Prescribing Protocol SESLHDPR/629
Ocrelizumab for Multiple Sclerosis

Prescribing Protocol	
Title	Ocrelizumab for Multiple Sclerosis
Areas where Protocol/Guideline applicable	Ambulatory Care areas
Areas where Protocol/Guideline not applicable	Inpatient Settings
Authorised Prescribers	Neurology Consultants
Indication for use	Relapsing forms of multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS) in accordance with PBS Section 100 criteria. For more information see: http://www.pbs.gov.au/medicine/item/11237K-11242Q
Clinical condition	Ocrelizumab is indicated for the treatment of patients with relapsing forms of multiple sclerosis (RMS) to delay the progression of physical disability and to reduce the frequency of relapse. Ocrelizumab is indicated for the treatment of patients with primary progressive multiple sclerosis (PPMS) to delay the progression of physical disability.
Contra-indications	Ocrelizumab is contraindicated in patients with a known hypersensitivity to ocrelizumab or any of the excipients.
Precautions	Infusion Related Reactions (IRRs), Infections (PML, respiratory tract, herpes, hepatitis B reactivation), Treatment with immunosuppressants before, during or after ocrelizumab, Vaccinations (live), Malignancy, pregnancy and breastfeeding, antihypertensive treatments
Place in Therapy	First line
If part of combination therapy, list other drugs	N/A
Dosage (Include dosage adjustment for specific patient groups)	The initial 600 mg dose is administered as two separate IV infusions; one 300 mg infusion, followed by a second 300 mg infusion two weeks later. Subsequent doses of ocrelizumab thereafter are administered as a single 600 mg IV infusion every 6 months. (A minimum interval of 5 months should be maintained between each dose of ocrelizumab.)
Duration of therapy	Ongoing according to response
Important Drug Interactions	No formal drug interaction studies have been performed as no drug interactions are expected via CYP and other metabolising enzymes or transporters

Administration instructions	Ocrelizumab should be prepared by a healthcare professional using aseptic technique. Prepare and administer in line with Work Health and Safety-Monoclonal Antibodies Safe handling and Management SESLHDPR/368 (moderate risk). Protective gloves, safety glasses and mask should be worn during drug preparation. Ocrelizumab may contain fine translucent and/or reflective particles associated with enhanced opalescence. Do not use the solution if discoloured or if the solution contains discrete foreign particulate matter. Ocrelizumab must be diluted before administration. Solutions of ocrelizumab for IV administration are prepared by dilution into an infusion bag containing 0.9% sodium chloride (300 mg/250 mL or 600 mg/500 mL), to a final drug concentration of approximately 1.2 mg/mL. The diluted infusion solution must be administered using an infusion set with a 0.2 or 0.22 micron in-line filter. Prior to the start of the IV infusion, the content of the infusion bag must be at room temperature to avoid an infusion reaction to the administration of the solution at low temperatures. **Initial doses** - Initiate the infusion at a rate of 30 mL/hr Thereafter the rate can be increased in 30 mL/hr increments every 30 minutes to a maximum of 180 mL/hr. Each 300mg infusion should be given over approximately 2.5 hours **Subsequent doses** - Initiate the infusion at a rate of 40 mL/hr Thereafter the rate can be increased in 40 mL/hr increments every 30 minutes to a maximum of 200 mL/hr Each 600mg infusion should be given over approximately 3.5 hours
Monitoring requirements	Monitor throughout the infusion for signs of infusion-related reactions (IRRs). Observe the patient for at least one hour after the completion of the infusion. Signs of IRRs include hypersensitivity, breathing difficulties, flushing, fever, throat pain and headache. Pre-medicate with 100mg IV methylprednisolone (or an equivalent) approximately 30 minutes prior to each ocrelizumab infusion and with an antihistamine approximately 30-60 minutes before each infusion of ocrelizumab to reduce the frequency and severity of IRRs. The addition of an antipyretic (e.g. paracetamol) may also be considered approximately 30-60 minutes before each infusion.
Management of complications	Life-threatening IRRs - Immediately stop Ocrelizumab if there are signs of a life-threatening or disabling IRR during an infusion, such as acute hypersensitivity or acute respiratory distress syndrome. The patient should receive appropriate supportive treatment. Permanently discontinue ocrelizumab in these patients. Severe IRRs- If a patient experiences a severe IRR or a complex of flushing, fever, and throat pain symptoms, the infusion should be interrupted immediately and the patient should receive symptomatic treatment. The infusion should be restarted only after all symptoms have resolved. The initial infusion rate at restart should be half the infusion rate at the time of onset of the reaction. Mild to Moderate IRRs- If a patient experiences a mild to moderate IRR (e.g. headache), the infusion rate should be reduced to half the rate at the onset of the event. This reduced rate should be maintained for at least 30 minutes. If tolerated, the infusion rate may then be increased according to the patient's initial infusion schedule.

Practice Points	HBV screening should be carried out prior to commencing on treatment. Patients should be informed IRRs can occur within 24 hours of an infusion. If IRR symptoms are noted post-discharge, the patient should be advised to contact their healthcare team immediately Store vial in a refrigerator at 2°C to 8°C. Keep vial in the outer carton in order to protect from light. Do not freeze. Do not shake. Do not use after the expiry date (EXP) shown on the pack. **First aid measures** Eye contact - rinse immediately with tap water for at least 20 minutes – open eyelids forcibly begin with medical treatment. Skin contact - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents Inhalation - remove the casualty to fresh air in the event of symptoms get medical treatment
Basis of Protocol/Guideline (including sources of evidence, references)	Ocrevus Product Information Roche PI 170623 Introducing OCREVUS® a guide for health professionals Roche Safety Data Sheet OCREVUS® Vials 300 mg/10 ml- Roche
Consultation	Pharmacy dept, POWH

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GOVERNANCE	
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