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| **Department of Origin:**<br>Pharmacy | **Effective Date:**<br>12/06/2023 |
| **Approved by:**<br>Pharmacy and Therapeutics Quality Management Subcommittee | **Date approved:**<br>12/06/2023 |
| **Pharmacy Clinical Policy Document:**<br>Lemtrada Prior Authorization | **Replaces Effective Policy Dated:**<br>5/24/2023 |
| **Reference #:**<br>PC/L004 | **Page:**<br>1 of 4 |

**PURPOSE:**
The intent of the Lemtrada Prior Authorization Pharmacy Clinical Policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

**POLICY:**
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

**GUIDELINES:**
Medical Necessity Criteria - Must satisfy any of the following: I – II

Table 1: Lemtrada (alemtuzumab)

| *Biologic* | FYI ONLY | | | *MS* Type | Route of Administration | Drug Class | *PML* Warning |
|---|---|---|---|---|---|---|---|
| | Molecule | Is this a Biosimilar? | Reference Product | | | | |
| Lemtrada | alemtuzumab | N | N/A | relapsing | intravenous infusion | CD20 antibody | N |

I. Request for Lemtrada (alemtuzumab) – must satisfy the following: A - B, and one of C - D

A. Diagnosis of relapsing-remitting or active secondary progressive multiple sclerosis (MS); and

B. Prescribed by or in consultation with a neurologist; and

C. The member has been previously treated with Lemtrada – at least 12 months has elapsed since the first treatment with Lemtrada, or 12 months will have elapsed prior to the next treatment with Lemtrada; or

D. The member has not been previously treated with Lemtrada – must satisfy all of the following:1 and 2
1. The member has not responded to (at least a 2-month trial), one self-administered medication (see Table 2); and
2. The member has not responded to (at least a 4-week trial), is intolerant to, or is a poor candidate for Ocrevus, one *rituximab* product, or Tysabri.

II. Continuation request – Authorize in 13-month increments

Table 2: Self-Administered Disease-Modifying Medications for Multiple Sclerosis *

| Drug | FYI ONLY | | | *MS* Type | Route of Administration | Drug Class | *PML* Warning |
|---|---|---|---|---|---|---|---|
| | Generic/ Molecule Name | Biosimilar | Generics available | | | | |
| Aubagio | teriflunomide | N | Y | relapsing | oral | selective immuno-suppressant | N |
| Avonex | interferon beta-1a | N | N | relapsing | intramuscular or subcutaneous injection | interferon | N |
| Bafiertam | monomethyl fumarate | N | N | relapsing and secondary progressive | oral | selective immuno-suppressant | Y |
| Betaseron | interferon beta-1b | N | N | relapsing | subcutaneous injection | interferon | N |
| Copaxone | glatiramer acetate | N | Y | relapsing | subcutaneous injection | other immuno-stimulant | N |
| Extavia | interferon beta-1b | N | N | relapsing | subcutaneous injection | interferon | N |
| Gilenya | fingolimod | N | Y | relapsing | oral | selective immuno-suppressant | Y |
| Glatopa | glatiramer acetate | N | Y | relapsing | subcutaneous injection | other immuno-stimulant | N |
| Kesimpta | ofatumumab | N | N | relapsing | subcutaneous injection | Anti-CD20 monoclonal antibody | N |
| Mavenclad | cladribine | N | N | relapsing and secondary progressive | oral | immune-modulator | N |
| Mayzent | siponimod | N | N | relapsing and secondary progressive | oral | immune-modulator | N |
| Plegridy | peginterferon beta-1a | N | N | relapsing | subcutaneous injection | interferon | N |

Table 2: Self-Administered Disease-Modifying Medications for Multiple Sclerosis * (continued)

| Drug | FYI ONLY | | | *MS* Type | Route of Administration | Drug Class | *PML* Warning |
|---|---|---|---|---|---|---|---|
| | Generic/ Molecule Name | Biosimilar | Generics available | | | | |
| Ponvory | ponesimod | N | N | relapsing and secondary progressive | oral | immune-modulator | N |
| Rebif | interferon beta-1a | N | N | relapsing | intramuscular or subcutaneous injection | interferon | N |
| Tecfidera | dimethyl fumarate | N | Y | relapsing | oral | selective immuno-suppressant | Y |
| Vumerity | diroximel fumarate | N | N | relapsing and secondary progressive | oral | selective immuno-suppressant | Y |
| Zeposia | ozanimod | N | N | relapsing and secondary progressive | oral | immune-modulator | N |

* Listing of drugs in table above does not ensure coverage. Please check member's prescription benefit.

**DEFINITIONS:**

Biologic (BLA):

Biologic agents are derived from natural sources (human, animal, microorganisms); these are large complex proteins applicable to the prevention, treatment, or cure of a disease or condition of human beings. Given the complexity of the drug and the difficulty to characterize a biologic, the manufacturing process is proprietary. Licensed by the Public Health Services Act (PHS) (section 351), the 351(a) pathway is utilized for the approval of biologics. Examples of biologics include: vaccine, blood products, antitoxin, allergy shots and cellular therapies.

Multiple Sclerosis (MS) Disease Courses

- Relapsing-remitting MS – Most common form; episodes of acute worsening of neurologic function occur with some amount of recovery and no progression in between.
- Secondary progressive MS – Involves an initial relapsing-remitting course; disease transitions to a steadily progressive form with function loss.
- Primary progressive MS – Involves continued worsening of MS course from onset without specific relapses.
- Progressive relapsing MS – Occurs as a progressive disease at onset; occasional acute relapses occur but with continuing disease progression.

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| **Reference #:**<br>PC/L004 | **Page:**<br>4 of 4 |

Progressive Multifocal Leukoencephalopathy (PML):
A neurological disorder characterized by destruction of cells that produce the myelin, an oily substance that helps protect nerve cells in the brain and spinal cord, also known as central nervous system (CNS) white matter. It can be caused by the John Cunningham virus (JCV) in immunocompromised individuals.

Rituximab:
Reference product or biosimilar

**BACKGROUND:**
This clinical policy is based on U.S. Food and Drug Administration (FDA) approved indications and dosing, expert consensus opinion and/or available reliable evidence.

Prior Authorization: Approve for up to 18 months to allow for completion of first and second course; continued use, authorize in 13-month increments

Administer Lemtrada by intravenous infusion over 4 hours for 2 treatment courses:
**First course**: 12 mg/day on 5 consecutive days.
**Second course**: 12 mg/day on 3 consecutive days 12 months after first treatment course.
Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment course.

**CODING:** HCPCS - 2023
J0202 Injection, alemtuzumab, 10mg (Lemtrada)

**REFERENCES**:

1. Hughes BL. Update on new and emerging therapies for the treatment and symptom management of multiple sclerosis. 2011. *American Health & Drug Benefits Supplement,* 4(4):S97-S100.
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6. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
7. Clinical Policy: MP/C009 Coverage Determination Guidelines
8. Pharmacy Clinical Policy: PP/O001 Off-label Drug Use
9. Pharmacy Clinical Policy: PP/O002 Off-label Drug Use for Business Process Outsourced Clients
10. Pharmacy Clinical Policy: PP/T002 Therapeutic Equivalence


**DOCUMENT HISTORY**:

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| **Created Date**: 04/16/21 |
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| **Revised Date:** |

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Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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