



5.50.037

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**Last Review Date:** March 6, 2026

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## Velsipity

### Description

#### Velsipity (etrasimod)

#### Background

Velsipity (etrasimod) is a sphingosine-1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1, 4, and 5 (S1P<sub>1,4,5</sub>). Velsipity partially and reversibly blocks the capacity of lymphocytes to egress from lymphoid organs, reducing the number of lymphocytes in peripheral blood. The mechanism by which Velsipity exerts therapeutic effects in ulcerative colitis is unknown but may involve the reduction of lymphocyte migration into the intestines (1).

#### Regulatory Status

FDA-approved indication: Velsipity is a sphingosine 1-phosphate receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults (1).

Before initiation of treatment with Velsipity, the following should be assessed: (1)

- Complete blood count (CBC) – Obtain a recent CBC including lymphocyte count
- Cardiac evaluation – Obtain an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present
- Liver function tests – Obtain recent (i.e., within the last 6 months) transaminase and bilirubin levels
- Ophthalmic assessment – Obtain a baseline evaluation of the fundus, including the macula, near the start of treatment
- Vaccination – Test patients for antibodies to varicella zoster virus (VZV) before initiating Velsipity; VZV vaccination of antibody-negative patients is recommended prior to

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commencing treatment with Velsipity. If live attenuated vaccine immunizations are required, administer at least 4 weeks prior to initiation of Velsipity.

- Skin examination – Obtain a skin examination prior to or shortly after initiation. Suspicious skin lesions should be promptly evaluated

Velsipity is contraindicated in patients who in the last 6 months experienced a myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure (1).

Velsipity is also contraindicated in patients with 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 (1).

The safety and effectiveness of Velsipity in pediatric patients less than 18 years of age have not been established (1).

## Related policies

Zeposia

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Velsipity may be considered **medically necessary** if the conditions indicated below are met.

Velsipity may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

## Diagnosis

Patient must have the following with provided documentation (e.g., medical records, laboratory reports):

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1. Moderately to severely active Ulcerative Colitis (UC)
  - a. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 1)
  - b. **NOT** to be used in combination with a biologic DMARD or targeted synthetic DMARD for UC (e.g., Entyvio, Humira, Simponi, Stelara, Xeljanz)
  - c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**AND ALL** of the following:

1. Baseline evaluations of **ALL** of the following have been done or will be done prior to starting therapy with Velsipity:
  - a. Complete blood count (CBC), including lymphocyte count
  - b. Electrocardiogram (ECG)
  - c. Liver function tests (LFTs)
2. Heart rate  $\geq$  50 bpm
3. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
4. **NO** presence of Mobitz Type II second-degree or third degree AV block, sick sinus syndrome, or sino-atrial block, unless patient has a pacemaker
5. **NO** significant QTc prolongation (QTcF  $\geq$ 450 msec in males,  $\geq$ 470 msec in females)
6. **NO** severe untreated sleep apnea
7. Patients with a history of uveitis and/or diabetes **ONLY**: will have an ophthalmic evaluation of fundus, including the macula, prior to initiation of therapy
8. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

## **Prior – Approval *Renewal* Requirements**

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**Age** 18 years of age or older

## Diagnosis

Patient must have the following with provided documentation (e.g., medical records, laboratory reports):

1. Ulcerative Colitis (UC)
  - a. Condition has improved or stabilized
  - b. **NOT** to be used in combination with a biologic DMARD or targeted synthetic DMARD for UC (e.g., Entyvio, Humira, Simponi, Stelara, Xeljanz)
  - c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**AND ALL** of the following:

1. Heart rate  $\geq$  50 bpm
2. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
3. **NO** presence of Mobitz Type II second-degree or third degree AV block, sick sinus syndrome, or sino-atrial block, unless patient has a pacemaker
4. **NO** significant QTc prolongation (QTcF  $\geq$ 450 msec in males,  $\geq$ 470 msec in females)
5. **NO** severe untreated sleep apnea
6. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

## Policy Guidelines

### Pre - PA Allowance

None

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## Prior - Approval Limits

**Quantity** 90 tablets per 90 days

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Velsipity (etrasimod) is a sphingosine-1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1, 4, and 5. Velsipity blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which Velsipity exerts therapeutic effects in ulcerative colitis is unknown but may involve the reduction of lymphocyte migration into the intestines. The safety and effectiveness of Velsipity in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Velsipity while maintaining optimal therapeutic outcomes.

### References

1. Velsipity [package insert], New York, NY: Pfizer Inc.; August 2025.

## Policy History

Date	Action
November 2023	Addition to PA
March 2024	Annual review and reference update
March 2025	Annual review and reference update
December 2025	Annual review. Added documentation requirement. Revised Appendix 2
March 2026	Annual review and reference update

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**

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### Appendix 1 – List of Conventional Therapies

<b>Conventional Therapy Options for UC</b>	
1. Mild to moderate disease - induction of remission:	<ul style="list-style-type: none"> <li>a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine</li> <li>b. Rectal mesalamine (e.g., Canasa, Rowasa)</li> <li>c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)</li> <li>d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine</li> </ul>
2. Mild to moderate disease - maintenance of remission:	<ul style="list-style-type: none"> <li>a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine</li> <li>b. Alternatives: azathioprine, mercaptopurine, sulfasalazine</li> </ul>
3. Severe disease - induction of remission:	<ul style="list-style-type: none"> <li>a. Prednisone, hydrocortisone IV, methylprednisolone IV</li> <li>b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine</li> </ul>
4. Severe disease - maintenance of remission:	<ul style="list-style-type: none"> <li>a. Azathioprine, mercaptopurine</li> <li>b. Alternative: sulfasalazine</li> </ul>
5. Pouchitis:	<ul style="list-style-type: none"> <li>a. Metronidazole, ciprofloxacin</li> <li>b. Alternative: rectal mesalamine</li> </ul>

### Appendix 2 - List of Preferred Products

List of preferred products:

[https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP\\_IndicationMedChx.pdf](https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf)

Refer to formulary documents for confirmation of coverage:

<https://www.fepblue.org/pharmacy/prescriptions#drug-lists>