CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Ponvory (ponesimod)
BILLING CODE	Must use valid NDC
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 tried and failed or is unable to try at least 1 preferred sphingosine-1-phosphate (S1P) receptor modulator; 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.

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.

References:

1. Ponvory [package insert]. Janssen Pharmaceuticals, Inc.; 2021.
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. 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

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