Mass General Brigham
Health Plan

Olpruva (sodium phenylbutyrate)
Effective 12/01/2023

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
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 is indicated as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m^2 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 Mass General Brigham Health Plan 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 for members meeting ALL the following criteria:

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. Members weight is greater than 20kg AND BSA of 1.2m2 or greater
5. Member has had adverse reaction, intolerance, or contraindication to sodium phenylbutyrate

<u>Continuation of Therapy</u>
Authorization may be granted for members for continued treatment when used for urea cycle disorder (UCD) including arginase deficiency when provider attests 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:

Olpruva	90 doses per 30 days

References

1. Olpruva [package insert]. Newton, MA: Acer Therapeutics, Inc.; December 2022.

Review History
10/11/2023 - Reviewed at Sept P&T, Effective 12/1/2023