



Final Appraisal Recommendation

Advice No: 1613 – June 2013

C1-esterase inhibitor (Berinert[®]) 500 units powder and solvent for solution for injection/infusion

Submission by CSL Behring UK Ltd

Recommendation of AWMSG

C1-esterase inhibitor (Berinert[®]) is recommended as an option for use within NHS Wales for the treatment of acute episodes of hereditary angioedema type I and II.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

Additional notes:

- AWMSG is of the opinion that C1-esterase inhibitor (Berinert[®]) therapy should be initiated under supervision of a physician experienced in the care of patients with hereditary angioedema.
- C1-esterase inhibitor (Berinert[®]) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.

In reaching the above recommendation, AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1425), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue:	CSL Behring UK Ltd
Date of first issue	June 2013
Last reviewed	September 2016



NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendation. Accreditation is valid for 5 years from October 2011. More information on accreditation can be viewed at www.evidence.nhs.uk.

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