



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **3 of 18**

Effective Date: **3/9/2026** Last Review Date: **1/2026**

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

Rheumatoid arthritis (RA)

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), reactive arthritis, hidradenitis suppurativa, uveitis, and immune checkpoint inhibitor-related inflammatory arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Behcet's disease (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

Pyoderma gangrenosum, sarcoidosis, Takayasu's arteritis, immune checkpoint inhibitor-related toxicity, and acute graft versus host disease (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Crohn's disease and ulcerative colitis: gastroenterologist



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- Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, Behcet’s disease, Takayasu’s arteritis, and reactive arthritis: rheumatologist
- Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
- Pyoderma gangrenosum: dermatologist
- Sarcoidosis: dermatologist, pulmonologist, rheumatologist, cardiologist, neurologist, or ophthalmologist
- Uveitis: ophthalmologist or rheumatologist
- Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
- Immune checkpoint inhibitor-related toxicity: gastroenterologist, oncologist, or hematologist
- Acute graft versus host disease: oncologist or hematologist

Coverage Criteria

Crohn’s disease (CD)^{1-6,9,10,42}

Authorization of 12 months may be granted for treatment of moderately to severely active CD.

Ulcerative colitis (UC)^{1-6,9,30}

Authorization of 12 months may be granted for treatment of moderately to severely active UC.

Rheumatoid arthritis (RA) (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)^{1-5,11-13,37,41,42}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug indicated for moderately to severely active rheumatoid arthritis (RA) within the past 120 days. The requested medication must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide (see Appendix).

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:

- Member meets either of the following:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)



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- 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)

Ulcerative colitis (UC)^{1-6,9,29,36}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any 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)

Rheumatoid arthritis (RA) (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)^{1-5,11-13,37,41,42}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)^{1-5,7,18,21}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial



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- Renflexis (infliximab-abda) injection 100 mg vial: 5 vials per 42 days
- Infliximab injection 100 mg vial: 5 vials per 42 days
- Zymfentra (infliximab-dyyb) injection 120 mg prefilled syringe/pen: 2 syringes/pens per 28 days

Exception Limit (based on indication)

Abbreviations: RA = rheumatoid arthritis; PsA = psoriatic arthritis; AS = ankylosing spondylitis; CD = Crohn’s disease; UC = ulcerative colitis; PsO = plaque psoriasis; IV = intravenous; SC = subcutaneous

Dose Type	Indication	Exception Limit
Induction dose	All (excluding high dose pediatric CD and UC, uveitis)	<ul style="list-style-type: none"> • Up to 100 kg: up to 15 vials per 42 days • Above 100 kg: up to 30 vials per 42 days
Induction dose	High dose pediatric CD and UC	<ul style="list-style-type: none"> • Up to 100 kg: up to 30 vials per 42 days • Above 100 kg: up to 60 vials per 42 days
Induction dose	Uveitis	<ul style="list-style-type: none"> • Up to 100 kg: up to 15 vials per 28 days • Above 100 kg: up to 30 vials per 28 days
Maintenance dose	High dose pediatric CD and UC/high dose pediatric UC transitioning into adulthood	<ul style="list-style-type: none"> • Up to 100 kg: up to 10 vials per 56 days • Above 100 kg: up to 20 vials per 56 days
Maintenance dose (not high dose or incomplete response)	CD/PsA/PsO/UC, above 100 kg	Up to 10 vials per 56 days
Maintenance dose (not high dose or incomplete response)	RA, above 100 kg	Up to 6 vials per 56 days
Maintenance dose (not high)	AS, above 100 kg	Up to 10 vials per 42 days



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dose or incomplete response)		
Maintenance dose	All other indications	<ul style="list-style-type: none"> Up to 100 kg: up to 10 vials per 28 days Above 100 kg: up to 20 vials per 28 days
Incomplete response	Adult/pediatric CD, adult/pediatric UC, PsA, PsO, and RA	<ul style="list-style-type: none"> Up to 100 kg: up to 10 vials per 28 days Above 100 kg: up to 20 vials per 28 days
Incomplete response	AS	<ul style="list-style-type: none"> Up to 100 kg: up to 8 vials per 28 days Above 100 kg: up to 15 vials per 28 days

FDA-recommended Dosing

Avsola, Inflectra, infliximab, Ixifi, Remicade, Renflexis

Adult CD

- Intravenously 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks (starting at week 14).
- May increase the maintenance dose up to 10 mg/kg for loss of response.

Adult/pediatric UC, PsA, PsO, pediatric CD

- Intravenously 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks (starting at week 14).

RA

- Intravenously 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks, in combination with methotrexate (may increase the dose up to 10 mg/kg or treat as often as every 4 weeks).

AS

- Intravenously 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.

Zymfentra

Adult CD/UC

- Intravenously 5 mg/kg at 0, 2, and 6 weeks, then subcutaneously 120 mg every 2 weeks (starting at week 10)
- To switch patients from IV maintenance therapy, administer the first SC dose in place of the next scheduled infusion and every 2 weeks thereafter

References:

- Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2025.
- Avsola [package insert]. Thousand Oaks, CA: Amgen; September 2021.
- Inflectra [package insert]. New York, NY: Pfizer Inc; April 2023.

