Health Alliance™

Pharmacy Drug Policy & Procedure

Policy Name:	Remicade (infliximab) and biosimilars	Policy#:	1846P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Remicade, Avsola, Inflectra, and Renflexis.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Remicade and its biosimilars; Avsola, Inflectra or Renflexis, under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Active Crohn's Disease

1.1 Ordered by a Gastroenterologist (stomach doctor)

1.2 Member age 6 and up

1.3 Documented moderate to severe active Crohn's Disease (patients with prominent symptoms such as fever, weight loss, abdominal pain and tenderness, intermittent nausea and vomiting, anemia, bleeding, diarrhea, internal fistulae, intestinal obstruction, megacolon, perianal disease, or extraintestinal manifestations: arthritis or spondylitis) meeting one of the following two requirements:

- Hospitalization due to severe Crohn's Disease or documentation that member's disease is severe enough that member cannot wait for the effect of other therapies (including patients with fistulizing disease; see Section 2)
- Documented failure, intolerance, or contraindication to any one of the following treatments used in mild to moderate disease:
  - Corticosteroids
  - Immunosuppressants (azathioprine, 6-MP, or methotrexate)
  - Biological Immunomodulator
- For new starts requesting brand Remicade
  Contraindication or intolerance to an infliximab biosimilar (Avsola, Renflexis or Inflectra) OR
  - Failure after maximizing dose and frequency of an infliximab biosirnilar (Avsola, Renflexis or Inflectra)

2. Coverage Criteria for Crohn's Disease with Fistulas

2.1 Ordered by a Gastroenterologist (stomach doctor)

2.2 Member age 6 and up

2.3 Documented fistulizing Crohn's Disease for at least 3 months

3. Coverage Criteria for Ulcerative Colitis

3.1 Ordered by a Gastroenterologist (stomach doctor)

3.2 Member age 6 and up

3.3 Documented moderate to severe Ulcerative Colitis, meeting one of the following three requirements:

- Hospitalization with fulminant Ulcerative Colitis defined as any one of the following:
  - 10 or more stools per day
  - Continuous bleeding
  - Abdominal pain and distention
  - Presence of acute, severe, toxic symptoms (fever and anorexia)
- Documented failure, intolerance, or contraindication to corticosteroids and immunosuppressants
  - Corticosteroids: Oral corticosteroids at a dose equivalent to 40 to 60mg prednisone daily, OR IV corticosteroids for 7-day duration
  - Immunosuppressants: 6-MP or azathioprine
- Documented failure, intolerance, or contraindication to corticosteroids and 5-ASA products
  - Corticosteroids: Oral corticosteroids at a dose equivalent to 40 to 60mg prednisone daily, OR IV corticosteroids for 7-day duration
  - 5-ASA products: mesalamine, sulfasalazine, balsalazide
- For new starts requesting brand Remicade
  - Contraindication or intolerance to an infliximab biosimilar (Avsola, Renflexis or Inflectra) OR
  - Failure after maximizing dose and frequency of an infliximab biosirnilar (Avsola, Renflexis or Inflectra)

4. Coverage Criteria for Rheumatoid Arthritis

4.1 Ordered by a Rheumatologist (musculoskeletal doctor)

4.2 Diagnosis of Rheumatoid Arthritis

4.3 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to a DMARD (Disease-Modifying Anti-Rheumatic Drug)): methotrexate, Arava (leflunornide), Plaquenil (hydroxychloroqyine), or sulfasalazine

4.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to one of the following preferred products:

- Cirnzia
- Covered adalimumab biosirnilars
- Simponi
- Xeljanz/XR
- Rinvoq

4.5 For new starts requesting brand Remicade

- Contraindication or intolerance to an infliximab biosirnilar (Avsola, Renflexis or Inflectra) OR
- Failure after maximizing dose and frequency of an infliximab biosimilar (Avsola, Renflexis or Inflectra)

5. Coverage Criteria for Juvenile Idiopathic Arthritis

5.1 Ordered by a Rheumatologist (musculoskeletal doctor)

5.2 Diagnosis of moderate to severe active polyarticular juvenile idiopathic arthritis

5.3 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to methotrexate

5.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to a covered adalimumab biosirnilar

6. Coverage Criteria for Plaque Psoriasis

6.1 Ordered by a Dermatologist (skin doctor)

6.2 Age 18 years or older

6.3 Diagnosis of moderate to severe plaque psoriasis defined as more than 5 to 10% of body surface area affected, OR involvement of the face, palm, sole, or genitals, OR disease that is otherwise disabling

6.4 Documented failure, intolerance, or contraindication to phototherapy, or documented barriers to phototherapy access that impede treatment (e.g., unmanageable distance from phototherapy treatment location or inability to schedule treatments)
6.5 Documented failure of 3-month trial on, intolerance of, or contraindication to traditional systemic therapy (methotrexate, cyclosporine, and acitretin)
6.6 Documented failure, intolerance, or contraindication to topical therapy
6.7 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to one of the following preferred products:
- Cimzia
- Covered adalimumab biosimilar
- Covered ustekinumab biosimilar
- Tremfya
- Otezla
- Skyrizi

