

Generic Name: Infliximab

Therapeutic Class or Brand Name: Infliximab

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

GPI Code: 52505040

Preferred: Renflexis®

Non-preferred: Inflectra®, Remicade®

Date of Origin: 11/30/2018

Date Last Reviewed / Revised: 6/25/2019

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 and criteria 1 and 2 are met:
 1. Diagnosis must be established by a rheumatologist or dermatologist.
 2. 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 a preferred product(s).

EXCLUSION CRITERIA

- Co-administration of infliximab with another biologic DMARD, Olumiant® (baricitinib), Otezla® (apremilast), or Xeljanz®/XR (tofacitinib). Examples of biologic DMARDS include the following:
 - Actemra® (tocilizumab)
 - Cosentyx® (secukinumab)
 - Entyvio® (vedolizumab)
 - Ilumya® (tildrakizumab)
 - Kevzara® (sarilumab)
 - Kineret® (anakinra)
 - Orencia® (abatacept)
 - Rituxan® (rituximab)
 - Siliq® (brodalumab)
 - Stelara® (Ustekinumab)
 - Taltz® (Ixekizumab)
 - TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Simponi®/Simponi® Aria® (golimumab)]
 - Tremfya™ (guselkumab)
 - Tysabri® (natalizumab)

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

APPENDIX

N/A

REFERENCES

1. Inflectra package insert.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125544s000lbl.pdf.
2. Remicade package insert. <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/REMICADE-pi.pdf>.
3. Renflexis package insert.
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.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
6/25/2019	<ol style="list-style-type: none">1. Added "Inflectra®, Remicade®" under Non-Preferred field in header section..2. Added generic names of drugs in parentheses under Applicable Drugs in header section.3. Changed formatting of journal names within citations to italics under References.
6/3/2019	<ol style="list-style-type: none">1. Policy approved by CAC.
11/30/2018	<ol style="list-style-type: none">1. New Policy.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.