



## WISCONSIN LEGISLATIVE COUNCIL ACT MEMO

**2019 Wisconsin Act 12**  
[2019 Senate Bill 26]

**Step Therapy Protocols**

2019 Wisconsin Act 12 sets specifications on the development and use of, and exceptions to, step therapy protocols for prescription drug coverage. “Step therapy protocol” is defined under the act as a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, whether self-administered or physician-administered, that are medically appropriate for a particular patient are covered under a policy or plan.

The act does all of the following: (1) sets clinical review criteria that apply to an insurer, pharmacy benefit manager, or utilization review organization that establishes a step therapy protocol; (2) mandates an exception process to a step therapy protocol; and (3) sets a time frame for an insurer, pharmacy benefit manager, or utilization review organization to make a decision on a step therapy exception request.

### CLINICAL REVIEW CRITERIA

The act provides that, when establishing a step therapy protocol, an insurer, pharmacy benefit manager, or utilization review organization must use clinical review criteria<sup>1</sup> that are based on clinical practice guidelines<sup>2</sup> that are derived from peer-review publications, evidence-based research, and widely accepted medical practice. If such clinical practice guidelines are unavailable, the insurer, pharmacy benefit manager, or utilization review organization must

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<sup>1</sup> The act defines “clinical review criteria” as written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by an insurer, pharmacy benefits manager, or utilization review organization to determine whether health care services are medically necessary and appropriate.

<sup>2</sup> The act defines a “clinical practice guideline” as a systemically developed statement to assist decision making by health care providers and patients about appropriate health care for specific clinical circumstances and conditions.

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This memo provides a brief description of the act. For more detailed information, consult the text of the law and related legislative documents at the Legislature’s Web site at: <http://www.legis.wisconsin.gov>.

derive clinical review criteria from peer-reviewed publications, evidence-based research, and widely accepted medical practice. The insurer, pharmacy benefit manager, or utilization review organization is also required to continually update the clinical review criteria based on an update to the clinical practice guidelines or a review of new evidence and research and newly developed treatments.

The act also provides that any individual involved in establishing a step therapy protocol must disclose to the insurer, pharmacy benefit manager, or utilization review organization any potential conflict of interest due to a financial or other relationship or payment from a pharmaceutical manufacturer and must recuse himself or herself from voting on a decision regarding the step therapy protocol if he or she has a conflict of interest. Additionally, the act requires an insurer, pharmacy benefit manager, or utilization review organization to describe on its Internet site the process and criteria used for selecting and evaluating clinical practice guidelines used to develop step therapy protocols.

The act also provides that insurers, pharmacy benefit managers, or the state are not required to create a new entity to develop clinical review criteria used for step therapy protocols.

### **STEP THERAPY EXCEPTIONS PROCESS**

The act requires an insurer, pharmacy benefit manager, or utilization review organization to provide a clear, readily accessible, and convenient process to request an exception to a step therapy protocol used when coverage of a prescription drug is restricted by the insurer, pharmacy benefit manager, or utilization review organization. An insurer, pharmacy benefit manager, or utilization review organization may use any existing medical exceptions process to satisfy this requirement, and the exception process must be made easily accessible on the entity's Internet site.

The act requires an insurer, pharmacy benefit manager, or utilization review organization to grant an exception to a step therapy protocol if the prescribing provider submits complete, clinically relevant written documentation supporting a step therapy exception request and any of the following are satisfied:

- 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 cause a serious adverse reaction in the patient, decrease the ability to achieve or maintain reasonable functional ability in performing daily activities, or cause physical or psychiatric harm to the patient.
- The prescription drug required under the step therapy protocol is expected to be ineffective based on sound clinical evidence or medical and scientific evidence, the known clinical characteristics of the patient, and the known characteristics of the prescription drug regimen as described in peer-reviewed literature or the manufacturer's prescribing information for the prescription drug.
- 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 time that allows 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.<sup>3</sup>

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

The act provides that an insurer, pharmacy benefit manager, or utilization review organization must authorize coverage for the prescription drug prescribed by the patient's treating health care provider upon granting an exception to a step therapy protocol and that an insured may appeal any request for an exception to the step therapy protocol that is denied. The act also clarifies that its provisions do not allow the use of a pharmaceutical sample to satisfy a criterion for a step therapy protocol exception, and that the act must not be construed to prevent either an insurer, pharmacy benefit manager, or utilization review organization from requiring a patient to try certain generic equivalent prescription drugs before providing coverage for the equivalent brand name drug, or a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

### **EXCEPTION REQUEST DECISION TIMING**

The act provides that an insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for any exception to the step therapy protocol within three business days of receipt of the complete, clinically relevant written documentation required to support a step therapy exception request or the receipt of a request to appeal a previous decision that includes the complete, clinically relevant written documentation supporting a step therapy exception request.

In exigent circumstances<sup>4</sup>, an insurer, pharmacy benefit manager, or utilization review organization must grant or deny a request for an exception to the step therapy protocol by the end of the next business day after receipt of the complete, clinically relevant written documentation 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, the exception is considered granted.

### **OTHER PROVISIONS**

The act also requires the commissioner of insurance to promulgate any rules necessary to implement or enforce step therapy protocol requirements, and specifies that the provisions of

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<sup>3</sup> The act provides that this specific criterion under which a step therapy protocol exception must be granted 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 clinical review criteria.

<sup>4</sup> The act defines "exigent circumstances" as when a patient is suffering from a health condition that may seriously jeopardize the patient's life, health, or ability to regain maximum function.

the act first applies to policies and plans inconsistent with the step therapy protocol requirements beginning on January 1st of the year following the year in which the provisions take effect.

*Effective date:* November 1, 2019

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