6.8 For new starts requesting brand Remicade
- Contraindication or intolerance to an infliximab biosimilar (Avsola, Renflexis or Inflectra) OR
- Failure after maximizing dose and frequency of an infliximab biosimilar (Avsola, Renflexis or Inflectra)

7. Coverage Criteria for Active Psoriatic Arthritis

7.1 Ordered by a Rheumatologist (musculoskeletal doctor)
7.2 Diagnosis of Psoriatic Arthritis
7.3 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to a DMARD (Disease-Modifying Anti-Rheumatic Drug): methotrexate, Arava (leflunomide), Plaquenil (hydroxychloroqyine), or sulfasalazine
7.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to one of the following preferred products:
- Cimzia
- Covered adalimumab biosimilar
- Simponi
- Covered ustekinumab biosimilar
- Otezla

7.5 For new starts requesting brand Remicade
- Contraindication or intolerance to an infliximab biosimilar (Avsola, Renflexis or Inflectra) OR
- Failure after maximizing dose and frequency of an infliximab biosimilar (Avsola, Renflexis or Inflectra)

8. Coverage Criteria for Ankylosing Spondylitis

8.1 Ordered by a Rheumatologist (musculoskeletal doctor)
8.2 Diagnosis of Ankylosing Spondylitis
8.3 Documented failure, intolerance, or contraindication to at least two formulary anti-inflammatory drugs during a single three-month period
8.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to one of the following preferred products:
- Cimzia
- Covered adalimumab biosimilars
- Simponi
- Enbrel

8.5 For new starts requesting brand Remicade
- Contraindication or intolerance to an infliximab biosimilar (Avsola, Renflexis or Inflectra) OR
- Failure after maximizing dose and frequency of an infliximab biosimilar (Avsola, Renflexis or Inflectra)

9. Coverage Criteria for Chronic Pulmonary Sarcoidosis

9.1 Ordered by a specialist
9.2 Diagnosis of chronic pulmonary sarcoidosis who remain symptomatic despite treatment for 3 or more months with steroids (10mg per day or more), and immunosuppressants (such as azathioprine,

cyclophosphamide, or methotrexate)

10. Coverage Criteria for Pyoderma Gangrenosum

10.1 Ordered by a specialist
10.2 Diagnosis of refractory pyoderma gangrenosum not responding to standard therapy
10.3 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to a covered adalimumab biosimilar

11. Coverage Criteria for Uveitis

11.1 Diagnosis of Uveitis
11.2 Ordered by an Ophthalmologist (eye doctor) or a specialist in the treatment of uveitis
11.3 Documented failure to respond to topical glucocorticoids
11.4 Documented failure to respond to systemic glucocorticoids or immunosuppressive agents
11.5 Documented failure, contraindication, or intolerance to a covered adalimumab biosimilar

12. Exclusion Criteria

12.1 Allergic reaction to murine proteins or humanized monoclonal antibody
12.2 Inadequate response to initial or previous infliximab therapy
12.3 Patients with Active infections or latent tuberculosis
12.4 Patients with moderate to severe heart failure (New York Heart Association [NYHA] Functional Class III/IV) should not receive doses >5 mg/kg
12.5 Infliximab and other agents that inhibit TNF have been associated in rare cases with CNS manifestation of systemic vasculitis, seizure and new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barre syndrome
12.6 Health Alliance does not cover concurrent therapy with other biologic immunomodulators based upon the possible increased risk for infections and other potential pharmacological interactions.
12.7 Off-label (non-FDA-Approved) dosing frequencies
12.8 Only certain NDCs of adalimumab biosimilars will be considered for coverage, please reference fonnulary files for most accurate list of covered biosimilars

13. Managed Dose Limitation

13.1 Ankylosing spondylitis: 5 mg/kg at week 0, 2, and 6 then every 6 weeks.
13.2 Crohn's Disease: 5 mg/kg at week 0, 2, and 6 then 5-10 mg/kg every 8 weeks. For persons who respond and then later lose response, consideration may be given to increase treatment with 10mg/kg IV every 8 weeks but discontinue if no response after week 14 after change.
13.3 Fistulizing Crohn's Disease: 5mg/kg IV every 8 weeks; for persons who respond and then later lose response, consideration may be given to increase treatment with 10mg/kg IV every 8 weeks but discontinue if no response after week 14 after change.
13.4 Plaque Psoriasis/Psoriatic Arthritis: 5 mg/kg at week 0, 2, and 6; then 5 mg/kg every 8 weeks.
13.5 Rheumatoid Arthritis: 3 mg/kg at week 0, 2, and 6; then 3 mg/kg every 8 weeks up to l0mg/kg every 8 weeks or 3mg/kg IV every 4 weeks.
13.6 Ulcerative Colitis: 5 mg/kg at week 0, 2, and 6 then 5 mg/kg every 8 weeks.

14. Approval Period

14.1 Initial Approval: 12 months
14.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

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16. Remicade (infliximab), Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), and Renflexis (infliximab-abda) Member Friendly (Plain Language) Policy

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