

Reference number(s)
7374-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	<input checked="" type="checkbox"/>
Standard Control Choice (SCCF)	<input checked="" type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input checked="" type="checkbox"/>
Advanced Control Specialty Choice (ACSCF)	<input checked="" 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"/>
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 type="checkbox"/>
Medical Benefit: Advanced Biosimilars First	<input type="checkbox"/>
Combined Benefit Management (CBM)	<input type="checkbox"/>
Combined Benefit Management Pharmacy (CBMP)	<input type="checkbox"/>
Medical Benefit Managed Medicaid (MMMB)	<input type="checkbox"/>

# 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: Standard Control Formulary (SF), Standard Control – Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF).

### 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 all members requesting treatment with Bkempv and Epysqli. This program applies to members who are new to treatment with Piasky and Voydeya 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	<ul style="list-style-type: none"> <li>• Empaveli (pegcetacoplan)</li> <li>• Soliris (eculizumab)</li> <li>• Ultomiris (ravulizumab-cwvz)</li> </ul>
Target	<ul style="list-style-type: none"> <li>• Bkempv (eculizumab-aeeb)</li> <li>• Epysqli (eculizumab-aagh)</li> </ul>

## 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	<ul style="list-style-type: none"> <li>• Soliris (eculizumab)</li> <li>• Ultomiris (ravulizumab-cwvz)</li> </ul>
Target	<ul style="list-style-type: none"> <li>• Piasky (crovalimab-akkz)</li> </ul>

## 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	<ul style="list-style-type: none"> <li>• Empaveli (pegcetacoplan)</li> </ul>
Target	<ul style="list-style-type: none"> <li>• Voydeya (danicopan)</li> </ul>

## Exception Criteria

This program applies to members requesting treatment for paroxysmal nocturnal hemoglobinuria (PNH).

## Table 1 Paroxysmal Nocturnal Hemoglobinuria (PNH) Products

Coverage for a targeted product is provided when both of the following criteria are met:

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- Coverage for the targeted product is provided when the member has had a documented intolerable adverse event to the preferred product, Soliris, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
- Member has a documented inadequate response or intolerable adverse event with both Empaveli and Ultomiris.

## 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 both of the preferred products.

## 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 eculizumab or ravulizumab to treat extravascular hemolysis.

## References

1. Bkembv [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2024.
2. Empaveli [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2024.
3. Epysqli [package insert]. Republic of Korea: Samsung Bioepis Co., Ltd.; February 2025.
4. Piasky [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
5. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; September 2024.
6. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2025.
7. Voydeya [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; April 2024.