

## PHARMACY POLICY STATEMENT

### Common Ground Healthcare Cooperative (CGHC)

<b>DRUG NAME</b>	<b>Ponvory (ponesimod)</b>
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ponvory was approved by the FDA in 2021 for the treatment of relapsing forms of multiple sclerosis (MS). It is the fourth, once-daily oral sphingosine-1-phosphate (S1P) receptor modulator, following Gilenya, Mayzent, and Zeposia. MS is a chronic autoimmune disease of the central nervous system. In the phase 3 OPTIMUM study, Ponvory was superior to teriflunomide at reducing the annualized relapse rate.

Ponvory (ponesimod) will be considered for coverage when the following criteria are met:

#### **Multiple Sclerosis (MS)**

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of a relapsing form of MS (i.e., clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease); AND
4. Member has had a trial and failure of **ONE** preferred brand MS product; AND
5. Medication will not be used concomitantly with any other disease modifying drugs for MS; AND
6. The following baseline assessments have been completed (or are scheduled):
  - a) A complete blood count (CBC)
  - b) An ophthalmic evaluation
  - c) Liver function tests
  - d) A cardiac evaluation by electrocardiogram (ECG); AND
7. Member has not experienced any of the following in the past 6 months: Myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure; AND
8. Member does not have Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome unless they have a functioning pacemaker.
9. **Dosage allowed/Quantity limit:** Following initial 14-day titration (see package insert), the maintenance dose is 20 mg orally once daily. (Limit 30 tablets per 30 days)

***If all the above requirements are met, the medication will be approved for 12 months.***



HEALTHCARE COOPERATIVE

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease such as fewer relapses or no new or enlarged brain lesions on MRI.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Ponvory (ponesimod) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
08/18/2021	New policy for Ponvory created.
12/02/2021	Added safety/monitoring components to be consistent with the rest of the policies in this class.
11/09/2022	Annual review; no changes.
09/24/2024	Replaced trial of one preferred sphingosine-1-phosphate (S1P) receptor modulator with trial and failure of one preferred brand MS product.

References:

1. Ponvory [package insert]. Janssen Pharmaceuticals, Inc.; 2023.
2. Kappos L, Fox RJ, Burcklen M, et al. Ponesimod Compared With Teriflunomide in Patients With Relapsing Multiple Sclerosis in the Active-Comparator Phase 3 OPTIMUM Study: A Randomized Clinical Trial. *JAMA Neurol.* 2021;78(5):558-567. doi:10.1001/jamaneurol.2021.0405
3. 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 [published correction appears in *Neurology.* 2019 Jan 8;92(2):112]. *Neurology.* 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347
4. National Multiple Sclerosis Society. The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. A Consensus Paper by the Multiple Sclerosis Coalition; 2019. Available from: [https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT\\_Consensus\\_MS\\_Coalition.pdf](https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf). Accessed August 18, 2021.
5. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol.* 2018;17(2):162-173. doi:10.1016/S1474-4422(17)30470-2

Effective date: 01/01/2025

Revised date: 09/24/2024