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), and Zinbryta™ (daclizumab).

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 5/4/17

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

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 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).

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® (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), Tysabri® (natalizumab), or Zinbryta™ (daclizumab).

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

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.
- Zinbryta™: 1 injection per 28 days.

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Approval Length:

- **Authorization:** 1 year.
- **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=.
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.zinbryta.com/content/dam/commercial/multiple-sclerosis/zinbryta/na/en_us/pdfs/zinbryta-prescribing-information.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
5/4/2017	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	1. **Added** 6240502500 **following GPI Code**.
8/16/2016	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**. 3. **Changed** "V. If request is for Extavia®, Lemtrada®…" **to** "V. If request is for Betaseron®, Extavia®, Lemtrada®…" **under Prior Authorization Criteria**.
5/28/2016	1. **Changed** "Plegridy™" **to** "Plegridy®" **and** "Lemtrada™" **to** "Lemtrada®" **throughout document**. 2. **Added** "Zinbryta™ (daclizumab)" **to Non-Preferred list under Applicable Drugs**. 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**. 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**.

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Historical Tracking Of Changes Made To Policy	
	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**. 6. **Added** "Zinbryta™: 1 injection per 28 days" **under Quantity/Days Supply Restrictions**. 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/cmg.emdserono_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**. 8. **Added** "https://www.zinbryta.com/content/dam/commercial/multiple-sclerosis/zinbryta/na/en_us/pdfs/zinbryta-prescribing-information.pdf" **under References**.
8/10/2015	1. **Added** "Glatopa™ (glatiramer)" **to list of Preferred products under Applicable Drugs**. 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**. 3. **Added** "Glatopa™: 30 injections per 30 days" **under Quantity/Days Supply Restrictions**. 4. **Added** "http://glatopa.com/cs/www.glatopa.com/assets/PDF/Glatopa-Package-Insert-06-2015.pdf" **under References**.
3/12/2015	1. **Added** "Plegridy™ (peginterferon beta-1a)" **to list of Preferred products and added** "Lemtrada™ (alemtuzumab)" **to list of Non-Preferred products under Applicable Drugs**. 2. **Added** "6240307530, 6240501000" **following GPI Code**. 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**. 4. **Changed** "N/A" **to** "Lemtrada™ is contraindicated in patients infected with Human Immunodeficiency Virus" **under Exclusion Criteria**. 5. **Changed** "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" **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**. 6. **Added** "NOTE: Lemtrada™ will not be authorized for more than a total of 2 treatment courses" **following Re-Authorization information under Approval Length**. 7. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/MSBiologicsforNTM.pdf" **to**

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Historical Tracking Of Changes Made To Policy	
	"https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/MSBiologicsNTM.pdf" **and** "http://www.emdserono.com/cmg.emdserono_us/en/images/rebif_tcm115_19765.pdf" **to** "http://emdserono.com/cmg.emdserono_us/en/images/Rebif%20PI_Jun2014_tcm115_19765.pdf?Version=" **under References**. 8. **Added** "https://www.plegridy.com/pdfs/plegridy-prescribing-information.pdf" **and** "http://products.sanofi.us/lemtrada/lemtrada.pdf" **under References**.
2/11/2014	1. **Adapted policy to new format.** 2. **Moved** Rebif® (interferon beta-1a) **from Preferred to Non-Preferred line under Applicable Drugs**. 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®)". 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". 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". 6. **Updated references** to include specific Utah Medicaid policy referred to, Regence policy, and package inserts.