plan or a previous policy or plan, the
17 patient was adherent to the prescription drug regimen for a time that allows for a
18 positive treatment outcome, and the patient's use of the prescription drug was
19 discontinued by the patient's provider due to lack of efficacy or effectiveness,
20 diminished effect, or adverse event. Nothing in this subdivision ^{does not} prohibits an insurer,
21 pharmacy benefit manager, or utilization review organization from requiring a
22 patient to try another drug in the same pharmacologic class or with the same
23 mechanism of action if that therapy sequence is supported by clinical review criteria
24 under sub. (2) (a).

1 4. The patient is stable on a prescription drug selected by his or her health care
2 provider for the medical condition under consideration while covered under the
3 policy or plan or a previous policy or plan.

4 (c) Nothing in this subsection shall be construed to allow the use of a
5 pharmaceutical sample to satisfy a criterion for an exception to a step therapy
6 protocol.

7 (d) Upon granting an exception to the step therapy protocol under par. (b), the
8 insurer, pharmacy benefit manager, or utilization review organization shall
9 authorize coverage for the prescription drug prescribed by the patient's treating
10 health care provider to the extent the prescribed drug is covered under the patient's
11 policy or plan.

12 (e) An insured may appeal any request for an exception to the step therapy
13 protocol that is denied.

14 (f) An insurer, pharmacy benefit manager, or utilization review organization
15 shall grant or deny a request for any exception to the step therapy protocol within
16 3 business days of receipt of the complete, ^eand clinically relevant written
17 documentation and clinical rationale required under par. (b) to support a step
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19 previous decision that includes the complete, ^eand clinically relevant written
20 documentation and clinical rationale supporting a step therapy exception request.
21 In exigent circumstances, an insurer, pharmacy benefit manager, or utilization
22 review organization shall grant or deny a request for an exception to the step therapy
23 protocol by the end of the next business day after receipt of the complete, ^eand
24 clinically relevant written documentation and clinical rationale supporting a step
25 therapy exception request under par. (b). If the insurer, pharmacy benefit manager,

1 or utilization review organization does not grant or deny a request or an appeal under
2 the time specified under this paragraph, the exception is considered granted.

3 (g) Nothing in this subsection shall be construed to prevent any of the following:

4 1. An insurer, pharmacy benefit manager, or utilization review organization
5 from requiring a patient to try an A-rated generic equivalent prescription drug, as
6 designated by the federal food and drug administration, or a biosimilar, as defined
7 under 42 USC 262 (i) (2), before providing coverage for the equivalent brand name
8 prescription drug.

9 2. A health care provider from prescribing a prescription drug that is
10 determined to be medically appropriate.

11 (4) RULES. The commissioner shall promulgate any rules necessary to
12 implement or enforce this section.

13 **SECTION 2. Initial applicability.**

14 (1) For policies and plans containing provisions inconsistent with this act, the
15 act first applies to policy or plan years beginning on January 1 of the year following
16 the year in which this subsection takes effect.

17 **SECTION 3. Effective date.**

18 (1) This act takes effect on the first day of the 4th month beginning after
19 publication.

20 (END)



Per Rachel, please flip 80016/P3 to /4 and jacket



State of Wisconsin
2019 - 2020 LEGISLATURE

LRBs0016/P3

TJD:ah&kjf

1

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION
SENATE SUBSTITUTE AMENDMENT ,
TO SENATE BILL 26

IN 3/25
Requested ASAP
today pls
NO CHANGES

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exception to the step therapy protocol if the prescribing provider submits complete, clinically relevant written documentation supporting the request and any of the circumstances specified in the bill apply, including when the drug is contraindicated for the patient or will likely cause a serious adverse event for the patient; the drug is expected to be ineffective based on certain evidence and the known characteristics of the patient and the drug regimen; the patient previously tried the drug or a similar drug and its use by the patient was discontinued under circumstances described in the bill; or the patient is stable on a different drug under this or a previous policy or plan. Upon granting an exception to the step therapy protocol, the insurer, pharmacy benefit manager, or utilization review organization must authorize coverage for the drug prescribed by the patient's treating health care provider to the extent the drug is covered under the patient's policy or plan. An insured may appeal a denied request for an exception to the step therapy protocol. An insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for an exception within three business days, or by the end of the next business day in exigent circumstances, of receipt of supporting documentation. If this deadline is not met, the exception is considered granted.

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8 pharmacy benefit manager, or utilization review organization to determine whether
9 health care services are medically necessary and appropriate.

10 (c) "Exigent circumstances" means when a patient is suffering from a health
11 condition that may seriously jeopardize the patient's life, health, or ability to regain
12 maximum function.

13 (d) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

1 (e) "Step therapy protocol" means a protocol or program that establishes the
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11 from peer-review publications, evidence-based research, and widely accepted
12 medical practice. If such clinical practice guidelines are unavailable, the insurer,
13 pharmacy benefit manager, or utilization review organization shall derive clinical
14 review criteria from peer-reviewed publications, evidence-based research, and
15 widely accepted medical practice. The insurer, pharmacy benefit manager, or
16 utilization review organization shall continually update the clinical review criteria
17 based on an update to the clinical practice guidelines or a review of new evidence and
18 research and newly developed treatments.

