LFC Requestor: Self Assigned

2025 LEGISLATIVE SESSION
AGENCY BILL ANALYSIS

Section I: General

Chamber: Senate
Category: Bill
Number: 39
Type: Introduced

Date (of **THIS** analysis)**:** 2/10/2025
Sponsor(s): Elizabeth ”Liz” Stefanics, Reena Szczepanski, Mimi Stewart and Carrie Hamblen
Short Title: Add Classes to Prior Authorization Drugs

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Section II: Fiscal Impact

APPROPRIATION (dollars in thousands)

Appropriation Contained		Recurring or Nonrecurring	Fund Affected
FY 25	FY 26		
$ 0.00	$ 0.00	N/A	N/A

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY 25	FY 26	FY 27		
$ 0.00	$ 0.00	$ 0.00	N/A	N/A

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY 25	FY 26	FY 27	3 Year Total Cost	Recurring or Non-recurring	Fund Affected
Total	$ 0.00	$ 0.00	$ 0.00	$ 0.00	N/A	N/A

Section III: Relationship to other legislation

Duplicates: None

Conflicts with: None

Companion to: None

Relates to: SB 207 Add Classes to Prior Authorization Drugs for certain health conditions

Duplicates/Relates to an Appropriation in the General Appropriation Act: N/A

Section IV: Narrative

1. BILL SUMMARY

a) Synopsis

SB39 proposes to amend the Prior Authorization Act to add more classes of drugs that will not be subject to step therapy or prior authorization. These would include medications used with an off-label indications and rare diseases/conditions. The prescriber would need to determine medical necessity and would only require prior authorization when a biolosimilar or generic biologic is available. The bill would also require determinations for approval be made within 7 days for standard determinations and 24 hours for emergency determinations.

Is this an amendment or substitution? ☐ Yes ☒ No

Is there an emergency clause? ☐ Yes ☒ No

b) Significant Issues

The Orphan Drug Act defines a rare disease as a disease or condition that affects less than 200,000 people in the United States. There are approximately 25-30 million are affected by those rare diseases in the United States and approximately 50% of individuals with rare diseases are children. Only 5-7% of rare diseases have an FDA approved treatment. Due to the lack of FDA approved treatments, most medication is prescribed off-label. In general, insurers and pharmacy benefit managers (PBM) will not reimburse off-label use of drugs or medical devices. Patients are required to mostly pay out of pocket or provide additional paperwork which delays medication access. These patients are forced to pay thousands of dollars just to access therapies prescribed by their physician. https://pmc.ncbi.nlm.nih.gov/articles/PMC8630459/#:~:text=Due%20to%20the%20rejection%20of,label%20(10%2C11).

Utilization management protocols, such as prior authorization, are tools that can help control costs and prevent the overuse of health care services. However, when used improperly or without consideration of a patient's unique medical situation or history, utilization management can delay necessary treatment by weeks or even months and aggravate health inequities. According to a survey of rare disease patients and caregivers conducted by NORD in 2019, 61% of people with

rare disorders have been denied, or faced delays accessing treatments that required pre-approval from an insurance company (including prescription drugs, medical devices or other treatments). In addition, 18% of respondents reported they were denied a referral to a specialist. Respondents earning less than $20,000 per year were twice as likely to be denied referral to a specialist compared to those earning $100,000 or more. https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report_FNL-2.pdf

For patients with rare diseases, the impact of inappropriate step therapy is especially severe. These individuals often endure years-long diagnostic journeys before finding a treatment that works. Forcing them to deviate from an established and effective therapy undermines and can negatively impact their health and recovery. For example, patients who switch insurance plans may be required by their new insurer to go off a successful treatment and take a less effective medicine, jeopardizing their stability and, in some cases, their health outcomes. https://rarediseases.org/policy-issues/step-therapy-fail-first/

Across health plans, variations in coverage, utilization management (such as prior authorization and step therapy), and plan tiering create access barriers for individuals with rare conditions. Many of the treatment criteria and diagnostic testing variants were not consistent with clinical practice guidelines (where available or applicable) or FDA label indications. The variation in coverage across plans for the same medication—such as coverage for orphan drugs (novel therapies used for rare conditions or clinical presentations) and high-frequency utilization management for therapies that treat rare conditions—creates significant complexities for individuals and families in navigating insurance coverage.https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report_FNL-2.pdf

2. PERFORMANCE IMPLICATIONS

- Does this bill impact the current delivery of NMDOH services or operations?

  ☐ Yes ☒ No

  If yes, describe how.

