EMICIZUMAB

CLINICAL CRITERIA FOR ACCESS

Access to be in line with clinical criteria described below, at authorised hospital sites, prescribed by a Pharmaceutical and Therapeutics Committee (PTC) authorised prescriber (preferably by clinical haemotologist).

Indication

Severe haemophilia A with factor VIII inhibitors, in patients where emicizumab therapy would be cost-neutral or cost-saving compared to the use of on-demand bypassing agents for the management of bleeds*; on a patient-by-patient basis.

This could include the following patients:

- Patients who have had an intracranial or other life-threatening bleed
- Patients who have an annualised bleeding rate (ABR) of ≥12 (any bleed**)

**Estimated at R2.5 million annual expenditure per patient (2024 prices). See costing report.*

*** Any bleeding event defined as:*

Major bleeds:

- » *central nervous system (CNS) – intracranial*
- » *gastrointestinal tract*
- » *urogenital tract including gross haematuria*
- » *severe injury*
- » *neck/throat (airway)*
- » *muscle compartment (e.g. forearm and calf)*
- » *advanced joint and soft tissue*
- » *hip and ilio-psoas muscle*

Minor bleeds

- » *early joint bleed (Pain/tingling in a joint of a patient with haemophilia suggests bleeding)*
- » *muscle*
- » *soft tissue*
- » *epistaxis*
- » *mild to moderate mouth and gum*
- » *mild to moderate haematuria*

Motivation for use should include the following information:

- Patient details and demographics
- Diagnosis of severe haemophilia
- Presence of factor VIII inhibitors
- Clinical status and prognosis
- Previous major bleeding episodes
- Extent of bypassing agent usage

Regimen

Medicine	Emicizumab	
Route	Subcutaneous injection	
Dose	LOADING DOSE:	3 mg/kg weekly for 4 weeks
	MAINTENANCE DOSE:	**THEN** 1.5 mg/kg weekly OR 3 mg/kg every 2 weeks OR 6 mg/kg monthly

» *Current available strength of emicizumab: 30 mg, 60 mg, 105 mg, 150 mg.*

» Adhere to the principle of rounding off dosage in mg, to appropriate vial(s), so as not to discard any product.

Monitoring

- Utilisation (of both emicizumab and bypassing agents to treat bleeds) and outcomes should be monitored by responsible Facility and Provincial Pharmaceutical and Therapeutic Committees (PTCs).