



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.

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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

<i>Drug Class</i>	<i>Preferred Products*</i>	<i>Non-Preferred Products**</i>
Biologics for Autoimmune and Inflammatory Conditions	<ul style="list-style-type: none"> ❖ Cosentyx (secukinumab) IV [J3247] ❖ Entyvio (vedolizumab) IV[†] [J3380] ❖ Simponi Aria (golimumab) [J1602] ❖ Skyrizi (risankizumab-rzaa) IV[†] [J2327] ❖ Tremfya (guselkumab) IV[†] [J1628] 	<ul style="list-style-type: none"> ❖ Cimzia (certolizumab pegol)[‡] [J0717] ❖ Ilumya (tildrakizumab-asmn) [J3245] ❖ Omvoh (mirikizumab-mrkz) IV [J2267] ❖ Orencia (abatacept) [J0129] ❖ Stelara (ustekinumab) IV[†] [J3358]
Ustekinumab Products	<ul style="list-style-type: none"> ❖ Yesintek (ustekinumab-kfce) IV/SC [Q5100] 	<ul style="list-style-type: none"> ❖ Imuldosa (ustekinumab-srlf) IV/SC [Q5098] ❖ Otulfi (ustekinumab-aaaz) IV/SC [Q9999] ❖ Pyzchiva (ustekinumab-ttwe) IV [Q9997] ❖ Pyzchiva (ustekinumab-ttwe) SC [Q9996] ❖ Selarsdi (ustekinumab-aekn) IV/SC [Q9998] ❖ Starjemza (ustekinumab-hmny) IV/SC ❖ Stelara (ustekinumab) IV[†] [J3358] ❖ Steqeyma (ustekinumab-stba) IV/SC [Q5099] ❖ Wezlana (ustekinumab-auub) IV [Q5138] ❖ Wezlana (ustekinumab-auub) SC [Q5137]

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

[‡]subject to Plan's Preferred Physician-Administered Drug(s) Additional Preferred 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.*

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

[‡]*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.

"[s]" indicates state mandates may apply.

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.

Clinical Indications

Additional Preferred Criteria

The Plan considers Entyvio (vedolizumab) IV, Skyrizi (risankizumab-rzaa) IV, or Tremfya (guselkumab) IV to be medically necessary when the member meets the following criteria:

1. IF the request is for Crohn's disease (CD) or ulcerative colitis (UC), the member is unable to use, or has tried and failed an ustekinumab IV.^[s]

Exception Criteria

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

2. IF the request is for a non-preferred biologic for autoimmune and inflammatory condition, the member meets ONE of the following criteria^[5]:
 - a. 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 there are no such preferred products; *or*
 - b. ALL preferred products have NOT received the requested FDA approval, is not supported by evidence-based guidelines, or is not clinically appropriate for the member's diagnosis; *or*
 - c. The member has a documented clinical reason to avoid ALL preferred products; *or*
 - d. The member is currently receiving treatment with the requested product, excluding when the requested product is obtained as samples or via assistance programs; *or*
 - e. Drug shortage or unavailability of ALL preferred products; *or*
 - f. The request is for a therapy regimen where clinical evidence and/or current treatment guidelines (e.g., NCCN) support the preferential use of the requested product over ALL preferred products; *or*
 - g. The request is for cancer treatment in a state prohibiting prerequisite trials per regulations; *AND*
3. IF the request for for a non-preferred ustekinumab product, the member meets ONE of the following criteria^[5]:
 - a. 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 there are no such preferred products; *or*
 - b. ALL preferred products have NOT received the requested FDA approval, is not supported by evidence-based guidelines, or is not clinically appropriate for the member's diagnosis; *or*
 - c. The member has a documented clinical reason to avoid ALL preferred products; *or*
 - d. The member is currently receiving treatment with the requested product, excluding when the requested product is obtained as samples or via assistance programs; *or*
 - e. Drug shortage or unavailability of ALL preferred products; *or*
 - f. The request is for a therapy regimen where clinical evidence and/or current treatment guidelines (e.g., NCCN) support the preferential use of the requested product over ALL preferred products; *or*
 - g. The request is for cancer treatment in a state prohibiting prerequisite trials per regulations; *AND*
4. Clinical documentation is provided to support the exception request. 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; *and/or*
- e. Notification of drug shortage or unavailability.

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

- For drug transition (if criteria 2d or 3d is met above)^[s]:
 - Initial approval - up to 3 months or other duration per provider clinical rationale.
- For drug shortage/unavailability^[s]:
 - Initial approval - up to 3 months;
 - May be extended based on continued documentation of shortage/unavailability.

Note: If the shortage/unavailability resolves before the authorization period ends, the Plan may require transition to the preferred product at the next authorization period.

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^[s]

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

Table 2	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
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

Table 2	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
J3358	Stelara IV Ustekinumab, for intravenous injection, 1 mg
Q5098	Imuldosa IV/SC Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg
Q9998	Selarsdi IV/SC Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg
C9399	Starjemza IV/SC Unclassified drugs or biologicals
J3590	Starjemza IV/SC Unclassified biologics
Q5099	Steqeyma IV/SC Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg
Q5100	Yesintek IV/SC Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg
Q5137	Wezlana SC Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg
Q5138	Wezlana IV Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q9996	Pyzchiva SC Injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 1 mg
Q9997	Pyzchiva IV Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9999	Otulfi IV/SC 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)

References

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