



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **1 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

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

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Infliximab-Remicade and biosimilars under the patient’s prescription drug benefit.

Description:

A. FDA-Approved Indications

1. Adult patients with moderately to severely active Crohn’s disease (CD) and fistulizing CD who have had an inadequate response to conventional therapy
2. Pediatric patients 6 years of age and older with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy
3. Moderately to severely active ulcerative colitis (UC) in patients 6 years of age or older who have had an inadequate response to conventional therapy
4. Adult patients with moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate
5. Adult patients with active ankylosing spondylitis (AS)
6. Adult patients with active psoriatic arthritis (PsA)
7. Adult patients with chronic severe plaque psoriasis (PsO) who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

B. Compendial Uses

1. Axial spondyloarthritis
2. Behcet’s disease
3. Hidradenitis suppurativa
4. Pyoderma gangrenosum
5. Sarcoidosis
6. Takayasu’s arteritis
7. Uveitis
8. Reactive arthritis
9. Immune checkpoint inhibitor toxicity
10. Acute graft versus host disease
11. Moderate to severe plaque psoriasis

All other indications are considered experimental/investigational and not medically necessary.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Infliximab-Remicade and Biosimilars Page: 3 of 16

Effective Date: 2/1/2024 Last Review Date: 11/2023

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

2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Plaque psoriasis (PsO)

1. Initial requests:

- i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- ii. 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.

2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

E. Behcet’s disease (initial requests only)

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

F. Pyoderma gangrenosum, sarcoidosis, Takayasu’s arteritis, immune checkpoint inhibitor 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 Specialty:

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

- A. Crohn’s disease and ulcerative colitis: gastroenterologist
- B. Rheumatoid arthritis, ankylosing spondylitis, axial spondyloarthritis, Behcet’s disease, Takayasu’s arteritis, and reactive arthritis: rheumatologist
- C. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
- D. Plaque psoriasis and pyoderma gangrenosum: dermatologist
- E. Sarcoidosis: dermatologist or pulmonologist
- F. Uveitis: ophthalmologist or rheumatologist
- G. Immune checkpoint inhibitor toxicity and acute graft versus host disease: oncologist or hematologist

Criteria for Initial Approval:

A. Crohn’s disease (CD)



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **4 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

Applies to:

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

Authorization of 12 months may be granted for members 6 years of age or older for treatment of moderately to severely active CD.

B. Ulcerative colitis (UC)

Authorization of 12 months may be granted for members 6 years of age or older for treatment of moderately to severely active UC.

C. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis. 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).
2. 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:
 - i. Member meets either of the following criteria:
 - a. Member has been tested for either of the following biomarkers and the test was positive:
 1. Rheumatoid factor (RF)
 2. Anti-cyclic citrullinated peptide (anti-CCP)
 - b. Member has been tested for ALL of the following biomarkers:
 1. RF
 2. Anti-CCP
 3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
 - ii. Member is prescribed the requested medication in combination with methotrexate or leflunomide, or has a clinical reason not to use methotrexate or leflunomide (see Appendix).
 - iii. Member meets either of the following criteria:
 - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
 - b. Member has an intolerance or contraindication to methotrexate (see Appendix).

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **5 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

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

- 2. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:
 - i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
 - ii. Member has an intolerance or contraindication to two or more NSAIDs.

E. Psoriatic arthritis (PsA)

- 1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.
- 2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
 - i. Member has mild to moderate disease and meets one of the following criteria:
 - a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
 - b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
 - c. Member has enthesitis or predominantly axial disease.
 - ii. Member has severe disease.

F. Plaque psoriasis (PsO)

- 1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis.
- 2. Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:
 - i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 - ii. At least 10% of body surface area (BSA) is affected.
 - iii. At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
 - a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **6 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

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

- b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

G. Behcet's disease

1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of Behcet's disease.
2. 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., apremilast, colchicine, systemic glucocorticoids, azathioprine).

H. Hidradenitis suppurativa

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of severe, refractory hidradenitis suppurativa.
2. Authorization of 12 months may be granted for treatment of severe, refractory hidradenitis suppurativa when either of the following is met:
 - i. Member has experienced an inadequate response to an oral antibiotic for at least 90 days.
 - ii. Member has an intolerance or contraindication to oral antibiotics.

I. Pyoderma gangrenosum

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of pyoderma gangrenosum.
2. Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when either of the following is met:
 - i. Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine or mycophenolate mofetil).
 - ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

J. Sarcoidosis

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

1. Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Infliximab-Remicade and Biosimilars Page: 7 of 16

Effective Date: 2/1/2024 Last Review Date: 11/2023

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

2. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy.

