



MEDICATION POLICY

Generic Name: MS Biologics

Therapeutic Class or Brand Name: MS Biologics

Applicable Drugs (if Therapeutic Class):

Preferred: Avonex® (interferon beta-1a), Copaxone® (glatiramer), Glatopa™ (glatiramer), and Plegridy® (peginterferon beta-1a).

Non-Preferred: Betaseron® (interferon beta-1b), Extavia® (interferon beta-1b), Lemtrada® (alemtuzumab), Ocrevus™ (ocrelizumab), Rebif® (interferon beta-1a), Tysabri® (natalizumab)

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 4/4/18

GPI Code: 6240003010, 6240306045, 6240306050, 6240307530, 6240501000, 6240502500, 6240506000, 6240505000

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
 - A. A primary progressive form of multiple sclerosis and criterion 1 is met:
 1. Request is for Ocrevus™.
 - B. A relapsing form of multiple sclerosis and criteria 1 or 2 is met:
 1. If request is for Avonex®, Copaxone®, Glatopa™, or Plegridy®: Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).
 2. If request is for Betaseron®, Extavia®, Lemtrada®, Ocrevus™, Rebif® or Tysabri® : must have a documented trial and failure of, intolerance, or contraindication to two preferred products (refer to plan document for the list of preferred products).
- II. Minimum age requirement: 18 years old.
- III. Prescribing physician must be a neurologist or a multiple sclerosis physician specialist.

Exclusion Criteria:

- Coadministration of a MS Biologic with another disease-modifying multiple sclerosis therapy such as Aubagio® (teriflunomide), Avonex® (interferon beta-1a), Betaseron® (interferon beta-1b), Copaxone®

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(glatiramer), Extavia® (interferon beta-1b), Gilenya® (fingolimod), Glatopa™ (glatiramer), Lemtrada® (alemtuzumab), Novantrone® (mitoxantrone), Ocrevus™ (ocrelizumab), Plegridy® (peginterferon beta-1a), Rebif® (interferon beta-1a), Tecfidera® (dimethyl fumarate) or Tysabri® (natalizumab)

- Lemtrada® is contraindicated in patients infected with Human Immunodeficiency Virus.
- Ocrevus™ is contraindicated in patients with active hepatitis B virus infection.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Avonex®: 4 injections per 28 days.
- Betaseron®: 14 injections per 28 days.
- Copaxone®:
 - 20mg/mL: 30 injections per 30 days.
 - 40mg/mL: 12 injections per 28 days.
- Extavia®: 15 injections per 30 days.
- Glatopa™: 30 injections per 30 days.
- Lemtrada®:
 - First 12 month period: 5 infusions (12mg per day on 5 consecutive days).
 - Second 12 month period: 3 infusions (12mg per day on 3 consecutive days).
- Ocrevus™:
 - First month: 300 mg infusion, followed two weeks later by a second 300 mg infusion.
 - Subsequent doses: 600 mg infusion every 6 months.
- Plegridy®: 2 injections per 28 days.
- Rebif®: 12 injections per 28 days.
- Tysabri®: 300mg infusion every 4 weeks

Approval Length:

- **Authorization:** 1 year.

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- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective. NOTE: Lemtrada® will not be authorized for more than a total of 2 treatment courses.

Appendix:

N/A

References:

1. <http://blue.regence.com/trgmedpol/drugs/dru108.pdf>.
2. [NPS](#).
3. https://www.avonex.com/content/dam/commercial/multiple-sclerosis/avonex/pat/en_us/pdf/Avonex%20US%20%20Prescribing%20Information.pdf.
4. <http://www.copaxone.com/Resources/pdfs/PrescribingInformation.pdf>.
5. http://labeling.bayerhealthcare.com/html/products/pi/Betaseron_PI.pdf.
6. <http://www.pharma.us.novartis.com/product/pi/pdf/extavia.pdf>.
7. [http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=.](http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=)
8. <https://www.plegridy.com/pdfs/plegridy-prescribing-information.pdf>.
9. <http://products.sanofi.us/lemtrada/lemtrada.pdf>.
10. https://www.gene.com/download/pdf/ocrevus_prescribing.pdf.
11. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5f01e40a-b6f6-40fb-b37c-3d06f1428e86>.
12. https://www.tysabri.com/content/dam/commercial/multiple-sclerosis/tysabri/pat/en_us/pdfs/tysabri_prescribing_information.pdf

