



EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

POLICY: Multiple Sclerosis – Vumerity® (diroximel fumarate delayed-release capsules – Biogen/Alkermes)

DATE REVIEWED: 11/06/2019

OVERVIEW

Vumerity 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 MS in adults.¹

Disease Overview

MS is a chronic, inflammatory, demyelinating, autoimmune disease of the central nervous system (CNS) that impacts almost 1,000,000 people in the US.² The condition is marked by inflammation and demyelination, as well as degenerative alterations. Patients usually experience relapses and remissions in their neurological symptoms. For most patients, the onset of MS symptoms occurs when patients are 20 to 40 years of age; however, children can get MS and new onset disease can occur in older adults. The MS disease course is heterogeneous but has some patterns. Approximately 85% to 90% of patients have a relapsing pattern at onset. However, this transitions over time in patients who are untreated to a worsening with very few or no relapses or magnetic resonance imaging (MRI) activity (secondary progressive MS). Around 10% to 15% of patients have a steady progression of symptoms over time (primary progressive MS), marked by some clinical manifestations or by MRI activity. Primary progressive MS is generally diagnosed in patients on the upper level of the typical age range (e.g., almost 40 years of age) and the distribution is equivalent among the two genders. Advances in the understanding of the MS disease process, as well as in MRI technology, spurred updated disease course descriptions in 2013,³ as well as in 2017.⁴ The revised disease courses are clinically isolated syndrome, relapsing remitting MS, primary progressive MS, and secondary progressive MS.²⁻⁴ Clinically isolated syndrome is now more recognized among the course descriptions of MS. It is the first clinical presentation of MS that displays characteristics of inflammatory demyelination that may possibly be MS but has yet to fulfill diagnostic criteria. It is notable that the other MS designations can be further characterized considering whether patients have active disease (or not active), as well as if disease is worsening or stable. Disability in MS is commonly graded on the deterioration of mobility per the Expanded Disability Status Scale (EDSS) an ordinal scale that ranges from 0 to 10, with higher scores indicating greater disability.

Safety

Progressive multifocal leukoencephalopathy has occurred in patients with MS treated with Tecfidera® (dimethyl fumarate delayed-release capsules), which has the same active metabolite as Vumerity.¹

Guidelines

In September 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS.² Many options from various disease classes, involving different mechanisms of action and modes of administration, have shown benefits in patients with MS.

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POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Vumerity. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vumerity as well as the monitoring required for adverse events and efficacy, approval requires Vumerity to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vumerity is recommended in those who meet the following criteria.

FDA-Approved Indication

- 1. Multiple Sclerosis (MS).** Approve for 1 year if the patient meets the following criteria (A and B):
 - A)** The patient has a relapsing form of MS; AND
 - B)** The agent is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Vumerity 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. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

- 1. Non-Relapsing Forms of Multiple Sclerosis (MS).** Note: An example of a non-relapsing form of MS is primary progressive MS. The efficacy of Vumerity has not been established in patients with MS with non-relapsing forms of MS.¹
- 2. Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS).** Note: Examples of disease modifying agents used for multiple sclerosis include Aubagio[®] (teriflunomide tablets), Avonex[®] (interferon beta 1a injection [intramuscular]), Betaseron[®]/Extavia[®] (interferon beta-1b injection), Rebif[®] (interferon beta-1a injection [subcutaneous]), Copaxone[®]/Glatopa[®] (glatiramer acetate injection), Plegridy[®] (peginterferon beta-1a injection), Gilenya[®] (fingolimod tablets), Mavenclad[®] (cladribine tablets), Mayzent[®] (siponamid tablets), Tecfidera[®] (dimethyl fumarate delayed-release capsules), Ocrevus[®] (ocrelizumab injection for intravenous use), Tysabri[®] (natalizumab injection for intravenous infusion), and Lemtrada[®] (alemtuzumab injection for intravenous use).² These agents are not indicated for use in combination. Additional data are required to determine if use of disease-modifying MS agents in combination is safe provides added efficacy.
- 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. Vumerity[®] delayed-release capsules [prescribing information]. Cambridge, MA and Waltham, MA: Biogen and Alkermes; October 2019.

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2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated June 2019. Available at: http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed on November 1, 2019.
3. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
4. 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.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New policy	---	11/06/2019

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>;

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