Cigna National Preferred Formulary Coverage Policy

Effective Date 1/1/2021
Next Review Date… 1/1/2022
Coverage Policy Number NPF389

Prior Authorization
Multiple Sclerosis – Kesimpta® (ofatumumab injection for subcutaneous use)

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

NPF Coverage Policy

Cigna covers ofatumumab (Kesimpta®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended for prescription benefit coverage of Kesimpta. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of individuals treated with Kesimpta as well as the monitoring required for adverse events and long-term efficacy, approval requires Kesimpta to be prescribed by or in consultation with a physician who specializes in the condition being treated.

FDA Indication(s)

1. **Multiple Sclerosis.** Approve for 1 year if the individual meets the following criteria (A, B and C):
   - **A)** Individual has a relapsing form of multiple sclerosis; AND
   - **B)** Individual is ≥ 18 years; AND

C) Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

Conditions Not Covered

Ofatumumab (Kesimpta®) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

1. Concurrent Use with Other Disease Modifying Agents Used for Multiple Sclerosis.

Note: Examples of disease modifying agents used for multiple sclerosis include Aubagio® (teriflunomide tablets), Avonex® (interferon beta 1a injection for intramuscular use), Betaseron®/Extavia® (interferon beta-1b injection for subcutaneous use), Rebif® (interferon beta-1a injection for subcutaneous use), Copaxone®/Glatopa® (glatiramer acetate injection for subcutaneous use), glatiramer acetate injection, Plegridy® (peginterferon beta-1a injection for subcutaneous use), Tecfidera® (dimethyl fumarate delayed-release capsules), Gilenya® (fingolimod capsules), Mavenclad® (cladribine tablets), Mayzent® (siponomid tablets), Bafiertam® (monomethyl fumarate delayed-release capsules), Vumerity® (diroximel fumarate delayed-release capsules), Zeposia® (ozanimod capsules), Ocrevus® (ocrelizumab injection for intravenous use), Tysabri® (natalizumab injection for intravenous infusion), and Lemtrada® (alemtuzumab injection for intravenous use).[2] These agents are not indicated for use in combination. Additional data are required to determine if use of disease-modifying multiple sclerosis agents in combination is safe provides added efficacy.

2. Non-Relapsing Forms of Multiple Sclerosis.

Note: An example of a non-relapsing form of multiple sclerosis is primary progressive multiple sclerosis. The efficacy of Kesimpta has not been established in individuals with multiple sclerosis with non-relapsing forms of multiple sclerosis.[1]

Background

Overview
Kesimpta, a CD20-directed cytolytic antibody, is indicated for the treatment of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive MS in adults.[1]

Disease Overview
MS is a chronic, inflammatory, demyelinating, autoimmune disease of the central nervous system (CNS) that impacts almost 1,000,000 people in the US.[2] The condition is marked by inflammation and demyelination, as well as degenerative alterations. Patients usually experience relapses and remissions in their neurological symptoms. For most patients, the onset of MS symptoms occurs when patients are 20 to 40 years of age; however, children can get MS and new onset disease can occur in older adults. The MS disease course is heterogeneous but has some patterns. Approximately 85% to 90% of patients have a relapsing pattern at onset. However, this transitions over time in patients who are untreated to a worsening with very few or no relapses or magnetic resonance imaging (MRI) activity (secondary progressive MS). Around 10% to 15% of patients have a steady progression of symptoms over time (primary progressive MS), marked by some clinical manifestations or by MRI activity. Primary progressive MS is generally diagnosed in patients on the upper level of the typical age range (e.g., almost 40 years of age) and the distribution is equivalent among the two genders. Advances in the understanding of the MS disease process, as well as in MRI technology, spurned updated disease course descriptions in 2013,[3] as well as in 2017.[4] The revised disease courses are clinically isolated syndrome, relapsing remitting MS, primary progressive MS, and secondary progressive MS.[2-4] Clinically isolated syndrome is now more recognized among the course descriptions of MS. It is the first clinical presentation of MS that displays characteristics of inflammatory demyelination that may possibly be MS but has yet to fulfill diagnostic criteria. It is notable that the other MS designations can be further characterized considering whether patients have active disease (or not active), as well as if disease is worsening or stable. Disability in MS is commonly

graded on the deterioration of mobility per the Expanded Disability Status Scale (EDSS) an ordinal scale that ranges from 0 to 10, with higher scores indicating greater disability.

Guidelines
In September 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS.[2] Many options from various disease classes, involving different mechanisms of action and modes of administration, have shown benefits in patients with MS.

References

1. Kesimpta® injection for subcutaneous use [prescribing information]. East Hanover, NJ: Novartis Pharmaceutical Corporation; August 2020.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. September 2019. Available at: http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed on August 23, 2020.
3. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
4. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.

Last Revision Details

New Policy	--	08/26/2020