Keystone First VIP Choice

Medical Policy Bulletin
Title:
Alemtuzumab (Lemtrada®)
Policy #:
MA08.015d

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

Alemtuzumab (Lemtrada) is considered medically necessary and, therefore, covered for:

- Individuals with relapsing forms of multiple sclerosis (MS), including relapsing-remitting multiple sclerosis and active secondary progressive disease when the following criteria are met:
  - Inadequate clinical response to two or more drugs indicated for the treatment of multiple sclerosis as defined by relapse, and/or accumulating disability, and/or multiple new or enlarging of lesions of brain and/or spinal cord
    - Inadequate clinical response to one or more drugs, if individual is considered high risk for disability (e.g., T the spinal MRI shows high burden of lesions, but the physical exam does not demonstrate the extent of disability)
  - Human immunodeficiency virus (HIV)--negative
- Individuals with aggressive relapsing-remitting multiple sclerosis defined as, but not limited to, accumulating disability, multiple new or enlarging of lesions of brain and/or spinal cord in the first year of illness
  - Human immunodeficiency virus (HIV)--negative

NOT ELIGIBLE FOR REIMBURSEMENT

Effective September 4, 2012, alemtuzumab (Campath®**)** is no longer available commercially and, therefore, not eligible for reimbursement. It may be provided through the Campath® Distribution Program free of charge. Please contact the manufacturer.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for alemtuzumab (Lemtrada) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Guidelines

There is no Medicare coverage determination addressing alemtuzumab (Lemtrada); therefore, the Company policy is applicable.

BENEFIT APPLICATION

Subject to the applicable Evidence of Coverage, alemtuzumab (Lemtrada) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

For Medicare Advantage members, certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when alemtuzumab (Lemtrada) is covered under a member's medical benefit (Part B benefit). It does not address instances when alemtuzumab (Lemtrada) is covered under a member's pharmacy benefit (Part D benefit).

DOSAGE INFORMATION

According to the FDA-approved label, the recommended dosage of alemtuzumab (Lemtrada) is 12 mg/day by intravenous infusion for two treatment courses. The first course is for five consecutive days. The second course is 12 months after the first treatment course for three consecutive days at 12 mg/day. Individuals should be given high-dose corticosteroids (1000 mg methylprednisolone or equivalent) immediately prior to infusion and for the first three days of each treatment course. Following the second course, subsequent treatment courses of 12 mg/day on three consecutive days may be administered, as needed, at least 12 months after the last dose of any prior treatment courses.

BLACK BOX WARNINGS

Refer to the specific manufacturer's prescribing information for any applicable Black Box Warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, alemtuzumab (Lemtrada) is covered under the medical benefits of the Company's products when the medical necessity criteria listed in this medical policy are met.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Alemtuzumab (Lemtrada) was approved by the FDA in November 2014 for the treatment of individuals with relapsing forms of multiple sclerosis.
PEDIATRIC USE
The safety and effectiveness of alemtuzumab (Lemtrada) in pediatric patients below the age of 17 years have not been established. Alemtuzumab (Lemtrada) is not indicated for use in pediatric patients due to the risk of severe adverse events.

Description

Alemtuzumab (Lemtrada) is a recombinant humanized monoclonal antibody directed against a cell surface glycoprotein found on T-lymphocytes and B-lymphocytes resulting in antibody-dependent cellular cytolysis and complement-mediated lysis. Alemtuzumab (Lemtrada) was originally approved as alemtuzumab (Campath®) in May 2001. In 2012, Genzyme pulled alemtuzumab (Campath®) from the market. In November 2014, alemtuzumab was

approved as (Lemtrada) for the treatment of individuals with relapsing forms of multiple sclerosis. In light of its safety profile, the US Food and Drug Administration (FDA) approved alemtuzumab (Lemtrada) for individuals who have had an inadequate response to two or more drugs indicated for the treatment of multiple sclerosis.

Multiple sclerosis is caused by an immune-mediated process in which the body's immune system has an abnormal response directed against the central nervous system causing demyelination with loss of oligodendrocytes and astroglial scarring.

PEER REVIEWED LITERATURE

The safety and efficacy of Alemtuzumab (Lemtrada) was evaluated in two randomized, controlled, phase 3 trials on individuals with relapsing-remitting multiple sclerosis who had experienced at least two relapses during the prior two years and at least one relapse during the prior year.

The Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis (CARE-MS-1) trial was a two-year randomized, open-label, rater-blinded study assessing the safety and efficacy of alemtuzumab (Lemtrada) as first-line treatment for relapsing-remitting multiple sclerosis. Individuals with an expanded disability status scale (EDSS) score of 3 or lower, cranial abnormalities on MRI due to multiple sclerosis, and no previous multiple sclerosis treatment, except corticosteroids, were randomized to receive alemtuzumab (Lemtrada) (N=376) or interferon beta 1a (N=187). The clinical outcome measures were annualized relapse rate (ARR) over two years and time to six-month sustained accumulation of disability. Alemtuzumab (Lemtrada) ARR was 0.18 compared to interferon beta 1a of 0.39, a 55 percent relative reduction in risk. At year two, 78 percent of individuals on alemtuzumab (Lemtrada) were relapse-free compared to 59 percent of the interferon beta 1a group. There was not a significant difference between the two groups for time to six-month sustained accumulation of disability. The most frequently reported adverse event for alemtuzumab was infusion-associated reactions (90 percent of 376 individuals), with 3 percent having serious adverse events. The most frequently reported adverse event for interferon beta 1a was infection (45 percent of 187), with 1 percent having a serious infection.

In the Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis (CARE-MS-2) trial, alemtuzumab (Lemtrada) was compared to interferon beta 1a to assess safety and efficacy in individuals with relapsing-remitting multiple sclerosis who have relapsed despite first-line therapy of interferon beta or glatiramer acetate for six months. In this two-year randomized, open-label, rater-blinded study, individuals with EDSS of 5 or lower and cranial and spinal MRI lesions were randomized to receive alemtuzumab (Lemtrada) (N=426) or interferon beta 1a (N=202). The clinical outcome measures were the same as the first study of ARR over two years and time to six-month sustained accumulation of disability. There was a significant reduction in ARR when the alemtuzumab (Lemtrada) group (0.26) was compared to interferon beta 1a (0.52) of 49 percent. Alemtuzumab (Lemtrada) significantly reduced the risk of sustained accumulation of disability by 42 percent compared to interferon beta 1a. At year two, 65.4 percent of the alemtuzumab (Lemtrada) group were relapse free as opposed to the interferon beta 1a group in which 46.7 percent were relapse free. The most frequently reported adverse event for alemtuzumab (Lemtrada) was infusion-associated reactions (90 percent of 435 individuals), with 3 percent having serious adverse events. The most frequently reported adverse event for interferon beta 1a was infection (66 percent of 187), with 1 percent having a serious infection.

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Alemtuzumab (Lemtrada) drug was approved by the US Food and Drug Administration (FDA) with a risk evaluation and mitigation strategy (REMS). The goal was to ensure that the benefits of the drug outweigh the risks of autoimmune conditions, infusion reactions, and malignancies through a restricted distribution program.

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company’s off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

References

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

N/A

ICD - 10 Procedure Code Number(s)

N/A

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ICD - 10 Diagnosis Code Number(s)
G35 Multiple sclerosis

HCPCS Level II Code Number(s)
J0202 Injection, alemtuzumab, 1 mg

Revenue Code Number(s)
N/A

Policy History

Revisions From MA08.015d:

05/07/24	The policy has been reviewed and reissued to communicate the Company's continuing position on alemtuzumab (Lemtrada®).
09/05/2023	The policy has been reviewed and reissued to communicate the Company's continuing position on alemtuzumab (Lemtrada®).
06/01/2022	The policy has been reviewed and reissued to communicate the Company's continuing position on alemtuzumab (Lemtrada®).
06/30/2021	The policy has been reviewed and reissued to communicate the Company's continuing position on alemtuzumab (Lemtrada®).
05/04/2020	This version of the policy will become effective 05/04/2020. This policy has been updated in consideration of revisions within the US Food and Drug Administration (FDA) labeling to include relapsing forms of multiple sclerosis (MS), and active secondary progressive disease as medically necessary.

Revisions From MA08.015c:

04/10/2019	The policy has been reviewed and reissued to communicate the Company's continuing position on alemtuzumab (Lemtrada®).
06/06/2018	This policy has been reissued in accordance with the Company's annual review process.
10/18/2017	This policy was updated to expand coverage to individuals deemed high risk for disability.

Revisions From MA08.015b:

08/03/2016	The policy has been reviewed and reissued to communicate the Company's continuing position on Alemtuzumab (Lemtrada™)
01/01/2016	This version of the policy will become effective 01/01/2016. The following HCPCS code has been **deleted** from this policy: J9010, Q9979 The following HCPCS code has been **added** to this policy: J0202

Revisions From MA08.015a:

10/01/2015	This version of the policy will become effective 10/01/2015. The following HCPCS code has been **deleted** from this policy: J3590 The following HCPCS code has been **added** to this policy: Q9979

Revisions From MA08.015:

08/28/2015	This version of the policy will become effective 08/28/2015. This new policy has been developed to communicate the Company's coverage criteria for Alemtuzumab (Lemtrada™).

Version Effective Date:

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05/04/2020
Version Issued Date:
05/04/2020
Version Reissued Date:
05/07/204