Ustekinumab (Stelara®)
Vials

Place of Service
Office Administration
Home Infusion Administration
Infusion Center Administration
Outpatient Facility Infusion Administration

HCPCS
- **J3358** per 1 mg (IV)
- **J3357** per 1 mg (SQ)

Conditions listed in policy (*see criteria for details*)
- Crohn's disease
- Plaque psoriasis
- Psoriatic arthritis
- Ulcerative colitis

AHFS therapeutic class: Immunomodulator

Mechanism of action: Ustekinumab, a monoclonal antibody, is an immunosuppressive agent.

(1) Special Instructions and pertinent Information

Stelara vials (IV and SQ) are managed under the Medical Benefit. Please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Stelara® (ustekinumab) must be sent for clinical review and receive authorization

Crohn's disease

1. Disease is moderate to severe, **AND**
2. Patient is 18 years or older, **AND**
3. Not being used with another targeted immunomodulator, **AND**
4. One of the following:
    a. Patient has had an inadequate response or intolerable side effect with preferred infliximab, Avsola, Inflectra, or Renflexis, or
    b. Patient has not been treated with infliximab AND has a contraindication to all infliximab products (Avsola, Inflectra, and Renflexis)

Covered Doses
Initial single IV dose:

Weight Range (kg)	Recommended Dosage
Up to 55 kg	260 mg (2 vials)
Greater than 55 kg to 85 kg	390 mg (3 vials)
Greater than 85 kg	520 mg (4 vials)

Coverage Period
One-time IV dose

ICD-10:
K50.00-K50.119, K50.80-K50.919

Plaque psoriasis

1. Age ≥ 6 years of age, **AND**
2. Prescribed by or in consultation with a rheumatologist or dermatologist, **AND**
3. One of the following:
    a. Baseline PASI score is 10 or more prior to starting targeted immunomodulator therapy, OR
    b. Baseline BSA (body surface area) affected is 3% or more prior to starting targeted immunomodulator therapy, OR
    c. Sensitive area is involved (i.e., groin, face, etc.), OR
    d. Disease is otherwise debilitating

AND

4. Inadequate response, intolerable side effect, or contraindication to one of the following:
    a. Methotrexate, cyclosporine (Neoral), acitretin (Soriatane), OR
    b. PUVA or UVB treatment

AND

5. Not being used in combination with another targeted biologic

Covered Doses

Pediatric (6 to 17):

Weight Range (kg)	Dosage Regimen
Less than 60 kg	0.75 mg/kg administered subcutaneously at Weeks 0 and 4, then every 12 weeks
60 kg to 100 kg	45 mg administered subcutaneously at Weeks 0 and 4, then every 12 weeks
Greater than 100 kg	90 mg administered subcutaneously at Weeks 0 and 4, then every 12 weeks

Adult:

Weight Range (kg)	Dosage Regimen
Less than or equal to 100 kg	45 mg administered subcutaneously initially and 4 weeks later, followed by 45 mg administered subcutaneously every 12 weeks
Greater than 100 kg	90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks

Coverage Period
Initial: 24 weeks
Reauthorization: Yearly if meets the following:

1. Not being used in combination with other targeted biologics, AND
2. One of the following:
    a. Improvement in PASI score from baseline, OR
    b. Improvement in BSA from baseline, OR
    c. Decrease in sensitive area disease severity, OR
    d. Decrease in debilitating disease severity

ICD-10:

L40.0-L40.4

Psoriatic arthritis

1. Prescribed by or in consultation with a Rheumatologist, **AND**
2. Inadequate response, intolerance, or contraindication to one or more disease modifying anti-rheumatic drugs (DMARDs) (*see section 5*), OR has a medical reason why methotrexate, sulfasalazine, and leflunomide cannot be used, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors, Otezla)

Covered Doses

Up to 45 mg SC initially and 4 weeks later, followed by 45 mg every 12 weeks.

For co-existent moderate-to-severe plaque psoriasis in patients weighing >100 kg (220lbs): up to 90 mg SC initially and 4 weeks later, followed by 90 mg every 12 weeks

Coverage Period

Cover yearly, based upon continued response.

ICD-10:

L40.50-L40.59

Ulcerative colitis

1. Disease is moderate to severe, **AND**
2. Patient is 18 years or older, **AND**
3. Not used in combination with a targeted immunomodulator, **AND**
4. One of the following:
    a. Patient has had an inadequate response or intolerable side effect with preferred infliximab,Avsola, Inflectra, or Renflexis, OR
    b. Patient has not been treated with infliximab AND has a contraindication to all infliximab products (Avsola, Inflectra, and Renflexis)

Covered Doses

Initial single IV dose:

Weight Range (kg)	Recommended Dosage
Up to 55 kg	260 mg (2 vials)
Greater than 55 kg to 85 kg	390 mg (3 vials)
Greater than 85 kg	520 mg (4 vials)

Coverage Period

One-time IV dose

ICD-10:

K51.0-K51.319, K51.5-K51.519, K51.80-K51.919

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Stelara® (ustekinumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Multiple Sclerosis

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
45 mg single-dose vial (for SC injection)
130 mg single-dose vial (for IV infusion)

DMARD examples:

- Auranofin (Ridaura®)
- Azathioprine (Imuran®)
- Cyclosporine (Neoral®)
- Hydroxychloroquine (Plaquenil®)
- Methotrexate (Rheumatrex®)
- D-Penicillamine (Cuprimine®)
- Sulfasalazine (Azulfidine®)
- Leflunomide (Arava®)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- 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
- Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2018;113:481-517.
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384-413.
- 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;145:1459-63.
- Stelara (ustekinumab) [Prescribing information]. Horsham, PA: Janssen Biotech, Inc.; 7/2020.

(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee