Clinical Policy Title:	ofatumumab
Policy Number:	RxA.658
Drug(s) Applied:	Kesimpta®
Original Policy Date:	11/03/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ofatumumab (Kesimpta®)	Relapsing MS	Initial dosing of 20 mg/0.4 ml by subcutaneous injection at weeks 0, 1, and 2, followed by subsequent dosing of 20 mg/0.4 ml by subcutaneous injection once monthly starting at Week 4.	Initial dose: 60 mg in 3 weeks Subsequent dose: 20 mg once monthly

Dosage Forms

- Injection: 20 mg/0.4 mL solution in a single-dose prefilled syringe
- Prefilled 20 mg/0.4 mL solution Sensoready® Pen

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Multiple Sclerosis

1. Diagnosis of one of the following (a, b, or c):
   a. Clinically isolated syndrome.
   b. Relapsing-remitting MS.
   c. Secondary progressive MS.
2. Age is ≥ 18 years.
3. Prescribed by or in consultation with a neurologist.
4. Member is evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV.
5. Member serum immunoglobulin baseline measured prior to the start of therapy.

6. Member has not received any live or live-attenuated vaccinations in the 4-weeks prior to, or non-live vaccinations in the 2-weeks prior to, the start of therapy.
7. Kesimpta® is not prescribed concurrently with other disease modifying therapies for MS (See Appendix D).
8. Dose does not exceed the maximum dose given in dosing information.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Multiple Sclerosis

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy.
2. Member is responding positively to therapy.
3. Kesimpta® is not prescribed concurrently with other disease modifying therapies for MS (See Appendix D).
4. If request is for dose increase, new dose does not exceed 20 mg/0.4 ml per month.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
MS: multiple sclerosis
HBV: Hepatitis B virus

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum dose
Ocrevus® (ocrelizumab)	300 mg, followed by a second 300 mg dose 2 weeks later followed by subsequent doses of 600 mg via intravenous infusion every 6 months	600 mg/6 months
dimethyl fumarate (Tecfidera®)	120 mg orally twice daily for 7 days, followed by 240 mg orally twice daily	480 mg/day
teriflunomide (Aubagio®)	7 mg or 14 mg orally once daily	14 mg/day
fingolimod (Gilenya®)	0.5 mg orally once daily	0.5 mg/day
glatiramer acetate (Copaxone®)	20 mg subcutaneously once daily or 40 mg subcutaneously three times weekly	20 mg/day or 40 mg three times weekly

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):

- Active HBV infection

- Boxed Warning(s):
  - None

APPENDIX D: General Information

Disease-modifying therapies for MS include:

- Infusion therapies
  - natalizumab (Tysabri®)
  - mitoxantrone
  - ocrelizumab (Ocrevus®)
  - alemtuzumab (Lemtrada®)
- Injectable therapies
  - glatiramer (Copaxone®, Glatopa®)
  - interferon beta-1a (Avonex®, Rebif®)
  - interferon beta-1b (Betaseron®, Extavia®)
  - peginterferon beta-1a (Plegridy®)
- Oral therapies
  - dimethyl fumarate (Tecfidera®)
  - monomethyl fumarate (Bafiertam™)
  - diroximel fumarate (Vumerity®)
  - teriflunomide (Aubagio®)
  - fingolimod (Gilenya®)
  - siponimod (Mayzent®)
  - ozanimod (Zeposia®)
  - cladribine (Mavenclad®)
  - dalfampridine (Ampyra®)

References

1. Novartis Pharmaceuticals. Kesimpta (ofatumumab) [package insert]. U.S. Food and Drug Administration website. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125326s070lbl.pdf . Accessed August 20, 2021.
2. Dieguez, Gabriela. "Site of Service and Cost Dispersion of Infused Drugs: A case study of patients with multiple sclerosis." milliman.com, 2019 (Milliman White Paper), Milliman Inc. Available at: https://www.milliman.com/en/insight/site-of-service-and-cost-dispersion-of-infused-drugs. Accessed August 20, 2021.
3. Hauser S, Bar-Or A, Cohen J, et al. Ofatumumab versus teriflunomide in relapsing multiple sclerosis: analysis of no evidence of disease activity (NEDA-3) from ASCLEPIOS I and II trials. Eur J Neurol. 2020;27(S1). Available at: https://pubmed.ncbi.nlm.nih.gov/32757523/. Accessed August 20, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	11/03/2020	12/07/2020
Policy was reviewed. 1. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when	08/20/2021	09/14/2021

the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 2. References were reviewed and updated.		