OCRELIZUMAB (OCREVUS™) MEDICAL POLICY[1]

POLICY NUMBER:
EFFECTIVE DATE: [MM/DD/YYYY] **LAST UPDATED:** [MM/DD/YYYY]
DEVELOPED BY: [Employee Name] **APPROVED BY:** [Employee Name]

POLICY:

Ocrelizumab is a CD20-directed cytolytic antibody indicated for the treatment of relapsing and primary progressive forms of MS. This facility is committed to providing high-quality care, promoting patient safety, and supporting staff adherence to best practices. This policy, in conjunction with relevant departmental policies, establishes a standardized process for the safe administration of ocrelizumab.

SCOPE:

This policy applies to all personnel at [facility] who are responsible for the preparation and/or administration of parenteral medications.

RESPONSIBILITIES:

It is the responsibility of [insert title of the responsible party] to ensure that all personnel responsible for the preparation and administration of parenteral medications complete the required education and training according to [insert facility policy on staff training and education].

It is the responsibility of every person responsible for the preparation and administration of parenteral medication to adhere to the contents of this policy and remain current with facility training.

ACRONYMS:

FDA- Food and Drug Administration
MRI- Magnetic resonance imaging
MS- Multiple Sclerosis
PPMS- Primary Progressive MS
RMS- Relapsing MS
USP- United States Pharmacopeia
VAD- Vascular access device

[1] The National Infusion Center Association (NICA) develops templates to be used as a reference to support, not replace, the use of professional judgment in the development of organization-specific policies. NICA templates are for informational purposes only and may not reflect all relevant regulations and requirements from applicable oversight agencies including but not limited to state/local health departments, departments of professional licensure, FDA, or other regulatory authorities. NICA assumes no responsibility for any damages or adverse effect(s) resulting from or related to the readers' interpretation or application of this information. For complete medication information, refer to www.ocrevus.com

CRITERIA AND INDICATIONS FOR USE:

- Ocrelizumab is indicated for the treatment of primary progressive and relapsing forms of multiple sclerosis (MS).
- Approved diagnoses[2]:
    - G35 Multiple Sclerosis

PROCEDURE:

1) Review Referral:
    a) Confirm that the order for ocrelizumab is complete and signed by a licensed independent practitioner with active prescriptive authority.
    b) All referrals must be accompanied by documentation supporting medical necessity, including but not limited to:
        i) Medical records confirming multiple sclerosis including:
            Results and date of MRI (within the last 6 months)
        ii) Negative hepatitis B screening
        iii) Serum quantitative immunoglobulins within normal limits
    c) If the referral is incomplete [insert facility protocol, e.g., "notify referring provider to request outstanding clinical documentation"]
    d) Confirm receipt of referral with the referring provider [per facility policy]
    e) Contact the patient/care partner to:
        i) Confirm receipt of the referral.
        ii) Inform the patient/care partner of the next steps and what to expect.
        iii) Obtain outstanding information required for referral (e.g., demographic and insurance information).
    f) Begin the insurance verification and authorization process.
    g) Upon treatment approval, contact the patient/care partner to schedule the ocrelizumab infusion. When scheduling, discuss the following with the patient: [e.g.:
        i) Bring a current list of prescriptions and over-the-counter medications (including vitamins and supplements).
        ii) Make a list of questions for the infusion team.
        iii) Patient preparation information.
        iv) Facility-specific arrival instructions.
2) Prior to treatment:
    a) Confirm the patient's identity using two unique patient identifiers.
    b) Review the medical record to confirm the dose/treatment number.
    c) Provide ocrelizumab education with the patient/care partner [insert facility patient education policy, e.g., "Provide and review written medication information (e.g., FDA approved patient medication guide) prior to initial treatment at a minimum, and offer written information prior to each subsequent treatment."]. Document education in the patient's medical record.
    d) Verify that current informed consent is on file. Alternatively, obtain informed consent prior to treatment.
    e) Confirm that the medical record contains complete and current clinical documentation

[2] The ICD-10 diagnosis codes above may be reasonably related to a diagnosis within the product's approved label. It is not all-inclusive, and other codes may be appropriate. NICA does not guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement.

prior to every treatment, including:
i) MRI
ii) Negative hepatitis B screening
iii) Serum quantitative immunoglobulin screening

f) Obtain a full set of vital signs [insert facility-specific protocol e.g., "to include blood pressure, pulse, temperature, respiratory rate, and oxygen saturation."]

g) Hold the infusion and notify the prescriber if:
i) vital signs are abnormal,
ii) fever or signs/symptoms of illness or active infection,
iii) planned/recent surgical procedure,
iv) neurological changes,
v) recent live vaccinations, or
vi) possibility of pregnancy.

h) Prior to preparing ocrelizumab, obtain vascular access [e.g., "per Vascular Access Device Placement policy"].

i) Select the required number of ocrelizumab vials for the ordered dose.
Ocrelizumab is supplied as 300 mg/15 mL solution in a single-dose vial.

