

# Clinical Oversight Review Board (CORB-FAST) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

## Ozanimod (Zeposia)

### Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as at least a 3-month treatment duration
- \* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- #Contraindications/serious precautions to ozanimod use include:
  - Myocardial infarction in the last 6 months
  - Unstable angina in the last 6 months
  - Stroke, or transient ischemic attack in the last 6 months
  - Decompensated heart failure requiring hospitalization, or class III or IV HF in the last 6 months
  - Mobitz type II second- or third-degree atrioventricular block, sick sinus syndrome, or sinoatrial block, unless the patient has a functioning pacemaker
  - Severe untreated sleep apnea
  - Heart Rate less than 55 beats per minute
  - QTc interval of 500 milliseconds or greater at baseline (within 3 months of initiation)
  - Concomitant use of a monoamine oxidase inhibitor (isocarboxazid, phenelzine, rasagiline, selegiline, tranylcypromine)

Non-formulary **ozanimod (Zeposia)** requires clinical review. Appropriateness of therapy will be based on the following criteria:

**Initiation (new start) criteria:** Non-formulary **ozanimod (Zeposia)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1.) Prescriber is a gastroenterologist and patient has a diagnosis of moderate to severe ulcerative colitis

- Patient is 18 years of age or older
- Patient has tried and failed an adequate trial<sup>^</sup> of, or patient has an allergy or intolerance<sup>\*</sup> to the following medications (or contraindication to all):
  - Infliximab product
  - Ustekinumab product (criteria based)
  - Tofacitinib (criteria based) or upadacitinib (criteria based)
  - Vedolizumab
  - Etrasimod (criteria based)
- Patient does not have any contraindications/serious precautions<sup>#</sup> to ozanimod use

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2.) Prescriber is a neurologist and patient has a diagnosis of relapsing form of multiple sclerosis (MS) including:

- Non-progressive relapsing MS
  - Progressive relapsing MS
  - Relapsing remitting MS
- Patient is 18 years of age or older
- Patient has failed an adequate trial<sup>^</sup> of, or patient has an allergy or intolerance\* to, or patient is not a candidate for (per neurologist documentation) the following medications:
  - Fingolimod (criteria based)
  - Rituximab product
  - Natalizumab
  - Ocrelizumab
- Patient does not have any contraindications/serious precautions<sup>#</sup> to ozanimod use

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-formulary **ozanimod (Zeposia)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1.) Prescriber is a gastroenterologist and patient has a diagnosis of moderate to severe ulcerative colitis

- Patient is currently stable on ozanimod
- Patient does not have any contraindications/serious precautions<sup>#</sup> to ozanimod use

2.) Prescriber is a neurologist and patient has a diagnosis of multiple sclerosis (MS)

- Patient has failed an adequate trial<sup>^</sup> of, or patient has an allergy or intolerance\* to, or patient is not a candidate for (per neurologist documentation) the below medications:
  - Fingolimod (criteria based)
  - Rituximab product
  - Natalizumab
  - Ocrelizumab
- Patient does not have any contraindications/serious precautions<sup>#</sup> to ozanimod use

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## Ozanimod (Zeposia)

**Continued use criteria for patients previously approved who are currently stable on the medication:** Non-formulary **ozanimod (Zeposia)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

1.) Prescriber is a gastroenterologist and patient has a diagnosis of moderate to severe ulcerative colitis

- Patient is currently stable on ozanimod
- Patient does not have any contraindications/serious precautions<sup>#</sup> to ozanimod use

2.) Prescriber is a neurologist and patient has a diagnosis of multiple sclerosis (MS)

- Patient is currently stable on ozanimod
- Patient does not have any contraindications/serious precautions<sup>#</sup> to ozanimod use
- Patient has had a scheduled appointment (telephone, video, or office visit) with a neurologist within the past 12 months
- Patient has completed the following labs within the past 6 months:
  - Complete blood cell count with differential (CBC w/ diff)
  - Liver function test (alanine aminotransferase, ALT)