

Ponvory (ponesimod)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year, unless otherwise noted below

Medications	Quantity Limit
Ponvory (ponesimod) Starter Pack	1 pack per fill, one time (starting dose titration regimen, 14 day supply)
Ponvory (ponesimod) 20mg tablets	1 tablet per day

APPROVAL CRITERIA

Requests for Ponvory (ponesimod) may be approved if the following criterion is met:

- I. Individual has a diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease).

Ponvory (ponesimod) may not be approved for the following:

- I. Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tascenso ODT, Tecfidera, Tysabri, Vumerity and Zeposia); **OR**
- II. Individual has had a recent (within the past 6 months) occurrence of one of the following:
 - A. Myocardial infarction; **OR**
 - B. Unstable angina; **OR**
 - C. Stroke; **OR**
 - D. Transient ischemic attack (TIA); **OR**
 - E. Decompensated heart failure requiring hospitalization; **OR**
 - F. Class III/IV heart failure; **OR**
- III. Individual has history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block, sick sinus syndrome or sino-atrial block, unless individual has a functioning pacemaker; **OR**
- IV. Individual has an active acute or chronic infection at the initiation of therapy; **OR**
- V. Individual with moderate or severe hepatic impairment (Child Pugh class B or C); **OR**
- VI. Individual is using to treat non-active secondary progressive multiple sclerosis.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 7, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020; 158:1450-1461.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Olek MJ, Howard J. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated: May 9, 2022. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 7, 2022.
6. 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. *Neurology*. 2018; 90: 777-788. Available from: <https://www.aan.com/Guidelines/home/GuidelineDetail/898>. Accessed: September 7, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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