Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 2117 – October 2017

C1 inhibitor (human) (Cinryze®) 500 International Units powder and solvent for solution for injection

Limited submission by Shire Pharmaceuticals Limited

Recommendation of AWMSG

C1 inhibitor (human) (Cinryze®) is recommended as an option for use within NHS Wales for the treatment and pre-procedure prevention of angioedema attacks in adults, adolescents and children (2 years old and above) with hereditary angioedema (HAE); routine prevention of angioedema attacks in adults, adolescents and children (6 years old and above) with severe and recurrent attacks of HAE, who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment.

Additional note(s):

- AWMSG considered that C1 inhibitor (human) (Cinryze®) satisfied the AWMSG criteria for a medicine developed specifically for rare diseases.
- AWMSG is of the opinion that C1 inhibitor (Cinryze®) therapy should be initiated under supervision of a physician experienced in the care of patients with hereditary angioedema (HAE).
- C1 inhibitor (Cinryze®) should be prescribed by brand name to avoid automatic substitution and therefore help with pharmacovigilance.
- This advice incorporates and replaces the existing AWMSG recommendation on C1 inhibitor (Cinryze®) for the treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with HAE, and routine prevention of angioedema attacks in adults and adolescents with severe and recurrent attacks of HAE who are intolerant to or insufficiently protected by oral prevention treatments or who are inadequately managed with repeated acute treatment (Advice number 0313, originally published March 2013).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3295), 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	Shire Pharmaceuticals Limited
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