

Legal Brief

Prescriptions - Step Therapy Protocols

This Legal Brief was drafted for general informational purposes only. It is not meant to be a comprehensive guide, nor should it be construed as legal advice. The information in this brief is current as of July 1, 2020; readers should consult the most recent versions of referenced statutes, regulations, and cases to ensure there have been no material changes.

Summary

For health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2021, a health carrier, health benefit plan, or utilization review organization may institute a step therapy protocol

A health care provider may request a step therapy protocol exception when the coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization under a step therapy protocol. The health carrier, health benefit plan, or utilization review organization shall make a determination as to whether to make a step therapy override exception within five calendar days; urgent requests must be completed within 72-hours.

Upon written request of a covered person, a health carrier, health benefit plan, or a utilization review organization shall provide any clinical review criteria applicable to a specific prescription drug covered by the health carrier, health benefit plan, or utilization review organization.

Discussion

Definition

“Step therapy protocol” is a protocol or program that establishes a specific sequence in which prescription drugs are covered under a pharmacy or medical benefit by a health carrier, a health benefit plan, or a utilization review organization for a specified medical condition and medically appropriate for a health carrier, a health benefit plan, or utilization review organization, including self-administered drugs and drugs administered by a health care professional.

Discussion

For health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2021, a health carrier, health benefit plan, or utilization review organization may institute a step therapy protocol. When establishing a step therapy protocol, a health carrier, health benefit plan, or utilization review organization shall consider available recognized evidence-based and peer-reviewed clinical practice guidelines. Upon written request of a covered person, a health carrier, health benefit plan, or utilization review organization shall provide any clinical review criteria applicable to a specific prescription drug covered by the health carrier, health benefit plan, or utilization review organization.

When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization through the use of a step therapy protocol, the covered person and the prescribing health care professional shall have access to a clear, readily accessible, and convenient process to request a step therapy override exception. A health carrier, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy this requirement.

The process used shall be easily accessible on the internet site of the health carrier, health benefit plan, or utilization review organization.

A step therapy override exception shall be approved by a health carrier, health benefit plan, or utilization review organization if any of the following circumstances apply:

1. The prescription drug required under the step therapy protocol is contraindicated pursuant to the drug manufacturer's prescribing information for the drug 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 a covered person;
 - (b) Decrease the ability of a covered person to achieve or maintain reasonable functional ability in performing daily activities;
 - (c) Cause physical or mental harm to a covered person;
2. The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person, such as the covered person's adherence to or compliance with the covered person's individual plan of care, and any of the following:
 - (a) The known characteristics of the prescription drug regimen as described in peer-reviewed literature or in the manufacturer's prescribing information for the drug;
 - (b) The health care professional's medical judgment based on clinical practice guidelines or peer-reviewed journals;
 - (c) The covered person's documented experience with the prescription drug regimen;
3. The covered person has had a trial of a therapeutically equivalent dose of the prescription drug under the step therapy protocol while under the covered person's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and such prescription drug was discontinued by the covered person's health care professional due to lack of effectiveness;
4. The covered person is currently receiving a positive therapeutic outcome on a prescription drug selected by the covered person's health care professional for the medical condition under consideration while under the covered person's current or previous health benefit plan. However, this circumstance may 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.

Upon approval of a step therapy override exception, the health carrier, health benefit plan, or utilization review organization shall authorize coverage for the prescription drug selected by the covered person's prescribing health care professional if the prescription drug is a covered prescription drug under the covered person's health benefit plan.

Except in the case of an urgent care request, a health carrier, health benefit plan, or utilization review organization shall make a determination to approve or deny a request for a step therapy override exception within five calendar days after receipt of complete, clinically relevant written documentation supporting a step therapy override exception under circumstances 1-4 listed above.

In the case of an urgent care request, a health carrier, health benefit plan, or utilization review organization shall approve or deny a request for a step therapy override exception within seventy-two hours after receipt of such documentation. Of note, the applicable time period for approval or denial begins upon the submission of all required information. If the health carrier, health benefit plan, or utilization review organization request additional "clinically relevant" information for the purpose of making a determination, the time period restarts upon the submission of the additional information.

Notwithstanding the step therapy protocol requirements and override exceptions, a health carrier, health benefit plan, or utilization review organization may require a covered person to try a prescription drug with the same generic name and demonstrated bioavailability or biological product that is an interchangeable biological product pursuant to SDCL §§ 36-11-46.1 and 36-11-46.9 before providing coverage for the equivalent branded prescription product. Additionally, notwithstanding the above requirements, nothing in the step therapy protocol statutes prohibits a health care professional from prescribing a prescription drug that is determined to be medically necessary.

Conclusion

A health care provider may request a step therapy protocol exception when the coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization pursuant to a step therapy protocol.

The health carrier, health benefit plan, or utilization review organization shall make a determination as to whether to make a step therapy override exception within five calendar days; urgent requests must be completed within 72-hours.

Upon written request of a covered person, a health carrier, health benefit plan, or a utilization review organization shall provide any clinical review criteria applicable to a specific prescription drug covered by the health carrier, health benefit plan, or utilization review organization.

Sources:

SDCL 58-17H-1; SDCL 58-17H-53; SDCL 58-17H-54; SDCL 55-17H-55; SDCL 58-17H-56; SDCL 58-17-156



SDSMA gratefully acknowledges the SDSMA Foundation for its support of this publication through funds awarded by The Physicians Foundation.