

# EPICrd Act

## FOCUS: Access to Rare Disease Therapies - Drugs

### Congress Must Act Now to Ensure Timely Access to Rare Disease Therapies In Medicaid

Restrictive Medicaid drug coverage policies are harming patients with rare diseases by taking medical decision-making out of the hands of their prescribers.

The **EPICrd** (Ensuring Parity through Individualized Care for Rare Disorders) Act is a comprehensive approach to ensuring coverage parity for patients with rare genetic conditions in accessing medicines, specialists, and other items and services within Medicaid. The solutions provided by EPICrd are driven by three core principles:

- 1 Access to rare disease therapies must not be hindered; rather, medical necessity determinations must be streamlined.
- 2 Access to specialized care must be easier.
- 3 Patients with rare genetic disorders need more than access to medicines.

**EPICrd Act will enable timely access to therapies that improve the standard of care or satisfy unmet need for rare disorders by streamlining the Medicaid prior authorization process for patients and prescribers. The bill would further policy goals of the MVP Act (H.R. 2666), the PROTECT Rare Act (H.R. 6094), and the Improving Seniors' Timely Access to Care Act.**

- ✓ Prescribers, not state Medicaid staff who lack familiarity with the rare disease, will determine the medical necessity of rare disease therapies for a patient.
- ✓ Following a simple electronic attestation by a prescriber supporting the use of the rare disease therapy in the individual patient, Medicaid would deem this medicine “medically necessary” and immediately authorize it for 12-months.
- ✓ These medically necessary rare disease therapies are expressly protected from step therapy and other coverage restrictions in Medicaid.



**EPICrD Act will elevate the voice of patients, caregivers, and clinicians with expertise in the rare disorder to influence Medicaid formulary placement and prior authorization coverage criteria for a rare disease therapy.**

- ✓ Medicaid drug utilization review boards, pharmacy and therapeutics committees, and similar entities will be required to take a patient-centric, evidence-based approach when establishing coverage policies for rare disease therapies.
- ✓ Medicaid would be required to:
  - consult with a minimum of three nationally recognized physician experts in the rare disease under review;
  - empanel as ad hoc voting members on the board or committee a patient and physician expert in the rare disorder that is the subject of the review, leveraging state rare disease advisory councils as feasible;
  - consider live or written testimony from local Medicaid patients and their caregivers or representatives affected by the rare disease, local physicians with expertise in the disease, and the manufacturer of the drug;
  - examine the most recently published consensus-based standard of care or treatment guidelines for the rare disease or condition, a peer-reviewed journal article analyzing data generated within the previous five years for the entire class of drugs approved for the rare disease, and real-world data.



**EPICrD Act will prevent Medicaid waivers that restrict prescription drug access.**

- ✓ Consistent with existing federal laws that prohibit federally funded health plans from discriminating against those individuals with disabilities, Medicaid would be expressly prohibited from establishing restrictive prescription drug coverage policies through section 1115 Medicaid demonstration waivers.



**EPICrD Act will leverage the expertise of the patient, scientific, and medical communities to define appropriate rare disease therapy categories and classes so that payer coverage policies reflect patient need, the latest science, and the current standard of care.**

- ✓ The NIH Office of Rare Diseases would collaborate with federal agencies, patient advocacy and research organizations, medical specialty societies, and biopharmaceutical companies to develop and maintain an appropriate list of rare disease therapy categories and classes for the minimum drug coverage requirements to which most public and private health plans must adhere.

**EPICrD Act**

Developed by Advocacy. Supported by BioMarin



For more information and legislative text, visit: [EPICrD.org](https://EPICrD.org)

Scan to see all provisions of bill.