Clinical Guideline

Oscar Clinical Guideline: Antineoplastic and Immunomodulating Agents - Biologics for Autoimmune and Inflammatory Conditions - Medical Benefit Preferred Physician-Administered Drug Exceptions Criteria (CG086, Ver. 6)

Antineoplastic and Immunomodulating Agents - Biologics for Autoimmune and Inflammatory Conditions - 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 Biologics for Autoimmune and Inflammatory Conditions:

Table 1: Biologics for Autoimmune and Inflammatory Conditions, Medical Preferred Drug List

Preferred Products[*]	*Non-Preferred Products*[ℳ*]
❖ Cosentyx (secukinumab) IV ❖ Entyvio (vedolizumab) IV[ɪ] ❖ Simponi Aria (golimumab) ❖ Skyrizi (risankizumab-rzaa) IV ❖ Stelara (ustekinumab) IV[ǂ] ❖ Tremfya (guselkumab) IV	❖ Cimzia (certolizumab pegol)↓↓ ❖ Ilumya (tildrakizumab-asmn) ❖ Omvoh (mirikizumab-mrkz) IV ❖ Orencia (abatacept) ❖ Imuldosa (ustekinumab-srlf) IV ❖ Otulfi (ustekinumab-aauz) IV ❖ Pyzchiva (ustekinumab-ttwe) IV ❖ Selarsdi (ustekinumab-aekn) IV ❖ Steqeyma (ustekinumab-stba) IV ❖ Wezlana (ustekinumab-auub) IV ❖ Yesintek (ustekinumab-kfce) IV

[ℳ]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.*

[ǂ]*Stelara intravenous (IV) infusion is indicated for a one-time induction dose in the treatment of Crohn's Disease and Ulcerative Colitis.*

[ɪ]*After initial induction therapy with intravenous Entyvio (vedolizumab), members are expected to transition to subcutaneous Entyvio (vedolizumab) for maintenance therapy unless specific exception criteria are met.*

↓↓Members are expected to use Cimzia (certolizumab pegol) subcutaneous prefilled syringe for injection formulation for therapy unless specific exception criteria are met.

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

The Plan considers a **Non-Preferred Product** to be medically necessary when the member meets **BOTH** of the following criteria:

1. Inadequate response, intolerance, or contraindication to **ALL** FDA, compendia, or evidence-based guideline-supported preferred products that are indicated and clinically appropriate for the diagnosis, unless:
    a. There are no such preferred products***; or***
    b. The member has a documented clinical reason to avoid **ALL** preferred products***; or***
    c. The member is currently receiving treatment with the requested product, excluding when the requested product is obtained as samples or via assistance programs; ***or***
    d. The request is for cancer treatment in a state prohibiting prerequisite trials per regulations***; AND***
2. Clinical documentation is provided showing inadequate response, treatment failure, intolerance/adverse event, contraindication or clinical reason to avoid **ALL** 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 **ALL** preferred products cannot be used.

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

Cimzia (certolizumab pegol) Subcutaneous (SC) Prefilled Syringe for Injection Requirement

Members are required to use Cimzia (certolizumab pegol) SC prefilled syringe for injection formulation for therapy unless the (*below*) **Exception Criteria for Continued Cimzia (certolizumab pegol) Lyophilized Powder for Injection Use** are met.

Exception Criteria for Continued Cimzia (certolizumab pegol) Lyophilized Powder for Injection Use

The Plan will authorize continued use of **Cimzia (certolizumab pegol) lyophilized powder** when the member meets **ONE** of the following criteria:

1. The member has a documented contraindication to the SC prefilled syringe formulation of Cimzia (certolizumab pegol) that would **NOT** be expected to occur with the lyophilized powder formulation (e.g., hypersensitivity to sodium acetate or sodium chloride)***; OR***
2. The member has physical or cognitive limitations that prevent SC self-administration or administration by a caregiver, including but not limited to visual impairment, limited manual dexterity, or impaired cognitive function (documentation required).

If one of the above exception criteria are met, Cimzia (certolizumab pegol) lyophilized powder will be approved for up to 12-months.

Entyvio (vedolizumab) Intravenous to Subcutaneous Transition Requirement

The Plan considers **Entyvio (vedolizumab) for intravenous (IV) infusion** to be medically necessary for initial induction therapy. After the induction period, members are required to transition to the subcutaneous (SC) formulation for maintenance therapy unless the (*below*) **Exception Criteria for Continued Intravenous Entyvio (vedolizumab)** are met.

