Mass General Brigham
Health Plan

Olpruva (sodium phenylbutyrate) oral suspension
Effective 02/01/2026

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Olpruva (sodium phenylbutyrate) is a nitrogen-binding agent indicated as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients 1 year of age or older weighing 7 kg or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS).

Coverage Guidelines

Authorization may be granted for members new to within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when all of the following criteria are met:

1. Member has a diagnosis of urea cycle disorder (UCD) including arginase deficiency
2. Diagnosis is confirmed by enzymatic, biochemical, or genetic testing
3. Medical charts confirming member has elevated plasma ammonia level at baseline
4. Member's weight is greater than 7 kg
5. Member has had adverse reaction, intolerance, or contraindication to sodium phenylbutyrate

Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

1. Member is experiencing benefit from therapy, as evidenced by a reduction in plasma ammonia level from baseline

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limits apply on the pharmacy benefit:

Drug Name and Dosage Form	Quantity Limit
Olpruva packet for suspension	90 doses per 30 days

References

1. Olpruva (sodium phenylbutyrate) oral suspension [prescribing information]. Newton, MA: Acer Therapeutics, Inc.; October 2025.

Review History

10/11/2023 - Reviewed at Sept P&T, Effective 12/1/2023
11/12/2025 – Reviewed and updated at November P&T. Updated policy to reflect updated weight indication and removed BSA requirement. Effective 02/01/2026.