I. Medication Description

Interferons are cytokines that mediate antiviral, antiproliferative and immunomodulatory activities in response to viral infection and other biological inducers. Three major interferons have been distinguished: alpha, beta, and gamma. Interferon beta inhibits the expression of pro-inflammatory cytokines including INF-G, which is believed to be a major factor responsible for triggering the autoimmune reaction leading to multiple sclerosis.

Glatiramer acetate is thought to act by modifying immune processes that are believed to be responsible for the pathogenesis of multiple sclerosis. The exact mechanism of action is unknown; however it is proposed that the drug serves as a decoy to locally-generated autoantibodies. These antibodies, along with certain T-cells, are thereby neutralized before they can cause tissue damage.

II. Position Statement

**Formulary 1:** Coverage of Avonex, Copaxone, glatopa, Plegridy, or Rebif is provided immediately when prescribed by a neurologist.

**Formulary 2:** Coverage of Avonex, Copaxone, glatopa, or Rebif is provided immediately when prescribed by a neurologist.

**Formulary 3/Exclusive:** Coverage of Avonex, Copaxone, glatopa, or Rebif is provided immediately when prescribed by a neurologist.

**Formulary 4/AON:** Coverage of Avonex, Copaxone, glatopa, or Rebif is provided immediately when prescribed by a neurologist.

Coverage for all other requests is determined through a prior authorization process with supporting clinical documentation.

III. Policy

**Formulary 1:** See Sections A, C, E, and F

**Formulary 2:** See Sections A, B, D, and F

**Formulary 3/Exclusive:** See Sections A, B, D, and F

**Formulary 4/AON:** See Sections A, B, D, and F

A. Coverage is provided when one of the following is true:

- Medication is prescribed by a neurologist for the treatment of a relapsing form of multiple sclerosis (MS) OR
- A neurology consult documenting a diagnosis of a relapsing form of MS is provided
B. Coverage of non-preferred medication Betaseron or Plegridy is provided when the member has had a documented trial with at least one plan-preferred medication (Avonex, Copaxone, glatopa, or Rebif) that has resulted in treatment failure or intolerable side effects.

C. Coverage of non-preferred medication Betaseron is provided when the member has had a documented trial with at least one plan-preferred medication (Avonex, Copaxone, glatopa, Plegridy, or Rebif) that has resulted in treatment failure or intolerable side effects.

D. Coverage of non-preferred medication Extavia is provided when:
   - Member has had a documented trial with at least one plan-preferred medication (Avonex, Copaxone, glatopa, or Rebif) that has resulted in treatment failure or intolerable side effects AND
   - Member has had a documented intolerance or contraindication to plan-preferred medication (Betaseron) that would not be expected to pertain to Extavia

E. Coverage of non-preferred medication Extavia is provided when:
   - Member has had a documented trial with at least one plan-preferred medication (Avonex, Copaxone, glatopa, Plegridy, or Rebif) that has resulted in treatment failure or intolerable side effects AND
   - Member has had a documented intolerance or contraindication to plan-preferred medication (Betaseron) that would not be expected to pertain to Extavia

F. Coverage of any non-preferred medication can be granted if the following criteria are met:
   - When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
   - At least one of the following is met:
     o The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
     o The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
     o The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
     o The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card).
     o The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.
IV. **Quantity Limitations**

Quantities are available for up to the maximum FDA-approved dosage of each individual medication.

V. **Coverage Duration**

Coverage is provided indefinitely. Approval for only one medication in this policy will be granted at a time.

VI. **Coverage Renewal Criteria**

n/a

VII. **Billing/Coding Information**

Pertinent diagnosis: Multiple sclerosis (G35)

VIII. **Summary of Policy Changes**

- 7/1/11: Addition of step therapy criteria to Extavia and Rebif
- 6/15/12:
  - Rebif moved to preferred status
  - Betaseron moved to non-preferred status
- 6/15/13: referred to individual PI for most warning information
- 7/1/13: Medicaid/FHP criteria differentiated
- 8/15/13: Medicaid/FHP prescriptions written by a neurologist do not require prior authorization
- 6/15/14: no policy changes
- 10/31/14: Plegridy added to policy
- 7/1/15: formulary distinctions made
- 9/15/15: no policy changes
- 10/1/15:
  - glatopa added to policy
  - ICD9 references removed
- 7/19/16: no policy changes
- 5/1/17: step therapy criteria added
- 6/21/17: no policy changes

IX. **References**


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.