Pharmacy Drug Policy & Procedure

Policy Name:	Remicade (infliximab), Avsola (infliximab), Inflectra (infliximab) and Renflexis (infliximab)	Policy#:	1846P

Purpose of the Policy

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

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Remicade or its biosimilars; Avsola, Inflectra, or Renflexis under the specialty medical benefit if the following criteria are 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 (budesonide)
  - Immunosuppressants (azathioprine, 6-MP, or methotrexate)
  - Biological Immunomodulator

1.4 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)

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 due to severe Ulcerative Colitis with sudden onset defined as any of the following

- 10 or more stools per day
- Continuous bleeding
- Abdominal pain and fullness
- Presence of acute, severe, toxic symptoms (fever and anorexia)

- Documented failure, intolerance, or contraindication to corticosteroids and immunosuppressants Corticosteroids (budesonide)
  - Corticosteroids: Oral corticosteroids at a dose equivalent to 40 to 60mg prednisone daily, OR IV corticosteroids for 7-day duration
  - Immunosuppressants (azathioprine, 6-MP, or methotrexate)
- 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

3.4 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)

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 (leflunomide), Plaquenil (hydroxychloroquine), or sulfasalazine

4.4 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
- Xeljanz/XR
- Rinvoq

4.5 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)

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 biosimilar

5.5 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)

6. Coverage Criteria for Plaque Psoriasis

6.1 Ordered by a dermatologist (skin doctor)
6.2 Member age 18 and up
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
- Stelara
- 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 (hydroxychloroquine), 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
- Stelara
- 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 a to at least two formulary anti-inflammatory drugs (corticosteroids, celecoxib, diclofenac) 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 biosimilar
- Simponi

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 refractory pyoderma gangrenosum not responding to standard therapy, such as topical and oral corticosteroids, topical tacrolimus, oral cyclosporine

9.3 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)

10. Coverage Criteria for Pyoderma Gangrenosum

10.1 Ordered by a specialist

10.2 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)

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

10.4 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)

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, intolerance, or contraindication a covered adalimumab biosimilar

11.6 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)

12. Exclusion Criteria

12.1 Allergic reaction to any part of a 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 with rare cases of serious central nervous system disorders such as: seizure; new onset or exacerbation of CNS disorders including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barre syndrome

12.6 Health Alliance does not cover more than one biologic immunomodulatory at a time because of the possible increased risk for infections and other potential drug 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 statement of policy for covered NDCs
- Covered adalimumab biosimilars (as of 7/1/2024) include: Amjevita (72511040001, 72511040002, 55513039901, 555130479**, 555130481**, 555130482**), Hadlima (78206018701, 78206018401, 78206018601, and 78206018301), Adalimumab-adaz (61314032720 and 61314032764), and Adalimumab-adbm (005970545**, 00597055580, 00597056520, 005970575**, 00597058589, and 00597059520).

13. Managed Dose Limitations

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 10mg/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 Subsequent approvals: 12 months with documented benefit from therapy

CPT Codes	
HCPCS Codes	
J1745	Injection, infliximab, [Remicade] 10mg
Q5103	Injection, infliximab, [Inflectra] 10mg
Q5104	Injection, infliximab, [Renflexis] 10mg
Q5121	Injection, infliximab [Avsola] 10mg

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