

Stelara® (ustekinumab)

When requesting Stelara® (ustekinumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

Stelara is indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Stelara is indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

Stelara is indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

Stelara is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

Coverage Guidelines

Crohn's Disease

The individual must meet the following criteria for initial authorization:

- Is 18 years of age or older; AND
- Stelara is prescribed by or in consultation with a gastroenterologist; AND
- Will receive, or has received, a single induction dose of Stelara IV within 2 months of initiating therapy with Stelara SC; AND
- Meets one of the following;
 - Has tried one other systemic agent for Crohn's disease (e.g., certolizumab pegol, vedolizumab, adalimumab, infliximab, azathioprine, 6-mercaptopurine, methotrexate); OR
 - Has tried or is currently taking corticosteroids; OR
 - Has a contraindication to corticosteroids; OR
 - Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas or had ileocolonic resection.

Ulcerative Colitis

The individual must meet all of the following criteria for initial authorization:

- Has tried one other systemic agent for ulcerative colitis (e.g., vedolizumab, adalimumab, golimumab, infliximab, azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus, corticosteroid);
- Will receive, or has received, a single induction dose of Stelara IV within 2 months of initiating therapy with Stelara SC;
- Is 18 years of age or older; AND
- Stelara is prescribed by or in consultation with a gastroenterologist.

Plaque psoriasis

The individual must meet the following criteria for initial authorization:

- Has had a 3-month trial of, or intolerance to, at least one systemic agent for psoriasis (e.g., adalimumab, etanercept, infliximab, tildrakizumab-asnm, methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light [PUVA]); OR
- Has a contraindication to methotrexate; AND
- Is 6 years of age or older; AND
- Stelara is prescribed by or in consultation with a dermatologist.

For reauthorization, the individual must meet the following criteria:

- Has been established on Stelara therapy for at least 90 days; AND
- Meets one of the following:
 - Has experienced an improvement in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
 - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, itching and/or burning).
- **Note:** A patient who has received < 90 days of therapy, or who is restarting therapy with Stelara, is reviewed under initial authorization criteria.

Psoriatic arthritis

The individual must meet the following criteria for initial authorization:

- Stelara is prescribed by or in consultation with a rheumatologist or a dermatologist.

For reauthorization (for all indications except plaque psoriasis), the individual must meet the following criteria:

- Has been established on Stelara therapy for at least 6 months; AND
- Meets one of the following:
 - Has experienced an improvement in at least one objective measure compared to baseline (e.g., Disease Activity Index for Psoriatic Arthritis [DAPSA], Minimal Disease Activity [MDA], improvement of serum markers such as C-reactive protein, reduced dose of corticosteroids); OR

- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, less morning stiffness, less fatigue, improved function or activities of daily living, decreased rectal bleeding).
- Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Stelara, is reviewed under initial authorization criteria.

Approval duration:

- Initial authorization: Plaque psoriasis 3 months; all other indications 6 months
- Reauthorization (all indications): 12 months

Dosing Recommendations

Crohn's Disease and Ulcerative Colitis

Intravenous induction dosage regimen (a single intravenous infusion)

- For patients weighing 55 kg or less, the recommended dose is 260 mg.
- For patients weighing 56 kg to 85 kg, the recommended dose is 390 mg.
- For patients weighing more than 85 kg, the recommended dose is 520 mg.

Subcutaneous maintenance dosage regimen

- The recommended dose is 90 mg administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

Plaque Psoriasis

Subcutaneous adult dosage regimen

- For patients weighing 100 kg or less, the recommended dose is 45 mg administered at weeks 0 and 4, then every 12 weeks.
- For patients weighing more than 100 kg, the recommended dose is 90 mg administered at weeks 0 and 4, then every 12 weeks.

Subcutaneous pediatric (6 to 17) dosage regimen

- For patients weighing less than 60 kg, the recommended dose is 0.75 mg/kg administered at weeks 0 and 4, then every 12 weeks.
- For patients weighing 60 kg to 100 kg, the recommended dose is 45 mg administered at weeks 0 and 4, then every 12 weeks.
- For patients weighing more than 100 kg, the recommended dose is 90 mg administered at weeks 0 and 4, then every 12 weeks.

Psoriatic arthritis

Subcutaneous dosage regimen

- The recommended dose is 45 mg administered at weeks 0 and 4, then every 12 weeks.
- For patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg, the recommended dose is 90 mg administered at weeks 0 and 4, then every 12 weeks.

References

1. Stelara® injection [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; December 2020.
2. 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.
3. 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.
4. 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.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020;158:1450-1461.
7. 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.