



May 13, 2020

Linda VanCamp  
Formulary Analyst  
Bureau of Medicaid Care Management & Customer Service  
Medical Services Administration  
P.O. Box 30479  
Lansing, Michigan 48909-7979

**Re: Michigan Medicaid Health Plan Common Formulary**

Dear Ms. VanCamp,

On behalf of the 1-in-10 individuals in Michigan with one of the approximately 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks you for the opportunity to comment on Michigan's Medicaid Health Plan Common Formulary. Specifically, NORD is submitting comments on the policies around prior authorization and step therapy to ensure patient needs are being properly met by Michigan's Medicaid program.

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. We are committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services. NORD believes strongly that all patients deserve the medical care that is best suited for their medical situation and will give them the best results.

Unfortunately, of the 7,000 identified rare diseases, more than 90% do not have a Food and Drug Administration (FDA) approved treatment. As a result, when there is an approved treatment or other medications that are available to help treat the disease, it is important that patients are able to access them in a timely manner.

Utilization management tools like prior authorization and step therapy are often used by insurers as an attempt to control health care costs, but they can often be applied inappropriately, without consideration of the clinical practicalities. As a result, in many cases, these requirements can delay appropriate treatment and ultimately increase costs, not lower them. As the use of prior authorization and step therapy have increased, so has the need for states to ensure that these requirements do not needlessly interfere with appropriate care for patients.

Therefore, NORD recommends modifying Michigan's current prior authorization and step therapy policies in the following ways:

- Allow overrides to step therapy requests when they are not in the patients' best interest such as when:
  - the prescription drug is contraindicated or will likely cause an adverse reaction;



- the drug is not approved by the FDA;
  - the prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the drug regimen;
  - the patient has tried the prescription drug or another drug with the same mechanism of action, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse effect; and/or
  - the patient is stable on a prescription drug selected by the patient's health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan.
- Ensure that urgent prior authorization and step therapy requests be acted upon respectively within 24 hours of submission; non-urgent requests within 72 hours. Michigan's current timeline of requiring a response within 72 hours for expedited consideration and 15 days for standard consideration is simply too long given rare disease patient needs.
  - Make an approved prior authorization request valid for one year or until the last day of coverage to reduce the administrative burden on rare disease patients and their health care providers
  - Notify the physician or health care provider, if a coverage request is denied, with the reasons for the denial and provide a remedy or next steps to obtain the requested treatment, bringing much needed transparency and clarity for rare disease patients and health care providers.
  - Provide the patient and their physician or health care provider at least 60 days of notice before implementing new prior authorization requirements that may impact their care.

In order to guarantee patient safety, Michigan needs to ensure that prior authorization and step therapy policies do not interfere with appropriate care. Implementing the protections outlined above will help protect patients while still enabling health plans to achieve the cost saving benefits of prior authorization and step therapy when appropriate.

Thank you for the opportunity to comment on necessary revisions to the Michigan Medicaid Plan Common Formulary. For further questions, please do not hesitate to contact me at [HRoss@rarediseases.org](mailto:HRoss@rarediseases.org).

Sincerely,

A handwritten signature in black ink that reads "Heidi Ross".

Heidi Ross  
Director of State Policy  
National Organization for Rare Disorders