STATE OF NEW MEXICO
OFFICE OF SUPERINTENDENT OF INSURANCE

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UPDATED BULLETIN 2025-005

August 14, 2025

TO: HEALTH INSURERS THAT OFFER OR ADMINISTER HEALTH BENEFIT PLANS SUBJECT TO THE PRIOR AUTHORIZATION ACT IN NEW MEXICO

RE: SENATE BILL 39, ADD CLASSES TO PRIOR AUTHORIZATION DRUGS

This is an update to Bulletin No. 2025-005, dated August 1, 2025, references to "calendar days" have been changed to "business days" on page 3 and page 4.

Senate Bill 39 (SB39) was signed into law by Governor Michelle Lujan Grisham on April 7, 2025, and became effective July 1, 2025. SB39 amends the Prior Authorization Act, NMSA 1978, Sections 59A-22B-2, 59A-22B-5, and 59A-22B-8 to include the following:

- removes prior-authorization and/or step therapy requirements for Food & Drug Administration (FDA) approved drugs used off-label for the treatment of rare diseases or conditions;
- requires coverage for these medications to be made pursuant to a medical necessity determination made by a health care professional from the same or similar practice specialty that typically manages the medical condition, procedure, or treatment under review;
- sets time frames for medical necessity determinations; and
- amended the definition for "prior authorization" and added new definitions to include "off label" and "rare disease or condition" in NMSA 1978, Section 59A-22B-2.

To ensure equal application of the provisions of SB39 and the requirements with respect to health plan coverage, the New Mexico Office of Superintendent of Insurance (OSI) provides further clarification and directs every subject health plan to comply with the following:

DEFINITIONS:

NMSA 1978, Section 59A-22B-2 of the Prior Authorization Act amended the definition of "prior authorization" to include mandatory and voluntary preservice determinations. It defines "off label" as "an FDA approved medication that does not have an FDA approved indication for a specific condition or disease but is prescribed to a covered person because there is sufficient clinical evidence for a prescribing clinician to reasonably consider the medication to be medically necessary to treat a covered person's condition or disease. Finally, it defines a "rare disease or condition" as a disease or condition that affects fewer than two hundred thousand people in the United States.

- Health insurers need to update their compliance documents and impacted forms to reflect these changes.
- OSI strongly encourages carriers to develop an active method of notification to the covered person when a request for prior authorization has been initiated.

PRIOR AUTHORIZATION PROHIBITIONS:

Prior authorization for prescription drugs or step therapy for the treatment of an autoimmune disorder, cancer, rare disease or condition or a substance abuse disorder is prohibited.

NMSA 1978, Section 59A-22B-8(A) was amended to include "rare disease or condition" in the list of medical conditions that cannot be subject to prior authorization. It is important to note that the prior authorization prohibition does not apply in cases in which a biosimilar, interchangeable biologic, or generic version is available. These reviews must be made by a health care professional from the same or similar practice specialty that typically manages the medical condition, procedure or treatment under review. Similarly, the health care provider who is managing the patient's rare disease or condition must have a baseline understanding of the nature of the patient's rare disease or condition and treatment or seek the help of someone in the same or

similar specialty and act under their direction even if that specialist is not available within the state. To ensure medically necessary determinations are completed in a timely manner, Subsection A of NMSA 1978, Section 59A-22B-8 was further amended to specify time frames for medically necessary determinations as follows:

- seven business days for standard determinations; and
- twenty-four hours for emergency determinations when a delay in treatment could be harmful to the patient.

The above referenced time frames begin for a medical necessity determination once notice for treatment of a rare disease or condition has been received by the health insurer. Medical necessity determinations shall be automatically approved if a health insurer does not meet the above response time frames. All processes for medical necessity determinations shall be reflected in members and providers facing materials as part of the entire contract.

NMSA 1978, Section 59A-22B-8(B) prohibits step therapy requirements on FDA approved medications prescribed for the treatment of an autoimmune disorder, cancer or substance use disorder pursuant to a medical necessity determination provided by a health care professional from the same or similar practice specialty that typically manages the medical condition, procedure or treatment under review. Step therapy cannot be applied when a medication is prescribed for the treatment of a rare disease or condition as treatment for most rare diseases is often limited by cost, availability, FDA approval and lack of treatment protocols. Step therapy is allowed in cases in which a biosimilar, interchangeable biologic or generic version is available for cost-containing purposes.

Rare diseases are addressed in NMSA 1978, Section 59A-22B-8(C) specifying that a health insurer shall not impose step therapy requirements before authorizing coverage for an off-label medication that is an FDA approved medication when it is prescribed for the treatment of a rare disease or condition, pursuant to a medical necessity determination. Subsection C of NMSA 1978, Section 59A-22B-8 specifies time frames for medically necessary determinations as stated in NMSA 1978, Section 59A-22B-8(A):

- seven business days for standard determinations; and
- twenty-four hours for emergency determinations when a delay in treatment could be harmful to the patient

The above referenced time frames begin for a medical necessity determination once notice for treatment of a rare disease or condition has been received by the health insurer. Medical necessity determinations shall be automatically approved if a health insurer does not meet the above response time frames.

For non-formulary medications, determination of medical necessity shall concurrently serve as the basis for exception request review; separate submission or evaluation processes shall not be required.

When medical necessity is determined by a healthcare professional of the same or similar specialty, off-label medication used in the treatment of rare diseases or conditions shall be exempt from prior authorization or step therapy protocols.

Health Insurers must develop internal processes for checking approved FDA drugs and rare disease statuses and submit to OSI as evidence of compliance.

Filings must be submitted via SERFF using the following instructions:

- TOI: H21- Health – Other
- Sub TOI: H21.000 Health-Other
- Filing Type: Informational
- The Project Name: [year]_Off-Label Use Policy for Treatment of Rare Diseases
- The Requested Filing Mode: Informational

Applicability:

All health insurers that issue or offer to issue a policy or certificate in the fully insured health insurance market on or after July 1, 2025, must comply with the requirements of SB39 and this Bulletin. There is no impact to those individual and group policies that were issued prior to July 1, 2025.

Any person aggrieved by a bulletin may request a hearing before the Superintendent in accordance with Section NMSA 1978, 59A-4-15.

Please direct any questions concerning this guidance to danelle.callan@osi.nm.gov.

ISSUED this 14th day of August 2025.

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