



Stelara® (Ustekinumab)

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Medical Guideline Disclaimer

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Definition

Stelara® is a human IgG1-kappa monoclonal antibody that binds to the p40 subunits of IL-12 and IL-23 cytokines and interferes with inflammatory and immune responses.

Length of Authorization

- **Crohn's Disease:**
 - Coverage will be provided for 1 intravenous induction dose

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

Indication	Max Units
Crohn's Disease	<u>Intravenous Induction (J3358):</u> <ul style="list-style-type: none">• 520 billable units

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

- Patient is 18 years or older (unless otherwise specified); **AND**

- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Patient is free of any clinically important active infections; **AND**
- Therapy will not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**

Crohn’s Disease †

- Documented moderate to severely active disease; **AND**
 - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of ONE corticosteroid or immunomodulator (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **OR**
 - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g. adalimumab, certolizumab, or infliximab)

† FDA Approved Indication(s)

Limitations/Exclusions

Stelara subcutaneous injection is considered a covered pharmacy benefit for all FDA approved indications, and is therefore not covered under the medical benefit.

II. RENEWAL CRITERIA

Coverage cannot be renewed.

Dosing/Administration

Indication	Dose
Crohn’s Disease	<u>Intravenous Induction Dose (one-time only):</u> <ul style="list-style-type: none"> • ≤ 55 kg: 260 mg • > 55 kg to 85 kg: 390 mg • > 85 kg: 520 mg

Applicable Procedure Codes

J3358	Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg
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Applicable NDC’s

57894-0054-xx	Stelara 130 mg (5 mg/mL) single-dose vial
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Applicable Diagnosis Codes	
ICD-10	ICD-10 Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications

Revision History

4/1/2019	Removal of J3357 (Ustekinumab, for subcutaneous injection) – Pharmacy benefit
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