Ocrelizumab

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2023-PH-21	**Version Control:** Version No. V1.0	**Effective Date:** 25th August 2023	**Last Update:** 25th July 2023
Approved by: Daman	**Responsible:** Medical Standards & Research	**Related Adjudication Guidelines:** NA		

Table of Contents

1. Abstract 3
   - 1.1 For Members 3
   - 1.2 For Medical Professionals 3
2. Scope 3
3. Adjudication Policy 3
   - 3.1 Eligibility / Coverage Criteria 3
   - 3.2 Requirements for Coverage 4
   - 3.3 Non-Coverage 4
   - 3.4 Payment and Coding Rules 4
4. Denial codes 4
5. Appendices 5
   - 5.1 References 5
   - 5.2 Revision History 5

1. Abstract

1.1 For Members

Ocrelizumab is indicated for the treatment of multiple sclerosis. This drug is administered as an intravenous infusion. Before receiving Ocrelizumab, the patient is required to discuss with the healthcare provider about all the medical conditions, including having ever taken, currently taking, or planning to take medication that may affect the immune system, or other treatments for MS. Furthermore, the patient should also reveal active hepatitis B infection or are a carrier of the hepatitis B virus. Your clinician should also know about the history of inflammatory bowel disease or colitis or have had a recent vaccination or are scheduled to receive any vaccinations.

1.2 For Medical Professionals

Ocrelizumab is a CD20-directed antibody approved by the FDA for the treatment of multiple sclerosis in adults. The medication is given in intravenously and the patient is observed for any infusion-related reactions. This medication may increase the risk of upper respiratory infection, re-activation of hepatitis, and decrease the level of immunity of the patient, and thus hepatitis test and quantitative serum immunoglobulin test are conducted prior to initiation of therapy.

2. Scope

The scope of this adjudication rule is to highlight the coverage and payment for Ocrelizumab for all Daman health insurance plans, subject to policy terms and conditions.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Ocrelizumab is considered medically necessary for the treatment of Relapsing forms of Multiple Sclerosis or primary progressive multiple sclerosis when blow criteria meet:

- 18 years of age or older.
- Documented diagnosis of Relapsing forms of Multiple Sclerosis, including Clinically isolated syndrome, Relapsing-remitting disease, Active secondary progressive disease
- Documented diagnosis Primary progressive Multiple Sclerosis.

Ocrelizumab Dose and administration:

- **Initial Dose:** The initial 600 mg dose is administered as two separate intravenous infusions. First as a 300 mg intravenous infusion. followed two weeks later by a second 300 mg intravenous infusion.
- **Subsequent doses:** single 600 mg intravenous infusion every 6 months. The first subsequent dose of 600 mg should be administered six months after the first infusion of the initial dose
  A minimum interval of 5 months should be maintained between each dose of ocrelizumab.

Ocrelizumab Dose:

Ocrelizumab Dose		Methods of administration
Initial dose (600 mg) divided into 2 infusions	First dose of 300mg 2nd dose 300 mg two weeks later from the first dose	Diluted solution is Intravenously administered over period of 3 hrs
Subsequent doses (600 mg) single infusion once every 6 months	600 mg in single dilution	Diluted solution is Intravenously administered over period of 3 hrs

3.2 Requirements for Coverage

- ICD and CPT / Drug codes must be coded to the highest level of specificity.
- Treatment should be initiated when the below requirements are met:
  - A Premedication antihistamine 30 to 60 minutes prior to each infusion to reduce the infusion-related reaction.
  - Premedication methylprednisolone 100 mg IV or an equivalent corticosteroid 30 minutes prior to each infusion to reduce the infusion-related reaction.
  - Before administering the first dose of Ocrelizumab hepatitis B and quantitative serum immunoglobulin tests are required.
  - Confirming vaccination status: No vaccination is administered during treatment. Therefore, it is advised to administer live or live-attenuated immunizations at least 4 weeks prior to initiating therapy and non-live vaccines.
  - Infection status confirmation is necessary to initiate the therapy.

Questionnaire link: ***https://www.damanhealth.ae/main/pdf/support/Questionnaire/Pre-approval%20Form%20for%20Ocrelizumab.pdf***

Eligible clinician Specialities:

Eligible Clinician Specialities
Neurology

3.3 Non-Coverage

- Ocrelizumab is not covered for the visitor plan Administered by Daman.
- Ocrelizumab is not covered in active hepatitis B virus (HBV) infection status.

3.4 Payment and Coding Rules

Please apply DOH payment rules and regulations and relevant coding manuals for ICD, CPT, etc.

4. Denial Codes

Code	Code Description
MNEC-004	Service is not medically indicated.
AUTH-001	Pre-approval was not acquired for rendered services.
CODE-010	Prescribing clinician is not eligible for this service.

5. Appendices

5.1 References

1- *https://www.ocrevus.com/*
2- *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761053s029s030lbl.pdf*
3- *https://www.medicines.org.uk/emc/product/8898/smpc#gref*
4- *https://www.uptodate.com/contents/ocrelizumab-drug-information?search=ocrelizumab&source=panel_search_result&selectedTitle=1~22&usage_type=panel&kp_tab=drug_general&display_rank=1*
5- *https://www.dynamed.com/drug-monograph/ocrelizumab*
6- *https://www.ema.europa.eu/en/documents/product-information/ocrevus-epar-product-information_en.pdf*
7- *https://www.genentech-access.com/content/dam/gene/accesssolutions/pdfs/coding/OCREVUS-Billing-Coding-for-MS.pdf*
8- *https://clinicaltrials.gov/ct2/show/NCT01247324*
9- *https://clinicaltrials.gov/ct2/show/NCT05123703*
10- *https://clinicaltrials.gov/ct2/show/NCT04877457*
11- *https://clinicaltrials.gov/ct2/show/NCT01194570*
12- *https://mstrust.org.uk/a-z/mcdonald-criteria*

5.2 Revision History

Date	Change(s)
25/07/2023	Release of V1.0