Clinical Policy: Ulcerative Colitis Agents

Reference Number: PHW.PDL.010
Effective Date: 01/01/2020
Last Review Date: 11/2023

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health and Wellness® that Ulcerative Colitis Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Ulcerative Colitis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Ulcerative Colitis Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Ulcerative Colitis Agent.

2. An Ulcerative Colitis Agent with a prescribed quantity that exceeds the quantity limit.

3. A prescription for a sphingosine 1-phosphate receptor (S1PR) modulator.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Ulcerative Colitis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For an S1PR modulator, one of the following:
   a. For treatment of multiple sclerosis, see PHW.PDL.043 Multiple Sclerosis Agents
   b. For treatment of ulcerative colitis (UC), **all** of the following:

      i. Is prescribed the requested medication for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication,

      ii. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., a gastroenterologist),

      iii. Does not have a contraindication to the requested medication,

      iv. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical

literature,

v. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

vi. **Both** of the following:

a) Has **one** of the following:
   (i) Mild UC that is associated with multiple poor prognostic factors[1]
   (ii) Moderate to severe UC
b) **One** of the following:
   (i) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids,
   (ii) **One** of the following:
      a. Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines (e.g., American College of Gastroenterology, American Gastroenterological Association. European Crohn's and Colitis Organization, etc.)
      b. Has a contraindication or an intolerance to immunomodulator in accordance with current consensus guidelines,
   (iii) **Both** of the following:
      a. Has achieved remission with the requested medication
      b. Will be using the requested medication as maintenance therapy to maintain remission

vii. **One** of the following:
   a) Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for treatment of ulcerative colitis
   b) Has a current history (within the past 90 days) of being prescribed the requested medication (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

   AND

2. For all other non-preferred Ulcerative Colitis Agent[2], **one** of the following:

   a. Has a history of therapeutic failure of or a contraindication, or an intolerance to the preferred Ulcerative Colitis Agents approved or medically accepted for the member's diagnosis
   b. Has a current history (within the past 90 days) of being prescribed the same non-

[1] Poor prognostic factors include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).
[2] All other non-preferred UC agents does not apply to S1PR modulators

preferred Ulcerative Colitis Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

AND

3. If a prescription for an Ulcerative Colitis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN S1PR MODULATOR:
The determination of medical necessity of a request for renewal of a prior authorization for an S1PR modulator that was previously approved will take into account whether the member:

1. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., a gastroenterologist); AND

2. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a contraindication to the requested medication; AND

4. Experienced improvement in disease activity and/or level of functioning since starting the requested medication; AND

5. If a prescription for an Ulcerative Colitis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Ulcerative Colitis Agent. If the guidelines in Section B. are met, the reviewer will

prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

C. **Approval Duration: 12 months**

D. References

1.Zeposia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; August 2023.
2.Velsipity [package insert]. New York, NY: Pfizer Labs; October 2023.
3.Harbord M, Eliakim R, Bettenworth D, et al. Third European evidence-based consensus on diagnosis and management of ulcerative colitis. Part 2: current management. J Crohns Colitis; 2017;11(7):769-784.
4.Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
5.Ko CW, Singh S, Feuerstein JD, Falck-Ytter C, Falck-Ytter Y, Cross RK. AGA clinical practice guidelines on the management of mild-to-moderate ulcerative colitis. Gastroenterology. 2019;156:748-764.
6.Feuerstein JD, Isaacs KL, Schneider Y, Siddique SM, Falck-Ytter Y, Singh S. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020;158:1450-1461.
7.Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: UpToDate [internet database]. Lamont JT, Robson KM, eds. Waltham, MA: UpToDate Inc. Updated August 23, 2021. Accessed August 26, 2021.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022: revised according to DHS revisions effective 01/03/2022	10/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024: revised according to DHS revisions effective 01/08/2024	11/2023