Effective Date: 2/19
Reviewed: 2/2019, 1/2020, 4/2020, 11/2020, 12/2020, 5/2021, 01/2022, 2/2022, 7/2022, 12/2022, 8/2023, 2/2024, 1/2025 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

Ustekinumab SC Products: Stelara, ustekinumab biosimilars

POLICY

I. INDICATIONS

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
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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL AND CONTINUATION OF THERAPY

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

III. CRITERIA FOR INITIAL APPROVAL

For all indications:

1. Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received ustekinumab or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.]*; AND
2. Member is free of any clinically important active infection, including clinically important localized infections; AND
3. Member will not receive live vaccines during therapy; AND
4. Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
5. Ustekinumab will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-

biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Velsipity (etrasimod), etc.)

6. If the request is for Stelara SC, the member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab SC at maximum tolerated doses

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 6 months may be granted for treatment of moderate to severe plaque psoriasis in members who are 6 years of age or older when all of the following criteria with documentation are met:

1. Ustekinumab is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
2. At least 10% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. Member meets either of the following criteria:
    i. Member has had an inadequate response to at least a 3-month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin
    ii. Member has had an inadequate response to at least a 3-month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced
4. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.
5. Dosing falls within the following FDA approved guidelines:
    a) Adult Subcutaneous Loading Dose:
        - <100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later
        - >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later
    b) Pediatric Subcutaneous Loading Dose:
        - <60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later
        - 60 – 100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later
        - >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later
    c) Pediatric Subcutaneous Maintenance Dose:
        - <60 kg: 0.75 mg/kg every 12 weeks
        - 60 – 100 kg: 45 mg every 12 weeks
        - >100 kg: 90 mg every 12 weeks

B. Active psoriatic arthritis (PsA)

Authorization of 6 months may be granted for treatment of active psoriatic arthritis in members who are 6 years of age or older when all of the following criteria are met:

1. Ustekinumab is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.

2. Documented moderate to severe active disease and member meets either of the following criteria:
    a. If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
    b. If member has peripheral arthritis, member has experienced an inadequate response to at least a 3-month trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, unless intolerance experienced or contraindicated in the member
3. Member has had an inadequate response, intolerance, or contraindication to adalimumab for at least a 3-month trial at maximum tolerated doses.
4. Dosing falls within the following FDA guidelines:
    a. Adult Subcutaneous Loading Dose:
        - 45mg at week 0 & 4, then begin maintenance dosing 12 weeks later
    b. Adult subcutaneous loading dose with co-existent moderate to severe plaque psoriasis weighing greater than 100 kg:
        - >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later

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

Authorization of 6 months may be granted for treatment of moderately to severely active CD in members who are 18 years of age or older when all of the following criteria are met:

1. Documented moderate to severe active disease; AND
2. Must be prescribed by, or in consultation with, a specialist in gastroenterology
3. Member has had an inadequate response, intolerance or contraindication to infliximab IV or adalimumab for at least a 3-month trial at maximum tolerated doses.

D. Moderately to severely active ulcerative colitis (UC)

Authorization of 6 months may be granted for treatment of moderately to severely active UC in members who are 18 years of age or older when all of the following criteria are met:

1. Documented moderate to severe UC
   Must be prescribed by, or in consultation with, a specialist in gastroenterology
2. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses.

CONTINUATION OF THERAPY

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 6 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 6 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 6 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 6 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 6 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 6 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)

IV. OTHER

Induction:

Ustekinumab for intravenous administration is FDA-approved for the treatment of Crohn's disease and ulcerative colitis and will only be authorized for these conditions as a single dose within the FDA guidelines.

- ≤ 55 kg: 260 mg
- > 55 kg to 85 kg: 390 mg
- > 85 kg: 520 mg

Maintenance:

The recommended subcutaneous maintenance dosage for Crohn's disease and ulcerative colitis is 90 mg administered 8 weeks after the initial intravenous dose.

Note: If requesting IV dose, this must be indicated on the request with the following information:

A. Where drug will be obtained - through pharmacy benefit (filled at specialty pharmacy) or through medical benefit ('buy and bill')

B. Servicing provider name and NPI for ustekinumab administration if requesting through medical benefit

V. QUANTITY LIMIT

1. Stelara 45 mg dose - 1 injection per 12 weeks, post-limit for loading dose of 2 injections per 35 days
2. Stelara 90mg dose - 1 injection per 8 weeks, post-limit for loading dose of 2 injections per 35 days
3. Ustekinumab 45mg or 90mg dose – 1 injection per 6 weeks, post-limit for loading dose of 2 injections per 35 days

VI. REFERENCES

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2022 .
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011;65(1):137-174.
3. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis.* 2016;75(3):499-510.
4. Gladman DD, Antoni C, P Mease, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis* 2005;64(Suppl II):ii14–ii17.
5. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol.* 2011;106(Suppl 1):S2-S25.
6. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.