BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Alemtuzumab (Lemtrada®)

File Name:	alemtuzumab_lemtrada
Origination:	12/2014
Last CAP Review:	5/2019
Next CAP Review:	5/2020
Last Review:	5/2019

Description of Procedure or Service

Alemtuzumab (Lemtrada®) is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of alemtuzumab (Lemtrada) should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Alemtuzumab (Lemtrada) is a recombinant humanized IgG1 kappa monoclonal antibody directed against the cell surface glycoprotein, CD52. The precise mechanism by which alemtuzumab exerts its therapeutic effects in multiple sclerosis is unknown but is presumed to involve binding to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes, and macrophages. Following cell surface binding to T and B lymphocytes, alemtuzumab results in antibody-dependent cellular cytolysis and complement-mediated lysis. Based on animal data, Alemtuzumab (Lemtrada) may cause fetal harm.

Related Policies
Natalizumab (Tysabri)

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Alemtuzumab (Lemtrada) for relapsing multiple sclerosis when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Alemtuzumab (Lemtrada) is covered

Alemtuzumab (Lemtrada) may be medically necessary when the following criteria are met:

1. The patient has relapsing multiple sclerosis, and

2. The patient has had an inadequate response to two or more drugs indicated for the treatment of multiple sclerosis.

When Alemtuzumab (Lemtrada) is not covered

Alemtuzumab (Lemtrada) is considered not medically necessary when criteria under "When Alemtuzumab (Lemtrada) is covered" are not met.

Policy Guidelines

Alemtuzumab (Lemtrada) is administered by intravenous infusion.

For the treatment of **relapsing multiple sclerosis**, the first treatment course of 12 mg/day administered on 5 consecutive days is followed by the second treatment course of 12 mg/day administered on 3 consecutive days (36 mg total dose) 12 months after the first treatment course. Subsequent treatment courses of 12 mg/day on 3 consecutive days may be administered, as needed, at least 12 months after the last dose of any prior treatment course.

Site of Care Eligibility

1. Alemtuzumab administration may be given in an inpatient setting if the inpatient setting is medically necessary. An inpatient admission for the sole purpose of alemtuzumab infusion is not medically necessary, OR
2. Alemtuzumab administration in a hospital outpatient setting is considered medically necessary if the following criteria are met:
    a. History of mild adverse events that have not been successfully managed through mild pre-medication (diphenhydramine, acetaminophen, steroids, fluids, etc.), OR
    b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity, OR
    c. First infusion, OR
    d. Less than 3 months since first alemtuzumab infusion, OR
    e. First infusion after six months of no alemtuzumab infusions, OR
    f. Requirement of a change in alemtuzumab product.
3. Members who do not meet the criteria above are appropriate for alemtuzumab administration in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional. Inpatient and hospital outpatient infusion, in the absence of the criteria in #1 or #2 above is considered not medically necessary.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *J0202*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Alemtuzumab (Lemtrada™). Prescribing information. November 2014. Available at: http://products.sanofi.us/lemtrada/lemtrada.pdf

U.S. Food and Drug Administration (FDA). http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM425409.pdf

Medical Director review 12/2014

Specialty Matched Consultant Advisory Panel 5/2016

Specialty Matched Consultant Advisory Panel 5/2017

Specialty Matched Consultant Advisory Panel 5/2018

Genzyme Corporation. Lemtrada (alemtuzumab) injection for intravenous use. Highlights of prescribing information. January 2019. Available at: http://products.sanofi.us/lemtrada/lemtrada.html#S2.6. Accessed April 2019.

Specialty Matched Consultant Advisory Panel 5/2019

Policy Implementation/Update Information

12/30/14	New medical policy issued. Alemtuzumab (Lemtrada™) may be medically necessary when the following criteria are met: 1. The patient has relapsing multiple sclerosis, and 2. The patient has had an inadequate response to two or more drugs indicated for the treatment of multiple sclerosis. Medical director review 12/2014. (sk)
9/1/15	Added new HCPCS code Q9979 for effective date 10/1/2015. (sk)
12/30/15	Code J0202 added and code Q9979 removed from Billing/Coding section. (sk)
7/1/16	Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)
6/30/17	Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
12/29/17	Site of care criteria added to Policy Guidelines. Policy notification given 12/29/17 for effective date 4/1/2018. (sk)
6/8/18	Specialty Matched Consultant Advisory Panel review 5/23/2018. No change to policy intent. (krc)
5/28/19	Updated Policy Guidelines to include additional dosing recommendations for subsequent dosing. Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. No change to policy intent. (krc)