

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Stelara (ustekinumab)
BILLING CODE	J3357 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel and Humira 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** 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 moderate to severe, active CD with demonstrated corticosteroid dependence; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a gastroenterologist; AND
4. Member has documented trial and failure of or contraindication to Humira. Treatment failure requires at least 12 weeks of therapy without an adequate response; AND
5. Member has had a documented inadequate response to 6-mercaptopurine, azathioprine or methotrexate; OR
6. Member has severe esophageal or gastroduodenal disease; OR
7. Member has extensive small-bowel disease involving more than 100 cm; OR
8. Member has a history of colonic resection; OR
9. Member has a history of two or more small bowel resections; OR
10. Member has perianal or rectal disease.
11. **Dosage allowed:** Induction: 260 mg - 520 mg (depending on weight) intravenously as a single dose then 8 weeks after induction dose, 90 mg subcutaneously every eight weeks.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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.

PLAQUE PSORIASIS (PP)

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PP involves 10% or more of the member's body surface area; AND
5. Member has tried and failed treatment with **both** Enbrel and Humira (Humira applied only for those who 18 years of age or older); AND
6. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
7. 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; tanning beds emit mostly UVA light and therefore would not meet this criteria).
 - c) At least a 4 week trial with topical antipsoriatic agents (i.e. anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
8. Member has tried and failed to respond to treatment of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial.
9. **Dosage allowed:** ≤ 100kg: 45mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter; ≥ 100kg: 90mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has tried and failed treatment with **both** Enbrel and Humira; AND
5. Member meets at least **one** of the following scenarios:
 - a) Member has predominantly axial disease (i.e. sacroiliitis or spondylitis) as indicated by radiographic evidence; OR
 - b) Member has shown symptoms of predominantly axial disease (i.e. sacroiliitis or spondylitis) for more than 3 months (i.e. limited spinal range of motion, spinal morning stiffness for more than 30 minutes) and has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response; OR
 - c) Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and NSAID.
6. **Dosage allowed:** 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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.

CareSource considers Stelara (ustekinumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Ankylosing Spondylitis
- Asthma
- Cellulitis
- Dissecting scalp cellulitis
- For use in combination with TNF-inhibitors (i.e. Enbrel, Humira, Remicade, Kineret)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Multiple sclerosis
- Osteoarthritis
- Relapsing polychondritis
- Rheumatoid Arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis
- Takayasu's arteritis
- Ulcerative colitis
- Vogt-Koyanagi

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 PP: 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 PP updated.

References:

1. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc; October, 2017.
2. US Food and Drug Administration Drug Safety Data.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125261s114lbl.pdf

(October 14, 2014)

3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011 Feb 7.
4. MCG 20th edition, 2016.
5. National Institutes of Health, Clinicaltrials.gov. [cited 9/16/2014]; Available from: <http://www.clinicaltrials.gov>
6. Feagan BG, Sandborn WJ, Gasink C, et al. Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease. *N Engl J Med* 2016; 375:1946-1960.
7. Feagan BG, Sandborn WJ, Gasink C, et al. Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease. *N Engl J Med* 2016; 375:1946-1960.
8. Leonardi CL, Kimball AB, Yeilding N, et al. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomized, double-blind, placebo-controlled trial (PHOENIX-1). *Lancet* 2008;371:1665–74.
9. Sandborn WJ, Feagan BG, Fedorak RN, et al. A randomized trial of Ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with moderate-to-severe Crohn's disease. *Gastroenterology*. 2008 Oct;135(4):1130-41. Epub 2008 Jul 17.
10. McInnes IB, Kavanaugh A, Gottlieb AB, et al. Efficacy and safety of ustekinumab in patients with active psoriatic arthritis: 1 year results of the phase 3, multicentre, double-blind, placebo-controlled PSUMMIT 1 trial. *Lancet*. 2013 Aug 31;382(9894):780-9. doi: 10.1016/S0140-6736(13)60594-2. Epub 2013 Jun 13.

Effective date: 11/29/2017

Revised date: 11/13/2017