PHARMACY POLICY STATEMENT
Ohio Medicaid

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.

Crohn's Disease (CD)

For initial authorization:

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. Member has tried and failed ONE preferred infliximab product (see appendix); AND
7.

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

For reauthorization

6. Member has tried and failed at least TWO preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Remicade); AND
7. Member has had a negative tuberculosis test within the past 12 months; AND
8. Member has tried and failed ONE preferred infliximab product (see appendix); AND
9. Dosage allowed/Quantity limit: 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks thereafter. 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 reauthorization :

1. Member has tried and failed ONE preferred infliximab product (see appendix); AND
2. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

If all the above req uirements are met, the medication will be approved for an additional 12 months. 1.

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Remicade created. Polices SRx-0041, SRx-0042, and SRx-0043 archived. For diagnosis of AS: trial of Humira and Enbrel requirement was added. For CD: Pediatric Crohn's Disease Activity Index (PCDAI) and Crohn's Disease Activity Index (CDAI) were requirements added; trial of Humira was added. For diagnosis of P DiitRxcohn'w EMC MC 0.53512.6 (c)8.8 (C)2.7 (r)-6 (ohn')2.6 80.7o11.9 (R)2.7 (x)]TJ ET Q c

1. Remicade [prescribing information]. Horsham, PA; Janssen Biotech, Inc.: 2021.
2. Avsola [prescribing information]. Thousand Oaks, CA; Amgen, Inc.: 2021.
3. Inflectra [prescribing information]. Republic of Korea; Celltrion, Inc.: 2023.
4. Renflexis [prescribing information]. Republic of Korea; Samsung Bioepis Co., Ltd.: 2023.
5. Zymfentra [prescribing information]. Republic of Korea; Celltrion, Inc.: 2023
6. Callhoff J, et al. Efficacy of TNFa blockers in patients with ankylosing spondylitis and non-radiographic axial spondyloarthritis: a meta-analysis. Ann Rheum Dis. 2015; 74:1241.
7. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613. doi: 10.1002/art.41042. Epub 2019 Aug 22.
8. Akgul O, Ozgocmen S. Classification criteria for spondyloarthropathies. World J Orthop. 2011;2(12):107-115. doi:10.5312/wjo.v2.i12.07.
9. Yu DT, Tubergen AV. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial