Reference number(s)
6910-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)	☑
New to Market (NTM)	☐

Formulary	Applies
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	☐
Combined Benefit Medical (CBM)	☐
Combined Benefit Medical Pharmacy (CBMP)	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Paroxysmal Nocturnal Hemoglobinuria (PNH) Agents

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: Value Formulary (VF).

Plan Design Summary

This program applies to the paroxysmal nocturnal hemoglobinuria (PNH) agents 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 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 1. Paroxysmal Nocturnal Hemoglobinuria (PNH) Agents

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

	Products
Preferred	• Empaveli (pegcetacoplan) • Ultomiris (ravulizumab-cwvz)
Target	• Fabhalta (iptacopan) • Soliris (eculizumab)

Table 2. Paroxysmal Nocturnal Hemoglobinuria (PNH) Agents

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

	Products
Preferred	• Ultomiris (ravulizumab-cwvz)
Target	• Piasky (crovalimab-akkz)

Table 3. Paroxysmal Nocturnal Hemoglobinuria (PNH) Agents

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

	Products
Preferred	• Empaveli (pegcetacoplan)
Target	• Voydeya (danicopan)

Exception Criteria

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

Table 1 Paroxysmal Nocturnal Hemoglobinuria (PNH) Products

Coverage for a targeted product is provided when any of the following criteria are 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 has a documented inadequate response or intolerable adverse event with both of the preferred products.

Table 2 Paroxysmal Nocturnal Hemoglobinuria (PNH) Products

Coverage for a targeted product is provided when any of the following criteria are 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 has a documented inadequate response or intolerable adverse event with the preferred product.

Table 3 Paroxysmal Nocturnal Hemoglobinuria (PNH) Products

Coverage for a targeted product is provided when any of the following criteria are 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 has a documented inadequate response or intolerable adverse event with the preferred product.
- The requested medication will be used as add-on therapy to Ultomiris or Soliris to treat extravascular hemolysis.

References

1. Empaveli [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2024.
2. Fabhalta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2025.
3. Piasky [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
4. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; September 2024.
5. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2025.
6. Voydeya [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; April 2024.