

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 12 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.

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

- Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker or
- Failed or were intolerant to treatment with one or more TNF blockers

Approved Off-Label Compendial Use(s)

None

Coverage Guidelines

For all approved indications, the individual must meet **all** of the following criteria for approval:

- Does not have any clinically active infection
- Stelara (ustekinumab) will not be used in combination with another biologic agent (e.g., IL-inhibitor, rituximab, TNF-inhibitor, T-cell costimulation modulator)
- Is at least 12 years of age
- For an initial authorization request, an individual has been screened for latent tuberculosis (TB). For positive latent TB, an individual has started/completed or will be treated for TB prior to starting Stelara (ustekinumab)
- For a re-authorization request, an individual's condition has improved or stabilized with Stelara (ustekinumab) therapy

For plaque psoriasis initial authorization:

- Has an inadequate response or intolerance to prior biologic therapy OR
- Has affected body surface area (BSA) greater than 5% OR has psoriasis in vulnerable areas such as the face, genitals, hands and feet, or scalp and adversely affects quality of life AND
- Has tried and failed phototherapy or traditional systemic therapy (e.g., methotrexate, cyclosporine, acitretin) unless has one of the following conditions:

- o Contraindicated to traditional systemic therapy
- o Intolerant to traditional systemic therapy
- o Phototherapy not accessible/available

For psoriatic arthritis initial authorization:

- Has an inadequate response or intolerance to prior TNF inhibitor (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab)

For Crohn's disease initial authorization:

- Has moderately to severely active disease AND
- Has an inadequate response or intolerance to a TNF inhibitor (e.g., Infliximab, adalimumab, certolizumab) OR
- Has an inadequate response or intolerance to an immunomodulator (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) OR
- Has an inadequate response, intolerance, or dependency to corticosteroids

Approval duration (initial and renewal): 12 months

Dosing Recommendations

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 adolescent 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

Crohn's disease

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

References

1. Stelara prescribing information. Horsham, PA; Janssen Biotech, Inc., February 2018.
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4. American Academy of Dermatology. 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;65:137-174.
5. Lichtenstein GR, Loftus JR EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol* 2018;113:481-517.
6. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Use of Thiopurines, Methotrexate, and Anti-TNF-alpha Biologic Drugs for the Induction and Maintenance of Remission in Inflammatory Crohn's Disease. *Gastroenterology* 2013;145:1459-1463.
7. Gomollon F, Dignass A, Annese V, et al. 3rd European Evidence-based Consensus on the Diagnosis and Management of Crohn's Disease 2016: Part 1: Diagnosis and Medical Management. *Journal of Crohn's and Colitis*. 2017:3-25