

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
- patients 6 years or older with active psoriatic arthritis (PsA)
- adult patients with moderately to severely active Crohn's disease
- adult patients with moderately to severely active ulcerative colitis (UC)

Coverage Guidelines

Crohn's Disease

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

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

The individual must meet **all** of the following criteria for re-authorization:

- Has been established on Stelara therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Stelara, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR

- o Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or blood in stool).

Ulcerative Colitis

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

- Is 18 years of age or older;
- Will receive or has received a single induction dose of Stelara intravenous within 2 months of initiating therapy with Stelara subcutaneous;
- Meets one of the following:
 - o Has tried one other systemic agent for ulcerative colitis (e.g., vedolizumab, adalimumab, golimumab, infliximab, azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus, corticosteroid); OR
 - o Has pouchitis and has tried one of the following: an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema (e.g., hydrocortisone enema), or mesalamine enema.
- Stelara is prescribed by or in consultation with a gastroenterologist.

The individual must meet **all** of the following criteria for re-authorization

- Has been established on Stelara therapy for at least 6 months (*NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Stelara should be considered under initial criteria*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR
 - o Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or blood in stool).

Plaque Psoriasis

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

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

The individual must meet **all** of the following criteria for re-authorization:

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- Has been established on Stelara therapy for at least 3 months (*Note: A patient who has received < 3 months of therapy, or who is restarting therapy with Stelara, is reviewed under initial authorization criteria.*);
- Has experienced an improvement from baseline in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis;
- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, itching, and/or burning).

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.

The individual must meet **all** of the following criteria for re-authorization:

- Has been established on Stelara therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Stelara, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - o Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Disease Activity Index for Psoriatic Arthritis [DAPSA], Composite Psoriatic Disease Activity Index [CPDAI], Psoriatic Arthritis Disease Activity Score [PsA DAS], Grace Index, Minimal Disease Activity [MDA], Psoriatic Arthritis Impact of Disease [PsAID-12], etc.); OR
 - o Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain or morning stiffness, less fatigue, or improvement in function or activities of daily living).

Approval duration (initial and renewal): 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 more than 55 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

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- 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 years old) 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.

Subcutaneous pediatric (6 to 17 years old) 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 or more, the recommended dose is 45 mg administered at weeks 0 and 4, then every 12 weeks.
- For patients weighing more than 100 kg with co-existent moderate-to-severe plaque psoriasis, the recommended dose is 90 mg administered at weeks 0 and 4, then every 12 weeks.

References

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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, 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.
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.