ConnectiCare

Commercial/Healthcare Exchange PA Criteria
Effective: 6/9/2021

<u>*Prior Authorization*</u>: Ponvory™ (ponesimod)

<u>*Products Affected*</u>: Ponvory (ponesimod) oral tablets

<u>*Medication Description*</u>: Ponvory (Ponesimod) is a sphingosine 1-phosphate (S1P) receptor 1 modulator that binds with high affinity to S1P receptor 1. Ponesimod blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which ponesimod exerts therapeutic effects in multiple sclerosis is unknown but may involve reduction of lymphocyte migration into the CNS.

<u>*Covered Uses*</u>: Treatment of relapsing forms of multiple sclerosis (MS)

<u>*Exclusion Criteria*</u>:
Ponvory is contraindicated in patients who:
1. In the last 6 months, have experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure.
2. Have presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker.

<u>*Required Medical Information*</u>:
- Diagnosis

<u>*Age Restrictions*</u>: 18 years of age or older

<u>*Prescriber Restrictions*</u>:
Prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of multiple sclerosis.
<u>*Coverage Duration*</u>: 1 year for initial and continuation of therapy

<u>*Other Criteria*</u>:
I. Initial Approval Criteria
    1. **Multiple Sclerosis.** Approve for 1 year if the patient meets the following criteria (A <u>and</u> B):
        A) Patient has a diagnosis of relapsing form of multiple sclerosis; AND
        <u>Note</u>: 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

II. Renewal Approval Criteria

Approve for 1 year if the patient meets the following criteria (A <u>and</u> B):

A) Member is responding positively to therapy as determined by the prescriber; AND
Member has not experienced unacceptable toxicity from the drug;

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.**
   <u>Note</u>: 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.**
   <u>Note</u>: 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.

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

References:

1. Ponvory (ponesimod) tablets [Package Insert]. Rockville, MD. Supernus Pharmaceuticals, Inc. Updated April 12, 2021. Accessed April 16, 2021. Available at:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aedf408d-0f84-418d-9416-7c39ddb0d29a
2. Ponvory (ponesimod) tablets. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated April 12, 2021. Accessed April 16, 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/9/2021

Confidential Information