



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

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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.

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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:

- 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.

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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.

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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:

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.

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.

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.

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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.

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.

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
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
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

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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.

SECTION 2. Initial applicability.

7
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.

SECTION 3. Effective date.

11
12 (1) This act takes effect on the first day of the 4th month beginning after
13 publication.

14 (END)