

EPICrD Act

Ensuring Parity through Individualized Care for Rare Disorders

EPICrD Act

. Developed by Advocacy. Supported by BioMarin.

Ensuring Parity through Individualized Care for Rare Disorders

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





Timely Access to Rare Disease Therapies in Medicaid

- Streamline prior authorization for rare disorder drugs
 - Prescriber attestation to medical necessity
 - Protection from step therapy and other coverage restrictions
 - Support for current policy objectives:
 - MVP Act
 - PROTECT Rare Act
 - Improving Seniors Timely Access to Care Act
- Include patients, caregivers, expert clinicians in decision-making about formulary placement and coverage criteria
 - Engagement in Medicaid drug utilization review boards and pharmacy & therapeutics committees
 - Review of consensus-based standards of care or treatment guidelines; peer-reviewed literature on drug class; and real-world data



Timely Access to Rare Disease Therapies in Medicaid

- Prevent use of section 115 Medicaid demonstration waivers to establish restrictive drug coverage
- Define appropriate rare disease therapy categories and classes to reflect patient need, latest science, and current standard of care
 - NIH Office of Rare Diseases to work with stakeholders to develop and maintain list of categories and classes to set minimum drug coverage requirements



Medicaid Access to Out-of-State Providers

- Set up five-year demonstration project to improve access to out-of-state specialists at centers of excellence, in person and via telehealth
 - Streamlined out-of-state provider screening and enrollment and medical licensure reciprocity for telehealth
 - Payment for telehealth (including both providers in peer-to-peer consult) and drug acquisition and administration at no less than that of provider's state's rate
 - Temporary Medicaid quarterly furnishing fee to the states to offset excess payments to out-of-state providers



Medicaid Access to Out-of-State Providers

- Ensure out-of-state access to physician-administered drugs, inpatient and outpatient for complex or disabling rare conditions
- Leverage telehealth services from full-range of clinical experts in multidisciplinary teams
 - Diagnosis, treatment, care management
 - Peer-to-peer consults
 - Patient education., including REMS requirements
 - Monitoring after gene therapy



Items and Services Critical to Medical Care

- Balance flexibility for states choosing to provide certain services with certainty in coverage for Medicaid patients with severe, disabling disorders
 - Home infusion equipment and related nursing services, in addition to drugs
 - Durable medical equipment (DME) with physician attestation of need
- Cover medical supplies for wound care and pain management with physician attestation of need



Items and Services Critical to Medical Care

- Cover prescribed medical foods for certain digestive, absorption, and inherited metabolic conditions
- Establish a two-year Medicaid Access to Care Demonstration Project to test payment to program navigators for rare conditions
 - Coordination with schools, social workers, and prescribers
- Clarify states' use of Title V Maternal and Child Health block grants
 - Enhancement of genetic screening of certain conditions
 - Promotion of long-term management of metabolic disorders that cause mental health conditions

**For more information,
EPICrd.org**

EPICrdAct