

## Clinical Policy: Etrasimod (Velsipity)

Reference Number: PA.CHIP.PHAR.661

Effective Date: 01/2026

Last Review Date: 10/2025

### Description

Etrasimod (Velsipity™) is a sphingosine 1-phosphate receptor modulator.

### FDA Approved Indication(s)

Velsipity is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

### Policy/Criteria

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

It is the policy of PA Health & Wellness® that Etrasimod (Velsipity) is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Ulcerative Colitis (must meet all):

1. Diagnosis of ulcerative colitis;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age  $\geq$  18 years;
4. Documentation of a Mayo Score  $\geq$  6 or modified Mayo Score  $\geq$  5 (*see Appendix E*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of one of the following, used for  $\geq$  3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):
  - a. One adalimumab product (e.g., *Hadlima*, *Simlandi*, *Yusimry*, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;
  - b. One ustekinumab product (e.g., *Otulf*®, *Pyzchiva*® (branded), *Steqeyma*®, *Yesintek*™ are preferred);
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed 2 mg (1 tablet) per day.

*\*Prior authorization may be required for adalimumab products and ustekinumab products*

**Approval duration: 6 months**

##### B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed

under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## I. Continued Therapy

### A. Ulcerative Colitis (must meet all):

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Fidelis benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed 2 mg (1 tablet) per day.

**Approval duration: 12 months**

### B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## II. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents;
- B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia<sup>®</sup>, Enbrel<sup>®</sup>, Humira<sup>®</sup> and its biosimilars, Remicade<sup>®</sup> and its biosimilars, Simponi<sup>®</sup>], interleukin agents [e.g., Actemra<sup>®</sup> (IL-6RA) and its biosimilars, Arcalyst<sup>®</sup> (IL-1 blocker), Bimzelx<sup>®</sup> (IL-17A and F antagonist), Cosentyx<sup>®</sup> (IL-17A inhibitor), Ilaris<sup>®</sup> (IL-1 blocker), Ilumya<sup>™</sup> (IL-23 inhibitor), Kevzara<sup>®</sup> (IL-6RA), Kineret<sup>®</sup> (IL-1RA), Omvoh<sup>™</sup> (IL-23 antagonist), Siliq<sup>™</sup> (IL-17RA), Skyrizi<sup>™</sup> (IL-23 inhibitor), Spevigo<sup>®</sup> (IL-36 antagonist), Stelara<sup>®</sup> (IL-12/23 inhibitor) and its biosimilars, Taltz<sup>®</sup> (IL-17A inhibitor), Tremfya<sup>®</sup> (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo<sup>™</sup>, Olumiant<sup>™</sup>, Rinvoq<sup>™</sup>, Xeljanz<sup>®</sup>/Xeljanz<sup>®</sup> XR,], anti-CD20 monoclonal antibodies [Rituxan<sup>®</sup> and its biosimilars], selective co-stimulation modulators [Orencia<sup>®</sup>], integrin receptor antagonists [Entyvio<sup>®</sup>], tyrosine kinase 2 inhibitors [Sotyktu<sup>™</sup>], and

sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

### III. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
corticosteroids	<i>Adult:</i> Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week  Budesonide (Uceris®) 9 mg PO QAM for up to 8 weeks	Various
Hadlima (adalimumab-bwwd), Simlandi (adalimumab-ryvk), Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®)	<u>Initial dose:</u> 160 mg SC on Day 1, then 80 mg SC on Day 15  <u>Maintenance dose:</u> 40 mg SC every other week starting on Day 29	40 mg every other week
Otulfi® (ustekinumab-aaaz), Pyzchiva® (ustekinumab-ttwe), Steqeyma® (ustekinumab-stba), Yesintek™ (ustekinumab-kfce)	<u>Weight based dosing IV at initial dose:</u> Weight ≤ 55 kg: 260 mg Weight > 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg  <u>Maintenance dose:</u>  90 mg SC every 8 weeks	90 mg every 8 weeks

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): in the last 6 months, experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure; history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker

- Boxed warning(s): none reported

*Appendix D: General Information*

- TNF blockers:
  - Etanercept (Enbrel<sup>®</sup>), adalimumab (Humira<sup>®</sup>) and its biosimilars, infliximab (Remicade<sup>®</sup>) and its biosimilars (Avsola<sup>™</sup>, Renflexis<sup>™</sup>, Inflectra<sup>®</sup>, Zymfentra<sup>®</sup>), certolizumab pegol (Cimzia<sup>®</sup>), and golimumab (Simponi<sup>®</sup>, Simponi Aria<sup>®</sup>).

*Appendix E: Mayo Score or Modified Mayo Score*

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
> 10	Severe activity

- Modified Mayo Score: developed from the full Mayo score and evaluates ulcerative colitis stage, based on three parameters: stool frequency, rectal bleeding, and endoscopic evaluation. The modified Mayo Score gives a maximum overall score of 9. The FDA currently accepts the modified Mayo Score for the assessment of disease activity in pivotal ulcerative colitis clinical trials.

**IV. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Ulcerative colitis	2 mg PO QD	2 mg/day

**V. Product Availability**

Tablet: 2 mg

**VI. References**

1. Velsipity Prescribing Information. New York, NY: Pfizer Inc.; June 2024. Available at: <https://labeling.pfizer.com/ShowLabeling.aspx?id=19776>. Accessed February 27, 2025.
2. Sandborn WJ, Vermeire S, Peyrin-Biroulet L, et al. Etrasimod as induction and maintenance therapy for ulcerative colitis (ELEVATE): two randomised, double-blind, placebo- controlled, phase 3 studies. *The Lancet* 2023; 401:1159-1171.
3. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology* 2020;158:1450–1461. <https://doi.org/10.1053/j.gastro.2020.01.006>.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical

- guideline: Ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413. doi: 10.14309/ajg.0000000000000152.
5. Ulcerative Colitis: Clinical Trial Endpoints Guidance for Industry. Silver Spring, MD. Food and Drug Administration.; July 2016. Available at: <https://www.fda.gov/files/drugs/published/Ulcerative-Colitis--Clinical-Trial-Endpoints-Guidance-for-Industry.pdf>. Accessed February 3, 2025.
  6. Naegeli AN, Hunter T, Dong Y, et al. Full, Partial, and Modified Permutations of the Mayo Score: Characterizing Clinical and Patient-Reported Outcomes in Ulcerative Colitis Patients. Crohns Colitis 360. 2021 Feb 23;3(1):otab007. doi: 10.1093/crocol/otab007. PMID: 36777063; PMCID: PMC9802037.
  7. 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. doi: 10.1053/j.gastro.2024.10.001. PMID: 39572132.

Reviews, Revisions, and Approvals	Date
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