



## Drug Coverage Policy

Effective Date .....02/15/2026  
Coverage Policy Number.....IP0691  
Policy Title.....Velsipity Prior  
Authorization Policy

# Inflammatory Conditions – Velsipity Prior Authorization Policy

- Velsipity® (etrasimod tablets – Pfizer)

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### **INSTRUCTIONS FOR USE**

*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

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## Overview

Velsipity, a sphingosine 1-phosphate receptor modulator, is indicated for the treatment of **ulcerative colitis** (UC), in adults with moderately to severely active disease.<sup>1</sup>

## Guidelines

The American Gastroenterological Association (2024) and the American College of Gastroenterology (2025) have clinical practice guidelines on the management of moderate to severe UC.<sup>2,3</sup> In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include tumor necrosis factor (TNF)-inhibitors, Entyvio® (vedolizumab intravenous infusion, subcutaneous injection), interleukin (IL)-23 inhibitors, IL-12/23 inhibitors, sphingosine-1-phosphate (S1P) receptor modulators, and Janus kinase (JAK) inhibitors. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Of note, guidelines state that corticosteroids may be avoided entirely when other effective induction strategies are planned.<sup>3</sup> Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.<sup>2,3</sup>

## Coverage Policy

### Policy Statement

Prior Authorization is required for benefit coverage of Velsipity. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Velsipity as well as the monitoring required for adverse events and long-term efficacy, approval requires Velsipity to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**NOTE: This product also requires the use of preferred products before approval of the requested product for Individual and Family Plans. Refer to the respective *Inflammatory Conditions Preferred Specialty Management Policy for Individual and Family Plans (PSM002)* for additional preferred product criteria requirements and exceptions.**

**Velsipity is considered medically necessary when the following are met:**

### FDA-Approved Indications

- 1. Ulcerative Colitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
  - A) Initial Therapy.** Approve for 6 months if the patient meets BOTH of the following (i and ii):
    - i.** Patient is  $\geq$  18 years of age; AND
    - ii.** The medication is prescribed by or in consultation with a gastroenterologist; OR
  - B) Patient is Currently Receiving Velsipity.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
    - i.** Patient has been established on therapy for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
    - ii.** Patient meets at least ONE of the following (a or b):
      - a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR

Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.

- b) Compared with baseline (prior to initiating Velsipity), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

## Conditions Not Covered

**Velsipity for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

- 1. Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
- 2. Concurrent Use with Other Potent Immunosuppressants.** In pivotal trials, patients who received Velsipity were not to receive concomitant treatment with non-corticosteroid immunosuppressive or immune-modulating therapies used for the treatment of ulcerative colitis. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of controlled clinical data supporting additive efficacy.<sup>1</sup>

Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, and methotrexate.

## References

- Velsipity® tablets [prescribing information]. New York, NY: Pfizer; August 2025.
- Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.
- Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol*. 2025 June;120(6):1187-1224.

## Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024
Selected revision	<b>Updated</b> the note associated with the trial of one systemic agent for ulcerative colitis with the following: A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. <b>Updated</b> the Preferred Specialty Management Policy note.	02/01/2025

Selected Revision	<b>Ulcerative Colitis:</b> For initial therapy, removed the requirement that the patient has had a trial of one systemic agent.	09/01/2025
Annual Revision	No criteria changes. <b>Appendix:</b> Otezla XR (apremilast extended-release tablet) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs.	02/15/2026

The policy effective date is in force until updated or retired.

## APPENDIX

	<b>Mechanism of Action</b>	<b>Examples of Indications*</b>
<b>Biologics</b>		
<b>Adalimumab SC Products</b> (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
<b>Cimzia</b> ® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
<b>Etanercept SC Products</b> (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
<b>Infliximab IV Products</b> (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
<b>Zymfentra</b> ® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
<b>Simponi</b> ®, <b>Simponi Aria</b> ® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC IV formulation: AS, PJIA, PsA, RA
<b>Tocilizumab Products</b> (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA
<b>Kevzara</b> ® (sarilumab SC injection)	Inhibition of IL-6	RA
<b>Orencia</b> ® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA IV formulation: JIA, PsA, RA
<b>Rituximab IV Products</b> (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
<b>Kineret</b> ® (anakinra SC injection)	Inhibition of IL-1	JIA <sup>^</sup> , RA
<b>Omvo</b> h® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
<b>Stelara</b> ® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC
<b>Siliq</b> ® (brodalumab SC injection)	Inhibition of IL-17	PsO
<b>Cosentyx</b> ® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA IV formulation: AS, nr-axSpA, PsA
<b>Taltz</b> ® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
<b>Bimzelx</b> ® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO, AS, HS, nr-axSpA, PsA
<b>Ilumya</b> ® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
<b>Skyrizi</b> ® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC IV formulation: CD, UC

<b>Tremfya</b> <sup>®</sup> (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: PsA, PsO, UC IV formulation: UC
<b>Entyvio</b> <sup>®</sup> (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
<b>Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs</b>		
<b>Otezla</b> <sup>®</sup> (apremilast tablets)	Inhibition of PDE4	PsO, PsA
<b>Otezla</b> <sup>®</sup> <b>XR</b> (apremilast extended-release tablets)	Inhibition of PDE4	PsO, PsA
<b>Cibinqo</b> <sup>™</sup> (abrocitinib tablets)	Inhibition of JAK pathways	AD
<b>Olumiant</b> <sup>®</sup> (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
<b>Litfulo</b> <sup>®</sup> (ritlecitinib capsules)	Inhibition of JAK pathways	AA
<b>Leqselvi</b> <sup>®</sup> (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
<b>Rinvoq</b> <sup>®</sup> (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
<b>Rinvoq</b> <sup>®</sup> <b>LQ</b> (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
<b>Sotyktu</b> <sup>®</sup> (deucravacitinib tablets)	Inhibition of TYK2	PsO
<b>Xeljanz</b> <sup>®</sup> (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
<b>Xeljanz</b> <sup>®</sup> <b>XR</b> (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
<b>Zeposia</b> <sup>®</sup> (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
<b>Velsipity</b> <sup>®</sup> (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

\* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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