[N.M. Stat. § 13-7-18.]

§ 13-7-18. Prescription drug coverage; step therapy protocols; clinical review criteria; exception: Health Care Purchasing Act

A. Group health coverage, including any form of self-insurance, offered, issued or renewed under the Health Care Purchasing Act that provides coverage for prescription drugs for which any step therapy protocols are required shall establish clinical review criteria for those step therapy protocols. The clinical review criteria shall be based on clinical practice guidelines that:

1. recommend that the prescription drugs subject to step therapy protocols be taken in the specific sequence required by the step therapy protocol;

2. are developed and endorsed by an interdisciplinary panel of experts that manages conflicts of interest among the members of the panel of experts by:

   a. requiring members to: 1) disclose any potential conflicts of interest with group health plan administrators, insurers, health maintenance organizations, health care plans, pharmaceutical manufacturers, pharmacy benefits managers and any other entities; and 2) recuse themselves if there is a conflict of interest; and

   b. using analytical and methodological experts to work to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus;

3. are based on high-quality studies, research and medical practice;

4. are created pursuant to an explicit and transparent process that:

   a. minimizes bias and conflicts of interest;

   b. explains the relationship between treatment options and outcomes;

   c. rates the quality of the evidence supporting recommendations; and

   d. considers relevant patient subgroups and preferences; and

5. take into account the needs of atypical patient populations and diagnoses.

B. In the absence of clinical guidelines that meet the requirements of Subsection A of this section, peer-reviewed publications may be substituted.
C. When a group health plan restricts coverage of a prescription drug for the treatment of any medical condition through the use of a step therapy protocol, an enrollee and the practitioner prescribing the prescription drug shall have access to a clear, readily accessible and convenient process to request a step therapy exception determination. A group health plan may use its existing medical exceptions process in accordance with the provisions of Subsections D through I of this section to satisfy this requirement. The process shall be made easily accessible for enrollees and practitioners on the group health plan’s publicly accessible website.

D. A group health plan shall expeditiously grant an exception to the group health plan’s step therapy protocol, based on medical necessity and a clinically valid explanation from the patient’s prescribing practitioner as to why a drug on the plan’s formulary that is therapeutically equivalent to the prescribed drug should not be substituted for the prescribed drug, if:

1. the prescription drug that is the subject of the exception request is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient;

2. the prescription drug that is the subject of the exception request is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

3. while under the enrollee’s current health coverage or previous health coverage, the enrollee has tried the prescription drug that is the subject of the exception request or another prescription drug in the same pharmacologic class or with the same mechanism of action as the prescription drug that is the subject of the exception request and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event; or

4. the prescription drug required pursuant to the step therapy protocol is not in the best interest of the patient, based on clinical appropriateness, because the patient’s use of the prescription drug is expected to:
   (a) cause a significant barrier to the patient’s adherence to or compliance with the patient’s plan of care;
   (b) worsen a comorbid condition of the patient; or
   (c) decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities.

E. Upon the granting of an exception to a group health plan’s step therapy protocol, the group health plan administrator shall authorize coverage for the prescription drug that is the subject of the exception request.

F. A group health plan shall respond with its decision on an enrollee’s exception request within seventy-two hours of receipt. In cases where exigent circumstances exist, a group health plan shall respond within twenty-four hours of receipt of the exception request. In the event the group health plan does not respond to an exception request within the time frames required pursuant to this subsection, the exception request shall be granted.
G. A group health plan administrator's denial of a request for an exception for step therapy protocols shall be subject to review and appeal pursuant to the Patient Protection Act [Chapter 59A, Article 57 NMSA 1978].

H. After an enrollee has made an exception request in accordance with the provisions of this section, a group health plan shall authorize continued coverage of a prescription drug that is the subject of the exception request pending the determination of the exception request.

I. The provisions of this section shall not be construed to prevent a:

1. group health plan from requiring a patient to try a generic equivalent of a prescription drug before providing coverage for the equivalent brand-name prescription drug; or

2. practitioner from prescribing a prescription drug that the practitioner has determined to be medically necessary.

J. The provisions of this section shall apply only to a group health plan delivered, issued for delivery or renewed on or after January 1, 2019.

K. As used in this section, "medical necessity" or "medically necessary" means health care services determined by a practitioner, in consultation with the group health plan administrator, to be appropriate or necessary according to:

1. any applicable, generally accepted principles and practices of good medical care;

2. practice guidelines developed by the federal government or national or professional medical societies, boards or associations; or

3. any applicable clinical protocols or practice guidelines developed by the group health plan consistent with federal, national and professional practice guidelines. These standards shall be applied to decisions related to the diagnosis or direct care and treatment of a physical or behavioral health condition, illness, injury or disease.