Generic Name: Ustekinumab

Therapeutic Class or Brand Name: Stelara®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 52504070

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/18/2018

Date Last Reviewed / Revised: 2/5/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - IV are met)

I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:

A. Active Psoriatic Arthritis and criteria 1 and 2 are met:

1. Diagnosis must be established by a rheumatologist or dermatologist.
2. Minimum age requirement: 18 years old.

B. Moderate to Severe Chronic Plaque Psoriasis and criteria 1 through 4 are met:

1. History of treatment failure, intolerance, or contraindications with phototherapy or photochemotherapy.
2. History of treatment failure, intolerance, or contraindication with at least one appropriate systemic agent (i.e. cyclosporine, methotrexate, acitretin, etc.).
3. Diagnosis must be established by a dermatologist or rheumatologist.
4. Minimum age requirement: 12 years old.

C. Moderately to severely active Crohn's Disease and criteria 1 through 3 are met:

1. History of treatment failure, intolerance to, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, budesonide, etc.).
2. Treatment must be prescribed by a gastroenterologist.
3. Minimum age requirement: 18 years old.

D. Moderately to severely active ulcerative colitis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, budesonide, etc.)
2. Treatment prescribed by a gastroenterologist.
3. Minimum age requirement: 18 years old.

II. Absence of active serious infection.

III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Co-administration of Stelara with another targeted immune modulator. Examples of targeted immune modulators include the following:
  - Actemra® (tocilizumab)
  - Cosentyx® (secukinumab)
  - Entyvio® (vedolizumab)
  - Ilumya® (tildrakizumab)
  - Kevzara® (sarilumab)
  - Kineret® (anakinra)
  - Olumiant® (baricitinib)
  - Orencia® (abatacept)
  - Otezla® (apremilast)
  - Rinvoq™ (upadacitinib)
  - Rituxan® (rituximab)
  - Siliq® (brodalumab)
  - Skyrizi® (risankizumab)
  - Taltz® (Ixekizumab)
  - TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis™ (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]
  - Tremfya™ (guselkumab)
  - Tysabri® (natalizumab)
  - Xeljanz® /Xeljanz® XR (tofacitinib)

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Stelara 45 mg vial/prefilled syringe:
    - Loading: 1 syringe at week 0 & 4,12 weeks.
- Stelara 90 mg vial/prefilled syringe:
    - Loading: 1 syringe at week 0 & 4.
    - Maintenance: 1 syringe every 8 weeks for Crohn's and 1 syringe every 12 weeks for psoriasis and psoriatic arthritis.
- Stelara 130 mg
    - Single intravenous infusion loading dose for Crohn's
        - Up to 55 kg: 260 mg (130 mg vial x 2)
        - >55 kg – 85 kg: 390 mg (130 mg vial x 3)
        - > 85 kg: 520 mg (130 mg vial x 4)

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

APPENDIX

N/A

REFERENCES

1. Stelara package insert. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf.
2. Singh JA et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2015 Nov 6. doi: 10.1002/acr.22783.
3. Lichtenstein GR et al. Practice Parameters Committee of American College of Gastroenterology. Management of Crohn's disease in adults. *Am J Gastroenterol.* 2009;104(2):465.
4. Hsu S et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol.* 2012 Jan;148(1):95-102.
5. Kornbluth A et al. Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol.* 2010 Mar;105(3):501-23.
6. Terdiman JP et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-a biologic drugs for the induction and maintenance

of remission in inflammatory Crohn's disease. *Gastroenterology*. 2013 Dec;145(6):1459-63. doi: 10.1053/j.gastro.2013.10.04.
7. Ward MM et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic *Axial Spondyloarthritis. Arthritis Rheumatol*. 2015 Sep 24. doi: 10.1002/art.39298

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
2/5/2020	1. **Added** "I.D. Moderately to severely active ulcerative colitis and criteria 1 through 3 are met: 1. History of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, budesonide, etc.) 2. Treatment prescribed by gastroenterologist. 3. Minimum age requirement: 18 years old" **Under Prior Authorization Criteria** 2. **Changed** "Coadministration of Stelara with another biologic DMARD, Otezla (apremilast), or Xeljanz/XeljanzXR (tofacitinib). Example biologic DMARDs include" **TO** " Coadministration of Stelara with another targeted immune modulator, examples of targeted immune modulators" 3. **Added** "Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast), Skyrizi (risankizumab), Xeljanz/XeljanzXR (tofacitinib)" **under Exclusion Criteria**.
12/18/2018	4. New Policy