j) Visually inspect vials of ocrelizumab for particulate matter and discoloration. Ocrelizumab is clear or slightly opalescent, and colorless to pale brown solution in a single-dose vial.
i) If particulate matter or discoloration is noted, do not use. Remove from inventory and complete the following:
(1) [insert facility protocol e.g., "refer to Adverse Event policy"]
(2) Report to [identify responsible party e.g., "nurse manager"].

k) Gather supplies:
i) Gloves
ii) Alcohol prep pads
iii) Empty syringe (one syringe is required for every vial of ocrelizumab)
iv) Blunt fill cannula (one cannula for every new vial of ocrelizumab)
v) Correct number of vial(s) required for ocrelizumab dose
vi) One infusion bag with 0.9% Sodium Chloride Injection, USP, volume is based upon dose as outlined below:

Dose of Ocrelizumab	Volume of Diluent
300 mg	250 mL 0.9% Sodium Chloride Injection, USP
600 mg	500 mL 0.9% Sodium Chloride Injection, USP

l) Prepare designated medication preparation area [e.g., "refer to Parenteral Medication Preparation policy," or "disinfect area…" etc.].

3) Medication preparation:
a) Using aseptic technique:
i) Remove the flip-off cap from ocrelizumab's vial(s) and disinfect the rubber stopper.
ii) Insert a sterile blunt fill cannula through the center of the rubber stopper into the ocrelizumab vial.
iii) Withdraw the required volume of ocrelizumab from the vial(s).
iv) Disinfect the injection port of an infusion bag containing 0.9% Sodium Chloride Injection, USP, and slowly inject the required volume of ocrelizumab.

v) Discard supplies [according to facility policy].
vi) Gently invert the infusion bag containing ocrelizumab to mix completely. Do not shake the bag.
vii) Allow the diluted ocrelizumab to warm to room temperature.
viii) Infuse the diluted ocrelizumab immediately. If not able to infuse immediately, may be stored at 2°C to 8°C (36°F to 46°F) for up to 4 hours, after which point it must be discarded.

4) Administration:

a) Prime the administration set and 0.2 or 0.22-micron in-line filter with prepared ocrelizumab.

b) Assess the patency of the vascular access device (VAD) by [insert facility protocol, e.g., "confirming blood return and flushing with 0.9% Sodium Chloride per Vascular Access policy"].

c) Disinfect the needleless connector. Attach the administration set and prepared ocrelizumab to VAD.

d) ["Set flow rate" or "program infusion pump"] to infuse the entire volume of diluted ocrelizumab according to the table below:

Initial Two Infusions (ocrelizumab 300 mg)		
Start	30 mL/hr	For 30 minutes
	60 mL/hr	For 30 minutes
	90 mL/hr	For 30 minutes
	120 mL/hr	For 30 minutes
	150 mL/hr	For 30 minutes
	180 mL/hr	For remainder of infusion
Estimated total infusion time: 2.5 hours		
Subsequent Infusions Option 1 (ocrelizumab 600 mg)		
0	40 mL/hr	For 30 minutes
30	80 mL/hr	For 30 minutes
60	120 mL/hr	For 30 minutes
90	160 mL/hr	For 30 minutes
120	200 mL/hr	For remainder of infusion
Estimated total infusion time: 3.5 hours		
Option 2: Subsequent Infusion (ocrelizumab 600 mg) (If no prior serious infusion reaction with any previous ocrelizumab infusion)		
0	100 mL/hr	For 15 minutes
15 min	200 mL/hr	For 15 minutes

30 min	250 mL/hr	For 30 minutes
60 min	300 mL/hr	For remainder of infusion
Estimated total infusion time: 2 hours		

e) Continually monitor the patient's treatment tolerance throughout the infusion, assessing for any signs or symptoms of an infusion-related reaction. If an infusion-related reaction is suspected, immediately stop the infusion and [insert facility-specific protocol e.g., "initiate Hypersensitivity Reaction Management Protocol"].

f) After the infusion is complete, flush the administration set to ensure the entire dose including residual volume is administered. Leave the VAD to saline lock for the observation period.

g) Continue to observe and monitor the patient for signs or symptoms of an infusion-related reaction for at least 60 minutes after the infusion is complete. If an infusion-related reaction is suspected, [insert facility-specific protocol e.g., "initiate Hypersensitivity Reaction Management Protocol"]

h) After the 60-minute observation period, obtain a full set of vital signs.

5) Discharge:

a) If vital signs are within normal limits and the patient is otherwise stable, remove VAD [e.g., "according to facility policy"], and document the patient's treatment tolerance and VAD site assessment.

b) Review discharge instructions with the patient/care partner:

i) Expected side effects.

ii) Symptoms to report and to whom they should be reported.

iii) Adverse reactions, whether confirmed or suspected, should be reported to the FDA at (800) FDA-1088 or www.fda.gov/medwatch.

iv) Remind the patient/care partner to complete blood work and diagnostic imaging (e.g., MRI), as applicable.

Medication Policy Protocol: This medication policy will be reviewed and updated if necessary [insert facility protocol e.g., "at least annually, or more frequently as necessary."]

References

1. Genentech, Inc. Prescribing Information. 2022.
2. National Infusion Center Association. Standards of Excellence for Ambulatory Infusion Centers (1st ed.). Madison, WI: Omnipress. 2023.