Effective Date: 2/19
Revised: 1/2020 Reviewed: 2/19, 1/20 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

STELARA (ustekinumab)

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

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

II. 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 Stelara 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 infections.

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 12 years of age or older when all of the following criteria are met:

1. Stelara 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:
   a. 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
   b. 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 a TNF-alpha inhibitor (e.g. adalimumab, infliximab) at maximum tolerated doses.

5. Stelara will not be used concomitantly with any other biologic DMARD (e.g. adalimumab, infliximab) or targeted synthetic DMARD (e.g. apremilast, tofacitinib).

B. Active psoriatic arthritis (PsA)

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

1. Stelara 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
3. Stelara will not be used concomitantly with any other biologic DMARD (e.g. adalimumab, infliximab) or targeted synthetic DMARD (e.g. apremilast, tofacitinib).

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. Member has had an inadequate response, intolerance or contraindication to at least a 3 month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6- mercaptopurine, or methotrexate) at maximum tolerated doses.
2. Member has had an inadequate response, intolerance or contraindication to at least a 3 month trial of a TNF-alpha inhibitor (e.g. adalimumab, infliximab) at maximum tolerated doses.
3. Stelara will not be used concomitantly with any other biologic DMARD (e.g. adalimumab, infliximab) or targeted synthetic DMARD (e.g. apremilast, tofacitinib).

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. Member has had an inadequate response, intolerance or contraindication to at least a 3 month trial of one conventional therapy option (e.g. mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine) at maximum tolerated doses.
2. Member has had an inadequate response, intolerance or contraindication to at least a 3 month trial of a TNF-alpha inhibitor (e.g. adalimumab, infliximab) at maximum tolerated doses.
3. Stelara will not be used concomitantly with any other biologic DMARD (e.g. adalimumab, infliximab) or targeted synthetic DMARD (e.g. apremilast, tofacitinib).

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members (including new members) who are being treated with Stelara for a compendia-supported indication at a compendia-supported dose and dosing regimen, are tolerating treatment with Stelara, and have achieved or maintained positive clinical response after at least 4 months of therapy with Stelara as evidenced by low disease activity or improvement in signs and symptoms of the condition.

IV. OTHER

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 as a single dose within the FDA guidelines.

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

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 Stelara 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

VI. REFERENCES

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2018.
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.