K. Takayasu's arteritis

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

1. Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, or mycophenolate mofetil).
2. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, or mycophenolate mofetil).

L. Uveitis

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for uveitis.
2. Authorization of 12 months may be granted for treatment of uveitis when either of the following criteria is met:
 - i. Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, or mycophenolate mofetil).
 - ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, or mycophenolate mofetil).

M. Reactive arthritis

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for reactive arthritis.
2. Authorization of 12 months may be granted for treatment of reactive arthritis when either of the following criteria is met:
 - i. Member has experienced an inadequate response to at least a 3-month trial of one of the following despite adequate dosing or maximally tolerated dose:
 - a. Sulfasalazine (i.e., titrated to 1000 mg twice daily)
 - b. Methotrexate (i.e., titrated to at least 15 mg/week)
 - ii. Member has an intolerance or contraindication to methotrexate (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **8 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

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

N. Immune checkpoint inhibitor toxicity

1. Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor toxicity when either of the following criteria is met:
 - i. Member has experienced an inadequate response, intolerance, or contraindication to corticosteroids.
 - ii. Member has moderate or severe diarrhea or colitis.
2. Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor toxicity when the member has severe inflammatory arthritis and has experienced an inadequate response, intolerance, or contraindication to corticosteroids.

O. Acute graft versus host disease

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

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

Continuation of Therapy:

A. Crohn’s disease (CD)

1. Authorization of 12 months may be granted for all members 6 years of age or older (including new members) who are using the requested medication for moderately to severely active Crohn’s disease and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all members 6 years of age or older (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:
 - i. Abdominal pain or tenderness
 - ii. Diarrhea
 - iii. Body weight
 - iv. Abdominal mass
 - v. Hematocrit
 - vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
 - vii. Improvement on a disease activity scoring tool (e.g., Crohn’s Disease Activity Index [CDAI] score)



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **9 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

Applies to:

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

B. Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for all members 6 years of age or older (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all members 6 years of age or older (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:
 - i. Stool frequency
 - ii. Rectal bleeding
 - iii. Urgency of defecation
 - iv. C-reactive protein (CRP)
 - v. Fecal calprotectin (FC)
 - vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
 - vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

C. Rheumatoid arthritis (RA)

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.

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

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

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **10 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

Applies to:

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

E. Psoriatic arthritis (PsA)

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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement

F. Plaque psoriasis (PsO)

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:

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

G. Hidradenitis suppurativa

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:

1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

H. Uveitis



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **11 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

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

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for uveitis 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 the patient meets any of the following:

1. Reduced frequency of recurrence compared to baseline
2. Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline
3. Decreased reliance on topical corticosteroids

I. Reactive arthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for reactive 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 (e.g., tender joint count, swollen joint count, pain).

J. Immune checkpoint inhibitor toxicity and acute graft versus host disease

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

K. All other indications

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in Section IV and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other Criteria:

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **12 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

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

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Dosage and Administration:

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Approval:

Initial and Renewal Approval: 12 months

Quantity Level Limit:

5 vials per 42 days	Remicade (infliximab) injection 100 mg vial
	Avsola (infliximab-axxq) injection 100 mg vial
	Inflectra (infliximab-dyyb) injection 100 mg vial
	Renflexis (infliximab-abda) injection 100 mg vial
	Infliximab injection 100 mg vial

Induction dose (excluding high dose pediatric CD and UC)

- Up to 100 kg: up to 15 vials per 43 days



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Infliximab-Remicade and Biosimilars Page: 13 of 16

Effective Date: 2/1/2024 Last Review Date: 11/2023

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

- Above 100 kg: up to 30 vials per 43 days

Induction dose for high dose pediatric CD and UC:

- Up to 100 kg: up to 30 vials per 43 days
- Above 100 kg: up to 60 vials per 43 days

Adult CD following loss of response/high dose pediatric CD and UC maintenance/high dose pediatric UC transitioning into adulthood maintenance/RA with incomplete response:

- Up to 100 kg: up to 10 vials per 56 days
- Above 100 kg: up to 20 vials per 56 days

Maintenance dose (above 100 kg)

- CD/PsA/PsO/UC: up to 10 vials per 56 days
- RA: up to 6 vials per 56 days
- AS: up to 10 vials per 42 days
- Other indications: up to 10 vials per 42 days

