Ocrelizumab

Adjudication Guideline

Rule Category:	Ref: No:	Version Control:	Effective Date:	Last Update:
Pharmaceutical	2023-PH-21	Version No.4	25/8/2023	16/01/2026

Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmaceutical Standards &Governance	NA

Table of Contents

1. Abstract

1.1 For Members

Ocrelizumab is indicated for the treatment of relapsing forms of multiple sclerosis and primary progressive multiple sclerosis and is administered either by intravenous infusion or by subcutaneous injection. 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 administered either as an intravenous infusion or as a subcutaneous injection (920 mg/23 mL every 6 months).Patients receiving the intravenous formulation should be observed for infusion-related reactions, while those receiving the subcutaneous formulation should be monitored for injection-related reactions.

Ocrelizumab may increase the risk of upper respiratory infections, re-activation of hepatitis B, and decrease immune function. Therefore, hepatitis B screening and quantitative serum immunoglobulin testing are required prior to initiation of therapy, and vaccination status should be reviewed before starting treatment.

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.
- initiation of ocrelizumab requires documented evidence of active disease as per below:
    - A careful history and neurological examination are essential.
    - Clinical relapses with objective findings on clinical examination separated by time and location provide evidence for DIT and DIS, respectively. Neuroimaging is recommended to avoid misdiagnosis.
    - MRI findings of Lesions in at least two of the following 5 topography:
        - Periventricular (PV)
        - Juxtacortical/cortical (JC/IC)
        - Infratentorial (IT)
        - Spinal cord (SC)
        - Optic Nerve (ON)

    - Dissemination in Time (DIT) Demonstrated by either New T2 or gadolinium-enhancing lesions on follow-up MRI or Simultaneous enhancing and non-enhancing lesions
    - Additional MRI markers [Six lesions with central vein sign (CVS)/ One paramagnetic rim lesion (PRL)]
    - Laboratory Evidence Supporting Active Disease as below:
        - Oligoclonal bands (OCBs) in CSF (≥2 bands) support inflammatory demyelination.
        - Positive OCBs can substitute for DIT.
        - Kappa free light chain (kFLC) index supports intrathecal Ig synthesis.
        - Neurofilament light chain (NfL) in blood/CSF monitors ongoing axonal damage.

- For relapsing MS, prior DMT failure may be considered a criterion for escalation to ocrelizumab. Prior DMT failure is defined as evidence of ongoing disease activity — including clinical relapse, MRI activity (new or enlarging T2 or gadolinium-enhancing lesions), or disability progression — despite adherence to a previous disease-modifying therapy

Ocrelizumab Dose and administration:

- **Initiation treatment Criteria:**

    - Initiation of this medication only for one month as per DOH guidline
    - 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.

