Ustekinumab

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Ustekinumab drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. For this program, Otulfi (ustekinumab-aauz) is the preferred product. Non-preferred products including Imuldosa, Pyzchiva, Selarsdi, Starjemza, Stelara, Steqeyma, Wezlana, and Yesintek are generally excluded from coverage. Coverage under select plans may be provided based on clinical circumstances that would exclude the use of the preferred products. The coverage review process will ascertain situations where a clinical exception can be made. Submission of medical records documenting relevant history, physician evaluation information, and supporting compendia or current literature (if applicable) will be required for review of these exceptions.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderate to severe plaque psoriasis (PsO) in patients 6 years or older who are candidates for phototherapy or systemic therapy
2. Active psoriatic arthritis (PsA) in patients 6 years or older
3. Moderately to severely active Crohn’s disease (CD) in adults
4. Moderately to severely active ulcerative colitis (UC) in adults

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A) Plaque psoriasis (PsO)

1. Initial requests:
   - **i.** Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
   - **ii.** Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

B) Psoriatic arthritis (PsA)

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C) Crohn's disease (CD)

1. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

D) Ulcerative colitis (UC)

1. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties (initial approvals only)

The medication must be prescribed by or in consultation with one of the following:

A. Plaque psoriasis: dermatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Crohn's disease and ulcerative colitis: gastroenterologist

Criteria for Initial Approval

A) Plaque psoriasis (PsO)

1. Authorization of 12 months may be granted for members 6 years of age or older who previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.
   OR
2. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis in members 6 years of age or older when any of the following criteria is met:
   - i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   - ii. At least 10% of the body surface area (BSA) is affected
   - iii. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
     - a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
     - b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix A).

B) Psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for members 6 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

OR

2. Authorization of 12 months may be granted for members 6 years of age or older for treatment of active psoriatic arthritis when either of the following criteria is met:
    i. Member has mild to moderate disease and meets one of the following criteria:
        a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
        b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix B), or another conventional synthetic drug (e.g., sulfasalazine).
        c. Member has enthesitis or predominantly axial disease.
    ii. Member has severe disease.

C) Crohn's disease (CD)

1. Authorization of 12 months may be granted for members for the treatment of moderately to severely active Crohn's Disease.

D) Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for members for the treatment of moderately to severely active Ulcerative Colitis.

Continuation of Therapy

A) Plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

B) Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement

C) Crohn's Disease (CD)

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

i. Abdominal pain or tenderness
ii. Diarrhea
iii. Body weight
iv. Abdominal mass
v. Hematocrit
vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

D) Ulcerative colitis

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation
   iv. C-reactive protein (CRP)
   v. Fecal calprotectin (FC)
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Note: Post Limit Quantity Exception Criteria available for Psoriasis (6 years and older) & Crohn's disease that will allow for dose escalation in patients experiencing a partial response, nonresponse, or a loss of response to the current dosing regimen.

<u>Other</u>
For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for tuberculosis (TB) is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Ustekinumab for intravenous administration will only be authorized to use for the treatment of Crohn's disease and ulcerative colitis.

Ustekinumab is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Quantity Limit
Ustekinumab 130 mg/26 mL single-dose vial	**CD, UC intravenous induction** • ≤ 55 kg: 260 mg (2 vials) • > 55 kg to 85 kg: 390 mg (3 vials) • > 85 kg: 520 mg (4 vials)
Ustekinumab subcutaneous injection 45 mg/0.5 mL vial/syringe	**Psoriasis (6 years and older)/ Psoriasis with or without co-existent PsA (adult)** • ≤ 100 kg: 2 vials/syringes per first 28 days (load); 1 vial/syringe every 12 weeks (maintenance) • > 100 kg: 2 vials/syringes per first 28 days (load); 1 vial/syringe every 12 weeks (maintenance) **PsA (6 years and older), without co-existent plaque psoriasis** • 2 vials/syringes per first 28 days (load) • 1 vial/syringe every 12 weeks (maintenance) **CD, UC maintenance dose** • 1 syringe every 8 weeks
Ustekinumab subcutaneous injection 90 mg/mL syringe	**Psoriasis (6 years and older)*/ Psoriasis with or without co-existent PsA (adult)** • ≤ 100 kg: 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks • > 100 kg: 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks **CD*, UC maintenance dose** • 1 syringe every 8 weeks

Abbreviations: PsA = psoriatic arthritis; CD = Crohn's disease, UC = ulcerative colitis
*Post Limit Quantity Exception Criteria available for Psoriasis (6 years and older) & CD

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide.

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3358 ustekinumab, for intravenous injection, 1 mg
- J3357 ustekinumab, subcutaneous injection, 1 mg
- Q9999 ustekinumab-aauz (otulfi), biosimilar, 1 mg
- Q9996 Pyzchiva (Ustekinumab-ttwe, biosimilar) for subcutaneous injection
- Q9997 Pyzchiva (Ustekinumab-ttwe, biosimilar) for intravenous injection
- Q9998 Selarsdi (Ustekinumab-aekn, biosimilar)
- Q5098 Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg (effective 7/1/25)
- Q5099 Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg (effective 7/1/25)
- Q5100 Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg (effective 7/1/25)
- Q5137 Wezlana (Ustekinumab-aaub, biosimilar) for subcutaneous injection
- Q5138 Wezlana (Ustekinumab-aaub, biosimilar) for intravenous injection
- J3590 – Unclassified biologics
- J3490 – Unclassified drugs

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POLICY HISTORY

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