



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIPONIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIPONIMOD	MAYZENT	45670		GPI-10 (6240707020)	

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, or 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 genotype?

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Mayzent 0.25mg starter pack for 2 mg maintenance dose: #12 tablets (1 pack) per fill.**
- **Mayzent 2mg: #1 per day.**

If no, continue to #3.

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

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Mayzent 0.25mg starter pack for 1 mg maintenance dose: #7 tablets (1 pack) per fill.**
- **Mayzent 0.25mg: #4 per day.**
- **Mayzent 1mg: #1 per day.**

If no, do not approve.

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 **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:

- A. You have relapsing forms of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (symptoms occur once), relapsing-remitting disease (symptoms return and go away), or active secondary progressive disease (advanced disease)
- B. You are 18 years of age or older
- C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype
(Initial denial text continued on next page)

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SIPONIMOD

INITIAL CRITERIA (CONTINUED)

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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease and meet **ALL** of the following criteria?
 - 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 or GPI-14 for all strengths as follows:**

- **Mayzent 0.25mg starter pack for 2 mg maintenance dose: #12 tablets (1 pack) per fill.**
- **Mayzent 2mg: #1 per day.**

If no, continue to #3.

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

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Mayzent 0.25mg starter pack for 1 mg maintenance dose: #7 tablets (1 pack) per fill.**
- **Mayzent 0.25mg: #4 per day.**
- **Mayzent 1mg: #1 per day.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SIPONIMOD

RENEWAL CRITERIA (CONTINUED)

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 **SIPONIMOD (Mayzent)** requires the following rule(s) be met for renewal:

- A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (symptoms occur once), relapsing-remitting disease (symptoms return and go away), or active secondary progressive disease (advanced disease)
- B. You have demonstrated a clinical benefit compared to pre-treatment baseline
- C. You do not have lymphopenia (low levels of a type of white blood cell)
- D. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

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 Mayzent.

REFERENCES

- Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/11/22

Created: 04/19

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P&T Approval: 10/19