FDA-recommended dosing

Adult CD

- 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks (may increase the dose up to 10 mg/kg for loss of response)

UC/PsA/Pediatric CD/UC/Plaque psoriasis

- 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks

RA

- 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

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

References:

1. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.
2. Avsola [package insert]. Thousand Oaks, CA: Amgen; September 2021.
3. Inflectra [package insert]. New York, NY: Pfizer Inc; March 2022.
4. Renflexis [package insert]. Jersey City, NJ. Organon LLC, Inc; January 2022.
5. Infliximab [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.
6. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;0:1-14.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Infliximab-Remicade and Biosimilars Page: 14 of 16

Effective Date: 2/1/2024 Last Review Date: 11/2023

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

7. IBM Micromedex® DRUGDEX® System (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed August 10, 2022.
8. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.
9. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113:481-517.
10. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. 2008;59(6):762-784.
11. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699. doi:10.1136/annrheumdis-2019-216655.
12. [Singh JA](#), [Saag KG](#), [Bridges SL Jr](#), et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1)1-26.
13. Menter A, Korman NJ, Elmetts CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
14. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
15. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis* 2005;64(Suppl II):ii14-ii17.
16. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18(8):465-479.
17. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis* 2011;70:896-904.
18. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. 2011;63(4):465-482.
19. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism*. 2013;65:2499-2512.
20. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613. doi:10.1002/art.41042.
21. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Infliximab-Remicade and Biosimilars Page: 15 of 16

Effective Date: 2/1/2024 Last Review Date: 11/2023

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

22. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behcet's syndrome. *Ann Rheum Dis.* 2018;77:808-818.
23. Agarwal A, Andrews JM. Systematic review: IBD-associated pyoderma gangrenosum in the biologic era, the response to therapy. *Aliment Pharmacol Ther.* 2013;38(6):563-572.
24. Arguelles-Arias F, Castro-Laria L, Lobaton T, et al. Characteristics and treatment of pyoderma gangrenosum in inflammatory bowel disease. *Dig Dis Sci.* 2013;58(10):2949-2954.
25. Marzano AV, Ishak RS, Saibeni S, et al. Autoinflammatory skin disorders in inflammatory bowel diseases, pyoderma gangrenosum and Sweet's syndrome: A comprehensive review and disease classification criteria. *Clin Rev Allergy Immunol.* 2013;45(2):202-210.
26. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed August 10, 2022.
27. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on August 9, 2022 from: <https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm>.
28. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32. doi:10.1002/art.40726.
29. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology.* 2020; 158:1450.
30. Flores D, Marquez J, Garza M, et al. Reactive arthritis: newer developments. *Rheum Dis Clin North Am.* 2003;29(1):37-vi.
31. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed August 10, 2022.
32. George, C, Deroide, F, Rustin, M. Pyoderma gangrenosum – a guide to diagnosis and management. *Clin Med.* 2019;19(3):224-8.
33. Menter A, Cordero KM, Davis DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol.* 2020;82(1):161-201.
34. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6): 1445-86.
35. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114:384-413.
36. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum.* 2010;62(9):2569-81.
37. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part I: Diagnosis, evaluation, and the use of complementary and procedural management. *J Am Acad Dermatol.* 2019; 81(1): 76-90.
38. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management. *J Am Acad Dermatol.* 2019; 81(1): 91-101.



AETNA BETTER HEALTH[®]
Coverage Policy/Guideline

Name: **Infliximab-Remicade and Biosimilars** Page: **16 of 16**

Effective Date: **2/1/2024** Last Review Date: **11/2023**

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

39. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
40. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res.* 2021;0:1-16.
41. Feuerstein J, Ho E, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology.* 2021;160:2496-2508.
42. Elmetts C, Korman N, et al. Guidelines of Care for the Management and Treatment of Psoriasis with Topical Therapy and Alternative Medicine Modalities for Psoriasis Severity Measures. *J Am Acad Dermatol.* 2021;84:432-470.
43. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569.
44. Angeles-Han ST, Ringold S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the screening, monitoring, and treatment of juvenile idiopathic arthritis-associated uveitis. *Arthritis Care Res.* 2019; 71(6):703-716.
45. Mehta, NA, Emani-Naeini P. A review of systemic biologics and local immunosuppressive medications in uveitis. *J Ophthalmic Vis Res.* 2022;17(2):276-289.
46. Azulfidine [package insert]. New York, NY: Pfizer; August 2021.