

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) in patients 6 years or older who are candidates for phototherapy or systemic therapy
2. Active psoriatic arthritis (PsA) alone or in combination with methotrexate (MTX).
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 not medically necessary.

II. DOCUMENTATION

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

A. Plaque psoriasis

1. Initial requests:
 - i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
 - 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: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Crohn's disease and ulcerative colitis

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 to therapy or remission.

III. 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 in members 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. Active psoriatic arthritis (PsA)

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 B).

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 C).

IV. 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)

V. 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, 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 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.

** 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 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.

VI. DOSAGE AND ADMINISTRATION

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

VII. APPENDICES

Appendix A: 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 B: 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 intravenous (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 C: 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

VIII. REFERENCES

- 1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2020.
- 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, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis.* 2020;79(6):700-712.
- 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.
- 7. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):1029-1072.
- 8. Tuberculosis (TB). TB risk factors. Centers for Disease Control and Prevention. Retrieved on 19 January 2021 from: <https://www.cdc.gov/tb/topic/basics/risk.htm>.
- 9. 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.
- 10. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114:384-413.

Reference number(s)
2010-A

11. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020; 158:1450.
12. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32. doi:10.1002/art.40726.
13. Menter, A, Cordero, KM, Davis, DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol.* 2020;82(1):161-201.
14. Menter, A, Gelfand, JM, Connor, C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6): 1445-86.
15. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology* 2021; 160: 2496-2508.