Infliximab Step Therapy

Preferred: Inflectra (infliximab-dyyb) Q5103, **Avsola** (infliximab-axxq) Q5121

Non-preferred: Remicade (infliximab) J1745, **Renflexis** (infliximab-abda) Q5104, **Zymfentra** (infliximab-dyyb) J1748

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.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	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	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐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)**

☐ **Crohn's disease (CD) when each of the following criteria are met:**

☐ Patient is 6 years of age or older with moderate to severe CD; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]);

OR

☐ C. Patient is 6 years of age or older with fistulizing CD;

☐ **Ulcerative colitis (UC) when each of the following criteria are met:**

☐ Patient is 6 years of age or older with moderate to severe UC; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]);

☐ **Rheumatoid arthritis (RA) when each of the following criteria are met:**

☐ Patient is 18 years of age or older with moderate to severe RA; AND

☐ Patient has had an inadequate response to methotrexate titrated to maximally tolerated dose; OR

☐ If methotrexate is not tolerated or contraindicated, Patient has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine);

☐ **Ankylosing spondylitis (AS) when each of the following criteria are met:**

☐ Patient is 18 years of age or older with moderate to severe AS; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)];

☐ **Psoriatic arthritis (PsA) when each of the following criteria are met:**

☐ Patient is 18 years of age or older with moderate to severe PsA; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)];

☐ **Plaque psoriasis (Ps) when each of the following criteria are met:**

☐ Patient is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):

- ☐ Plaque Ps involving greater than three percent (3%) body surface area (BSA); OR
- ☐ Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);

☐ **Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:**

☐ Patient is 2 years of age or older with moderately to severe PJIA; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate)];

☐ **Non-infectious uveitis (UV) when each of the following criteria are met:**

☐ Patient has chronic, recurrent, treatment-refractory or vision-threatening disease; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as corticosteroids or immunosuppressants (azathioprine, cyclosporine, or methotrexate)];

☐ **Immune checkpoint inhibitor therapy-related toxicities with ANY of the following conditions:**

☐ Moderate to Severe diarrhea or colitis unresponsive to high-dose systemic corticosteroids; OR

☐ Moderate to Severe pneumonitis if no improvement after 48 hours of high-dose systemic corticosteroids; OR

☐ Severe or life-threatening renal failure or elevated serum creatinine (that is, greater than 3 times baseline or greater than 4.0 mg/dL) if toxicity remains greater than grade 2 after 4-6 weeks of corticosteroids; OR

☐ Myocarditis if unresponsive to high-dose systemic corticosteroids; OR

☐ Moderate, Severe, or life-threatening inflammatory arthritis unresponsive to corticosteroids or anti-inflammatory agents; OR

☐ Severe or life-threatening steroid-refractory myalgias or myositis; OR

☐ Grade 1-4 uveitis that is refractory to high-dose systemic corticosteroids;

☐ Sarcoidosis when each of the following criteria are met:

☐ Patient is 18 years of age or older; AND

☐ Patient has chronic, progressive, treatment-refractory disease; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids; AND

☐ Patient has had an inadequate response to, is intolerant of, or has a contraindication to nonbiologic DMARDs (such as methotrexate or azathioprine).

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

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

☐ 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 – Infliximab Products (Biologic DMARD) PA

Drug Name(s):

AVSOLA	**INFLECTRA**
REMICADE	**INFLIXIMAB**
RENFLEXIS	**ZYMFENTRA**

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: **Inflectra, 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, Renflexis, Avsola

- 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:

Inflectra

FDA Indications:

- 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

Off-Label Uses:

Remicade, Renflexis, Inflectra, Avsola, Zymfentra

- 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