

**VELSIPITY
(etrasimod)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

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 ≥ 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 ≥ 450 msec in males, ≥ 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

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Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

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 ≥ 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 ≥ 450 msec in males, ≥ 470 msec in females)
5. **NO** severe untreated sleep apnea
6. **NOT** given concurrently with live vaccines

Prior - Approval *Renewal* Limits

Same as above

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Appendix 1 – List of Conventional Therapies

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

Appendix 2 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Ulcerative colitis (UC)	<p>*must try TWO preferred products:</p> <ul style="list-style-type: none"> Humira** Rinvoq Skyrizi Stelara (SC) 	Humira**

**Including all preferred biosimilars (see reference product criteria)