**Generic Name:** Infliximab

**Therapeutic Class or Brand Name:** Infliximab

**Applicable Drugs (if Therapeutic Class):** Avsola® (infliximab-axxq), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis® (infliximab-abda)

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 11/30/2018

**Date Last Reviewed / Revised:** 1/28/2021

## PRIOR AUTHORIZATION CRITERIA

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

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

A. Active Ankylosing Spondylitis and criteria 1 and 2 are met:

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

B. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication to methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.).
2. Diagnosis must be established by a rheumatologist.
3. Minimum age requirement: 18 years old.

C. Active Psoriatic Arthritis (PsA) and criteria 1 through 4 are met:

1. History of treatment failure, intolerance to, or contraindication to methotrexate or a second line DMARD.
2. Patient has severe PsA and severe psoriasis or has predominantly axial disease. See Table 1 under Appendix.
3. Diagnosis must be established by a rheumatologist or dermatologist.
4. Minimum age requirement: 18 years old.

D. 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: 18 years old.

E. 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: 6 years old.

F. 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 must be prescribed by a gastroenterologist.
   3. Minimum age requirement: 6 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 preferred product(s).

## EXCLUSION CRITERIA

- Coadministration of infliximab with another targeted immune modulator. Examples of targeted immune modulators include the following:
  - Actemra® (tocilizumab)
  - Cosentyx® (secukinumab)
  - Dupixent® (dupilumab)
  - Entyvio® (vedolizumab)
  - Ilaris® (canakinumab)
  - Ilumya™ (tildrakizumab-asmn)
  - Kevzara® (sarilumab)
  - Kineret® (anakinra)
  - Olumiant® (baricitinib)
  - Orencia® (abatacept)
  - Otezla® (apremilast)
  - Riabni™ (rituximab-arrx)
  - Rinvoq™ (upadacitinib)

- Rituxan® (rituximab)
- Ruxience® (rituximab-pvvr)
- Siliq™ (brodalumab)
- Stelara® (ustekinumab)
- Skyrizi® (risankizumab)
- Taltz® (Ixekizumab)
- TNF inhibitors [Avsola® (infliximab-axxq), Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis® (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]
- Tremfya™ (guselkumab)
- Truxima® (rituximab-abbs)
- Tysabri® (natalizumab)
- Xeljanz®/XR (tofacitinib)

## Other Criteria

- N/A

## Quantity / Days Supply Restrictions

- Maximum dose: 10 mg/kg every 30 days, with a max of 100 mg/10ml vial X 10 vials (1,000 mg) every 30 days.

## Approval Length

- **Authorization:** 4 months.
- **Re-Authorization:** 1 year, an updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

## Appendix

- Table 1 - Examples of severe psoriatic arthritis and severe psoriasis:

| Severe Psoriatic Arthritis | Severe Psoriasis |
|---|---|
| • Erosive disease<br>• Elevated markers of inflammation (ESR, CRP) attributable to PsA<br>• Long-term damage that interferes with function (i.e., joint deformities)<br>• Highly active disease that causes a major impairment in quality of life<br>• Active PsA at many sites including dactylitis, enthesitis<br>• Function-limiting PsA at a few sites<br>• Rapidly progressive disease | • PASI of 12 or more<br>• BSA of 5-10% or more<br>• Significant involvement in specific areas<br>  • (e.g., face, hands or feet, nails, intertriginous areas, scalp) where the burden of the disease causes significant disability<br>• Impairment of physical or mental functioning can warrant a designation of moderate-to-severe disease despite the lower amount of surface area of skin involved |

## REFERENCES

1. Inflectra® [package insert]. New York, NY: Pfizer. Last updated August 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125544s000lbl.pdf.
2. Remicade® [package insert]. Horsham, PA: Janssen Biotech. Last updated May 2020. Available at: http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/REMICADE-pi.pdf.
3. Renflexis® [package insert]. Whitehouse Station, NJ: Merck. Last updated June 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761054orig1s000lbl.pdf.
4. 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.
5. 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.
6. Hsu S et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012 Jan;148(1):95-102.
7. 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.
8. 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.

9. 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.
10. Menter A.,et. al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019 Apr;80(4):1029-1072. doi: 10.1016/j.jaad.2018.11.057. Epub 2019 Feb 13.