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<i>Historical Tracking Of Changes Made To Policy</i>	
4/4/2018	<ol style="list-style-type: none"> 1. Removed “Zibryta™ (daclizumab) Non-Preferred List, Prior Authorization Criteria, Exclusion Criteria and Days Supply- voluntarily removed from market due to cases of serious inflammatory brain disorders. 2. Removed https://www.zinbryta.com/content/dam/commercial/multiple-sclerosis/zinbryta/na/en_us/pdfs/zinbryta-prescribing-information.pdf from References (drug no longer on market) 3. Added “Tysabri® (natalizumab) to Non-Preferred List under Applicable Drugs 4. Added “6240505000” following GPI Code. 5. Added “Tysabri®” to Prior Authorization Criteria 6. Added “Tysabri® 300 mg infusion every 4 weeks” to Quantity/ Days Supply
5/4/2017	<ol style="list-style-type: none"> 1. Added “Ocrevus™ (ocrelizumab)” to Non-Preferred list under Applicable Drugs. 2. Added “6240506000” following GPI Code. 3. Changed “I. Documented diagnosis of a relapsing form of multiple sclerosis; IV. If request is for Avonex®, Copaxone®, Glatopa™, or Plegridy®: Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s); V. If request is for Betaseron®, Extavia®, Lemtrada®, Rebif®, or Zinbryta™: must have a documented trial and failure of, intolerance, or contraindication to two preferred products (refer to plan document for the list of preferred products)” to “I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. A primary progressive form of multiple sclerosis and criterion 1 is met: 1. Request is for Ocrevus™; B. A relapsing form of multiple sclerosis and criteria 1 or 2 is met: 1. If request is for Avonex®, Copaxone®, Glatopa™, or Plegridy®: Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s); 2. If request is for Betaseron®, Extavia®, Lemtrada®, Ocrevus™, Rebif®, or Zinbryta™: must have a documented trial and failure of, intolerance, or contraindication to two preferred products (refer to plan document for the list of preferred products)” under Prior Authorization Criteria. 4. Added “Ocrevus™ (ocrelizumab)” to list following “Coadministration of a MS Biologic with another disease-modifying multiple sclerosis therapy such as…” under Exclusion Criteria. 5. Added “Ocrevus™ is contraindicated in patients with active hepatitis B virus infection” under Exclusion Criteria. 6. Added “Ocrevus™: First month: 300 mg infusion, followed two weeks later by a second 300 mg infusion; Subsequent doses: 600 mg infusion every 6 months” under Quantity/Days Supply Restrictions. 7. Removed “https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MSBiologicsNTM.pdf” from References (link no longer valid). 8. Added “https://www.gene.com/download/pdf/ocrevus_prescribing.pdf” under References.
9/12/2016	<ol style="list-style-type: none"> 1. Added 6240502500 following GPI Code.
8/16/2016	<ol style="list-style-type: none"> 1. Moved “Betaseron® (interferon beta-1b)” from Preferred list to Non-Preferred list under Applicable Drugs. 2. Changed “IV. If request is for Avonex®, Betaseron®, Copaxone®, Glatopa™, or Plegridy®: Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product” to “IV. If request is for Avonex®, Copaxone®, Glatopa™, or Plegridy®: Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).” under Prior Authorization Criteria.

