Clinical Guideline

Oscar Clinical Guideline: Complement Inhibitors - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG098, Ver. 3)

Complement Inhibitors - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan has a Medical Preferred Drug List to encourage use of cost-effective and clinically appropriate physician-administered specialty drugs. Table 1 lists the preferred and non-preferred Complement Inhibitor products:

Table 1: Complement Inhibitors, Medical Preferred Drug List

*Preferred Products**	*Non-Preferred Products†/**
❖ Soliris (eculizumab) ❖ Ultomiris (ravulizumab-cwvz)	❖ Empaveli (pegcetacoplan) ❖ PiaSky (crovalimab-akkz)

[N]subject to Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria.

[*]*Other drug-specific or class-specific clinical guidelines may also be applicable.*

- *Products considered Formulary or Preferred for the Plan may still require a clinical prior authorization review.*
- *The Plan may review all requests made under the Medical or Pharmacy benefit against specific prior authorization criteria, as applicable and at its discretion.*

This policy outlines the Plan's preferred products and exception criteria for non-preferred products through prior authorization. The coverage review process will determine if a clinical exception can be made.

- The program applies to all members requesting treatment with a non-preferred product (see Table 1).
- Preferred drugs are selected based on clinical effectiveness, safety, FDA approval, and treatment guidelines. In most cases, preferred medications must be tried first as long as they are considered safe and effective by the provider.
- Requests for non-preferred medications may require meeting Medical Benefit Preferred Drug Exceptions Criteria. Approval may be given if the member has tried and failed, or cannot use the Plan's preferred drug(s). Exceptions may include, but are not limited to the following:
    1. The member has a documented trial and failure, inadequate response, intolerance, or contraindication to ALL preferred drug(s), as applicable; ***or***
    2. The member has a risk factor(s) for poor response to the preferred drug(s); ***or***
    3. The member is not a candidate for the preferred drug(s) based on the member's condition(s), individual needs, treatment history, or accepted standards of medical practice.

For more information or to request an exception, please contact the Plan.

Definitions

"**Compendia**" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Elsevier Clinical Pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"**Contraindication**" refers to a pre-existing condition or factor that precludes use of a drug due to risk of harm.

"**Intolerance**" refers to the inability to tolerate or endure something, often due to experiencing subjectively difficult or harmful side effects, reactions, or hypersensitivities when using a medication or treatment that negatively impacts quality of life, ability to adhere, or overall health. Documentation is expected to detail the specific intolerable effects and their impact on treatment.

"**Documentation**" refers to written information, including but not limited to:

1. Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses;
2. Prescription claims records, and/or prescription receipts to support prior trials of alternatives.

"**Experimental or Investigational**" are procedures, drugs, or devices that haven't been proven effective or which haven't been approved by the appropriate regulatory bodies.

"**FDA**" refers to the Federal Food and Drug Administration.

"**Medical Benefit Preferred Drug Exceptions Criteria**" are Plan requirements that must be met for a non-preferred drug to be approved for coverage, such as trial and failure of preferred drugs first.

State Law Conflicts

For any provision of this policy that directly conflicts with or is prohibited by state law, the provisions of the state law will apply instead of the provisions of this policy. This means that in instances where state regulations diverge from or directly oppose the Plan's Preferred Physician-Administered Drug(s) Exceptions Criteria or requirements, the policy's criteria will not apply.

Exception Criteria

Coverage of a **Non-Preferred Product** will be provided when the member meets **BOTH** of the following criteria:

1. Inadequate response, intolerance, or contraindication to at least **ONE** preferred product, unless:
    a. **NEITHER** of the preferred products have received FDA approval, are supported by evidence-based guidelines, or are clinically appropriate for the member's diagnosis***; or***

b. The member is currently receiving treatment with the requested product, excluding when the requested product is obtained as samples or via assistance programs***; AND***

2. Clinical documentation is provided showing inadequate response, treatment failure, intolerance/adverse event, or contraindication specific to the preferred products. Examples of supporting documentation include:
    a. Specific details of inadequate response/treatment failure***; and/or***
    b. Nature and severity of adverse events***; and/or***
    c. Specific contraindications***; and/or***
    d. Specific reason(s) why the preferred products cannot be used.

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.

Experimental or Investigational / Not Medically Necessary

The Plan does not cover non-preferred products when used for experimental, investigational, or medically unnecessary indications. Use of non-preferred products is considered experimental, investigational, or not medically necessary if the indication is outside FDA-approved labeling or not supported by current medical evidence and standards of care. The Plan does not cover non-preferred products for the following non-approved indications (not all-inclusive):

1. Uses not considered clinically appropriate based on indication, including age, dosing (dosage, frequency, duration of therapy, and site of administration), and contraindication.
    a. Non-FDA approved indications or off label use without sufficient evidence supporting safety and efficacy.
    b. Doses exceeding the FDA-approved label or clinical practice guidelines without sufficient evidence supporting safety and efficacy.
2. Uses not required for treatment or management of the member's medical condition.
3. Uses not aligned with generally accepted medical practice.
4. Uses primarily for the convenience of the member, family, or provider.

Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
C9151	Empaveli (pegcetacoplan) Injection, pegcetacoplan, 1 mg
J1300	Soliris Injection, eculizumab, 10 mg
J1303	Ultomiris Injection, ravulizumab-cwvz, 10 mg
J1307	PiaSky Injection, crovalimab-akkz, 10 mg

References

1. Empaveli (pegcetacoplan) [prescribing information]. Waltham, MA: Apellis Pharmaceuticals Inc; September 2023.
2. Piasky (crovalimab) [prescribing information]. South San Francisco, CA: Genentech Inc; June 2024.
3. Soliris (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals Inc; November 2020.
4. Ultomiris (ravulizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals; July 2022.

Clinical Guideline Revision / History Information

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