

Reference number(s)
6656-D

This document applies to the following:

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

Formulary	Applies
New to Market (NTM)	<input type="checkbox"/>
Standard Formulary Chart (SFC)	<input type="checkbox"/>
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	<input type="checkbox"/>
Advanced Control Specialty Formulary Chart (ACSFC)	<input type="checkbox"/>
Value Formulary Chart (VFC)	<input type="checkbox"/>
Medical Benefit	<input checked="" type="checkbox"/>
Medical Benefit: Advanced Biosimilars First	<input type="checkbox"/>
Medical Benefit: Managed Medicaid (MMMB)	<input type="checkbox"/>
Medicare Part B	<input type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input type="checkbox"/>

# Exceptions Criteria

## Fabry Disease

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: Medical Benefit.

### Plan Design Summary

This program applies to the Fabry disease 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 members who are new to treatment with a targeted product for the first time.

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

### Table. Fabry Disease

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

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	Product(s)
Preferred	<ul style="list-style-type: none"> <li>Elfabrio (pegunigalsidase alfa-iwxj)</li> </ul>
Target	<ul style="list-style-type: none"> <li>Fabrazyme (agalsidase beta)</li> </ul>

## Exception Criteria

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

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

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer’s patient assistance programs.
- Member is 2 to 17 years of age.
- Member has a documented inadequate response or intolerable adverse event with the preferred product.

## References

1. Elfabrio [package insert]. Cary, NC: Chiesi USA, Inc.; May 2024.
2. Fabrazyme [package insert]. Cambridge, MA: Genzyme Corporation; July 2024.