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Department:
Health
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NOTICE: CRITERIA FOR EMICIZUMAB USE AS ROUTINE PROPHYLAXIS IN THE MANAGEMENT OF PATIENTS WITH HAEMOPHILIA A WITH FACTOR VIII INHIBITORS

The National Essential Medicines List Committee (NEMLC) has approved the inclusion of emicizumab as routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in adults and children with severe haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors, as a special access medicine on the Tertiary and Quaternary Level Essential Medicines List (EML).[1] A guidance document outlining the criteria for the special access use has been developed.[2]

As per the Criteria for Use document[2], access should be in line with the specified clinical criteria, at authorised hospital sites, prescribed by a Pharmaceutical and Therapeutics Committee (PTC) authorised prescriber (preferably by clinical haematologist).

Emicizumab is indicated for severe haemophilia A with factor VIII inhibitors in patients where emicizumab prophylaxis therapy would be **cost-neutral or cost-saving** compared to use of on-demand bypassing agents for the management of bleeds.
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 bleeding event).

Any bleeding event is 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

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

The use of emicizumab should be managed through motivation/ appropriate restrictions at facilities and the motivation should include:

- Patient details and demographics
- Clinical status and prognosis

[1] https://www.health.gov.za/wp-content/uploads/2024/09/hltaqReview-Emicizumab_20230309_N_30-Mar-2023-updated-Aug-2024_2.pdf
[2] https://www.health.gov.za/wp-content/uploads/2024/09/hltaqClinical-criteria-access-to-Emicizumab-N-August-2024.pdf

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- Diagnosis of severe haemophilia
- Presence of factor VIII inhibitors
- Previous major bleeding episodes
- Extent of bypassing agent usage

The recommended regimen is as follows:

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

The medicine review, criteria for use document and other related documents can be accessed on the NHI webpage, Hospital Level – Tertiary and Quaternary tab on the following link: https://www.health.gov.za/nhi-edp-stgs-eml/.

The National Department of Health (NDoH) is in the process of developing a tool to monitor the utilisation and treatment outcomes of both emicizumab and bypassing agents in the group of patients with haemophilia A with inhibitors. Treatment Centres and Provincial PTCs are responsible for monitoring the utilisation and outcomes.

Provinces and Healthcare Facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees. Kindly share with all healthcare professionals and relevant stakeholders.

Kind regards,

K Jamaloodien

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