CareSource

| PHARMACY POLICY STATEMENT<br>**Indiana Medicaid** | |
|---|---|
| DRUG NAME | Stelara (ustekinumab) |
| BILLING CODE | J3357 (1 unit = 1 mg)<br>Must have valid NDC for self-administered product |
| BENEFIT TYPE | Medical or Pharmacy |
| SITE OF SERVICE ALLOWED | Office/Outpatient/Home |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product)<br>Alternative preferred products include Enbrel, Cimzia, Cosentyx, Xeljanz, Otezla and Siliq<br>QUANTITY LIMIT— 90 units per 56 days (after loading dose) |
| LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY | Click Here |

Stelara (ustekinumab) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

## 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 a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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; AND
6. Member has tried and failed at least 12 weeks of an anti-TNF agent (e.g., Cimzia, Humira), unless not tolerated or contraindicated.
7. **Dosage allowed:**
   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 member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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 a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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; AND
7. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq (if member is < 18 years of age, only Enbrel trial is needed). Treatment failure requires at least 12 weeks of therapy with each drug.
8. **Dosage allowed:**
   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 member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

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## PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 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 a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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); AND
6. Member has tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug.
7. **Dosage allowed:** 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.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, 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 a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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:**
   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 member meets all the requirements listed above, the medication will be approved for 12 months.***

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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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## CareSource considers Stelara (ustekinumab) not medically necessary for the treatment of the diseases that are not listed in this document.

| 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.<br>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.<br>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.<br>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.).<br>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. |

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Effective date: 04/01/2021
Revised date: 11/23/2020