

# Specialty Guideline Management infliximab-Remicade and Biosimilars

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Remicade	infliximab
Avsola	infliximab-axxq
Inflectra	infliximab-dyyb
Renflexis	infliximab-abda
Zymfentra	infliximab-dyyb
infliximab (unbranded Remicade)	infliximab

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications<sup>1-6</sup>

#### infliximab/Avsola/Inflectra/Remicade/Renflexis

- Adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy and adult patients with fistulizing CD
- 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
- Moderately to severely active ulcerative colitis (UC) in patients 6 years of age and older who have had an inadequate response to conventional therapy

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- Adult patients with moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate
- Adult patients with active ankylosing spondylitis (AS)
- Adult patients with active psoriatic arthritis (PsA)
- Adult patients with chronic severe plaque psoriasis (PsO) who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

## Zymfentra

- Maintenance treatment of moderately to severely active ulcerative colitis in adults following treatment with an infliximab product administered intravenously
- Maintenance treatment of moderately to severely active Crohn's disease in adults following treatment with an infliximab product administered intravenously

## Compendial Uses

- Non-radiographic axial spondyloarthritis<sup>7</sup>
- Behcet's disease<sup>8,32</sup>
- Hidradenitis suppurativa<sup>8</sup>
- Pyoderma gangrenosum<sup>8,33</sup>
- Sarcoidosis<sup>8</sup>
- Takayasu's arteritis<sup>8</sup>
- Uveitis<sup>8</sup>
- Reactive arthritis<sup>31</sup>
- Immune checkpoint inhibitor-related toxicity<sup>27</sup>
- Acute graft versus host disease<sup>27</sup>
- Moderate to severe plaque psoriasis<sup>22</sup>

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

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

### Crohn's disease (CD) and ulcerative colitis (UC)

#### Continuation requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

## 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.

## Plaque psoriasis (PsO)

### Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- 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 of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

## Behcet's disease (initial requests only)

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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
- 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/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 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)
    - Anti-cyclic citrullinated peptide (anti-CCP)
  - Member has been tested for ALL of the following biomarkers:
    - RF
    - Anti-CCP
    - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
  - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
    - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
    - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
    - Member has a documented contraindication to hydroxychloroquine (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
    - Member has moderate to high disease activity.
  - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
    - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
    - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
    - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.

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- Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
- Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix), discontinues MTX, and meets any of the following conditions:
  - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
  - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
  - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
  - Member has moderate to high disease activity.
- 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).

## **Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)<sup>1-5,7,18,21</sup>**

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.

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:

- Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

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

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.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:

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- Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
- Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
- Member has enthesitis or predominantly axial disease.
- Member has severe disease.

## Plaque psoriasis (PsO) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)<sup>1-5,14,17,22,43</sup>

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.

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:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
  - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
  - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

## Behcet's disease (Avsola/Inflectra/infliximab/Remicade/Renflexis only)<sup>8,23,32</sup>

Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for treatment of Behcet's disease.

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/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.

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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/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/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/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:

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

## Uveitis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)<sup>8,45,46</sup>

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

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

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

## Reactive arthritis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)<sup>31,41,47</sup>

Authorization of 12 months may be granted for members who have previously received a biologic indicated for reactive arthritis.

Authorization of 12 months may be granted for treatment of reactive arthritis when either of the following criteria is met:

- Member has had an inadequate response to methotrexate or sulfasalazine.
- Member has an intolerance or contraindication to methotrexate (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

## Immune checkpoint inhibitor-related toxicity (Avsola/Inflectra/infliximab/Remicade/Renflexis only)<sup>27</sup>

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and either of the following is met:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- 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 any 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/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>

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)

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

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/Remicade/Renflexis only)<sup>1-5,7,18,21</sup>

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 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:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

## Psoriatic arthritis (PsA) (Avsola/Inflectra/infliximab/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

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- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

## Plaque psoriasis (PsO) (Avsola/Inflectra/infliximab/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/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

## Uveitis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)<sup>8</sup>

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:

- Reduced frequency of flare recurrence compared to baseline
- Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline
- Decreased reliance on topical corticosteroids

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## Reactive arthritis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)<sup>31</sup>

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).

## Immune checkpoint inhibitor-related inflammatory arthritis (Avsola/Inflectra/infliximab/Remicade/ Renflexis only)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory 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.

## Immune checkpoint inhibitor-related toxicity and acute graft versus host disease (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

## All other indications (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in the coverage criteria section 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<sup>1-6</sup>

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 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 (e.g., chest x-ray). 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 for the same indication.

## Appendix

### Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, Hydroxychloroquine, or Leflunomide<sup>35</sup>

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

## Dosage and Administration

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

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