AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Infliximab-Remicade and Biosimilars	Page:	1 of 16
Effective Date:	11/15/2023	Last Review Date:	10/2023
Applies to:	☐Illinois ☐New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia	☒Florida Kids ☐Michigan ☒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.

Applicable Drug List:

Non-Preferred:
Remicade (infliximab)
Avsola (infliximab-axxq)
Inflectra (infliximab-dyyb)
Renflexis (infliximab-abda)
Infliximab

Policy/Guideline:

Documentation for all indications:
The patient is unable to take THREE preferred products (Enbrel, preferred adalimumab product and Kevzara), where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

A. **Crohn's disease (CD) and ulcerative colitis (UC)**
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

B. **Rheumatoid arthritis (RA)**
1. For initial requests:
   i. 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.
   ii. 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).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. A**nkylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), reactive arthritis, hidradenitis suppurativa, and uveitis**
1. 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.

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)

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.

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.

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.

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 previous 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).

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)

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)

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

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.

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

- 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

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