Pharmacy Drug Policy & Procedure

Policy Name:	Crohn's Disease Immunomodulator Therapies	Policy #:	2749P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of immunomodulators used in the treatment of Crohn's Disease (CD).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Cimzia, covered adalimumab biosimilars, Skyrizi, Rinvoq, covered ustekinumab biosimilars, Omvoh, Tremfya, or Entyvio under the specialty benefit when the following criteria have been met.

Please refer to most recent formulary file for covered adalimumab biosimilars.

Criteria

1. Coverage Criteria of Preferred Products (Cimzia, covered adalimumab biosimilars, Skyrizi, covered ustekinumab biosimilars, Tremfya)

1.1 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 the member's disease is severe enough that the member cannot wait for the effect of other therapies
- Documented failure, intolerance, or contraindication to treatments used in mild to moderate disease:
  - Corticosteroids (prednisone, budesonide)
  - Immunosuppressants (azathioprine, 6-MP, or methotrexate)

1.2 Ordered by a Gastroenterologist (stomach doctor)

1.3 Age 18 years or older (age 6 years or older for adalimumab)

2. Coverage Criteria of Preferred Products with Single Step-Edit (Rinvoq)

2.1 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 the member's disease is severe enough that the member cannot wait for the effect of other therapies
- Documented failure, intolerance, or contraindication to treatments used in mild to moderate disease:
  - Corticosteroids (prednisone, budesonide)

- Immunosuppressants (azathioprine, 6-MP, or methotrexate)

2.2 Ordered by a Gastroenterologist (stomach doctor)

2.3 Age 18 years or older

2.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to one or more TNF inhibitors (e.g., Cimzia)

3. Coverage Criteria of Non-Preferred Products with Double Step-Edit (Entyvio IV or Sub-Q, Omvoh)

3.1 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 the member's disease is severe enough that the member cannot wait for the effect of other therapies
- Documented failure, intolerance, or contraindication to treatments used in mild to moderate disease:
  - Corticosteroids
  - Immunosuppressants (azathioprine, 6-MP, or methotrexate)

3.2 Ordered by a Gastroenterologist

3.3 Age 18 years or older

3.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to TWO of the following:

- Cimzia
- Covered adalimumab biosimilar
- Skyrizi
- Covered ustekinumab biosimilar
- Tremfya
- Rinvoq

4. Immunomodulators for the Treatment of Crohn's Disease under the Medical Benefit ONLY

4.1 Remicade is not covered under the pharmacy benefit

4.2 See Remicade policy for Crohn's Disease coverage criteria under the medical benefit

5. Exclusion Criteria

5.1 Allergic reaction to murine proteins or humanized monoclonal antibody

5.2 Inadequate response to initial or previous therapy with requested immunomodulator

5.3 Patients with active infections, active or latent tuberculosis, and symptomatic or deteriorating congestive heart failure

5.4 Off-label (non FDA approved) dosing frequencies

5.5 Health Alliance does not cover more than one biologic immunomodulator because of the possible increased risk for infections and potential drug interactions

5.6 Only certain NDCs of biosimilars will be considered for coverage, please reference most recent formulary file for covered NDCs

6. FDA Approved Dosages for Crohn's Disease

6.1 Cimzia: 400mg sub-q at week 0, 2, and 4, then maintenance dose of 400mg sub-q every 4 weeks

6.2 Covered adalimumab biosimilars: 160mg sub-q on day 1, then 80mg sub-q on day 15, then 40mg sub-q every other week beginning on day 29

6.3 Covered ustekinumab biosimilars: 90mg sub-q every 8 weeks after the IV induction dose

6.4 Tremfya: 400mg sub-q or 200mg IV at weeks 0, 4, and 8, then maintenance dose of 100mg sub-q every 8 weeks OR 200mg every 4 weeks

6.5 Rinvoq: 45mg by mouth once daily for 12 weeks followed by 15mg by mouth once daily

6.6 Skyrizi: 600mg IV at weeks 0, 4, and 8 followed by 180-360mg sub-q at week 12 and every 8 weeks

6.7 Entyvio: 300 mg IV at 0, 2, and 6 weeks and then every 8 weeks thereafter OR 108 mg sub-q once every 2 weeks beginning after at least 2 IV infusions

6.8 Omvoh: 900 mg IV at weeks 0, 4, and 8 followed by 300mg at week 12 and every 4 weeks thereafter

7. Approval Period

7.1 Initial authorization will be placed for 12 months

7.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

HCPCS Codes	

References

1. Lightner A, Vogel J, Carmichael J, Keller D, et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Surgical Management of Crohn's Disease. Diseases of the Colon & Rectum: August 2020 - Volume 63 - Issue 8 - p 1028-1052.
2. Lichtenstein G, Loftus E, Isaacs K, et al. Clinical Guideline: Management of Crohn's Disease in Adults, American Journal of Gastroenterology: April 2018 - Volume 113 - Issue 4 - p 481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021 Jun;160(7):2496-2508.

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