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	<p>3. Changed “V. If request is for Extavia®, Lemtrada®...” to “V. If request is for Betaseron®, Extavia®, Lemtrada®...” under Prior Authorization Criteria.</p>
5/28/2016	<p>1. Changed “Plegridy™” to “Plegridy®” and “Lemtrada™” to “Lemtrada®” throughout document.</p> <p>2. Added “Zinbryta™ (daclizumab)” to Non-Preferred list under Applicable Drugs.</p> <p>3. Changed “V. If request is for Extavia®, Lemtrada®, or Rebif®:...” to “V. If request is for Extavia®, Lemtrada®, Rebif®, or Zinbryta™:...” under Prior Authorization Criteria.</p> <p>4. Added “Coadministration of a MS Biologic with another disease-modifying multiple sclerosis therapy such as Aubagio® (teriflunomide), Avonex® (interferon beta-1a), Betaseron® (interferon beta-1b), Copaxone® (glatiramer), Extavia® (interferon beta-1b), Gilenya® (fingolimod), Glatopa™ (glatiramer), Lemtrada® (alemtuzumab), Novantrone® (mitoxantrone), Plegridy® (peginterferon beta-1a), Rebif® (interferon beta-1a), Tecfidera® (dimethyl fumarate), Tysabri® (natalizumab), or Zinbryta™ (daclizumab)” under Exclusion Criteria.</p> <p>5. Added “Zinbryta™ is contraindicated in patients with pre-existing hepatic disease or hepatic impairment (including ALT or AST at least 2 times the upper limit of normal) or in patients with a history of autoimmune hepatitis or other autoimmune condition involving the liver” under Exclusion Criteria.</p> <p>6. Added “Zinbryta™: 1 injection per 28 days” under Quantity/Days Supply Restrictions.</p> <p>7. Updated “http://www.avonex.com/pdfs/guides/Avonex_Prescribing_Information.pdf” to “https://www.avonex.com/content/dam/commercial/multiple-sclerosis/avonex/pat/en_us/pdf/Avonex%20US%20%20Prescribing%20Information.pdf”, “http://emdserono.com/cmge.mdserono_us/en/images/Rebif%20PI_Jun2014_tcm115_19765.pdf?Version=” to “http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=”, and “http://glatopa.com/cs/www.glatopa.com/assets/PDF/Glatopa-Package-Insert-06-2015.pdf” to “https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5f01e40a-b6f6-40fb-b37c-3d06f1428e86” under References.</p> <p>8. Added “https://www.zinbryta.com/content/dam/commercial/multiple-sclerosis/zinbryta/na/en_us/pdfs/zinbryta-prescribing-information.pdf” under References.</p>
8/10/2015	<p>1. Added “Glatopa™ (glatiramer)” to list of Preferred products under Applicable Drugs.</p> <p>2. Changed “IV. If request is for Avonex®, Betaseron®, Copaxone®, or Plegridy™:...” to “IV. If request is for Avonex®, Betaseron®, Copaxone®, Glatopa™, or Plegridy™:...” under Prior Authorization Criteria.</p> <p>3. Added “Glatopa™: 30 injections per 30 days” under Quantity/Days Supply Restrictions.</p> <p>4. Added “http://glatopa.com/cs/www.glatopa.com/assets/PDF/Glatopa-Package-Insert-06-2015.pdf” under References.</p>
3/12/2015	<p>1. Added “Plegridy™ (peginterferon beta-1a)” to list of Preferred products and added “Lemtrada™ (alemtuzumab)” to list of Non-Preferred products under Applicable Drugs.</p> <p>2. Added “6240307530, 6240501000” following GPI Code.</p> <p>3. Changed “I. Documented diagnosis of Multiple Sclerosis...IV. Non-preferred products (Extavia® and Rebif®) require a documented trial and failure of, intolerance to, or contraindication to two preferred products (Avonex®, Betaseron®, and Copaxone®)” to “I. Documented diagnosis of a relapsing form of multiple sclerosis...IV. If request is for Avonex®, Betaseron®, Copaxone®, or Plegridy™: Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product. V. If request is for Extavia®, Lemtrada™, or Rebif®: must have a documented trial and failure of, intolerance, or contraindication to two preferred products (refer to plan document for the list of preferred products)” under Prior Authorization Criteria.</p> <p>4. Changed “N/A” to “Lemtrada™ is contraindicated in patients infected with Human Immunodeficiency Virus” under Exclusion Criteria.</p> <p>5. Changed “Avonex®: Quantities for up to 4 injections per 28 days; Betaseron®: Quantities for up to 15</p>

