PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Infliximab (Avsola, Inflectra, Remicade, Renflexis, Zymfentra)
BENEFIT TYPE	Medical: Avsola, Inflectra, Remicade, Renflexis Pharmacy: Zymfentra
STATUS	Prior Authorization Required

Remicade is a tumor necrosis factor (TNF) alpha-inhibitor initially approved by the FDA in 1998 for adults with moderate to severe Crohn's disease. Since that time, infliximab has been approved for five additional indications: Rheumatoid Arthritis, Psoriatic Arthritis, Plaque Psoriasis, Ankylosing Spondylitis and Ulcerative Colitis. Multiple biosimilars have been approved for Remicade including Avsola, Inflectra and Renflexis. In 2023, Zymfentra was approved as a "biobetter" of Inflectra designed to be given subcutaneously rather than as an intravenous infusion.

Infliximab (Avsola, Inflectra, Remicade, Renflexis, Zymfentra) will be considered for coverage when the following criteria are met:

Ankylosing Spondylitis (AS)

1. Member is 6 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has had a negative tuberculosis test within the past 12 months; AND
4. Member has had a documented trial and inadequate response, or intolerance to at least **ONE** of the following conventional therapies: a 4-week trial of a corticosteroid OR a 12-week trial of 6-mercaptopurine, azathioprine, or methotrexate; OR
5. Member has severe disease that requires immediate use of a biologic agent, as indicated by **ONE** of the following:
   a) Extensive small bowel disease involving more than 100 cm;
   b) History of bowel or colon resection and is at high risk for CD recurrence (e.g., smoker, <30 years old, 2 or more resections, penetrating/fistulizing disease, etc);
   c) Fistulizing disease; AND
6. For a non-preferred product, intolerance to **ALL** preferred products is required (see Appendix I); AND
7. **Dosage allowed/Quantity limit:** 5mg/kg at 0, 2, and 6 weeks, then every 8 weeks thereafter. Prior to any dosages or dosing frequencies greater than listed, medical necessity documentation must be supplied to justify coverage.
   Zymfentra Only:

Prior to any changes in dose or frequency, documentation of medical necessity for increase is required (including assessment for adherence and description of residual symptoms, etc.). The max that will be considered is up to 10 mg/kg every 8 weeks or treating as often as every 4 weeks.

If all the above requirements are met, the medication will be approved for 12 months.

For

Appendix I: Preferred Infliximab Products	
Preferred	**Non-Preferred**
• Inflectra • Renflexis	• Remicade • Avsola • Zymfentra

Appendix II: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira