

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
ULCERATIVE COLITIS AGENTS

Proposed Effective Date: January 5, 2026

Revisions are noted with a ~~striketrough~~ for deletions and **bold and underline** for additions.

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. See the Preferred Drug List (PDL) for the list of preferred Ulcerative Colitis Agents at: <https://papdl.com/preferred-drug-list>.
2. An Ulcerative Colitis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.
3. A prescription for a sphingosine 1-phosphate receptor (S1PR) modulator.

B. Revisions to 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 beneficiary:

1. For an S1PR modulator, **one** of the following:
 - a. For treatment of multiple sclerosis, see the prior authorization guideline related to Multiple Sclerosis Agents
 - b. For treatment of ulcerative colitis (UC), **all** of the following:
 - i. Is prescribed the requested drug 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 age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - iii. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - iv. Is prescribed the requested drug by or in consultation with an appropriate specialist (e.g., a gastroenterologist),

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- v. Does not have a contraindication to the requested drug,
- vi. ~~Both~~ of the following:
- a) Has **one** of the following:
 - (i) A diagnosis of moderate to severe UC,
 - (ii) A diagnosis of mild UC that is associated with multiple poor prognostic factors,¹
 - 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 immunomodulators in accordance with current consensus guidelines,~~
 - (iii) **Both** of the following:
 - a. Has achieved remission with the requested drug
 - b. Will be using the requested drug 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 **an S1PR modulator** ~~the requested drug (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),~~
- viii. For a non-preferred S1PR modulator, **one** of the following:

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).

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- a) Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred S1PR modulators approved or medically accepted for treatment of ulcerative colitis
- b) Has a current history (within the past 90 days) of being prescribed the same S1PR modulator (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 Agents, **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 beneficiary's diagnosis
 - b. Has a current history (within the past 90 days) of being prescribed the same non-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 the Quantity Limits Chapter.

NOTE: If the beneficiary 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 beneficiary, 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 beneficiary:

- 1. Experienced improvement in disease activity and/or level of functioning since starting the requested drug; **AND**
- 2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 3. Is prescribed the requested drug by or in consultation with an appropriate specialist (e.g., gastroenterologist); **AND**
- 4. Does not have a contraindication to the requested drug; **AND**

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5. For a non-preferred S1PR modulator with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug; **AND**
6. If a prescription for the requested drug 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 the Quantity Limits Chapter.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

C. 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 beneficiary.

D. References

1. Zeposia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; August 2023 **2024.**
2. Velsipity [package insert]. New York, NY: Pfizer Labs; ~~October 2023~~ **August 2025.**
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.