Initial Approval for Intravenous Entyvio (vedolizumab):

I. Entyvio (vedolizumab) IV will be approved for initial induction therapy for a period of 2 months (to cover doses at weeks 0, 2, and 6).
   - ➢ *The initial authorization will allow for 3 total infusions of Entyvio (vedolizumab) IV.*

- ➢ *Transition from IV to SC should occur after the third IV dose unless exception criteria are met (see below, Exception Criteria for Continued Intravenous Entyvio (vedolizumab)).*

Transition to Subcutaneous Entyvio (vedolizumab):

II. After the initial 2-month induction period with Entyvio (vedolizumab) IV, members are required to transition to Entyvio (vedolizumab) SC for maintenance therapy.
   - ➢ *Entyvio (vedolizumab) SC will be approved through the Pharmacy benefit for maintenance therapy.*
   - ➢ *Total authorization period (including both Medical and Pharmacy benefit coverage) will not exceed 12 months.*

Exception Criteria for Continued Intravenous Entyvio (vedolizumab)

The Plan will authorize continued use of **Entyvio (vedolizumab) IV** beyond the initial 2-month induction period when the member meets **ONE** of the following criteria:

1. The member has a documented contraindication to the SC formulation of Entyvio (vedolizumab) that would **NOT** be expected to occur with the IV formulation***; OR***
2. The member experienced a documented intolerable adverse event to the SC formulation of Entyvio (vedolizumab) that would **NOT** be expected to occur with the IV formulation***; OR***
3. The member has physical or cognitive limitations that prevent SC self-administration or administration by a caregiver, including but not limited to visual impairment, limited manual dexterity, or impaired cognitive function (documentation required)***; OR***
4. The member has a documented medical condition that significantly impairs subcutaneous absorption, making IV administration necessary for effective treatment***; OR***
5. The member requires a dose that is not available or feasible for SC administration.

If one of the above exception criteria are met, Entyvio (vedolizumab) IV will be approved 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.

Additionally, long-term use of intravenous Entyvio (vedolizumab) when the member is able to transition to subcutaneous administration is considered not medically necessary unless exception criteria are met.

Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
J0129	Orencia; Orencia ClickJect Injection, abatacept, 10 mg
J0717	Cimzia; Cimzia Prefilled; Cimzia Starter Kit Injection, certolizumab pegol, 1 mg
J1602	Simponi Aria Injection, golimumab, 1 mg, for intravenous use
J1628	Tremfya IV Injection, guselkumab, 1 mg
J2267	Omvoh IV Injection, mirikizumab-mrkz, 1 mg
J2327	Skyrizi (intravenous) Injection, risankizumab-rzaa, intravenous, 1 mg
J3245	Ilumya

	Injection, tildrakizumab, 1 mg
J3247	Cosentyx IV Injection, secukinumab, intravenous, 1 mg
J3358	Stelara IV Ustekinumab, for intravenous injection, 1 mg
C9399	Imuldosa IV Unclassified drugs or biologicals
J3590	Imuldosa IV Unclassified biologics
C9399	Selarsdi IV Unclassified drugs or biologicals
J3590	Selarsdi IV Unclassified biologics
C9399	Steqeyma IV Unclassified drugs or biologicals
J3590	Steqeyma IV Unclassified biologics
C9399	Yesintek IV Unclassified drugs or biologicals
J3590	Yesintek IV Unclassified biologics
Q5138	Wezlana IV Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q9997	Pyzchiva IV Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9999	Otulfi IV Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg
J3380	Entyvio IV Injection, vedolizumab, intravenous, 1 mg
J3590	Entyvio SC (vedolizumab) Unclassified biologics
C9399	Entyvio SC (vedolizumab) Unclassified drugs or biologicals

Appendix

Common Tumor Necrosis Factor (TNF) Blocking Agents

1. Adalimumab (Humira)
2. Certolizumab Pegol (Cimzia)
3. Etanercept (Enbrel)
4. Golimumab (Simponi)
5. InFLIXimab (Remicade)

Common Contraindications and Precautions for Anti-TNF Therapy

1. Active infections (e.g. TB, hepatitis B/C, HIV, herpes zoster) or sepsis
2. History of hypersensitivity reaction to the agent or components
3. Congestive heart failure NYHA Class III or IV
4. Concurrent use of another biological immunosuppressive agent (select agents)
5. History of malignancy
6. Underlying demyelinating disorder
7. Recent or planned major surgery
8. Pregnancy/planning pregnancy (select agents)

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