AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Infliximab Products (MEDICAL)

PREFERRED				
❑ **Renflexis®** (infliximab-abda) **(Q5104)**				
NON-PREFERRED				
❑ **Avsola™** (infliximab-axxq) **(Q5121)**	❑ **Inflectra®** (infliximab-dyyb) **(Q5103)**	❑ **Infliximab (JI745)**	❑ **Remicade®** (infliximab) **(J1745)**	❑ **Zymfentra™** (infliximab-dyyb) **SQ (J1748)**

NOTE: Zymfentra is only FDA approved for maintenance treatment of moderately to severely active Crohn's disease or ulcerative colitis following treatment with an infliximab product administered intravenously

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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- **Renflexis® is the preferred infliximab product. Remicade®, Avsola™, Inflectra®, Infliximab & Zymfentra™ are non-preferred.**
- **For new and renewal authorizations, members are required to use preferred Renflexis®, unless contraindicated.**

CLINICAL CRITERIA: Check below all that apply. All criteria/diagnosis must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied. If requesting an increase in dose, recent lab values and symptoms documenting active disease must be submitted with request.

❑ Diagnosis: Rheumatoid Arthritis or Psoriatic Arthritis

Recommended Dosage:

- **Rheumatoid Arthritis:** IV – 3 mg/kg at 0, 2, and 6 weeks, followed by a maintenance regimen of 3 mg/kg every 8 weeks
- **Psoriatic Arthritis:** IV – 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks

❑ Member has a diagnosis of **ONE** of the following
- ❑ Rheumatoid Arthritis
- ❑ Psoriatic Arthritis

AND

❑ Medication must be prescribed by or in consultation with a **Rheumatologist**

AND

❑ Member tried and failed at least **one (1) DMARD** therapy for at least **three (3) months** **(check each tried below)**:

❑ 6-mercaptopurine	❑ methotrexate	❑ azathioprine	❑ hydroxychloroquine
❑ auranofin	❑ sulfasalazine	❑ leflunomide	❑ aminosalicylates
❑ Other: _____			

AND

❑ **For non-preferred infliximab product requests (e.g., Avsola™, Inflectra®, Infliximab & Remicade®):** Member must have trial and failure or intolerance to preferred Renflexis®

❑ Diagnosis: Ankylosing Spondylitis

Recommended Dosage:

- IV – 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 6 weeks

❑ Medication must be prescribed by or in consultation with a **Rheumatologist**

AND

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- ❑ Member must have a trial and failure, contraindication, or intolerance to **TWO** NSAIDs

AND

- ❑ **For Avsola™ or Inflectra® requests:** Member must have trial and failure or intolerance to preferred Renflexis®

AND

- ❑ **For Remicade® or Infliximab requests:** Member must have trial and failure or intolerance to preferred Renflexis® **AND** Inflectra®

❑ Diagnosis - Plaque Psoriasis

Recommended Dosage:

- IV – 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks

- ❑ Medication must be prescribed by or in consultation with a **Dermatologist**

AND

- ❑ Member's psoriasis must involve palms, soles, face, genitalia, or greater than 10% of total body surface area

AND

- ❑ Member tried and failed at least **ONE** of either Phototherapy or Alternative Systemic Therapy for at least **three (3) months** **(check each tried below)**:

❑ **Phototherapy:** ❑ **UV Light Therapy** ❑ NB UV-B ❑ PUVA	❑ **Alternative Systemic Therapy:** ❑ **Oral Medications** ❑ acitretin ❑ methotrexate ❑ cyclosporine

AND

- ❑ **For non-preferred infliximab product requests (e.g., Avsola™, Inflectra®, Infliximab & Remicade®):** Member must have trial and failure or intolerance to preferred Renflexis®

❑ Diagnosis - Ocular Sarcoidosis

Recommended Dosage:

- **Ocular Sarcoidosis:** IV – 3 to 5 mg/kg at weeks 0, 2, and 6, followed by 3 to 5 mg/kg every 4 to 8 weeks thereafter

- ❑ Medication must be prescribed by or in consultation with an **Ophthalmologist**

AND

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❑ Member tried and failed at least **one (1) DMARD** therapy for at least **three (3) months** **(check each tried below)**:

❑ 6-mercaptopurine	❑ methotrexate	❑ azathioprine	❑ hydroxychloroquine
❑ auranofin	❑ sulfasalazine	❑ leflunomide	❑ aminosalicylates
❑ Other: _____			

AND

❑ Member must have a trial and failure or inadequate response to budesonide or high dose steroids (40-60 mg prednisone)

AND

❑ **For non-preferred infliximab product requests (e.g., Avsola™, Inflectra®, Infliximab & Remicade®):** Member must have trial and failure or intolerance to preferred Renflexis®

❑ Diagnosis: Moderate-to-Severe Crohn's Disease (CD) or Ulcerative Colitis (UC)

Recommended Dosage:

- IV – 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks
- **SQ Zymfentra** – 120 mg subcutaneously once every two weeks starting at week 10 and thereafter, following treatment with an infliximab product administered intravenously

NOTE: Zymfentra is only FDA approved for maintenance treatment of moderately to severely active Crohn's disease or ulcerative colitis following treatment with an infliximab product administered intravenously. All requests for SQ maintenance administration of Zymfentra will need to be submitted & billed under the pharmacy benefit.

❑ Member has a diagnosis of **ONE** of the following

- ❑ Crohn's Disease
- ❑ Ulcerative Colitis

AND

❑ Medication must be prescribed by or in consultation with a **Gastroenterologist**

AND

❑ Member tried and failed at least **one (1) DMARD** therapy for at least **three (3) months** **(check each tried below)**:

❑ 6-mercaptopurine	❑ methotrexate	❑ azathioprine	❑ hydroxychloroquine
❑ auranofin	❑ sulfasalazine	❑ leflunomide	❑ aminosalicylates
❑ Other: _____			

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AND

- ❑ Member must have a trial and failure or inadequate response to budesonide or high dose steroids (40-60 mg prednisone)

AND

- ❑ **For non-preferred infliximab product requests (e.g., Avsola™, Inflectra®, Infliximab, Remicade®, Zymfentra®):** Member must have trial and failure or intolerance to preferred Renflexis®

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy & Therapeutic Committee:** ~~10/18/2018; 7/16/2020;~~ **11/21/2024**
REVISED/UPDATED: ~~12/30/2018; 3/16/2019; 7/7/2019; 9/28/2019; 11/11/2019; 11/12/2020; 4/1/2021; 6/14/2021; 2/16/2022;~~ **12/17/2024**