SIPONIMOD

Generic	Brand	HICL	GCN	Exception/Other
SIPONIMOD	MAYZENT	45670		

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 the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotypes?

   If yes, **approve for 12 months by GPID for all strengths as follows:**
   - **Mayzent 0.25mg starter pack (GPID 46135): 1 pack (#12 tablets) per fill.**
   - **Mayzent 2mg (GPID 46133): #1 tablet per day.**

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotypes?

   If yes, **approve Mayzent 0.25mg tablet by GPID (46134) for 12 months with a quantity limit of #4 tablets per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **SIPONIMOD (Mayzent)** requires a diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. In addition, the following criteria must be met:
   - The patient is 18 years of age or older
   - The patient has CYP2C9 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

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SIPONIMOD

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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?
   - Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

   If yes, **approve for 12 months by GPID for all strengths as follows:**
   - **Mayzent 0.25mg starter pack (GPID 46135): 1 pack (#12 tablets) per fill.**
   - **Mayzent 2mg (GPID 46133): #1 tablet per day.**

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

   If yes, **approve Mayzent 0.25mg tablet by GPID (46134) for 12 months with a quantity limit of #4 tablets per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **SIPONIMOD (Mayzent)** requires a diagnosis of relapsing forms of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. In addition, the following criteria must be met:
   - Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia
   - The patient has CYP2C9 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

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RATIONALE

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

REFERENCES

- Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 04/19
Client Approval: 11/19
P&T Approval: 10/19