Emicizumab

Adjudication Guideline

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Daman	Medical Standards & Research	**N/A**

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1. Abstract

1.1 For Members

Emicizumab is a medication that gives to patients with haemophilia A with or without factor VIII inhibitors, which is a condition where blood doesn't clot as it should. It's like a substitute clotting factor, stepping in to prevent and manage bleeding episodes. Its typically prescribed and administered by eligible clinician specialities. These professionals have the expertise to assess the individual needs of patients with haemophilia and determine the appropriate use and dose of Emicizumab based on factors like the type and severity of haemophilia.

1.2 For Medical Professionals

Haemophilia A is a rare condition that affects the blood's ability to clot. Haemophilia A is usually inherited and usually occurs in males. Instances of haemophilia in females are rare.

Symptoms of haemophilia A can be mild to severe, depending on the patient's level of clotting factor VIII. People with haemophilia A may bruise easily and bleed for longer than people who do not have haemophilia A.

People with haemophilia A are currently treated by replacing the missing factor VIII.

Emicizumab is indicated for routine **prophylaxis** of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency):

- With factor VIII inhibitors.
- Without factor VIII inhibitors who have:
    i. severe disease (FVIII < 1%).
    ii. moderate disease (FVIII ≥ 1% and ≤ 5%) with severe bleeding phenotype.

Emicizumab can be used in all patient age.

2. Scope

This guideline provides information on the coverage criteria for Emicizumab, a medication used for the prevention or reduction of bleeding episodes in patients with haemophilia A with or without factor VIII inhibitors. It is designed to ensure appropriate use and allocation of resources for this therapy.

DOSAGE AND ADMINISTRATION

Table A.

Level	Dosage	Interval
Initiation or loading dose	3 mg/kg	Once weekly for first 4 weeks
Maintenance dose	1.5mg/kg	Once weekly or every 2 weeks or every 4 weeks.

Dosage forms and Name/Strengths of the medicinal products available:

Package Name	Generic Name	Dosage form
Hemlibra	Emicizumab	30 mg/mL in a single-dose vial
Hemlibra	Emicizumab	60 mg/0.4 mL in a single-dose vial
Hemlibra	Emicizumab	105 mg/0.7 mL in a single-dose vial
Hemlibra	Emicizumab	150 mg/mL in a single-dose vial

Table B.

Discontinue prophylactic use of bypassing medications the day before starting Emicizumab. The prophylactic use of Factor VIII products may be continued during the first week of Emicizumab prophylaxis.

- If appropriate, a patient or caregiver may self-inject Emicizumab.
- Self-administration is not recommended for children < 7 years of age.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

- Patient must have a confirmed diagnosis of haemophilia A with or without factor VIII inhibitors.
- Documentation of clinical symptoms, family history, factor VIII activity level
- Inhibitor levels and history of inhibitor development should be evaluated.
- Documentation of previous treatment(s) with factor VIII replacement therapy and evidence of suboptimal response or adverse effects should be provided.

Table C. Initial therapy for patients:

Condition	Description
Haemophilia A with Factor VIII Inhibitors	Positive Factor VIII inhibitor titre if it is greater than 5 Bethesda Units **OR**
	Positive Factor VIII inhibitor titre less than or equal to 5 Bethesda Units **AND** Patient experienced an inadequate clinical response of Factor VIII product treatment dosing.
Haemophilia A without Factor VIII Inhibitors	Severe to moderate severe disease as defined by pre-treatment Factor VIII levels ≤ 2% of normal: **OR**
	Patient has moderate to mild disease as defined by pre-treatment Factor VIII levels greater than 2% of normal AND has **one** of the following: A. Patient has experienced a severe, traumatic, or spontaneous bleeding episode. B. Patient has haemophilia-related joint damage, has experienced a joint bleed, or has a specific joint that is subject to recurrent bleeding (presence of a target joint). C. Patient is in a perioperative situation and/or has an additional clinical scenario regarding bleeding/bleeding risk in which the prescriber determines the use of Emicizumab is warranted.

- Investigations prior to initiation, dosing, and re-initiation:

Table D.

Test	Reference range
Chromogenic FVIII activity tests	Decreased or absent factor VIII levels: Severe: <0.01 international units/mL Moderate: 0.01 to 0.05 international units/mL Mild: >0.05 but <0.40 international units/mL
Anti-Emicizumab antibodies once yearly	

3.2 Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.
- Kindly code the ICD-10 and the CPT codes to the highest level of specificity.
- Covered only for eligible clinician specialties.

Eligible clinician speciality
Internal Medicine
Haematology
Paediatric Oncology and Haematology
Medical Oncology
Critical Care Medicine

3.3 Non-Coverage

Visitor plan

3.4 Payment and Coding Rules

DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC-004	Service is not clinically indicated based on good clinical practice
MNEC-003	Diagnoses are not covered
AUTH-001	Prior approval is required and was not obtained

5. Appendices

5.1 References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761083s000lbl.pdf
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5.2 Revision History

Date	Change(s)
28/01/2024	New version