Clinical Policy Title:	Peginterferon Beta-1a (Plegridy)
Policy Number:	RxA.446
Drug(s) Applied:	Peginterferon beta-1a (Plegridy®)
Original Policy Date:	01/2020
Last Review Date:	9/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Peginterferon beta-1a (Plegridy®) is an amino acid glycoprotein.

It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Peginterferon Beta-1a (Plegridy)	Relapsing MS	63 mcg on day 1, 94 mcg on day 15, and 125 mcg on day 29 and every 14 days thereafter	125 mcg/14 days

Dosage Forms

- Single-dose prefilled pen or syringe: 63 mcg/0.5 mL, 94 mcg/0.5 mL, 125 mcg/0.5 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. Clinically isolated syndrome;
   b. Relapsing-remitting MS;
   c. Secondary progressive MS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Plegridy is not prescribed concurrently with other disease modifying therapies for MS (*see AppendixB*);
5. Dose does not exceed 125 mcg (1 pen or syringe) every 14 days.

Approval Duration:

Commercial: 6 months or to the member's renewal date, whichever is longer
Medicaid/HIM: 6 months

II. Continued Therapy Approval

A. Multiple Sclerosis (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Plegridy is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix B*);
4. If request is for a dose increase, new dose does not exceed 125 mcg (1 pen or syringe) every 14 days.

Approval Duration
Commercial: 6 months or to the member's renewal date, whichever is longer
Medicaid/HIM: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MS: multiple sclerosis

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Disease-modifying therapies for MS include:

- Infusion therapies
  - natalizumab (Tysabri®)
  - mitoxantrone
  - ocrelizumab (Ocrevus™)
  - alemtuzumab (Lemtrada®)
- Injectable therapies
  - glatiramer (Copaxone®, Glatopa®)
  - interferon beta-1a (Avonex®, Rebif®)
  - interferon beta-1b (Betaseron®, Extavia®)
  - peginterferon beta-1a (Plegridy®)
- Oral therapies
  - dimethyl fumarate (Tecfidera®)
  - monomethyl fumarate (Bafiertam™)
  - diroximel fumarate (Vumerity®)
  - teriflunomide (Aubagio®)
  - fingolimod (Gilenya™)
  - siponimod (Mayzent®)
  - ozanimod (Zeposia®)
  - cladribine (Mavenclad®)
  - dalfampridine (Ampyra®)

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Contraindication(s): history of hypersensitivity to natural or recombinant interferon beta or peginterferon, or any other component of the formulation

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information
None listed

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References

1. Plegridy Prescribing Information. Cambridge, MA: Biogen Inc.; July 2019. Available at http://www.plegridy.com. Accessed August 2, 2019.
2. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002; 58(2): 169-178.
3. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. March 2017. Accessed February 4, 2019.
4. 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(17): 777-788. Full guideline available at: https://www.aan.com/Guidelines/home/GetGuidelineContent/904.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy Updated Policy changes: 1. Lines of business to All 2. Continued therapy language updated to: Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy 3. Appendix B list of drugs updated 4. Appendix D updated	8/27/2020	9/14/2020