Reference number(s)
6156-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☑
Value Formulary Chart (VFC)	☑
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria

Urea Cycle Disorders

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), Advanced Control Specialty Formulary Chart (ACSFC), and Value Formulary Chart (VFC).

Plan Design Summary

This program applies to the urea cycle disorder products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Urea Cycle Disorders Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Pheburane (sodium phenylbutyrate) • sodium phenylbutyrate (generic)
Target	• Buphenyl (sodium phenylbutyrate) • Olpruva (sodium phenylbutyrate) • Ravicti (glycerol phenylbutyrate)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Buphenyl

Coverage for the targeted product is provided when the member has experienced a documented intolerable adverse event to both of the preferred products, generic sodium phenylbutyrate and Pheburane, and the adverse event was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information.

Olpruva

Coverage for the targeted product is provided when the member meets any of the following criteria:

- Member meets both of the following criteria:
    - Member has a documented inability to ingest a sufficient amount of the preferred product, generic sodium phenylbutyrate, as prescribed due to an aversion to the taste or smell.
    - Member has a documented intolerable adverse event with the preferred product, Pheburane, and the adverse event was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member meets both of the following criteria:
    - Member has a documented inability to tolerate the necessary pill burden with the preferred product, generic sodium phenylbutyrate.
    - Member has a documented intolerable adverse event with the preferred product, Pheburane, and the adverse event was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented intolerable adverse event with both of the preferred products, generic sodium phenylbutyrate and Pheburane, and the adverse event was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information.

Ravicti

Coverage for the targeted product is provided when the member meets any of the following criteria:

- Member has a documented diagnosis associated with sodium retention with edema [e.g., uncontrolled congestive heart failure, uncontrolled hypertension, or severe renal impairment (i.e., creatinine clearance less than 30 mL/min), or cirrhosis] and is on a documented sodium-restricted diet.
- Member meets both of the following criteria:
    - Member has a documented inability to ingest a sufficient amount of the preferred product, generic sodium phenylbutyrate, as prescribed due to an aversion to the taste or smell.
    - Member has a documented inadequate response or intolerable adverse event with the preferred product, Pheburane.
- Member meets both of the following criteria:
    - Member has a documented inability to tolerate the necessary pill burden with the preferred product, generic sodium phenylbutyrate.
    - Member has a documented inadequate response or intolerable adverse event with the preferred product, Pheburane.
- Member has a documented inadequate response or intolerable adverse event with both of the preferred products, generic sodium phenylbutyrate and Pheburane.

References

1. Buphenyl [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; October 2024.
2. Olpruva [package insert]. Newton, MA: Acer Therapecutics Inc., December 2022.
3. Pheburane [package insert]. Princeton, NJ: Medunik USA, Inc.; August 2023
4. Raviciti [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; September 2021.
5. sodium phenylbutyrate [package insert]. Malvern, PA: Endo USA; June 2024.