This policy applies to the following:

✓	Standard Opt-in	✓	ACSF		VF		Marketplace
	Standard Opt-in NTMB	✓	PDPD		MMT		Medical Benefit
	Standard Opt-out		Generics First				Medical Benefit: Managed Medicaid

Reference #
3051-D

EXCEPTIONS CRITERIA
MULTIPLE SCLEROSIS

PREFERRED PRODUCT FOR EXTAVIA: Betaseron
PREFERRED PRODUCTS FOR MAVENCLAD: Aubagio, Betaseron, Copaxone, Gilenya, glatiramer, Rebif, Tecfidera, Tysabri
PREFERRED PRODUCTS FOR MAYZENT: Aubagio, Betaseron, Copaxone, Gilenya, glatiramer, Rebif, Tecfidera, Tysabri

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

I. PLAN DESIGN SUMMARY
This program applies to the multiple sclerosis products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product 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 Betaseron. This program applies to members requesting treatment with Mayzent and Mavenclad for the first time.

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

Table 1. Extavia

	Products
Preferred	• **Betaseron** (interferon beta-1b)
Targeted	• **Extavia** (interferon beta-1b)

Table 2. Mavenclad

	Products
Preferred	• **Aubagio** (teriflunomide) • **Betaseron** (interferon beta-1b) • **Copaxone** (glatiramer) • **Gilenya** (fingolimod) • **glatiramer** • **Rebif** (interferon beta-1a) • **Tecfidera** (dimethyl fumarate) • **Tysabri** (natalizumab)
Targeted	• **Mavenclad** (cladribine)

This policy applies to the following:

✓	Standard Opt-in	✓	ACSF		VF		Marketplace
	Standard Opt-in NTMB	✓	PDPD		MMT		Medical Benefit
	Standard Opt-out		Generics First				Medical Benefit: Managed Medicaid

Reference #
3051-D

Table 3. Mayzent

	Products
Preferred	• **Aubagio** (teriflunomide) • **Betaseron** (interferon beta-1b) • **Copaxone** (glatiramer) • **Gilenya** (fingolimod) • **glatiramer** • **Rebif** (interferon beta-1a) • **Tecfidera** (dimethyl fumarate) • **Tysabri** (natalizumab)
Targeted	• **Mayzent** (siponimod)

II. EXCEPTION CRITERIA

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

A. Extavia

Coverage for Extavia is provided when the member meets the following criteria:

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, which are made in the same manufacturing facility.)*

B. Mavenclad

Coverage for Mavenclad is provided when the member meets any of the following criteria:

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

C. Mayzent

Coverage for Mayzent is provided when the member meets any of the following criteria:

1. Member has had a documented inadequate response or intolerable adverse effect to treatment with Gilenya and two other preferred products.
2. Member has a documented contraindication to therapy with all of the preferred products.
3. Member is currently receiving therapy with Mayzent, excluding when Mayzent is obtained as samples or via manufacturer's patient assistance programs.
4. Member is being treated for clinically isolated syndrome.

REFERENCES

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; March 2019.
2. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2018.
3. Copaxone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2018.
4. Extavia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; December 2018.

This policy applies to the following:

✓	**Standard Opt-in**	✓	**ACSF**		**VF**		**Marketplace**
	Standard Opt-in NTMB	✓	**PDPD**		**MMT**		**Medical Benefit**
	Standard Opt-out		**Generics First**				**Medical Benefit: Managed Medicaid**

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5. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2019.
6. Glatiramer acetate 20mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2018.
7. Mavenclad [package insert]. Rockland, MA: EMD Serono; March 2019.
8. Mayzent [package insert]. East Hanover, NJ: Novaritis; March 2019.
9. Rebif [package insert]. Rockland, MA: EMD Serono Inc.; November 2015.
10. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; December 2017.
11. Tysabri [package insert]. Cambridge, MA: Biogen Idec, Inc; April 2018.
12. National Multiple Sclerosis Society. Disease modification in multiple sclerosis. Available at: http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Brochure-Disease-Modifying-Therapies-Overview.pdf. Current as of April 1, 2013. Accessed September 13, 2018.
13. Medical review(s) for Extavia. Application number: 125290. U.S. Food and Drug Administration website. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/125290_extavia_toc.cfm. Accessed September 13, 2018.