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DRUG POLICY

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)
2. Active psoriatic arthritis (PsA)
3. Moderately to severely active Crohn's disease (CD)
4. Moderately to severely active ulcerative colitis (UC)

POLICY

Criteria for Initial Approval

A) Moderate to severe plaque psoriasis (PsO)

1. Authorization of 12 months may be granted for members who have 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 all of the following criteria are met:
 - a.) At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 - b.) Member meets any of the following criteria:

- i). Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or a 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).
- iii). Member has severe psoriasis that warrants a biologic DMARD as first-line therapy (i.e. at least 10% of the body surface area (BSA) or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected).

B) Active psoriatic arthritis (PsA)

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

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.
Authorization of 12 months may be granted for the treatment of moderately to severely active CD in members who had an inadequate response, intolerance or contraindication to at least one conventional therapy option (See Appendix C)

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 DMARD (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 for members who had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix D).

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) who are using Stelara for an indication outlined in the Criteria for Initial Approval and who achieve or maintain a positive clinical response with Stelara as evidenced by low disease activity or improvement in signs and symptoms of the condition.

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 (e.g., Xeljanz), and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

* If the screening testing for TB is positive, there must be documentation of further testing to confirm there is no active disease. Do not administer ustekinumab to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of ustekinumab.

** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use Stelara concomitantly with any other biologic DMARD or targeted synthetic DMARD.

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 <ul style="list-style-type: none"> ≤ 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) <ul style="list-style-type: none"> ≤ 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, without co-existent plaque psoriasis <ul style="list-style-type: none"> 2 vials/syringes per first 28 days (load) 1 vial/syringe every 12 weeks (maintenance) CD, UC maintenance dose <ul style="list-style-type: none"> 1 syringe every 8 weeks
Stelara (ustekinumab) subcutaneous injection 90 mg/mL syringe	Psoriasis (6 years and older)/ Psoriasis with or without co-existent PsA (adult) <ul style="list-style-type: none"> ≤ 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 <ul style="list-style-type: none"> 1 syringe every 8 weeks

Abbreviations: PsA = psoriatic arthritis; CD = Crohn's disease, UC = ulcerative colitis

*Post Limit Quantity Exception Criteria available for 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 with traditional systemic agent
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
5. Pouchitis: Metronidazole, ciprofloxacin
 - a. Alternative: rectal mesalamine

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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POLICY HISTORY

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