This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)	✓	ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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EXCEPTIONS CRITERIA
UREA CYCLE DISORDERS

PREFERRED PRODUCT: SODIUM PHENYLBUTYRATE

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

I. PLAN DESIGN SUMMARY

This program applies to the urea cycle disorder products specified in this policy. 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 Disorder Agents

	Product(s)
Preferred*	• **sodium phenylbutyrate** (generic)
Targeted	• **Buphenyl** (sodium phenylbutyrate) • **Ravicti** (glycerol phenylbutyrate)

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

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

A. Buphenyl
Coverage for the targeted product is provided when the member has experienced a documented intolerable adverse event to the preferred product (generic sodium phenylbutyrate) and the adverse event was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information.

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

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)	✓	ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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1. Member has documented uncontrolled congestive heart failure, uncontrolled hypertension, or severe renal impairment (i.e., creatinine clearance less than 30 mL/min) and is on a documented sodium-restricted diet.
2. Member has documented inability to ingest a sufficient amount of the preferred product as prescribed due to an aversion to the taste or smell.
3. Member has documented inability to tolerate the necessary pill burden with the preferred product.
4. Member has a documented inadequate response or intolerable adverse event with the preferred product, generic sodium phenylbutyrate.

REFERENCES

1. Buphenyl [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; March 2023.
2. Raviciti [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; September 2021.
3. sodium phenylbutyrate [package insert]. Chestnut Ridge, NY: Par Pharmaceutical Companies, Inc.; July 2017