- Is this proposal related to the NMDOH Strategic Plan? ☒ Yes ☐ No

  ☐ **Goal 1**: We expand equitable access to services for all New Mexicans

  ☐ **Goal 2**: We ensure safety in New Mexico healthcare environments

  ☒ **Goal 3**: We improve health status for all New Mexicans

  ☐ **Goal 4**: We support each other by promoting an environment of mutual respect, trust, open communication, and needed resources for staff to serve New Mexicans and to grow and reach their professional goals

3. FISCAL IMPLICATIONS

- If there is an appropriation, is it included in the Executive Budget Request?

  ☐ Yes ☐ No ☒ N/A

- If there is an appropriation, is it included in the LFC Budget Request?

  ☐ Yes ☐ No ☒ N/A

- Does this bill have a fiscal impact on NMDOH? ☐ Yes ☒ No

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4. ADMINISTRATIVE IMPLICATIONS

Will this bill have an administrative impact on NMDOH? ☐ Yes ☒ No

5. DUPLICATION, CONFLICT, COMPANIONSHIP OR RELATIONSHIP

SB39 is related to SB 207, to add classes to prior authorization drugs for certain health conditions, where it outlines amendments to the Prior Authorization Act when a medical necessity is determined for either on or off label use of a prescribed medication for a rare disease.

6. TECHNICAL ISSUES

Are there technical issues with the bill? ☐ Yes ☒ No

7. LEGAL/REGULATORY ISSUES (OTHER SUBSTANTIVE ISSUES)

- Will administrative rules need to be updated or new rules written? ☐ Yes ☒ No
- Have there been changes in federal/state/local laws and regulations that make this legislation necessary (or unnecessary)? ☐ Yes ☒ No
- Does this bill conflict with federal grant requirements or associated regulations? ☐ Yes ☒ No
- Are there any legal problems or conflicts with existing laws, regulations, policies, or programs? ☐ Yes ☒ No

8. DISPARITIES ISSUES

- Health literacy may affect the ability of insured patients, their families, and caregivers to understand the coverage provided by a plan and successfully coordinate and advocate for needed services or care. https://mn.gov/commerce-stat/pdfs/Comm-AIR-HF626-EvalRprt-508.pdf
- Patients of lower socioeconomic status with health care insurance are less likely to be able to afford to pay out of pocket for medications that are denied due to off-label indication, prior-authorization, or step therapy requirements.

9. HEALTH IMPACT(S)

- For children with rare diseases, receiving an accurate diagnosis and promptly starting treatment can be critical. Delayed diagnosis leads to delayed treatment and missed opportunities for early intervention services. Many rare diseases have treatments that are most effective when started early. For example, enzyme replacement therapy for certain lysosomal storage disorders can prevent severe complications if administered promptly. Early intervention can halt or slow disease progression. For example, early use of disease-modifying therapies in spinal muscular atrophy (SMA) has significantly improved motor function and survival rates. Early intervention often improves quality of life by minimizing symptoms and preventing secondary complications. This can result in better physical and cognitive development, enabling children to lead more fulfilling lives. https://www.tgen.org/patients/center-for-rare-childhood-disorders/stories/early-intervention-is-crucial-for-better-outcomes-for-children-with-rare-diseases/#:~:text=For%20children%20with%20rare%20diseases%2C%20receiving%20a

n%20accurate%20diagnosis%20and,developmental%20potential%20and%20improve%20outcomes.

- The American Academy of Family Physicians believes step therapy protocols can delay access to treatments, hinder adherence, increase the risks of side effects, and could result in disease progression for patients. Patients should not be required to repeat protocols if they are on a current effective course of treatment. Ongoing care should ensue while step therapy approvals are obtained and should be tailored to each patient's unique clinical case. https://www.aafp.org/about/policies/all/prior-authorizations.html
- According to the National Organization for Rare Disorders, if step therapies are not implemented appropriately, necessary treatments can be delayed, leading to adverse reactions that will ultimately increase health care costs. https://rarediseases.org/policyissues/step-therapy/

10. ALTERNATIVES

30 state legislatures have established Rare Disease Advisory Councils (RDAC) through state law, which act as advisory bodies. RDACs enable states to strategically identify and address barriers that prevent individuals living with rare diseases from accessing adequate and effective treatment and care.https://rarediseases.org/policy-issues/rare-disease-advisory-councils/.

11. WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL?

If SB39 is not enacted, new sections to the Prior Authorization Act will not be enacted that prevent insurers from imposing step therapy requirements for on-label and off-label treatments of certain health conditions (autoimmune disorders, cancer, rare diseases, or substance abuse disorders).

12. AMENDMENTS

None.