

POLICY NAME	Ulcerative Colitis Immunomodulator Therapies	POLICY #	2748P
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Criteria

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

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