

# EVH Clinical Guideline 5015.CC for Infliximab Products

<b>Guideline Number:</b> EVH_CG_5015.CC	<b><u>Applicable Codes</u></b>	
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# STATEMENT

## General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

## Purpose

The purpose of this guideline to define the prior authorization process for the following drug(s): Remicade® (infliximab), Inflectra® (infliximab-dyyb), Renflexis®, (infliximab-abda), Avsola™ (infliximab-axxq), Zymfentra (infliximab-dyyb, subcutaneous), and Ixifi (infliximab-qbtx). Please note, Ixifi is not currently on the U.S. market but is included in this guideline due to having an assigned HCPCS code.

## Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

## Special Note

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex®, UpToDate® Lexidrug™, Elsevier Clinical Pharmacology).

## Plan Design Summary

Requests for infliximab products are subject to the preferred medical drug list program. This program applies to the products specified in this guideline and only to indications that are FDA-approved for the preferred product (as applicable). Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

Preferred Product Table	
<b>Preferred</b>	<ul style="list-style-type: none"> <li>• Inflectra® (infliximab-dyyb) – Q5103</li> <li>• Remicade® (infliximab) – J1745</li> <li>• Renflexis® (infliximab-abda) – Q5104</li> <li>• Zymfentra™ (infliximab-dyyb) – J1748</li> </ul>

Preferred Product Table	
Non-Preferred	<ul style="list-style-type: none"> <li>• Avsola™ (infliximab-axxq) – Q5121</li> <li>• Ixifi (infliximab-qbtx) – Q5109</li> </ul>

## INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

### General Criteria

- Requests for non-preferred products must have documented trial and failure or intolerance or contraindication to ALL preferred products
- Must have a negative tuberculosis skin test collected within the last 6 months
  - Example acceptable testing includes the Tuberculin PPD (purified protein derivative test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with the Infliximab product
- Must have no evidence of infection
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)

### Ankylosing Spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

*(Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)*

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of ankylosing spondylitis
- Must have an adequate trial (of at least 4 weeks) with at least **TWO** NSAIDs at anti-inflammatory dose, with an inadequate response, significant side effects/toxicity, or have a contraindication to these therapies

### Crohn's Disease

- Must be prescribed by a gastroenterologist
- Must be age:
  - 6 years or older (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

- 18 years or older (Zymfentra only)
- Must have a diagnosis of moderate to severely active Crohn's disease or fistulizing Crohn's disease, as described in the 2018 ACG guidelines ([Appendix 2](#))

## **Plaque Psoriasis**

*(Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)*

- Must be prescribed by a dermatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate-to-severe chronic plaque psoriasis
- Must have documentation of ONE of the following:
  - Affected area(s) include hands, feet, face, neck, scalp, genitals/groin, intertriginous areas
  - Minimum body surface area (BSA) involvement of >10%
  - At least 3% of BSA affected AND the member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) OR pharmacologic treatment with methotrexate, cyclosporine, or acitretin (unless there is a clinical reason to not take pharmacologic treatment – see [Appendix 1](#))

## **Psoriatic Arthritis**

*(Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)*

- Must be prescribed by a rheumatologist or dermatologist
- Must be age 18 years or older
- Must have a diagnosis of active psoriatic arthritis, with the severity of disease documented
- For mild-to-moderate disease only, must have ONE of the following:
  - Must have had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) or have a contraindication or intolerance to all drugs (see [Appendix 1](#))
  - Must have enthesitis or predominantly axial disease

## **Rheumatoid Arthritis**

*(Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)*

- Must be prescribed by a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have documentation of testing of the following:
  - Rheumatoid factor (RF)

- Anti-cyclic citrullinated peptide (anti-CCP)
- C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) – not required if RF & anti-CP are positive
- Must be prescribed the requested medication in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see **Appendix 1**)
- Must have documentation showing ONE of the following:
  - Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week)
  - Member has an intolerance or contraindication to methotrexate (see **Appendix 1**)

## **Ulcerative Colitis**

- Must be prescribed by a gastroenterologist
- Must be age:
  - 6 years or older (Avsola/Inflectra/infliximab/Remicade/Renflexis only)
  - 18 years or older (Zymfentra only)
- Must have a diagnosis of moderate to severely active Ulcerative Colitis, as evidenced by ONE of the following:
  - Dependency on or refractory to corticosteroids
  - Severe endoscopic disease activity (e.g., presence of ulcers)
  - High risk of colectomy
  - Mayo Clinic scores of 6-12, with an endoscopic subscore of 2 or 3
  - Hospitalized with ≥6 bloody bowel movements per day with at least 1 marker of systemic toxicity (e.g., heart rate >90 beats/min, temperature >37.8C, hemoglobin <10.5 g/dL, and/or erythrocyte sedimentation rate >30 mm/h)

## **Acute Graft Versus Host Disease (*off-label supported indication*)**

- Must have had an inadequate response to systemic corticosteroids

## **Behcet's Disease (*off-label supported indication*)**

- Must have an inadequate response to at least one non-biologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids)

## **Hidradenitis Suppurativa (*off-label supported indication*)**

- Must have a diagnosis of severe, refractory hidradenitis suppurativa
- Must have had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa (e.g., clindamycin, metronidazole, moxifloxacin, rifampin,

tetracyclines) for at least 90 days

### **Immune Checkpoint Inhibitor-related Toxicity (*off-label supported indication*)**

- Must have had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)

### **Pyroderma Gangrenosum (*off-label supported indication*)**

- Must have had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)

### **Reactive arteritis (*off-label supported indication*)**

- Must have had an inadequate response to methotrexate or sulfasalazine

### **Sarcoidosis (*off-label supported indication*)**

- Must have had an inadequate response to corticosteroids or immunosuppressive therapy

### **Takayasu's arteritis (*off-label supported indication*)**

- Must have had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)

### **Uveitis (*off-label supported indication*)**

- Must have had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine, methotrexate, azathioprine, mycophenolate mofetil)

## **REAUTHORIZATION CRITERIA**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

**EXCEPTION:** Reauthorization requests for immune checkpoint inhibitor related toxicity and acute graft versus host disease must meet initial criteria.

