

Clinical Policy Title:	sodium phenylbutyrate
Policy Number:	RxA.354
Drug(s) Applied:	sodium phenylbutyrate, Pheburane, Ravicti, Buphenyl
Original Policy Date:	03/06/2020
Last Review Date:	03/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Urea Cycle Disorder (must meet all):

1. Diagnosis of UCD confirmed by enzymatic, biochemical, or genetic testing;
2. Medication is prescribed in conjugation with a protein-restricted diet;
3. For Ravicti and Buphenyl:
 - a. Trial and failure of sodium phenylbutyrate or Pheburane, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Urea Cycle Disorder:

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval duration:

All Lines of Business (except Medicare): 12 months

References

Not Applicable

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title was updated 2. Drug(s) Applied was updated 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Commercial approval duration and 	06/22/2020	09/14/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Medicaid approval duration updated. 6. References were updated		
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	5/31/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	03/21/2022	07/18/2022
Policy was reviewed: 1. References were reviewed and updated.	04/19/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed.	2/28/2024	2/28/2024