SmartHealth

Ascension

Ustekinumab

(Stelara®) J3357 (SC), J3358(IV) (1mg)

Covered with prior authorization

Ustekinumab (Stelara) may be authorized when the following criteria are met:

- Individual is 18 years of age or older; **AND**
- The medication will be used as induction therapy; **AND**
- Diagnosis of Crohn's Disease; **AND**
    - Individual has tried or is currently taking a systemic corticosteroid, or a systemic corticosteroid is contraindicated in this individual; **OR**
    - Individual has failed (TNF-***α***) therapy such as adalimumab or infliximab; **OR**
    - Individual has tried one other conventional systemic therapy for Crohn's disease; **OR**
    - Individual has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; **OR**
    - Individual had ileocolonic resection (to reduce the chance of Crohn's disease recurrence);

  AND
- Prescribed by, or in consultation with a gastroenterologist or a prescriber who specializes in Crohn's disease; **AND**
- Dosing is single (induction) intravenous infusion using weight based dosing
    - Up to 55 kg 260 mg
    - > than 55 kg to 85 kg 390 mg
    - > 85 kg 520 mg;
- Dosing (maintenance) 90 mg subcutaneous 8 weeks after intravenous dose, then every 8 weeks thereafter;

OR

- Diagnosis of Ulcerative colitis; **AND**
    - Individual has had a trial of one systemic agent for ulcerative colitis;

      ⋆*Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus , or corticosteroids such as prednisone or methylprednisolone. A trial of a biologic also counts as a trial of one systemic agent for ulcerative colitis.*

  AND
- Prescribed by or in consultation with a gastroenterologist or a prescriber who specializes in ulcerative colitis; **AND**
- Dosing is single (induction) intravenous infusion using weight based dosing
    - Up to 55 kg 260 mg
    - > than 55 kg to 85 kg 390 mg
    - > 85 kg 520 mg;
- Dosing (maintenance) 90 mg subcutaneous 8 weeks after intravenous dose, then every 8 weeks thereafter.

Exclusion criteria:
Requests may not be approved for the following:

- Ankylosing Spondylitis (AS)
- Plaque Psoriasis
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Pediatric individuals (＜18 years of age)
- Concomitant use with any other biological including all non-tumor necrosis factor (non-TNF) biologics, anti-TNF biologics, or oral immunomodulatory agents (for example, Otelza or Xeljanz/Xeljanz XR)
- Doses, duration, or dosing intervals that exceed FDA maximum limits for any FDA approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
STELARA® is a human interleukin-12 and -23 antagonist indicated for the treatment of:

- Adult patients with:
  - moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy.
  - active psoriatic arthritis (PsA), alone or in combination with methotrexate.
  - moderately to severely active Crohn's disease (CD).
  - moderately to severely active ulcerative colitis.
- Pediatric patients 6 years and older with:
  - moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.

References:
Stelara® injection [prescribing information]. Horsham, PA: Janssen Biotech; December 2020.
Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113(4):481-517.
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.
Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation

Guideline for the treatment of psoriatic arthritis. Arthritis Care Res (Hoboken). 2019;71(1):2-29.
Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413.
Feuerstein JD, Isaac s KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020;158:1450-1461.
Poddubnyy D, Hermann KG, Callhoff J, et al. Ustekinumab for the treatment of patients with active ankylosing spondylitis: results of a 28-week, prospective, open-label, proof-of-concept study (TOPAS). Ann Rheum Dis. 2014;73(5):817-823.
Stelara (ustekinumab) label. (2020, July). Accessdata.fda.gov. Retrieved June 14, 2022 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125261s150lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Ambulatory Care Expert Review Panel
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.