This policy applies to the following:

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

Reference #
4977-D

EXCEPTIONS CRITERIA
COMPLEMENT INHIBITORS

PREFERRED PRODUCT: EMPAVELI

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 complement inhibitor 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 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. Complement Inhibitor Products

	Product(s)
Preferred*	• **Empaveli** (pegcetacoplan)
Targeted	• **Ultomiris** (ravulizumab-cwvz)

*: 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 any of the preferred products.

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

A. Member is currently receiving treatment with the targeted product, Ultomiris, excluding when the requested targeted product is obtained as samples or via manufacturer’s patient assistance programs.
B. Member has a documented inadequate response or intolerable adverse event with the preferred product, Empaveli.
C. Member is less than 18 years of age.

REFERENCES

1. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; June 2021.

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This policy applies to the following:

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

Reference #
4977-D

2. Empaveli [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; May 2021.

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