### **General Criteria**

- Requests for non-preferred products must have documented trial and failure or intolerance or contraindication to ALL preferred products
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)

### **Ankylosing Spondylitis (AS) and non-radiographic axial**

## **spondyloarthritis (nr-axSpA)**

*(Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)*

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Functional status
  - Total spinal pain
  - Inflammation (e.g., morning stiffness)
  - Swollen joints
  - Tender joints
  - C-reactive protein (CRP)

## **Crohn's Disease**

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Abdominal pain or tenderness
  - Diarrhea
  - Body weight
  - Abdominal mass
  - Hematocrit
  - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
  - Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

## **Plaque Psoriasis**

*(Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)*

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Body surface area (BSA)
  - Signs and Symptoms (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

## **Psoriatic Arthritis**

*(Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)*

- Must have recent chart note documentation showing achievement or maintenance of a



positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

## **Rheumatoid Arthritis**

*(Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)*

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by disease activity or improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

## **Ulcerative Colitis**

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Stool frequency
  - Rectal bleeding
  - Urgency of defecation
  - C-reactive protein (CRP)
  - Fecal calprotectin (FC)
  - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
  - Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

## **Hidradenitis Suppurativa (*off-label supported indication*)**

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Reduction in abscess and inflammatory nodule count from baseline
  - Reduced formation of new sinus tracts and scarring
  - Decrease in frequency of inflammatory lesions from baseline
  - Reduction in pain from baseline

- Reduction in suppuration from baseline
- Improvement in frequency of relapses from baseline
- Improvement in quality of life from baseline
- Improvement on a disease severity assessment tool from baseline

### **Reactive arteritis (*off-label supported indication*)**

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by disease activity or improvement in signs and symptoms of the condition (e.g., tender joint count, swollen joint count, pain).

### **Uveitis (*off-label supported indication*)**

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
  - Reduced frequency of flare recurrence compared to baseline
  - Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline
  - Decreased reliance on topical corticosteroids

### **All Other Indications**

- Must have recent chart documentation showing achievement or maintenance of a clinical response and/or remission, as evidenced by low disease activity or improvement in signs and symptoms of the condition.

## **APPROVAL DURATIONS**

<b>Initial Authorization</b>	Up to 1 year
<b>Reauthorization</b>	Same as initial

## **APPENDICES**

### **Appendix 1 - Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide**

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction

- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

## Appendix 2 - 2018 ACG Clinical Guidelines Classification of Moderate-to-Severe Disease

Moderate-to-Severe Disease	Severe-Fulminant Disease
<p><i>One of the following:</i></p> <ul style="list-style-type: none"> <li>• CDAI 220-450</li> <li>• Have failed treatment for mild to moderate disease</li> <li>• Prominent symptoms such as fever, weight loss, abdominal pain and tenderness, intermittent nausea or vomiting, or anemia</li> <li>• Moderate to severely active endoscopic mucosal disease</li> </ul>	<p><i>One of the following:</i></p> <ul style="list-style-type: none"> <li>• CDAI &gt;450</li> <li>• Persistent symptoms despite glucocorticoids or biologic agents</li> <li>• Individuals presenting with high fever, persistent vomiting, intestinal obstruction, peritoneal signs, cachexia, or evidence of an abscess</li> </ul>

## CODING AND STANDARDS

### Codes

Code	Brand	Description
J1745	Remicade	INJ, INFLIXIMAB, EXCLUDES BIOSIMILAR, 10 MG
J1748	Zymfentra	INJECTION, INFLIXIMAB-DYYB (ZYMFENTRA), 10MG
Q5103	Inflectra	INJ INFLIXIMAB-DYYB BIOSIMILR 10 MG
Q5104	Renflexis	INJ INFLIXIMAB-ABDA BIOSIMILR 10 MG
Q5109	Ixifi	INJECTION, INFLIXIMAB-QBTX, BIOSIMILAR (IXIFI), 10 MG

Code	Brand	Description
Q5121	Avsola	INJ INFLIXIMAB-AXXQ BIOSIMILR 10 MG

## Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

## POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> <li>Added Ixifi</li> <li>Updated reauthorization criteria for all indications</li> </ul>
July 2024	<ul style="list-style-type: none"> <li>Added Zymfentra</li> <li>Updated criteria for RA, psoriasis, psoriatic arthritis, and ankylosing spondylitis</li> <li>Removed prerequisite trials for Crohn's and Ulcerative Colitis; Added diagnostic criteria for Crohn's and Ulcerative Colitis</li> <li>Added 9 indications: Bechet's disease, Hidradenitis suppurativa, Pyoderma gangrenosum, Sarcoidosis, Takayasu's arteritis, Uveitis, Reactive arteritis, Immune checkpoint inhibitor-related, Acute Graft Versus Host</li> </ul>
March 2022	<ul style="list-style-type: none"> <li>New Guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

## **Committee**

**Reviewed / Approved by Evolent Administrative Services Medical Policy Committee**

## **Disclaimer**

*Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.*

*Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.*

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