

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Stelara (ustekinumab)
BILLING CODE	J3357 (1 unit = 1 mg) 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) Alternative preferred products include Enbrel, Humira, Taltz, and Xeljanz 5 mg tablet 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 treatment with Humira for 12 weeks. Note: if member previously tried a non-preferred TNF inhibitor (e.g., Cimzia) that is indicated for CD, then the trial can be accepted.
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: Humira, Enbrel or Taltz (if member is < 18 years of age, only Enbrel trial is needed). Treatment failure requires at least 12 weeks of therapy with each drug. Note: if member previously tried a non-preferred IL-17 inhibitor (e.g., Cosentyx) or TNF inhibitor (e.g., Cimzia) that is indicated for PsO, then the trial can be accepted.
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.

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: Humira, Enbrel, Taltz, or Xeljanz 5mg tablet. Treatment failure requires at least 12 weeks of therapy with each drug. Note: if member previously tried a non-preferred IL-17 inhibitor (e.g., Cosentyx) or TNF inhibitor (e.g., Cimzia) that is indicated for PsA, then the trial can be accepted.
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.

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. Based on the Ohio Department of Medicaid requirement Cimzia, Otezla, Siliq and Xeljanz were removed from trial agents list; Humira was added back.
11/01/2020	Updated list of preferred agents and drug trials for all diagnoses to match Ohio Department of Medicaid Unified Preferred Drug List. Added that if member previously tried a non-preferred option in the same drug class as preferred options, the trial is accepted.
11/23/2020	Removed repeat TB for reauth for all diagnoses. For <u>CD</u> : 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 <u>PsO</u> : 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 <u>PsA</u> : 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 <u>UC</u> : 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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