

Reference number(s)
5710-D

#### This document applies to the following:

Formulary	Applies
Standard Control (SF)	<b>V</b>
Standard Control – Choice (SCCF)	<b>7</b>
Preferred Drug Plan Design (PDPD)	
Advanced Control Specialty (ACSF)	<b>V</b>
Advanced Control Specialty – Choice (ACSCF)	<b>V</b>
Managed Medicaid Template (MMT)	
Marketplace (MF)	
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	
Aetna Individual Lives (IVL)	
Value (VF)	V

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)	<b>V</b>
Medical Benefit	
Medical Benefit: Advanced Biosimilars First	
Medical Benefit: Managed Medicaid (MMMB)	
Medicare Part B	
Medicare Part B: Advanced Biosimilars First	

# Exceptions Criteria Hyperammonemia

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), and Value Formulary Chart (VFC).

## **Plan Design Summary**

This program applies to the hyperammonemia products specified in this document. Coverage for the targeted product 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. Homocystinuria agents

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

	Products
Preferred	carglumic acid (generic)
Target	Carbaglu (carglumic acid)

Specialty Exceptions Hyperammonemia SF-SCCF-ACSF-ACSCF-VF-VFC 5710-D P2025\\_R.docx

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# **Exception Criteria**

Coverage for a targeted product is provided when the member had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

### References

- 1. Carbaglu [package insert]. Lebanon, NJ: Recordati Rare Diseases, Inc.; January 2024.
- 2. Carglumic acid [package insert]. Mason, OH: Burel Pharmaceuticals, LLC.; January 2024.