MONOGRAPH

Eculizumab

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

⚠ HIGH RISK MEDICINE ⚠

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Complement C5 inhibitor humanised monoclonal antibody[1, 2, 3]

Eculizumab is a High Risk Medicine.

Emetogenic Rating: Minimal. Refer to Anti-cancer Induced Nausea and Vomiting (AINV) Management Guideline.

INDICATIONS AND RESTRICTIONS

Indications for paediatric patients:

- Atypical haemolytic uraemic syndrome (aHUS)[2, 4, 5]
- Transplant-associated thrombotic microangiopathy (TA-TMA)[6]

All Non-PBS indications require Individual Patient Approval (IPA) from the hospital's Drug and Therapeutics Committee. The IPA form is accessible at PCH from the Formulary One page.

CONTRAINDICATIONS

- Hypersensitivity to eculizumab, murine proteins or any component of the formulation.[2, 4]
- Unresolved *Neisseria meningitis* infection.[1, 2, 4, 8]
- Patients not currently vaccinated against *Neisseria meningitis* (unless risk of treatment delay outweighs the risk of developing a meningococcal infection. These patients should receive appropriate prophylactic antibiotic treatment until at least 2 weeks after vaccination).[1, 2, 4]

PRECAUTIONS

- The use of eculizumab increases the patient's susceptibility to meningococcal infection (*Neisseria meningitis)*.[4] Meningococcal infection due to any serogroup may occur.[4] All patients must be vaccinated at least 2 weeks prior to receiving eculizumab.[4] Vaccines against serogroups A, B,C,Y and W135 are recommended. Patients who initiate eculizumab treatment less than 2 weeks after receiving a meningococcal vaccine must receive appropriate prophylactic antibiotics until 2 weeks after vaccination.[4]
- Vaccination reduces, but does not eliminate, the risk of meningococcal infections.[9] Monitor for early signs of meningococcal infection.[4] Evaluate immediately if infection is suspected and treat with appropriate antibiotics if necessary.[4]
- The risk of other infections, especially encapsulated bacteria (e.g. *Streptococcus pneumoniae*, *H. influenzae*) is increased with eculizumab treatment.[1] Aspergillus infections have occurred in immunocompromised and neutropenic patients.[1, 10] Patients under 18 years of age must be vaccinated against *Haemophilus influenzae* and *Streptococcus pneumoniae* and strictly adhere to the national vaccination recommendations of each age group.
- Use with caution when administering to patients with any systemic infections.[1]
- Infusion reactions, including anaphylaxis or hypersensitivity may occur; interrupt infusion for severe reactions (e.g. cardiovascular instability, respiratory compromise).[1, 10, 11]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Eculizumab 300 mg/30 mL vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

IV Infusion

Atypical haemolytic uraemic syndrome (aHUS)[1, 2]

Patient Body Weight	Induction dose	Maintenance dose
5 kg to < 10 kg	300 mg weekly x 1 dose	300 mg on week 2; then 300 mg every 3 weeks
10 kg to < 20 kg	600 mg weekly x 1 dose	300 mg on week 2; then 300 mg every 2 weeks
20 kg to < 30 kg	600 mg weekly x 2 doses	600 mg on week 3; then 600 mg every 2 weeks
30 kg to < 40 kg	600 mg weekly x 2 doses	900 mg on week 3; then 900 mg every 2 weeks
≥ 40 kg	900 mg weekly x 4 doses	1200 mg on week 5; then 1200 mg every 2 weeks

- Eculizumab should be administered at the recommended dosage regimen time points, or within 2 days of these time points.[2] If a scheduled dose is missed, monitor for signs and symptoms of TMA complication and resume the regular schedule as soon as possible.[2]

Supplemental dosing of eculizumab for patients receiving plasmapheresis, plasma exchange or fresh frozen plasma infusion[1, 2]

Type of Intervention	Most recent Eculizumab dose	Eculizumab dose with each intervention	Timing of supplemental Eculizumab dose
Plasmapheresis or plasma exchange	300 mg	300 mg for each plasmapheresis or plasma exchange session.	Within 60 minutes **after** each plasmapheresis or plasma exchange session.
	600 mg or more	600 mg for each plasmapheresis or plasma exchange session.	
Fresh frozen plasma infusion	300 mg or more	300 mg per infusion of fresh frozen plasma.	60 minutes **prior** to each infusion of fresh frozen plasma.

Transplant-associated thrombotic microangiopathy (TA – TMA)

Starting dose recommendations[6]:

Patient Body Weight	Dose	Interval	
		Elevated sC5b-9	Normal sC5b-9
< 10 kg	300 mg IV over 60 minutes	May be given at 72-hour intervals until sC5b-9 normalises, then transition to weekly dosing depending on the patient's clinical response.	Weekly
10 kg – 39 kg	600 mg IV over 60 minutes		
≥ 40 kg	900 mg IV over 60 minutes		

sC5b-9 = soluble terminal complement complex activity.

Maintenance Therapy

- Patients < 10 kg: 300 mg every 14 days for 2 doses
- Patients ≥ 10 kg: reduce current dose by 300 mg and give every 7 days for 4 doses
    - When tapering therapy, the lowest dose for patients 10-20 kg is 300 mg every 7 days and the lowest dose for patients > 20 kg is 600 mg every 7 days. This should be continued for at least 2 doses.

Renal impairment:

- No dosage adjustments provided by manufacturer's labelling[1, 2]

Hepatic impairment:

- No dosage adjustments provided by manufacturer's labelling[1, 2]

RECONSTITUTION & ADMINISTRATION

- Eculizumab infusion is prepared by Pharmacy Compounding Service (PCS). During pharmacy operating hours, all orders must be reviewed by a clinical pharmacist prior to preparation by PCS.
- Eculizumab should not be prepared by staff who are pregnant or immunocompromised.
- At the ward level, the following Personal Protective Equipment should be worn during administration[3]:
    - N95 mask
    - Gloves
    - Protective eye wear – to be worn during preparation and when connecting and disconnecting the infusion.
    - Gowns are not required.

