Reference number(s)
5896-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Multiple Sclerosis

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Value Formulary (VF).

Plan Design Summary

This program applies to the multiple sclerosis products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with Aubagio, Bafiertam, Copaxone 20 mg, Extavia, Gilenya, Plegridy, Ponvory, Tascenso ODT, Tecfidera or Vumerity. This program also applies to members who are new to treatment with Briumvi, Lemtrada, or Mavenclad for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Multiple Sclerosis (MS) Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Avonex (interferon beta-1a) • Betaseron (interferon beta-1b) • Copaxone 40 mg (glatiramer acetate) • dimethyl fumarate (generic) • fingolimod (generic) • glatiramer acetate (generic) • Glatopa (glatiramer acetate) • Kesimpta (ofatumumab) • Mayzent (siponimod) • Ocrevus (ocrelizumab) • Rebif (interferon beta-1a) • teriflunomide (generic) • Tysabri (natalizumab) • Zeposia (ozanimod)
Target	• Aubagio (teriflunomide) • Bafiertam (monomethyl fumarate) • Briumvi (ublituximab-xiiy) • Copaxone 20 mg (glatiramer acetate) • Extavia (interferon beta-1b) • Gilenya (fingolimod) • Lemtrada (alemtuzumab) • Mavenclad (cladribine) • Plegridy (peginterferon beta-1a) • Ponvory (ponesimod) • Tascenso ODT (fingolimod) • Tecfidera (dimethyl fumarate) • Vumerity (diroximel fumarate)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Aubagio

Coverage of Aubagio is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to generic teriflunomide, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than generic teriflunomide.

Bafiertam or Vumerity

Coverage for Bafiertam is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to treatment with dimethyl fumarate (including intolerable gastrointestinal adverse events from dimethyl fumarate).
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than dimethyl fumarate.

Briumvi

Coverage for Briumvi is provided when either of the following criteria is met:

- Member is currently receiving therapy with Briumvi, excluding when Briumvi is obtained as samples or via manufacturer's patient assistance programs.
- Member meets both of the following criteria:
  - Member has had a documented intolerable adverse event to treatment with Kesimpta or Ocrevus.
  - Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than Kesimpta or Ocrevus.

Copaxone 20 mg

Coverage for Copaxone 20 mg is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to generic glatiramer acetate, Glatopa, or Copaxone 40 mg, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than generic glatiramer acetate, Glatopa, or Copaxone 40 mg.

Extavia

Coverage for Extavia is provided when both of the following criteria are met:

- There is a documented clinical reason that the member must use Extavia over Betaseron. (Please note that Extavia and Betaseron are the exact same products with different labels and brand names.)
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than Betaseron.

Gilenya or Tascenso ODT

Coverage for Gilenya or Tascenso ODT is provided when both of the following criteria are met:

- Member meets either of the following criteria:
  - Member has had a documented intolerable adverse event to generic fingolimod, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - The requested product is Tascenso ODT and the member is unable to swallow generic fingolimod capsules.
- Member meets either of the following criteria:
  - Member has had a documented inadequate response or intolerable adverse event with at least two of the preferred products other than generic fingolimod.
  - Member is less than 18 years of age.

Lemtrada

Coverage for Lemtrada is provided when either of the following criteria is met:

- Member is currently receiving therapy with Lemtrada, excluding when Lemtrada is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event to at least three of the preferred products.

Mavenclad

Coverage for Mavenclad is provided when either of the following criteria is met:

- Member is currently receiving therapy with Mavenclad, excluding when Mavenclad is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event to treatment with at least three of the preferred products.

Plegridy

Coverage for Plegridy is provided when both of the following criteria are met:

- Member has a documented contraindication to treatment with Avonex or Rebif.
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than Rebif or Avonex.

Ponvory

Coverage for Ponvory is provided when both of the following criteria are met:

- Member has a documented intolerable adverse event with fingolimod, Mayzent, or Zeposia.

- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than fingolimod, Mayzent, or Zeposia.

Tecfidera

Coverage for Tecfidera is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to generic dimethyl fumarate, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with at least two of the preferred products other than generic dimethyl fumarate.

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