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Historical Tracking Of Changes Made To Policy

	<p>injections per 30 days; Copaxone® 20mg/mL: Quantities for up to 30 injections per 30 days; Copaxone® 40mg/mL: Quantities for up to 12 injections per 28 days; Extavia®: Quantities for up to 15 injections per 30 days; Rebif®: Quantities for up to 12 injections per 28 days” to “Avonex®: 4 injections per 28 days; Betaseron®: 14 injections per 28 days; Copaxone®: 20mg/mL: 30 injections per 30 days, 40mg/mL: 12 injections per 28 days; Extavia®: 15 injections per 30 days; Lemtrada™: First 12 month period: 5 infusions (12mg per day on 5 consecutive days), Second 12 month period: 3 infusions (12mg per day on 3 consecutive days); Plegridy™: 2 injections per 28 days; Rebif®: 12 injections per 28 days” under Quantity/Days Supply Restrictions.</p> <p>6. Added “NOTE: Lemtrada™ will not be authorized for more than a total of 2 treatment courses” following Re-Authorization information under Approval Length.</p> <p>7. Updated “http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/MSBiologicsforNTM.pdf” to “https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MSBiologicsNTM.pdf” and “http://www.emdserono.com/cmgeemdserono_us/en/images/rebif_tcm115_19765.pdf” to “http://emdserono.com/cmgeemdserono_us/en/images/Rebif%20PI_Jun2014_tcm115_19765.pdf?Version=” under References.</p> <p>8. Added “https://www.plegridy.com/pdfs/plegridy-prescribing-information.pdf” and “http://products.sanofi.us/lemtrada/lemtrada.pdf” under References.</p>
2/11/2014	<p>1. Adapted policy to new format.</p> <p>2. Moved Rebif® (interferon beta-1a) from Preferred to Non-Preferred line under Applicable Drugs.</p> <p>3. Changed Prior Authorization Criteria from: “Documented diagnosis of Multiple Sclerosis; Extavia requires a documented trial and failure of or contraindication to a preferred product (Avonex®, Betaseron®, Copaxone®, or Rebif®)” to: “Documented diagnosis of Multiple Sclerosis; Minimum age requirement: 18 years old; Prescribing physician must be a neurologist or a multiple sclerosis physician specialist; Non-preferred products (Extavia® and Rebif®) require a documented trial and failure of, intolerance to, or contraindication to two preferred products (Avonex®, Betaseron®, and Copaxone®)”</p> <p>4. Changed Quantity/Days Supply Restrictions from “Avonex®: 1 kit per 28 days; Betaseron®: 15 syringes per 30 days; Copaxone®: 1 kit per 30 days; Rebif®: 12ml per 30 days; Extavia®: 1 kit per 30 days” to “Avonex®: Quantities for up to 4 injections per 28 days; Betaseron®: Quantities for up to 15 injections per 30 days; Copaxone® 20mg/mL: Quantities for up to 30 injections per 30 days; Copaxone® 40mg/mL: Quantities for up to 12 injections per 28 days; Extavia®: Quantities for up to 15 injections per 30 days; Rebif®: Quantities for up to 12 injections per 28 days”</p> <p>5. Changed Re-Authorization under Approval Length from “Updated letter of medical necessity” to “An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective”.</p> <p>6. Updated references to include specific Utah Medicaid policy referred to, Regence policy, and package inserts.</p>

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