

PRIOR AUTHORIZATION POLICY

POLICY: Multiple Sclerosis – Ponvory Prior Authorization Policy

- Ponvory™ (ponesimod tablets – Janssen)

REVIEW DATE: 03/31/2021

OVERVIEW

Ponvory, a sphingosine 1-phosphate receptor modulator, is indicated for the treatment of patients with relapsing forms of **multiple sclerosis (MS)**, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease in adults.¹

Guidelines

In September 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS.² Ponvory is not addressed. Many options from various disease classes, involving different mechanisms of action and modes of administration, have shown benefits in patients with MS.² The American Academy of Neurology has practice guidelines regarding disease-modifying therapies for adults with MS.³ The guidelines cite Gilenya® (fingolimod capsules) as one of the agents to consider for patients with MS who have highly active disease.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ponvory. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ponvory as well as the monitoring required for adverse events and efficacy, approval requires Ponvory to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ponvory is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Sclerosis.** Approve for 1 year if the patient meets the following criteria (A and B):
 - A) Patient has a relapsing form of multiple sclerosis; AND
Note: Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
 - B) The medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ponvory is not recommended in the following situations:

1. **Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.**
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Note: Examples of disease-modifying agents used for multiple sclerosis include Avonex (interferon beta 1a injection [intramuscular]), Betaseron/Extavia (interferon beta-1b injection [subcutaneous]), Rebif (interferon beta-1a injection [subcutaneous]), glatiramer acetate injection (Copaxone, Glatopa, generic), Plegridy® (peginterferon beta-1a injection), Gilenya (fingolimod capsules), Aubagio (teriflunomide tablets), Mavenclad (cladribine tablets), Mayzent (siponimod tablets), Tecfidera (dimethyl fumarate delayed-release capsules, generic), Bafiertam (monomethyl fumarate delayed-release capsules), Vumerity (diroximel fumarate delayed-release capsules), Zeposia (ozanimod capsules), Ocrevus (ocrelizumab injection for intravenous use), Tysabri (natalizumab injection for intravenous infusion), Lemtrada (alemtuzumab injection for intravenous use), and Kesimpta (ofatumumab injection for subcutaneous use).² These agents are not indicated for use in combination. Additional data are required to determine if use of disease-modifying multiple sclerosis agents in combination is safe and provides added efficacy.

2. Non-Relapsing Forms of Multiple Sclerosis.

Note: An example of a non-relapsing form of multiple sclerosis is primary progressive multiple sclerosis. The effectiveness of Ponvory in patients with primary progressive multiple sclerosis has not been established.

- Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

- Ponvory™ [prescribing information]. Titusville, NJ: Janssen; March 2021.
- A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. September 2019. Available at: http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed on March 22, 2021.
- Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018;90:777-788.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/31/2021