Pharmacy Policy Bulletin: J-1089 Ponvory (ponesimod) – Commercial and Healthcare Reform	
Number: J-1089	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1089-007	**Original Date:** 06/02/2021
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Ponvory (ponesimod)
FDA-Approved Indication(s):	• Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Background:	• Ponvory is a sphingosine 1-phosphate (S1P) receptor 1 modulator that binds with high affinity to S1P receptor 1. Ponvory blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which Ponvory exerts therapeutic effects in multiple sclerosis is unknown but may involve reduction of lymphocyte migration into the central nervous system.
	• Clinically isolated syndrome is the first episode of neurological symptoms caused by inflammation and demyelination in the central nervous system. Relapsing-remitting MS (RRMS) is characterized by clearly defined attacks of new or increasing neurologic symptoms. The attacks are followed by periods of partial or complete recovery (remissions). Secondary progressive disease follows an initial relapsing remitting course, with disability gradually increasing over time.
	• Prescribing Considerations:
	  ○ Ponvory should be prescribed under the supervision of a neurologist.
	  ○ First-dose monitoring is recommended for patients with sinus bradycardia, first- or second-degree [Mobitz type I] atrioventricular block, or history of myocardial infarction or heart failure.
	  ○ Assessments are required prior to initiating Ponvory. These include a complete blood count, an electrocardiogram, liver function tests, and an ophthalmic evaluation.
	  ○ A 14-day starter pack must be used for patients initiating treatment with Ponvory.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Ponvory may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of MS (ICD-10: G35), classified as one (1) of the following relapsing forms **(1., 2., or 3.):**

1. Clinically isolated syndrome

2. Relapsing remitting disease

3. Active secondary progressive disease

C. If the member is a new start to Ponvory, the member has experienced therapeutic failure, contraindication, or intolerance to one (1) of the plan-preferred products **(1. or 2.):**

1. generic fingolimod

2. generic dimethyl fumarate

II. Reauthorization

When a benefit, reauthorization of Ponvory may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(1., 2., or 3.):**

1. Disease stability

2. Disease improvement

3. Delayed disease progression

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Combination use of disease modifying MS agents (e.g. Aubagio, Gilenya, interferons, Copaxone, Tysabri, etc.) will not be authorized.

II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 24 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Ponvory [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; June 2024.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. *Neurol*. 2018 April 24;90(17):1-228.
3. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed February 3, 2025.