

## Drug Monograph

Drug Name: **Avsola™ (infliximab-axxq) Vial**  
Drug Class: **Targeted Immune Modulators (Biologics/DMARDs)**  
Prepared For: MO HealthNet  
Prepared By: Conduent

**New Criteria**

**Revision of Existing Criteria**

### Executive Summary

<b>Purpose:</b>	The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.
<b>Dosage Forms:</b>	Avsola is available as 100 mg of infliximab-axxq in a single-dose vial for intravenous use.
<b>Manufacturer:</b>	Amgen Inc., Thousand Oaks, CA 91320.
<b>Indications:</b>	<p>Avsola is indicated for the following:</p> <ol style="list-style-type: none"><li>1) Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had inadequate response to conventional therapy; for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease</li><li>2) Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy</li><li>3) Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy</li><li>4) Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy</li><li>5) In combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis</li><li>6) Reducing signs and symptoms in patients with active ankylosing spondylitis</li></ol>

7) Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis

**Costs:** \$500 per vial Wholesale Acquisition Cost

**Summary of Findings:** This drug is being considered for inclusion in the state specific Preferred Drug List (PDL).

**Status Recommendation:**  Clinical Edit  PA Required  
 Open Access  PDL

**Type of PA Criteria:**  Appropriate Indications  Non-Preferred  
 No PA Required  Preferred

Prepared by: Megan Fast, PharmD  
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