Infliximab Step Therapy

Remicade (infliximab) J1745 and Inflectra (infliximab-dyyb) Q5103 are non-preferred. The preferred product is Avsola (infliximab-axxq) Q5121

Prior Authorization Step Therapy
Medicare Part B Request Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**NEW START - Start Date:_____**	☐	**Continuation** (within 365 days)**:** Date of last treatment _____
☐	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug ☐ Self-administered	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – TNF-Alpha Blockers (Biologic DMARD) PA

Drug Name(s):
AVSOLA
INFLECTRA
REMICADE
INFLIXIMAB

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE of the formulary alternatives: **Avsola** OR
   - There is clinical documentation stating formulary alternatives are contraindicated.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
N/A

Coverage Duration:
Approval will be for 12 months

FDA Indications:
Remicade, Inflectra

- Ankylosing spondylitis, Active
- Crohn's disease, Fistulizing
- Crohn's disease (Moderate to Severe), In patients with an inadequate response to conventional therapy
- Plaque psoriasis, chronic (Severe)
- Psoriatic arthritis
- Rheumatoid arthritis (Moderate to Severe), In combination with methotrexate
- Ulcerative colitis (Moderate to Severe), In patients with an inadequate response to conventional therapy

Step Therapy:
Avsola
FDA Indications:

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Off-Label Uses:

Remicade, Inflectra, Avsola

- Adult-onset Still's disease
- Arthritis – Arthritis co-current and due to Crohn's disease
- Behcet's syndrome
- Graft versus host disease
- Granulomatosis with polyangiitis, Refractory, in combination with corticosteroids
- Hidradenitis suppurativa, Severe, refractory
- Juvenile idiopathic arthritis (Severe), Refractory to other therapies
- Kawasaki disease, Refractory
- Rheumatoid arthritis, Monotherapy
- Synovitis
- Takayasu's disease, Refractory
- Uveitis, Refractory; Adjunct
- Multisystem inflammatory syndrome in children, Refractory; associated with SARS-CoV-2 (COVID-19) (pediatrics)
- SAPHO syndrome (severe), Refractory
- Sarcoidosis, Refractory; Adjunct

Age Restrictions:

N/A

Other Clinical Consideration:

- Perform test for latent TB; if positive, start treatment for TB prior to starting REMICADE. Monitor all patients for active TB during treatment, even if initial latent TB test is negative
- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including REMICADE
- Inflectra - Heart failure, moderate to severe; do not administer doses greater than 5 mg/kg

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout

https://careweb.careguidelines.com/ed24/ac/ac04_010.htm