19 (b) Any individual involved in establishing a step therapy protocol under this
20 subsection shall disclose to the insurer, pharmacy benefit manager, or utilization
21 review organization any potential conflict of interest due to a financial or other
22 relationship or payment from a pharmaceutical manufacturer and shall recuse
23 himself or herself from voting on a decision regarding the step therapy protocol if he
24 or she has a conflict of interest.

1 (c) An insurer, pharmacy benefit manager, or utilization review organization
2 shall describe on its Internet site the process and criteria used for selecting and
3 evaluating clinical practice guidelines used under par. (a) to develop step therapy
4 protocols.

5 (d) Nothing in this subsection shall be construed to require insurers, pharmacy
6 benefit managers, or the state to create a new entity to develop clinical review
7 criteria used for step therapy protocols.

8 **(3) TRANSPARENCY OF EXCEPTIONS PROCESS.** (a) When coverage of a prescription
9 drug for the treatment of any medical condition is restricted for use by an insurer,
10 pharmacy benefit manager, or utilization review organization through the use of a
11 step therapy protocol, the insurer, pharmacy benefit manager, or utilization review
12 organization shall provide access to a clear, readily accessible and convenient process
13 to request an exception to the step therapy protocol. An insurer, pharmacy benefit
14 manager, or utilization review organization may use any existing medical exceptions
15 process to satisfy the requirement under this paragraph. The exception process shall
16 be made easily accessible on the Internet site of the insurer, pharmacy benefit
17 manager, or utilization review organization.

18 (b) An insurer, pharmacy benefit manager, or utilization review organization
19 shall grant an exception to the step therapy protocol if the prescribing provider
20 submits complete, clinically relevant written documentation supporting a step
21 therapy exception request and any of the following are satisfied:

22 1. The prescription drug required under the step therapy protocol is
23 contraindicated or, due to a documented adverse event with a previous use or a
24 documented medical condition, including a comorbid condition, is likely to do any of
25 the following:

1 a. Cause a serious adverse reaction in the patient.

2 b. Decrease the ability to achieve or maintain reasonable functional ability in
3 performing daily activities.

4 c. Cause physical or psychiatric harm to the patient.

5 2. The prescription drug required under the step therapy protocol is expected
6 to be ineffective based on all of the following:

7 a. Sound clinical evidence or medical and scientific evidence.

8 b. The known clinical characteristics of the patient.

9 c. The known characteristics of the prescription drug regimen as described in
10 peer-reviewed literature or the manufacturer's prescribing information for the
11 prescription drug.

12 3. The patient has tried the prescription drug required under the step therapy
13 protocol, or another prescription drug in the same pharmacologic class or with the
14 same mechanism of action, under the policy or plan or a previous policy or plan, the
15 patient was adherent to the prescription drug regimen for a time that allows for a
16 positive treatment outcome, and the patient's use of the prescription drug was
17 discontinued by the patient's provider due to lack of efficacy or effectiveness,
18 diminished effect, or adverse event. This subdivision does not prohibit an insurer,
19 pharmacy benefit manager, or utilization review organization from requiring a
20 patient to try another drug in the same pharmacologic class or with the same
21 mechanism of action if that therapy sequence is supported by clinical review criteria
22 under sub. (2) (a).

23 4. The patient is stable on a prescription drug selected by his or her health care
24 provider for the medical condition under consideration while covered under the
25 policy or plan or a previous policy or plan.

1 (c) Nothing in this subsection shall be construed to allow the use of a
2 pharmaceutical sample to satisfy a criterion for an exception to a step therapy
3 protocol.

4 (d) Upon granting an exception to the step therapy protocol under par. (b), the
5 insurer, pharmacy benefit manager, or utilization review organization shall
6 authorize coverage for the prescription drug prescribed by the patient's treating
7 health care provider to the extent the prescribed drug is covered under the patient's
8 policy or plan.

9 (e) An insured may appeal any request for an exception to the step therapy
10 protocol that is denied.

11 (f) An insurer, pharmacy benefit manager, or utilization review organization
12 shall grant or deny a request for any exception to the step therapy protocol within
13 3 business days of receipt of the complete, clinically relevant written documentation
14 required under par. (b) to support a step therapy exception request under par. (b) or
15 the receipt of a request to appeal a previous decision that includes the complete,
16 clinically relevant written documentation supporting a step therapy exception
17 request. In exigent circumstances, an insurer, pharmacy benefit manager, or
18 utilization review organization shall grant or deny a request for an exception to the
19 step therapy protocol by the end of the next business day after receipt of the complete,
20 clinically relevant written documentation supporting a step therapy exception
21 request under par. (b). If the insurer, pharmacy benefit manager, or utilization
22 review organization does not grant or deny a request or an appeal under the time
23 specified under this paragraph, the exception is considered granted.

24 (g) Nothing in this subsection shall be construed to prevent any of the following:

