Pharmacy Drug Policy & Procedure

Policy Name:	Ulcerative Colitis Immunomodulator Therapies	Policy #:	2748P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of immunomodulators used in the treatment of Ulcerative Colitis (UC) for new starts to therapy. This includes covered adalimumab biosimilars, Simponi, Simponi Aria, covered ustekinumab biosimilars, Skyrizi, Tremfya, Xeljanz, Xeljanz XR, Rinvoq, Zeposia, or Entyvio.

Please refer to most recent formulary file for covered biosimilars.

Statement of the Policy

Health Alliance Medical Plans will approve the use of the above drugs under the specialty benefit when the following criteria have been met.

Criteria

1. Coverage Criteria of Preferred Products (covered adalimumab biosimilars, Simponi, Simponi Aria, covered ustekinumab biosimilars, Skyrizi IV or Sub-Q, Tremfya IV or Sub-Q)

1.1 Documented moderate to severe Ulcerative Colitis, meeting one of the following two requirements:
- 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
  - Imunosuppressants: 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

1.2 Ordered by a Gastroenterologist (stomach doctor)

1.3 Age 18 years or older (5 years or older for adalimumab)

2. Coverage Criteria of Preferred Products with Single Step-Edit (Xeljanz/XR, Rinvoq)

2.1 Documented moderate to severe Ulcerative Colitis, meeting one of the following two requirements:
- 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
  - Imunosuppressants: 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

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 (such as Simponi)

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

3.1 Documented moderate to severe Ulcerative Colitis, meeting one of the following two requirements:
- 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
  - Imunosuppressants: 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

3.2 Ordered by a Gastroenterologist (stomach doctor)
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:
- Covered adalimumab biosimilars
- Simponi
- Covered ustekinumab biosimilars
- Skyrizi
- Tremfya
- Rinvoq
- Xeljanz/XR

4. Immunomodulators for the Treatment of Ulcerative Colitis not under the pharmacy benefit

4.1 Remicade and biosimilars are not covered under the pharmacy benefit
4.2 See Remicade and biosimilars policy for UC coverage criteria under the medical benefit

5. Exclusion Criteria

5.1 Allergic reaction to any monoclonal antibody
5.2 Inadequate response to initial or previous therapy with requested immunomodulator
5.3 Patients with active infections, latent tuberculosis, or 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 immunomodulatory because of the possible increased risk for infections and other 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 Ulcerative Colitis

6.1 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
6.2 Simponi: 200mg sub-q at week 0, then 100mg sub-q at week 2, followed by maintenance therapy of 100mg sub-q every 4 weeks
6.3 Covered ustekinumab biosimilars: 90 mg sub-q every 8 weeks after the IV induction dose

6.4 Skyrizi: 180-360mg sub-q at week 12 and every 8 weeks after the 3 IV induction doses
6.5 Tremfya: 100mg sub-q every 8 weeks or 200mg sub-q every 4 weeks after 3 IV induction doses
6.6 Xeljanz: 10mg orally twice daily for at least 8 weeks (maximum of 16 weeks), then maintenance dose of 5mg twice daily
6.7 Xeljanz XR: 22mg orally once daily for at least 8 weeks (maximum of 16 weeks), then maintenance dose of 11mg orally once daily
6.8 Rinvoq: 45mg orally once daily for 8 weeks, then maintenance dose of 15mg orally once daily. Max increase to 30mg orally once daily in patients with refractory, severe, or extensive disease
6.9 Zeposia: 0.23mg orally once daily on days 1 through 4, then 0.46mg once daily on days 5 through 7, then maintenance dose of 0.92mg once daily starting on day 8
6.10 Entyvio: 300mg at 0, 2, 6 weeks then every 8 weeks (IV) or every 2 weeks (sub-q)
6.11 Omvoh: 200mg sub-q every 4 weeks after the 3 IV induction doses

7. Approval Period

7.1 Initial authorization will be placed for 12 months
7.2 All following authorizations will be placed for 12 months, based upon clinical response to therapy

CPT Codes	

HCPCS Codes	

References

1. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384.
2. 2. Singh S, Loftus EV Jr, Limketkai BN, et al; AGA Clinical Guidelines Committee. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Gastroenterology. 2024 Dec;167(7):1307-1343.

Created Date: 04/01/20
Effective Date: 04/01/20
Posted to Website: 04/03/24
Revision Date: 04/01/25

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1- 800851-3379 for verification of coverage.