Medical Drug Clinical Criteria

Subject:	Beta Interferons and Glatiramer Acetate for Treatment of Multiple Sclerosis		
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Overview

This document addresses the use of beta interferon agents and glatiramer acetate agents, injectable disease modifying therapies approved by the Food and Drug Administration (FDA) to treat relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease.

Interferon beta-1a agents:

- Avonex (interferon beta-1a)
- Plegridy (peginterferon beta-1a)
- Rebif (interferon beta-1a)

Interferon beta-1b agents:

- Betaseron (interferon beta-1b)
- Extavia (interferon beta-1b)

Glatiramer acetate agents:

- Copaxone (glatiramer acetate)
- Glatopa (glatiramer acetate)

Multiple sclerosis is an autoimmune inflammatory demyelinating disease of the central nervous system. Common symptoms of the disease include fatigue, numbness, coordination and balance problems, bowel and bladder dysfunction, emotional and cognitive changes, spasticity, vision problems, dizziness, sexual dysfunction and pain. Multiple sclerosis can be subdivided into four phenotypes: clinically isolated syndrome (CIS), relapsing remitting (RRMS), primary progressive (PPMS) and secondary progressive (SPMS). Relapsing multiple sclerosis (RMS) is a general term for all relapsing forms of multiple sclerosis including CIS, RRMS and active SPMS.

The treatment goal for multiple sclerosis is to prevent relapses and progressive worsening of the disease. Currently available disease-modifying therapies (DMT) are most effective for the relapsing-remitting form of multiple sclerosis and less effective for secondary progressive decline. DMT include injectable agents, infusion therapies and oral agents.

The American Academy of Neurology (AAN) guidelines suggest starting disease-modifying therapy in individuals with relapsing forms of multiple sclerosis with recent clinical relapses or MRI activity. The guidelines also suggest DMT for individuals who have experienced a single clinical demyelinating event and two or more brain lesions consistent with multiple sclerosis if the individual wishes to start therapy after a risks and benefits discussion. The guidelines do not recommend one DMT over another.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Beta Interferons [Avonex, Plegridy, Rebif (interferon beta-1a); Betaseron, Extavia (interferon beta-1b)]

Requests for beta interferons [Avonex, Plegridy, Rebif (interferon beta-1a); Betaseron, Extavia (interferon beta-1b)] may be approved if the following criteria are met:

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

Beta interferons [Avonex, Plegridy, Rebif (interferon beta-1a); Betaseron, Extavia (interferon beta-1b)] may not be approved for the following:

I. Individual is using to treat primary progressive multiple sclerosis (PPMS); **OR**
II. Individual is using to treat non-active secondary progressive multiple sclerosis (SPMS); **OR**
III. Use in combination with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Ocrevus Zunovo, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Tyruko, Tysabri, Vumerity and Zeposia); **OR**
IV. May not be approved when the above criteria are not met and for all other indications.

Glatiramer acetate (Copaxone, Glatopa)

Requests for glatiramer acetate (Copaxone, Glatopa) may be approved if the following criteria are met:

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

Glatiramer acetate (Copaxone, Glatopa) may not be approved for the following:

I. Individual is using to treat primary progressive multiple sclerosis (PPMS); **OR**
II. Individual is using to treat non-active secondary progressive multiple sclerosis (SPMS); **OR**
III. Use in combination with other MS disease modifying agents (including Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, Extavia, Gilenya, Kesimpta, Lemtrada, Mavenclad, Mayzent, Ocrevus, Ocrevus Zunovo, Plegridy, Ponvory, Rebif, Tascenso ODT, Tecfidera, Tyruko, Tysabri, Vumerity and Zeposia); **OR**
IV. May not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Beta Interferons and Glatiramer Acetate Quantity Limits

