

Clinical Oversight Review Board (CORB) 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

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

Initiation (new start) criteria and criteria for current Kaiser Permanente members 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:

For Ulcerative Colitis:

- Prescriber is a gastroenterologist
- Patient has a diagnosis of ulcerative colitis
- Patient has tried and failed, has a documented intolerance*, or contraindication to all of the following:
 - Infliximab product
 - Tofacitinib (criteria based)
 - Vedolizumab
 - Adalimumab (criteria based)
 - Ustekinumab (criteria based)
- Patient does NOT have any of the following:
 - Contraindications/serious precautions# to ozanimod use
 - 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)

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For Multiple Sclerosis:

- Prescriber is a neurologist
- Patient has a diagnosis of relapsing form of multiple sclerosis (MS) including:
 - Non-progressive relapsing MS
 - Progressive relapsing MS
 - Relapsing remitting MS
- Patient has failed an adequate trial[^] of, or patient has an allergy or intolerance* to, or patient is not a candidate for the following medications:
 - Fingolimod (criteria based)
 - Rituximab product
 - Natalizumab
 - Ocrelizumab
- Patient does NOT have any of the following:
 - Contraindications/serious precautions[#] to ozanimod use
 - 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)

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:

For Ulcerative Colitis:

- Prescriber is a gastroenterologist
- Patient has a diagnosis of ulcerative colitis
- Patient has tried and failed, has a documented intolerance, or contraindication to all of the following:
 - Infliximab product
 - Tofacitinib (criteria based)
 - Vedolizumab
 - Adalimumab (criteria based)
 - Ustekinumab (criteria based)
- Patient does NOT have any of the following:
 - Contraindications/serious precautions[#] to ozanimod use

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- QTc interval of 500 milliseconds or greater
- Concomitant use of a monoamine oxidase inhibitor (isocarboxazid, phenelzine, rasagiline, selegiline, tranylcypromine)

For Multiple Sclerosis:

- Prescriber is a neurologist
- Patient has a diagnosis of multiple sclerosis (MS)
- Patient has failed an adequate trial[^] of, or patient has an allergy or intolerance* to, or patient is not a candidate for the following medications:
 - Fingolimod (criteria based)
 - Rituximab product
 - Natalizumab
 - Ocrelizumab
- Patient does NOT have any of the following:
 - Contraindications/serious precautions[#] to ozanimod use
 - QTc interval of 500 milliseconds or greater
 - Concomitant use of a monoamine oxidase inhibitor (isocarboxazid, phenelzine, rasagiline, selegiline, tranylcypromine)

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:

- Prescriber is a gastroenterologist (if used for ulcerative colitis) **OR** a neurologist (if used for multiple sclerosis)
- Patient does NOT have any of the following:
 - Contraindications/serious precautions[#] to ozanimod use
 - Concomitant use of a monoamine oxidase inhibitor (isocarboxazid, phenelzine, rasagiline, selegiline, tranylcypromine)
- Patient has had a scheduled appointment (telephone, video, or office visit) with a gastroenterologist or 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)

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