NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Denecimig (Mim8) for preventing bleeding episodes in haemophilia A in people of any age [ID6400]

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of denecimig (Mim8) within its marketing authorisation for preventing bleeding episodes in haemophilia A in people of any age, with or without inhibitors.

Background

Haemophilia is a rare, lifelong genetic condition that affects the ability of blood to clot. This is caused by the inability or reduced ability of the body to produce proteins called clotting factors which are needed for clotting. In haemophilia A the factor affected is called factor VIII (eight). Haemophilia A is an inherited condition predominantly found in males. Females who carry the haemophilia gene may have mild or, rarely, moderate to severe symptoms of bleeding.

The main symptom of haemophilia is prolonged bleeding. Other complications can include bleeding into joints and muscles without having had an injury. Severity of haemophilia is classed according to how much clotting factor is missing compared with normal expected levels of clotting factor. Mild haemophilia is classed as having between 5% to 40% of normal clotting factor. Moderate haemophilia is classed as having between 1% and 5% of normal clotting factor. Severe haemophilia is classed as having less than 1% of normal clotting factor.

About 5 to 7% of people with haemophilia A develop antibodies to replacement clotting factor, called inhibitors, which makes treatment with clotting factor replacement less effective.[2] Having inhibitors makes controlling bleeding more difficult and is associated with increased risk of medical complications, pain and quality of life.[1]

The prevalence of haemophilia A is estimated at around 20 per 100,000 male births.[2] Registry data suggests that in 2024/2025 there were 4,395 people with mild, 800 with moderate and 2,404 with severe haemophilia A in the UK.[3]

Current clinical management of haemophilia A involves prophylactic treatment to prevent bleeding and long-term damage caused by bleeding, and on-demand treatment in response to bleeding episodes. Replacement of the missing clotting factor VIII in the blood through an intravenous infusion of clotting factor concentrate is used as a prophylactic and on-demand treatment. However, this is ineffective for people with inhibitors, so bypassing agents (BPA) can also be used in acute treatment to bypass the inhibitors and activate the blood clotting system.[4]

For people aged 2 years and over with severe haemophilia A, NICE technology appraisal guidance 1051, recommends efanesoctocog alfa as acute and prophylactic treatment. NHS England has a clinical commissioning policy for emicizumab as a

further prophylactic treatment option in people with haemophilia A with inhibitors, and in people with severe and moderate haemophilia A without inhibitors.[4, 5, 6]

The technology

Denecimig (Mim8; brand name unknown, Novo Nordisk) does not currently have a marketing authorisation in the UK. It has been studied in clinical trials in adults and children with haemophilia A with or without inhibitors.

Intervention(s)	Denecimig (Mim8)
Population(s)	People with haemophilia A
Subgroups	If the evidence allows the following subgroups will be considered: • severity of haemophilia • presence or development of inhibitors • previous treatment status

Comparators	Prophylactic treatments:
	• For people with inhibitors, or severe or moderate disease without inhibitors:
	  • Emicizumab (in accordance with NHS England's clinical commissioning policies)
	• For people 2 years and over with severe disease:
	  • Efanesoctocog alfa
	• For all people:
	  • Factor VIII replacement therapy (excluding efanesoctocog alfa)
	  • Standard care with or without prophylaxis

Outcomes	The outcome measures to be considered include: • annualised bleeding rate • need for further treatment with factor VIII injections or bypassing agents (BPA) • duration of response to treatment • complications and resolutions to complications of the disease (for example joint problems and joint surgeries) • mortality • adverse effects of treatment • development of antibodies to the technology (anti-drug antibodies) • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account. The use of denecimig (Mim8) may be conditional on the presence of anti-drug antibodies (antibodies against denecimig (Mim8). If so, the economic modelling should include the costs associated with testing for anti-drug antibodies in people with haemophilia A who would not otherwise have been tested.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:**

	Marstacimab for treating severe haemophilia A or B in people 12 years and over without anti-factor antibodies. (2025) NICE Technology appraisal guidance 1073. Efanesoctocog alfa for treating and preventing bleeding episodes in haemophilia A in people 2 years and over (2025) NICE Technology appraisal guidance 1051. **Related technology appraisals in development:** Valoctocogene roxaparvovec for treating severe haemophilia A. NICE technology appraisal guidance [ID3806] Publication date to be confirmed. Concizumab for treating severe haemophilia A or moderate to severe haemophilia B in people 12 years and over without inhibitors. NICE technology appraisal guidance [ID5099] Publication date to be confirmed. Concizumab for treating haemophilia A or B in people 12 years and over with inhibitors. NICE technology appraisal guidance [ID6665] Publication date to be confirmed. Marstacimab for treating severe haemophilia A or B in people 12 years and over with inhibitors to factor-replacement therapy. NICE technology appraisal guidance [TSID12143] Publication date to be confirmed
Related National Policy	NHS England (2013) 2013/14 NHS standard contract for haemophilia (all ages) section B part 1 - service specifications The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019). Chapter 132. NHS England. 2013/14 NHS Standard Contract for haemophilia A (all ages). B05/S/a NHS England. Clinical Commissioning Policy: Emicizumab as prophylaxis in people with severe congenital haemophilia A without factor VIII inhibitors (all ages). 170134P. August 2019. NHS England. Clinical Commissioning Policy: Emicizumab as prophylaxis in people with congenital haemophilia A with factor VIII inhibitors (all ages). 170067/P. July 2018. NHS England. Clinical Commissioning Policy: Emicizumab for prophylaxis of bleeding episodes in people with moderate haemophilia A without inhibitors (all ages) [URN 2333]. July 2025

References

1 World Federation of Haemophilia (WFH) guidelines for the Management of Hemophilia (2020), 3rd edition. Chapter 8: Inhibitors to Clotting Factor. Accessed 23/01/25. Available: https://onlinelibrary.wiley.com/doi/10.1111/hae.14046

2 National Organisation for Rare Disorders. Hemophilia A. (2022). Available from: https://rarediseases.org/rare-diseases/hemophilia-a/ [Accessed November 2025]

3 United Kingdom Haemophilia Centres Doctors' Association (2025). Available from: UKHCDO Annual Report 2024 & Bleeding Disorder Statistics for 2023/2024 [Accessed January 2025]

4 NHS England. Emicizumab as prophylaxis in people with congenital haemophilia A with factor VIII inhibitors (all ages). Clinical Commissioning Policy 170067/P. July 2018. [Accessed January 2026]

5 NHS England. Emicizumab as prophylaxis in people with severe congenital haemophilia A without factor VIII inhibitors (all ages). Clinical Commissioning Policy 170134P. August 2019. [Accessed November 2025]

6 NHS England. Emicizumab for prophylaxis of bleeding episodes in people with moderate haemophilia A without inhibitors (all ages). Clinical Commissioning Policy URN 2333. July 2025. [Accessed January 2026]