CLINICAL UPDATE

Brand Name	Plegridy®
Generic Name	peginterferon beta-1a
Drug Manufacturer	Biogen Inc.

Clinical Update

TYPE OF CLINICAL UPDATE

New Dosage Form (Intramuscular [IM] Syringe)

FDA APPROVAL DATE

January 29, 2021

LAUNCH DATE

March 02, 2021

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

N/A; Biologic License Application (BLA): 125499

DISPENSING RESTRICTIONS

Specialty

Overview

INDICATION(S) FOR USE

For the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

MECHANISMS OF ACTION

Interferon beta suppresses proliferation of myelin-basic protein-specific T-cells and inhibits the expression of pro-inflammatory cytokines including interleukin-17, osteopontin, and INF-G, which is believed to be a major factor responsible for triggering the autoimmune reaction leading to multiple sclerosis (MS).

DOSAGE FORM(S) AND STRENGTH(S)

Subcutaneous (SC) Administration:

- Injection: 125 mcg/0.5 mL in a single-dose prefilled pen or single-dose prefilled syringe
- Injection: 63 mcg/0.5 mL in a single-dose prefilled pen or single-dose prefilled syringe
- Injection: 94 mcg/0.5 mL in a single-dose prefilled pen or single-dose prefilled syringe

Intramuscular Administration:

- Injection: 125 mcg/0.5 mL solution in a single-dose prefilled syringe

DOSE & ADMINISTRATION

Plegridy® may only be administered subcutaneously (SC) or intramuscularly (IM).

Initial titration dosing: Dose should be titrated, starting with 63 micrograms once on day 1, 94 micrograms once on day 15, and 125 micrograms (full dose) once on day 29.

Maintenance dose: 125 micrograms every 14 days.

EFFICACY

According to Biogen, the FDA's approval of the IM administration for Plegridy® is based on data evaluating bioequivalence and adverse reactions associated with IM administration compared to SC administration in healthy volunteers. Bioequivalence between the two dosing regimens was confirmed and data show that participants receiving Plegridy® through IM administration experienced fewer injection site reactions in comparison to participants receiving SC administration (14.4% vs. 32.1%). The overall safety profiles were generally similar and there were no new safety signals observed.