STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OZANIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OZANIMOD HYDROCHLORIDE	ZEPOSIA	46431		GPI-10 (6240705020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of ONE sphingosine-1-phosphate receptor modulator (e.g., Gilenya [fingolimod], Mayzent [Siponimod])
   - The patient had a trial of ONE agent indicated for the treatment of multiple sclerosis (e.g., Aubagio [teriflunomide], Tecfidera [dimethyl fumarate], Mavenclad [cladribine])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial text at the end of the guideline.

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OZANIMIOD (Zeposia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. A relapsing form of multiple sclerosis (MS: type of nerve disorder) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive condition)

B. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of ONE sphingosine-1-phosphate receptor modulator (such as Gilenya [fingolimod], Mayzent [Siponimod])
   3. You had a trial of ONE agent indicated for the treatment of multiple sclerosis (such as Aubagio [teriflunomide], Tecfidera [dimethyl fumarate], Mavenclad [cladribine])

C. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You had a trial of or contraindication (harmful for) to ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, mesalamine
   4. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate release or extended release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OZANIMOD

RENEWAL CRITERIA

NOTE: For the diagnosis of multiple sclerosis, please refer to the Initial Criteria section.

1. Does that patient have a diagnosis of moderate to severe ulcerative colitis (UC) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
     If no, do not approve.
     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **OZANIMIOD (Zeposia)** requires the following rule(s) be met for renewal:
     A. You have moderate to severe ulcerative colitis (UC: a type of digestive condition)
     B. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate release or extended release), Rinvoq (upadacitinib), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

     Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zeposia.

REFERENCES

- Zeposia [Prescribing Information]. Summit, NJ: Celgene Corporation, November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 06/20
Client Approval: 07/23
P&T Approval: 04/23