Reference number
2393-A

STANDARD MEDICARE PART B 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.

A. FDA-Approved Indications
   1. For the treatment of patients 6 years or older with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy.
   2. For the treatment of patients 6 years or older with active psoriatic arthritis (PsA).
   3. For the treatment of adult patients with moderately to severely active Crohn's disease (CD).
   4. For the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

B. Compendial Uses
   Immune checkpoint inhibitor-related toxicity

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Ulcerative colitis (UC) and Crohn's disease (CD)
   For continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

B. Immune checkpoint inhibitor-related toxicity (initial requests only)
   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.

C. All other indications
   For continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy.

III. CRITERIA FOR INITIAL APPROVAL

A. Plaque psoriasis (PsO)
Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis.

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

C. Crohn's disease (CD)
Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

D. Ulcerative colitis (UC)
Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

E. **Immune checkpoint inhibitor-related toxicity**
Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related diarrhea or colitis when the member has had an inadequate response, intolerance, or contraindication to infliximab or vedolizumab.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

A. Crohn's disease (CD)
Authorization for 12 months may be granted for moderately to severely active Crohn's disease when both of the following criteria are met:
1. The member is currently receiving therapy with Stelara.
2. The member is receiving benefit from therapy. Benefit is defined as one of the following:
    i. Member has achieved or maintained remission.
    ii. Member has achieved or maintained 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:
        a. Abdominal pain or tenderness
        b. Diarrhea
        c. Body weight
        d. Abdominal mass
        e. Hematocrit
        f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
        g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

B. Ulcerative colitis (UC)
Authorization for 12 months may be granted for moderately to severely active ulcerative colitis when both of the following criteria are met:
1. The member is currently receiving therapy with Stelara.
2. The member is receiving benefit from therapy. Benefit is defined as one of the following:
    i. Member has achieved or maintained remission.

ii. Member has achieved or maintained 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:
   a. Stool frequency
   b. Rectal bleeding
   c. Urgency of defecation
   d. C-reactive protein (CRP)
   e. Fecal calprotectin (FC)
   f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   g. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

C. Immune checkpoint inhibitor-related toxicity
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

D. All other indications
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Stelara.
2. Stelara is being used to treat an indication enumerated in Section III.
3. The member is receiving benefit from therapy.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Stelara.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: Management of immunotherapy-related toxicities
4. An evidence-based systematic review on medical therapies for inflammatory bowel disease.
5. ACG Clinical Guideline: Management of Crohn's Disease in Adults
6. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults
7. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis
8. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Stelara are covered in addition to immune checkpoint inhibitor-related toxicity.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Stelara to manage immune checkpoint inhibitor-related toxicity can be found in the National Comprehensive Cancer Network's guideline for the management of immunotherapy-related toxicities. The NCCN Guideline for the management of immunotherapy-related toxicities supports the use of adding Stelara for mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin. Additionally, consider Stelara for infliximab- and/or vedolizumab-refractory moderate (G2) or severe (G3-4) diarrhea or colitis.

VII. REFERENCES

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2022.
2. 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.
3. 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.
4. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114:384-413.
5. 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.
6. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 20, 2023.
7. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of Immunotherapy-Related Toxicities. Version 1.2022. Available at: www.nccn.org. Accessed January 16, 2023.
8. 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.