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.

POLICY STATEMENT
This policy involves the use of Ponvory. Prior authorization is recommended for pharmacy benefit coverage of Ponvory. Approval is recommended for those who meet the conditions of coverage in the Criteria and Initial/Extended Approval for the diagnosis provided. Conditions Not Recommended for Approval are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 long-term efficacy, initial approval requires Ponvory be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

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

1. **Multiple Sclerosis**
   **Criteria. Patient must meet the following criteria**
   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 patient is 18 years of age or older; AND
   C) The medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

Initial Approval/ Extended Approval.
Drug Policy

A) Initial Approval:  1 year
B) Extended Approval:  1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Ponvory has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.  (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.
   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 (dixotin fumarate delayed-release capsules), Zeposia (ozanimod capsules), Ocrevus (ocrelizumab injection for intravenous use), Tysabri (natalizumab injection for intravenous infusion), Lentrada (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.

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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