Medicare Part B
Infliximab
Prior Authorization

FDA APPROVED INDICATIONS AND DOSAGE[1-4]

Agent(s)	Indication(s)	Dosage
Avsola™ (infliximab-axxq) Intravenous infusion	AS, CD (≥6 yrs), PS, PSA, RA, UC (≥6 yrs)	**PS, PSA, UC:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks **AS:** 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks **CD:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks; for adults only may increase dose to 10 mg/kg **RA:** 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks with methotrexate; may increase dose up to 10 mg/kg or treat as often as every 4 weeks
Inflectra® (infliximab-dyyb) Intravenous infusion	AS, CD (≥6 yrs), PS, PSA, RA, UC (≥6 yrs)	**PS, PSA, UC:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks **AS:** 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks **CD:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks; for adults only may increase dose to 10 mg/kg **RA:** 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks with methotrexate; may increase dose up to 10 mg/kg or treat as often as every 4 weeks
Remicade® (infliximab) Intravenous infusion	AS, CD (≥6 yrs), PS, PSA, RA, UC (≥6 yrs)	**PS, PSA, UC:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks **AS:** 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks **CD:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks; for adults only may increase dose to 10 mg/kg **RA:** 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks with methotrexate; may increase dose up to 10 mg/kg or treat as often as every 4 weeks
Renflexis (infliximab-abda) Intravenous infusion	AS, CD (≥6 yrs), PS, PSA, RA, UC (≥6 yrs)	**PS, PSA, UC:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks **AS:** 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks **CD:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks; for adults only may increase dose to 10 mg/kg **RA:** 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks with methotrexate; may increase dose up to 10 mg/kg or treat as often as every 4 weeks

AS=Ankylosing Spondylitis, CD=Crohn's Disease, PS=Psoriasis, PSA=Psoriatic Arthritis, RA=Rheumatoid Arthritis, UC=Ulcerative Colitis

CLINICAL RATIONALE

Safety[1-4]

Infliximab

Infliximab products carry the following boxed warning:

- Increased risk for developing serious infections that may lead to hospitalization or death, including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections. Perform test for latent TB, and if positive, start treatment for TB prior to initiating therapy. 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 TNF blockers.
- Post marketing cases of hepatosplenic T-cell lymphoma have occurred in adolescents and young adults with inflammatory bowel disease treated with TNF blockers

Infliximab products have the following contraindications for use:

- Should not be administered at doses >5 mg/kg in patients with moderate to severe heart failure
- Should not be re-administered to patients who have experienced a severe hypersensitivity reaction to infliximab products, to the inactive components, or to murine proteins

REFERENCES

1. Inflectra prescribing information. Celltrion, Inc. June 2019.
2. Remicade prescribing information. Janssen Biotech, Inc. May 2020.
3. Renflexis prescribing information. Merck Sharp & Dohme Corp. February 2020.
4. Avsola prescribing information. Amgen Inc. December 2019.

Document History
Original Prime Standard Part B criteria, approved by P&T UM Committee 12/2021

Medicare Part B Infliximab Prior Authorization

Coverage and policy application are contingent on National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). An NCD or LCD that is applicable to the drug or product must be used in lieu of applicable medical necessity criteria. Also, please note that Prior Authorization criteria cannot be stricter than an NCD or LCD with specified step therapy requirements.

TARGET PREFERRED AGENT(S)	TARGET NON-PREFERRED AGENT(S)
Target preferred and non-preferred agent(s) to be determined client	Target preferred and non-preferred agent(s) to be determined client
Avsola (infliximab-axxq) **Inflectra** (infliximab-dyyb) **Remicade®** (infliximab) **Renflexis** (infliximab-abda)	

Brand (generic)	GPI	Multisource Code	HCPCS/ J Code
Avsola (infliximab-axxq)			
100 mg/20 mL vial	52505040132120	M, N, O, or Y	Q5121
Inflectra (infliximab-dyyb)			
100 mg/20 mL vial	52505040202120	M, N, O, or Y	Q5103
Remicade (infliximab)			
100 mg/20 mL vial	52505040002120	M, N, O, or Y	J1745
Renflexis (infliximab-abda)			
100 mg/20 mL vial	52505040102120	M, N, O, or Y	Q5104

CRITERIA FOR APPROVAL
Evaluation
Target Agent(s) will be approved when ALL of the following are met:

1. The requested agent is being used for ONE of the following:
    a. An FDA approved indication
    OR
    b. An indication in CMS approved compendia

    AND
2. If the client has preferred agents, then ONE of the following:
    a. The requested agent is the preferred agent
    OR
    b. Information has been provided that indicates the patient has been treated with the requested agent in the past 365 days
    OR
    c. There is documentation that the patient has had an ineffective treatment response to the active ingredient(s) of ALL preferred agent(s)
    OR
    d. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to the active ingredient(s) of ALL preferred agent(s)
    OR
    e. The prescriber has submitted documentation indicating ALL preferred agent(s) are likely to be ineffective or are likely to cause an adverse reaction or other harm to the patient

    AND

3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
4. The requested quantity (dose) is within FDA labeled dosing or supported in compendia for the requested indication

Length of Approval: up to 12 months