

POLICY Document for RENFLEXIS

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product

- Policy information specific to preferred medications

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA

DISEASE-MODIFYING ANTIRHEUMATIC DRUGS FOR AUTOIMMUNE CONDITIONS

I. PREFERRED PRODUCTS: ORENCIA, REMICADE, SIMPONI ARIA

This prior authorization program informs prescribers of preferred autoimmune products for treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. This program limits coverage to certain autoimmune drugs for treatment of specific conditions, and therefore not all FDA labeled uses of a drug are covered.

The prior authorization process evaluates if a clinical exception exists for use of a non-preferred autoimmune drug for these specific conditions. Coverage for a non-preferred autoimmune drug is provided when all preferred drugs have been tried, and either are not tolerated, ineffective, or contraindicated for the patient.

II. PLAN DESIGN SUMMARY

This program applies to non-preferred autoimmune products used in the treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. Coverage for these products (those which are non-preferred and not covered for the

Specialty Exceptions Medical Benefit Autoimmune P2018

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prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. Coverage for non-preferred products will continue in situations where the patient is currently receiving treatment.

Each PA request is reviewed based on all utilization management (UM) programs implemented.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

	Products*
Preferred	<ul style="list-style-type: none"> • Orencia (abatacept) • Remicade (infliximab) • Simponi Aria (golimumab, intravenous)
Non-Preferred	<ul style="list-style-type: none"> • Actemra (tocilizumab) • Cimzia (certolizumab pegol) • Entyvio (vedolizumab) • Inflectra (infliximab-dyyb) • Renflexis (infliximab-abda) • Stelara (ustekinumab)

*If applicable for approved indication

III. EXCEPTION CRITERIA

A. Coverage for a non-preferred product is provided when ANY of the following criteria are met:

1. Member has had a documented inadequate response to treatment with a preferred product
2. Member has experienced a documented intolerable adverse event to all preferred products indicated for the condition being treated
3. For indications where Remicade is the only preferred product option (e.g., Crohn’s disease, ulcerative colitis, etc.), member has a documented clinical reason to avoid Remicade (see Appendix) (*Note: does not apply to Inflectra or Renflexis*)
4. Member is currently receiving therapy with the requested product, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

IV. APPENDIX: Clinical reasons to avoid Remicade

- History of demyelinating disorder
- History of congestive heart failure

- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome
- Risk of lymphoma

Section 2: Clinical Criteria

RENFLXIS (infliximab-abda)

I. 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.

A. FDA-Approved Indications

1. Moderately to severely active Crohn's disease
2. Moderately to severely active ulcerative colitis
3. Moderately to severely active rheumatoid arthritis in combination with methotrexate
4. Active ankylosing spondylitis
5. Active psoriatic arthritis
6. Chronic severe plaque psoriasis

B. Compendial Uses

1. Axial spondyloarthritis
2. Behçet's syndrome
3. Granulomatosis with polyangiitis (Wegener's granulomatosis)
4. Hidradenitis suppurativa
5. Juvenile idiopathic arthritis
6. Pyoderma gangrenosum
7. Sarcoidosis
8. Takayasu's arteritis
9. Uveitis

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Moderately to severely active Crohn's disease (CD)

1. Authorization of 24 months may be granted for members who have previously received Remicade, Inflectra, Renflexis, or any other biologic indicated for the treatment of Crohn's disease.

2. Authorization of 24 months may be granted for treatment of moderately to severely active CD when any of the following criteria is met:
 - a. Member has fistulizing disease.
 - b. Member has an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix A).

B. Moderately to severely active ulcerative colitis (UC)

1. Authorization of 24 months may be granted for members who have previously received Remicade, Inflectra, Renflexis, or any other biologic indicated for moderately to severely active ulcerative colitis.
2. Authorization of 24 months may be granted for treatment of moderately to severely active UC when the member has an inadequate response, intolerance or contraindication to at least ONE conventional therapy option (see Appendix B).

C. Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 24 months may be granted for members who have previously received Remicade, Inflectra, Renflexis, or any other biologic DMARD or non-preferred synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis. Remicade, Inflectra, or Renflexis must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide.
2. Authorization of 24 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
 - a. Member is prescribed Remicade, Inflectra, or Renflexis in combination with methotrexate or leflunomide, or has a clinical reason not to use methotrexate or leflunomide.
 - b. Member has any of the following:
 - i. Inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week)
 - ii. Intolerance or contraindication to methotrexate (see Appendix C)

D. Active ankylosing spondylitis (AS) and axial spondyloarthritis

1. Authorization of 24 months may be granted for members who have previously received Remicade, Inflectra, Renflexis, or any other biologic DMARD indicated for active ankylosing spondylitis.
2. Authorization of 24 months may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when any of the following criteria is met:
 - a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).

- b. Member has an intolerance or contraindication to two or more NSAIDs.

E. Active psoriatic arthritis (PsA)

Authorization of 24 months may be granted for treatment of active psoriatic arthritis (PsA).

F. Chronic severe plaque psoriasis

1. Authorization of 24 months may be granted for members who have previously received Remicade, Inflectra, Renflexis, Otezla, or any other biologic DMARD indicated for the treatment of severe psoriasis.
2. Authorization of 24 months may be granted for treatment of chronic severe plaque psoriasis when all of the following criteria are met:
 - a. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 - b. Member meets any of the following criteria:
 - i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
 - ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix D).
 - iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

G. Behçet's syndrome

Authorization of 24 months may be granted for treatment of Behçet's syndrome.

H. Granulomatosis with polyangiitis (Wegener's granulomatosis)

Authorization of 24 months may be granted for treatment of granulomatosis with polyangiitis.

I. Hidradenitis suppurativa

Authorization of 24 months may be granted for treatment of severe, refractory hidradenitis suppurativa.

J. Juvenile Idiopathic arthritis (JIA)

1. Authorization of 24 months may be granted for members who have previously received Remicade, Inflectra, or Renflexis.
2. Authorization of 24 months may be granted for treatment of JIA when any of the following criteria is met:

- a. Member has experienced an inadequate response to at least a 3-month trial of a self-injectable TNF inhibitor indicated for JIA (e.g., Enbrel or Humira).
- b. Member has experienced an intolerable adverse event (e.g., hypersensitivity reaction) to a self-injectable TNF inhibitor indicated for JIA.
- c. Member has developed antibodies against Enbrel or Humira.

K. Pyoderma gangrenosum

Authorization of 24 months may be granted for treatment of pyoderma gangrenosum.

L. Sarcoidosis

Authorization of 24 months may be granted for treatment of sarcoidosis.

M. Takayasu's arteritis

Authorization of 24 months may be granted for treatment of Takayasu's arteritis.

N. Uveitis

Authorization of 24 months may be granted for treatment of uveitis in members who have experienced an inadequate response or intolerance or have a contraindication to a trial of immunosuppressive therapy for uveitis (e.g., methotrexate, azathioprine, or mycophenolate mofetil).

III. CONTINUATION OF THERAPY

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Remicade or Inflectra as evidenced by low disease activity or improvement in signs and symptoms of the condition.

IV. OTHER

For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).

Note: Members who have received Remicade, Inflectra, Renflexis or any other biologic DMARD or non-preferred synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

V. APPENDICES

Appendix A: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
 - a. Oral budesonide, oral mesalamine
 - b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
 - a. Azathioprine, mercaptopurine
 - b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
 - a. Prednisone, methylprednisolone intravenously (IV)
 - b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission:
 - a. Azathioprine, mercaptopurine
 - b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission
 - a. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission
 - a. Azathioprine, mercaptopurine
 - b. Alternative: methotrexate IM

Appendix B: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
 - a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
 - b. Rectal mesalamine (e.g., Canasa, Rowasa)
 - c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
 - d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
 - a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
 - b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
 - a. Prednisone, hydrocortisone IV, methylprednisolone IV
 - b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
 - a. Azathioprine, mercaptopurine
 - b. Alternative: sulfasalazine
5. Pouchitis: Metronidazole, ciprofloxacin
 - a. Alternative: rectal mesalamine

Appendix C: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix D: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

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