









AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **4 of 19**

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

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input 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

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
- 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
- Plaque psoriasis and 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)<sup>1-6,9,10,42</sup>

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

Ulcerative colitis (UC)<sup>1-6,9,30</sup>

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)<sup>1-5,11-13,37,41,42</sup>

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









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Authorization of 12 months may be granted for the treatment of Behcet's disease when the member has had an inadequate response to at least one non-biologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids).

Hidradenitis suppurativa (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)<sup>8</sup>

Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of severe, refractory hidradenitis suppurativa.

Authorization of 12 months may be granted for treatment of severe, refractory hidradenitis suppurativa when either of the following is met:

- Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines) for at least 90 days.
- Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Pyoderma gangrenosum (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)<sup>8,24-26,33</sup>

Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of pyoderma gangrenosum.

Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when either of the following is met:

- Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).
- Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

Sarcoidosis (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)<sup>8</sup>

Authorization of 12 months may be granted for treatment of sarcoidosis in members when either of the following criteria is met:

- Member has had an inadequate response to corticosteroids or immunosuppressive therapy.
- Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy.

Takayasu's arteritis (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)<sup>8</sup>

Authorization of 12 months may be granted for treatment of refractory Takayasu's arteritis when either of the following criteria is met:





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- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.
- Member has immune checkpoint inhibitor-related diarrhea or colitis.

Acute graft versus host disease (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)<sup>27</sup>

Authorization of 12 months may be granted for treatment of acute graft versus host disease when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

**Continuation of Therapy**

Crohn's disease (CD)<sup>1-6,9,42</sup>

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease 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 Crohn's disease 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:

- Abdominal pain or tenderness
- Diarrhea
- 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)<sup>1-6,9,29,36</sup>





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- C-reactive protein (CRP)

Psoriatic arthritis (PsA) (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)<sup>1-5,14-17,29</sup>

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for psoriatic arthritis 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:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Plaque psoriasis (PsO) (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)<sup>1-5,14,22,43</sup>

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis 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 either of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Hidradenitis suppurativa (Avsola/Inflectra/infliximab/Ixifi/Remicade/Renflexis only)<sup>8,38,39</sup>

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for severe, refractory hidradenitis suppurativa 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 any of the following is met:

- Reduction in abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring
- Decrease in frequency of inflammatory lesions from baseline
- Reduction in pain from baseline
- Reduction in suppuration from baseline
- Improvement in frequency of relapses from baseline
- Improvement in quality of life from baseline
- Improvement on a disease severity assessment tool from baseline







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- Inflectra (infliximab-dyyb) injection 100 mg vial: 5 vials per 42 days
- Ixifi (Infliximab-qbtx) injection 100 mg vial: 5 vials per 42 days
- 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

<b>Dose Type</b>	<b>Indication</b>	<b>Exception Limit</b>
Induction dose	All (excluding high dose pediatric CD and UC, uveitis)	<ul style="list-style-type: none"> <li>• Up to 100 kg: up to 15 vials per 42 days</li> <li>• Above 100 kg: up to 30 vials per 42 days</li> </ul>
Induction dose	High dose pediatric CD and UC	<ul style="list-style-type: none"> <li>• Up to 100 kg: up to 30 vials per 42 days</li> <li>• Above 100 kg: up to 60 vials per 42 days</li> </ul>
Induction dose	Uveitis	<ul style="list-style-type: none"> <li>• Up to 100 kg: up to 15 vials per 28 days</li> <li>• Above 100 kg: up to 30 vials per 28 days</li> </ul>
Maintenance dose	High dose pediatric CD and UC/high dose pediatric UC transitioning into adulthood	<ul style="list-style-type: none"> <li>• Up to 100 kg: up to 10 vials per 56 days</li> <li>• Above 100 kg: up to 20 vials per 56 days</li> </ul>
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



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Maintenance dose (not high dose or incomplete response)	AS, above 100 kg	Up to 10 vials per 42 days
Maintenance dose	All other indications	<ul style="list-style-type: none"> <li>Up to 100 kg: up to 10 vials per 28 days</li> <li>Above 100 kg: up to 20 vials per 28 days</li> </ul>
Incomplete response	Adult/pediatric CD, adult/pediatric UC, PsA, PsO, and RA	<ul style="list-style-type: none"> <li>Up to 100 kg: up to 10 vials per 28 days</li> <li>Above 100 kg: up to 20 vials per 28 days</li> </ul>
Incomplete response	AS	<ul style="list-style-type: none"> <li>Up to 100 kg: up to 8 vials per 28 days</li> <li>Above 100 kg: up to 15 vials per 28 days</li> </ul>

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

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