Drug	Limit
Avonex (interferon beta-1a) Administration Dose Pack 30 mcg/0.5 mL prefilled autoinjector pen	4 pens (1 pack) per 28 days
Avonex (interferon beta-1a) Administration Dose Pack 30 mcg/0.5 mL prefilled syringe	4 syringes (1 pack) per 28 days
Betaseron (interferon beta-1b) 0.3 mg vial	15 single-use vials per 30 days
Copaxone (glatiramer acetate) 20 mg/mL prefilled syringe	1 syringe per day
Copaxone (glatiramer acetate) 40 mg/mL prefilled syringe	12 syringes per 28 days
Extavia (interferon beta-1b) 0.3 mg vial	15 single-use vials per 30 days
Glatopa (glatiramer acetate) 20 mg/mL prefilled syringe	1 syringe per day
Glatopa (glatiramer acetate) 40 mg/mL prefilled syringe	12 syringes per 28 days
Plegridy (peginterferon beta-1a) Starter Pack (prefilled autoinjector pen, prefilled syringe)	1 pack (1 mL) per fill, one time fill (28 day supply)
Plegridy (peginterferon beta-1a) Titration Kit (prefilled syringe)	1 pack per fill, one time fill (28 day supply)
Plegridy (peginterferon beta-1a) 125 mcg/0.5 mL prefilled autoinjector pen/syringe	2 pens/syringes per 28 days
Rebif/Rebidose (interferon beta-1a) 22 mcg/0.5 mL, 44 mcg/0.5 mL prefilled syringe/autoinjector	12 syringes/autoinjectors per 28 days
Rebif/Rebidose (interferon beta-1a) Titration Pack (prefilled syringe, prefilled syringe autoinjector)	1 pack (4.2 mL) per fill, one time fill (28 day supply)

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [Plegridy] (Hospital Outpatient Use ONLY)
J1595	Injection, glatiramer acetate, 20 mg [Copaxone, Glatopa]

J1826	Injection, interferon beta-1a, 30 mcg [Avonex, Rebif]
J1830	Injection, interferon beta-1b, 0.25 mg [Betaseron, Extavia]
J3590	Unclassified drugs [when specified as peginterferon beta-1a Plegridy]
Q3027	Injection, interferon beta-1a, 1 mcg for intramuscular use [Avonex]
Q3028	Injection, interferon beta-1a, 1 mcg for subcutaneous use [Rebif]
S9559	Home injectable therapy, interferon, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment; per diem

ICD-10 Diagnosis

G35	Multiple sclerosis

Document History

Revised: 11/15/2024
Document History:

- 11/15/2024 – Annual Review: Add Tyruko and Ocrevus Zunovo to exclusion for concurrent use with other disease modifying therapy criteria. Coding Reviewed: Delete ICD-10-CM T50.995A - T50.995S.
- 11/17/2023 – Annual Review: Add Briumvi and Tascenso ODT to exclusion for concurrent use with other disease modifying therapy criteria. Wording and formatting changes. Coding Reviewed: No changes.
- 8/19/2022 – Annual Review: Update trial of preferred language in Non-Preferred Glatiramer Acetate Agent Step Therapy. Wording and formatting changes. Coding reviewed: Added HCPCS C9399.
- 8/20/2021 – Annual Review: Update drug list in exclusion for concurrent use with other disease modifying therapy. Add quantity limit for new Plegridy dosage form. Wording and formatting changes. Coding reviewed: No changes.
- 11/20/2020 – Select Review: Clarify inadequate response step therapy language. Wording and formatting changes. Coding Reviewed: No changes.
- 10/26/2020 – Administrative update to add drug specific quantity limits.
- 8/21/2020 – Annual Review: Update drug list in exclusion for concurrent use with other disease modifying therapy. Remove Avonex vial as obsolete. Wording and formatting changes. Coding reviewed: Added ICD-10-CM T50.995A-T50.995S
- 08/16/2019 – Annual Review: Update Beta Interferons and Glatiramer Acetate criteria to align with updated labeled indication. Add Non-Preferred Glatiramer Acetate Agent Step Therapy. Wording and formatting changes. Coding Reviewed: No changes.
- 11/8/2018 – Coding update: revised Plegridy J3490 to J3590, change Q3027 to specify Avonex and Q3028 to specify Plegridy instead of both [Avonex, Rebif].
- 08/17/2018 – Annual Review: Initial review of ING-CC-0014 Beta Interferons and Glatiramer Acetate for Treatment of Multiple Sclerosis. Align criteria with labeled indications. Update combination MS therapy exclusion criteria wording to align with criteria for other MS agents. Add references for non-label-based criteria elements.

References

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