CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Stelara (ustekinumab)
BILLING CODE	J3357
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Stelara is a human interleukin-12 and interleukin-23 antagonist initially approved by the FDA in 2009. It is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis. Pediatric patients 6 years and older are also approved to have Stelara for moderate to severe plaque psoriasis treatment.

Stelara (ustekinumab) will be considered for coverage when the following criteria are met:

Crohn's Disease (CD)

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Must have had a negative TB test within the last 12 months; AND
4. Member has had a documented trial and inadequate response, or intolerance to at least **one** of the following conventional therapies: a 4-week trial of a corticosteroid OR a 12-week trial of 6-mercaptopurine, azathioprine, or methotrexate. Note: Trial is not required if member is switching from another biologic agent; OR
5. Member has severe disease that requires immediate use of a biologic agent, as indicated by one of the following:
   a) Extensive small bowel disease involving more than 100 cm;
   b) History of bowel or colon resection and is at high risk for CD recurrence (e.g., smoker, <30 years old, 2 or more resections, penetrating/fistulizing disease, etc.);
   c) Fistulizing disease.
6. **Dosage allowed/Quantity limit:**
   a) Induction (medical benefit): a one-time IV infusion based on weight. 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);
   b) Maintenance (pharmacy or medical benefit): subcutaneous injection of 90 mg dose 8 weeks after induction and every 8 weeks thereafter.

Note to reviewer: A one-time induction dose is approved on the medical benefit. Maintenance therapy is approved on either pharmacy OR medical benefit. Please inactivate any duplicate prior authorization.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of CD (defined as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Plaque Psoriasis (PsO)

For **initial** authorization:
1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Must have had a negative TB test within the last 12 months; AND
5. Member has tried and failed to respond to treatment with at least **one** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
7. **Dosage allowed/Quantity limit:**
   a) Adults: 100 kg or less: 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter; more than 100 kg: 90 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter;
   b) Pediatrics (6 to 17): subcutaneous dose by weight at week 0, week 4, and every 12 weeks thereafter. Less than 60 kg: 0.75 mg/kg; 60 kg to 100 kg: 45 mg; more than 100 kg: 90 mg.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:
1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Must have had a negative TB test within the last 12 months; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **one** of the following situations is met:
   a) Non-biologic DMARD is not required for:

i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR

b) NSAID and non-biologic DMARD are not required for:

i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life).

6. **Dosage allowed/Quantity limit:**

a) Adults: 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter. If member has co-existent moderate-to-severe PsO, use the dosing regimen for adult PsO.

b) Pediatrics (6 to 17): subcutaneous dose by weight at week 0, week 4, and every 12 weeks thereafter.

Weight Range (kilograms)	Dosage Regimen
Less than 60 kg	0.75 mg/kg
60 kg or more	45 mg
Greater than 100 kg with co-existent moderate-to-severe plaque psoriasis	90 mg

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active UC; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Must have had a negative TB test within the last 12 months; AND
4. Member have had a documented trial and inadequate response with **one** of the following:
   a) 3 months of 6-mercaptopurine or azathioprine;
   b) 30 days of corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
   c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).
5. **Dosage allowed/Quantity limit:**
   a) Induction (medical benefit): a one-time IV infusion based on weight. 55 kg or less = 260 mg (2 vials); greater than 55 kg to 85 kg = 390 mg (3 vials); greater than 85 kg = 520 mg (4 vials);
   b) Maintenance (pharmacy or medical benefit): subcutaneous injection of 90 mg dose 8 weeks after induction and every 8 weeks thereafter.

Note to reviewer: A one-time induction dose is approved on the medical benefit. Maintenance therapy is approved on either pharmacy OR medical benefit. Please inactivate any duplicate prior authorization.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of UC (defined as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Stelara (ustekinumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/10/2017	Policy for Stelara created. Policies SRx-0042 and SRx-0043 archived. New diagnosis of Crohn's disease was added. For diagnosis of PsO: immunosuppressive criterion was separated from phototherapies and topical agents trials; TNF inhibitors Humira and Enbrel were listed as required trials; Psoriasis Area and Severity Index (PASI) score requirement was added. For diagnosis of PsA: TNF inhibitors Humira and Enbrel were listed as required trials. List of diagnoses considered not medically necessary was added.
11/13/2017	Age requirement for diagnosis of PsO updated.
02/26/2019	Humira was removed from criteria; Cimzia, Cosentyx, Otezla, Siliq and Xeljanz added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
10/31/2019	New indication of Ulcerative Colitis added.
11/23/2020	Removed repeat TB for reauth for all diagnoses. For CD: specified length of trials for conventional therapies, previously not specified. For severe disease, removed esophageal/gastroduodenal disease, specified that history of colonic resection must also be high risk for recurrence. Updated dosage section and added note for internal PA review. For PsO: Age requirement expanded to include 6 years or older. Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. For PsA: Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). For UC: removed Mayo score requirement; removed TNF as a trial option; specified the length of trials for conventional therapies (previously not specified). Updated dosage section and added note for internal PA review.
03/05/2022	Transferred to new template. Updated references. Simplified wording for TB test and DMARD requirements. Removed initial criteria requirement from reauthorization. Removed TNF trial requirement for CD.
03/17/2022	Removed preferred biologic trials.
08/19/2022	Lowered age for PsA to at least 6 years of age. Updated dosing section. Updated references.

References:

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