- The final infusion volume:[3]

Eculizumab Dose	Final Volume
300 mg	60 mL
600 mg	120 mL
900 mg	180 mL
1200 mg	240 mL

- Allow the infusion to reach room temperature prior to administration.[1, 2] The infusion bag should be inspected visually for particulate matter and discolouration prior to administration.[2] **Do not shake**.[3]
- Administer as an intravenous infusion over 1 - 4 hours via an infusion pump.[2] If an adverse reaction occurs, slow or stop the infusion at the discretion of the treating physician.[1, 2, 3] If the infusion is slowed, the total infusion time should not exceed **FOUR** hours.[1, 2]
- The diluted solution does not require light protection during administration.
- Do not administer as an IV push or bolus injection.[1, 2, 3]
- Adrenaline (epinephrine) must be available for immediate use. It is recommended that emergency medication doses are calculated and prescribed on the WA Paediatric Hospital Medication Chart (pHMC) for use if required for anaphylactic reactions.

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

Sodium chloride 0.9%; Sodium chloride 0.45%; Glucose 5%; Ringer's[3]

Compatible and INCOMPATIBLE drugs:

Eculizumab is not routinely administered with other medications. *Compatibilities of IV drugs* must be checked when two or more drugs are given concurrently.

MONITORING

Prior to administration

- Review vaccination history.[2] (see Precautions)
- Baseline full blood count (FBC) with differential, lactic dehydrogenase (LDH), serum creatinine, LFTs, urinalysis.[1, 2]
- Full observations should be recorded on the age-appropriate observation and response chart including temperature, pulse, respiratory rate, blood pressure and oxygen saturation.

During infusion

- Temperature, pulse, respiratory rate, blood pressure, and oxygen saturation every 15 minutes for the first 2 hours of infusion, then every half an hour until completion of infusion.

- Monitor for signs and symptoms of infusion reactions.[2, 3] Infusion reactions are common and include chills, fever and flu-like symptoms.[3] In the event of an infusion reaction, the medical team must be notified immediately. The infusion can be slowed or stopped at the discretion of the treating physician.

Post administration

- Monitor patient for 1 hour post infusion for signs and symptoms of infusion reactions.[2, 3] Consider further monitoring at the discretion of the treating physician.

Meningococcal infection is the most serious adverse reaction. Monitor for signs and symptoms of meningococcal infection.[3]

Monitoring during therapy for TA-TMA[6]

Prior to the first eculizumab dose	• CH50 (total complement activity) • sC5b-9 • ADAMTS13 activity • Cystatin C GFR • Multi-organ dysfunction syndrome (MODS) assessment
During therapy	• *Before each dose*: CH50 • *Twice a week*: LDH • *Weekly*: sC5b-9, urine protein:creatinine ratio, haptoglobin, red blood cell or platelet transfusion requirement, Cystatin C GFR, MODS assessment
Stop eculizumab therapy when	• sCb5-9 remains normal • No active haematologic TA-TMA signs • MODS improved or no progression • The above listed criteria are sustained for at least 2 dosing cycles on the minimum planned dose as part of therapy taper.

Monitoring after treatment discontinuation

Monitor any patient who discontinues eculizumab for at least 12 weeks to detect thrombotic microangiopathy complications.[2] This can be identified by either any TWO, or repeated measurement of any one of the following[2]:

- A decrease in platelet count of 25% or more as compared to either baseline or to peak platelet count during eculizumab treatment.[2]
- An increase in serum creatinine of 25% or more as compared to baseline or to nadir during eculizumab treatment.[2]
- An increase in serum LDH of 25% or more as compared to baseline or to nadir during eculizumab treatment.[2]

Thrombotic microangiopathy complications should be suspected if the patient develops any one of the following[2]:

- A change in mental status or seizures[2]
- Angina or dyspnoea[2]
- Thrombosis[2]

ADVERSE EFFECTS

Common: Hypertension, tachycardia, peripheral oedema, hypotension, headache, insomnia, fatigue, skin rash, pruritus, hypokalaemia, diarrhoea, vomiting, nausea, abdominal pain, gastroenteritis, urinary tract infection, proteinuria, infection, asthenia, arthralgia, musculoskeletal pain, eye disease, renal insufficiency, cough, nasopharyngitis, nasal congestion, upper respiratory tract infection, rhinitis, bronchitis, fever.[1, 4, 11]

Infrequent: Meningococcal infection, fungal infection, sepsis, septic shock, alopecia, anaphylactic reaction, hypersensitivity, gastroenteritis, oropharyngeal pain, antibody development.[1, 4, 11]

Rare: Aspergillosis, genitourinary infection, septic meningitis, systemic lupus erythematosus, abnormal clotting factor, abnormal dreams, gastroesophageal reflux disease.[1, 4]

STORAGE

- Vial: Store at 2 – 8 °C in the original carton until time of use. Protect from light. Do not freeze. Do not shake.[2, 3]
- Vials in original packaging may be removed from refrigerated storage (up to 25 °C) for only one excursion of up to 3 days.[2, 3] May be returned to the fridge.[2, 3]
- Diluted solutions of eculizumab are stable for 24 hours at 2 – 8 °C and below 25 °C.[3]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **Eculizumab**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Anti-Cancer Therapy Induced Nausea and Vomiting (AINV) Management

Antineoplastic (Cytotoxic) Agents Safe Handling and Administration

Extravasation of Antineoplastic (Cytotoxic) Agents

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