ALASKA MEDICAID
Prior Authorization Criteria

Infliximab

(Avsola™, Inflectra®, Remicade®, & Renflexis®)

FDA INDICATIONS AND USAGE[1,2,3,4]

Infliximab is a tumor necrosis factor (TNF) blocker indicated for Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, plaque psoriasis, and hydradenitis suppurativa. Avsola™, Inflectra®, and Renflexis® are considered biosimilars to Remicade®. Biosimilar drugs are biological products approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

APPROVAL CRITERIA[1,2,3,4,5,6,7,8,9]

1. Patient has **one** (a,b,c,d,e,f,g,h)of the following diagnosis, is age appropriate and meets trial criteria:
    a. Crohn's disease and is 6 years of age or older
        i. Patient has had a trial and inadequate response or contraindication to two conventional therapies (i.e. mesalamine, sulfasalazine, azathioprine/6-mercaptopurine, methotrexate, etc.).
    b. Ulcerative colitis and is 6 years of age or older
        i. Patient has had a trial and inadequate response or contraindication to two conventional therapies (i.e. mesalamine, sulfasalazine, azathioprine/6-mercaptopurine, methotrexate, etc.)
    c. Rheumatoid arthritis and is 4 years of age or older
        i. Patient has had a trial and inadequate response or contraindication to two disease modifying anti-rheumatic drugs (DMARDs) used concurrently
    d. Psoriatic arthritis and is 18 years of age or older
        i. Patient has had a trial and inadequate response or contraindication to two conventional therapies (i.e. methotrexate, sulfasalazine, leflunomide, etc.)
    e. Ankylosing spondylitis and is 18 years of age or older
        i. Patient has had a trial and inadequate response or contraindication to two non-steroidal anti-inflammatories (NSAIDs) at maximum therapeutic dose for at least 3 months **AND;**
        ii. Patient had a trial and inadequate response or contraindication to one conventional DMARD for at least 30 days.
    f. Juvenile idiopathic arthritis and is 4 years of age or older
        i. Patient has had a trial, and inadequate response or contraindication to intraarticular glucocorticoid injection **AND;**
        ii. Patient had a trial and inadequate response or contraindication to two conventional therapies (i.e. methotrexate, sulfasalazine, leflunomide, etc.)
    g. Plaque psoriasis in adults 18 years of age and older
        i. Patient has had a trial and inadequate response or contraindication to phototherapy, systemic retinoids (oral isotretinoin), methotrexate, or cyclosporine

h. Hydradenitis suppurativa (HS)
   i. No trial required.

DENIAL CRITERIA [1,2,3,4]

1. Failure to meet approval criteria **OR**;
2. Patient has not been screened for Tuberculosis **OR**;
3. Patient has not been screened for hepatitis B or C **OR**;
4. Patient has or develops a serious infection **OR**;
5. The dose is greater than 5 mg/kg in moderate to severe heart failure **OR**;
6. The patient's weight has not been submitted.

CAUTIONS[1,2,3,4]

- See Package Insert
  - Remicade®: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/REMICADE-pi.pdf
  - Avsola™: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/avsola/avsola_pi_english.ashx
  - Inflectra®: https://labeling.pfizer.com/ShowLabeling.aspx?id=9271
  - Renflexis®: https://www.organon.com/product/usa/pi_circulars/r/renflexis/renflexis-pi.pdf

DURATION OF APPROVAL

- Initial Approval: up to 6 months
- Reauthorization Approval: up to 12 months if the prescriber documents the patient has disease improvement or stabilization.

QUANTITY LIMIT

- Crohn's Disease - 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response.
- Pediatric Crohn's Disease - 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
- Ulcerative Colitis - 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
- Pediatric Ulcerative Colitis - 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
- Rheumatoid Arthritis - In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
- Ankylosing Spondylitis - 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks.
- Psoriatic Arthritis and Plaque Psoriasis - 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

- HCPCS:
    - Remicade® - J1745
    - Avsola™ – Q5121
    - Inflectra® – Q5103
    - Renflexis® -Q5104

REFERENCES / FOOTNOTES:

1. Remicade® [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.
2. Avsola™ [package insert]. Thousand Oaks, CA: Amgen; September 2021.
3. Inflectra® [package insert]. Lake Forest, IL: Hospira, a Pfizer Company; January 2022.
4. Renflexis® [package insert]. Kenilworth, NJ. Merck &Co., Inc; June 2021.
5. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.
6. 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;65(1):137-174.
7. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. Arthritis & Rheumatism. 2013;65:2499-2512.
8. Adedokun OJ, Sandborn WJ, Feagan BG, et al. Association between serum concentration of infliximab and efficacy in adult patients with ulcerative colitis. Gastroenterology. 2014;147(6):1296-1307.
9. Aeberli D, Oertle S, Mauron H, et al. Inhibition of the TNF-pathway: Use of infliximab and etanercept as remission-inducing agents in cases of therapy-resistant chronic inflammatory disorders. Swiss Med Wkly. 2002;132(29-30):414-422.