VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Multiple Sclerosis – Plegridy Prior Authorization Policy

- Plegridy® (peginterferon beta-1a injection for subcutaneous or intramuscular use – Biogen Idec)

REVIEW DATE: 08/05/2020; selected revision 09/09/2020 and 02/17/2021

OVERVIEW

Plegridy, an interferon beta product, is indicated for the treatment of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease in adults.[1]

Disease Overview

MS is a chronic, inflammatory, demyelinating, autoimmune disease of the central nervous system 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, spurned 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.

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.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Plegridy. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Plegridy as well as the monitoring required for adverse events and long-

term efficacy, approval requires Plegridy to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Plegridy is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Sclerosis.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient has a relapsing form of multiple sclerosis; AND
     Note: Examples of relapsing forms of multiple sclerosis (MS) include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.
   - **B)** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Plegridy is not recommended in the following situations:

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), Rebif® (interferon beta-1a injection [subcutaneous]), Copaxone®/Glatopa® (glatiramer acetate injection), Aubagio® (teriflunomide tablets), Gilenya® (fingolimod tablets), Mavenclad® (cladribine tablets), Mayzent® (siponimod tablets), Tecfidera® (dimethyl fumarate delayed-release capsules), 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.**
   Note: An example of a non-relapsing form of multiple sclerosis is primary progressive multiple sclerosis. The efficacy of Plegridy has not been established in patients with multiple sclerosis with non-relapsing forms of multiple sclerosis.[1]

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. Plegridy® injection for subcutaneous or intramuscular use [prescribing information]. Cambridge, MA: Biogen, Idec; January 2021.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. September 2019. Available at: http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed on September 9, 2020.

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	Review Date
Early Annual Revision	The following criteria changes were made: **Multiple Sclerosis:** The criteria was changed to require that the patient has a relapsing form of MS. The criteria that previously required the patient have a diagnosis of multiple sclerosis or has experienced an attack and is at risk of MS. **Conditions Not Recommended for Approval:** The condition of Non-Relapsing Forms of MS was added as an exclusion. A note is provided that an example of a non-relapsing form is primary progressive MS. Regarding Use with Other Disease-Modifying Agents for MS, the examples are now listed as a note with Mavenclad and Mayzent added.	07/17/2019
Annual Revision	The following criteria changes were made: **Conditions Not Recommended for Approval:** Bafiertam, Vumerity, and Zeposia were added to the Note that provides examples of disease-modifying MS agents in which Plegridy should not be used with concurrently.	08/05/2020
Selected Revision	**Multiple Sclerosis:** Examples of relapsing forms of MS were added in a Note. **Conditions Not Recommended for Approval:** Regarding Use with Other Disease-Modifying Agents for MS, Kesimpta was added to the list of examples provided in the Note.	09/09/2020
Selected Revision	New Plegridy products that are administered intramuscularly were added to the policy with the same criteria as those applied to the subcutaneous products. There were no other changes to the criteria.	02/17/2021

MS – Multiple sclerosis.