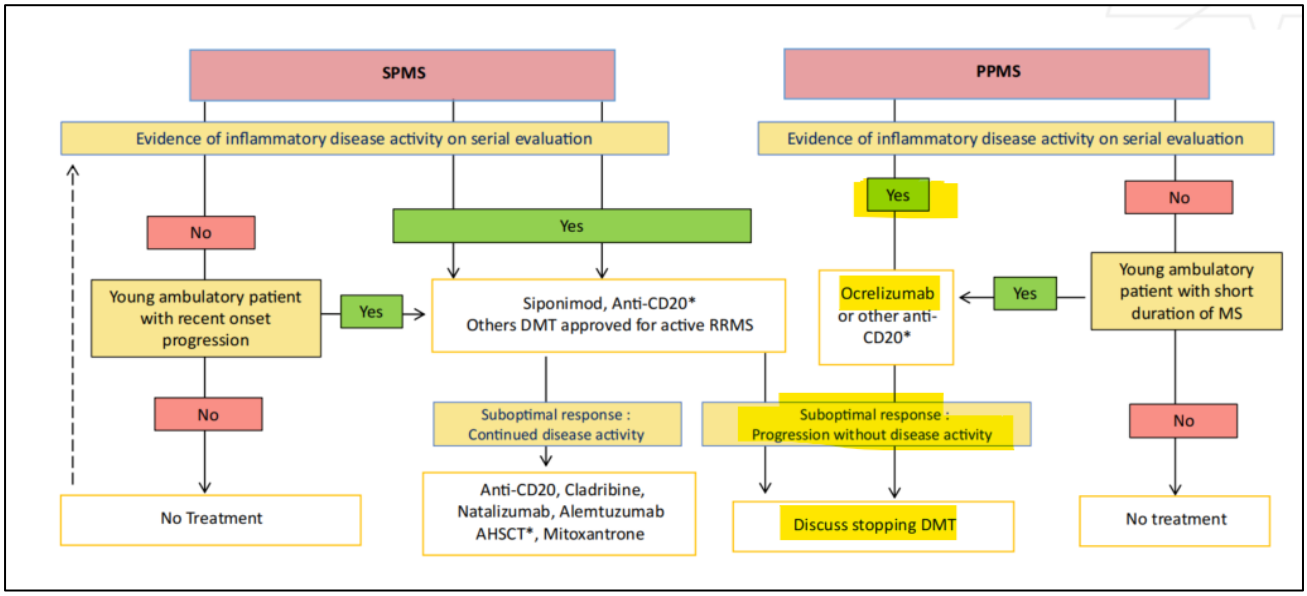
- **Refill treatment criteria:**

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.

- **Stop treatment criteria:**

Treatment with ocrelizumab should be discontinued if:

- There is Suboptimal response: progression without disease activity
- The person develops adverse events or safety concerns that make continued treatment inappropriate.
- There is no evidence of clinical benefit, based on assessment of disability progression, symptoms, and MRI findings, after an appropriate treatment interval.
- The person chooses to stop treatment following a discussion of the risks and benefits.
- A clinician determines that the risks outweigh the potential benefits, taking into account comorbidities, infection risk, immunoglobulin levels, and overall disease course.



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

Subcutaneous Injection- Ocrelizumab 920mg

The recommended dosage of OCREVUS is 920 mg/23,000 units (920 mg ocrelizumab and 23,000 units of hyaluronidase) administered as a single 23 mL subcutaneous injection in the abdomen over approximately 10 minutes every 6 months.

Monitor the patient closely during injections, with access to appropriate medical support to manage severe injection reactions. For the initial dose, monitor the patient for at least one-hour post-injection. For subsequent doses, monitor the patient for at least 15 minutes post-injection

Drug Ingredient	Strength	No of injection in 6 Months Duration
Ocrelizumab	920 mg/1 vial	1

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/Preapproval%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-druginformation?search=ocrelizumab&source=panel_search_result&selectedTitle=1~22&usage_type=panel&kp_t ab=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-BillingCoding-for-MS.pdf*
8- *https://clinicaltrials.gov/ct2/show/NCT01247324*
9- *https://clinicaltrials.gov/ct2/show/NCT05123703*
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12- *https://mstrust.org.uk/a-z/mcdonald-criteria*
13- https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761371s000lbl.pdf
14- *https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761053s036lbl.pdf*
15- *MS Management Seclorsis Guideline_PD (3).pdf*
16- *Ocrelizumab for treating primary progressive multiple sclerosis*

5.2 Revision History

Date	Version No.	Change(s)
25/07/2023	V1.0	Release of V1.0
08/11/2024	V2.0	No changes/ updated in the new format
27/11/2025	V3.0	Guideline review/ Ocrelizumab new dose strength added
16/1/2026	V4.0	Guideline review/ to add disease activity/ criterion for relapsing MS cases.

Medical Standards & Research Pre-approval Form For Ocrelizumab

This is a pre-requisite form provided upon request for the **"Ocrelizumab"**.
Kindly fill in all the requested information given below. This is a mandatory step to proceed further. Failure to provide information relevant to approval will delay the processing of the applicant's request. The provider will be contacted in case further clarifications are required.

GENERAL INFORMATION

- Member's Name:
  ☐ New ☐ Established
- Member Card #:
- Policy:
- Age:
- Gender: ☐ Female ☐ Male
- Date: / /202_

PROVIDER INFORMATION

- Provider's Name:
- Ordering Clinician (ID # & Name):
- Performing Provider Name:
- Performing Clinician Specialty (ID # & Name):
- Referring Physician (ID # & Name):

SERVICE REQUESTED

- Principal/ Primary Diagnosis:
- ICD-10:
- Requested Drug and Dose:
  Initial Dose: ☐
  Subsequent Dose: ☐

ADDITIONAL INFORMATION
To confirm the diagnosis, the patient's medical records must be reviewed, and relate following information With Reported Diagnosis. MRI report: ☐
Mac Donald criteria: ☐
Expanded Disability Status Scale (EDSS) score 0 to 5.5 inclusive: ☐
History of relapse: ☐

All pre-approval forms need Line managers approval prior to publishing.
Add more rows if needed.