Stelara (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 Stelara drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies.

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 alone or in combination with methotrexate (MTX).
3. Moderately to severely active Crohn’s disease (CD)
4. Moderately to severely active ulcerative colitis (UC)

POLICY

Required Documentation

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

A) Plaque psoriasis

1. Initial requests:
   a). Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.

b). 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: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C) Crohn's disease and ulcerative colitis

1. Initial requests:
   i. 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.
   ii. Chart notes or medical record documentation supporting diagnosis of fistulizing Crohn's disease (if applicable)
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Criteria for Initial Approval

A) Moderate to severe plaque psoriasis (PsO)

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

B) Active psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA).

C) Moderately to severely active Crohn's disease (CD)

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of Crohn's disease.
2. Authorization of 12 months may be granted for the treatment of moderately to severely active CD when the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (See Appendix C)
3. Authorization of 12 months may be granted for the treatment of fistulizing CD.

D) Moderately to severely active ulcerative colitis (UC)

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis.
2. Authorization of 12 months may be granted for the treatment of moderately to severely active UC when the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix D).

Continuation of Therapy

A) Moderate to severe 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) Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active 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. Skin and/or nail involvement

C) Moderately to severely active 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). Endoscopic appearance of the mucosa
    vii). Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

D) Moderately to severely active 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). Endoscopic appearance of the mucosa
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.

Other
For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. 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.

Stelara for intravenous administration is FDA-approved for the treatment of Crohn's disease and ulcerative colitis and will only be authorized for these conditions.

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

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
Stelara (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)
Stelara (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

Medication	Quantity Limit
Stelara (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: Clinical reasons to avoid TNF-inhibitors

1. History of demyelinating disorder
2. History of congestive heart failure
3. History of hepatitis B infection
4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

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

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 (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix C: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
   a.) Oral budesonide
   b.) Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
   a.) Azathioprine, mercaptopurine
   b.) Alternatives: oral budesonide, methotrexate intramuscular (IM) or subcutaneous (SC), sulfasalazine
3. Moderate to severe disease – induction of remission:
   a.) Prednisone, methylprednisolone intravenously (IV)
   b.) Alternatives: methotrexate IM or SC
4. Moderate to severe disease – maintenance of remission:
   a.) Azathioprine, mercaptopurine
   b.) Alternative: methotrexate IM or SC
5. Perianal and fistulizing disease – induction of remission:
   a.) Metronidazole ± ciprofloxacin, tacrolimus
6. Perianal and fistulizing disease – maintenance of remission:
   a.) Azathioprine, mercaptopurine
   b.) Alternative: methotrexate IM or SC

Appendix D: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:

a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
b. Rectal mesalamine (e.g., Canasa, Rowasa)
c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine

2. Mild to moderate disease – maintenance of remission:
   a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
   b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
   a. Prednisone, hydrocortisone IV, methylprednisolone IV
   b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: sulfasalazine

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 Injection, ustekinumab, 1mg for Intravenous use

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*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.28
Reviewed: October 2022
Revised: October 2022
Current Effective Date: December 11, 2022