

<b>POLICY NAME</b>	Ulcerative Colitis Immunomodulator Therapies	<b>POLICY #</b>	<b>2748P</b>
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## Criteria

### 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 – 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
- ☐ **1.2** Ordered by a Gastroenterologist (stomach doctor)
- ☐ **1.3** Age 18 years or older (5 years or older for adalimumab)

### 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 – 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
- ☐ **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)

## 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 – 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
- ☐ **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

## 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

## Exclusion Criteria – Any of the following prevents coverage

- ☐ **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