Pharmacy Drug Policy Checklist

POLICY NAME	Crohn's Disease Immunomodulator Therapies	POLICY #	2749P

Criteria

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)

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: o Corticosteroids (prednisone, budesonide) o 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)

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: o Corticosteroids o 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

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

Exclusion Criteria – Any of the following prevents coverage

- ☐ **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