

Final Appraisal Recommendation

Advice No: 0217 – February 2017

Human alpha1-proteinase inhibitor (Respreeza[®]) 1,000 mg powder and solvent for solution for infusion

Submission by CSL Behring UK Ltd

Recommendation of AWMSG

Human alpha1-proteinase inhibitor (Respreeza[®]) is not recommended for use within NHS Wales for maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha1-proteinase inhibitor deficiency (e.g. genotypes PiZZ, PiZ(null), Pi(null,null), PiSZ).

The case for clinical effectiveness and cost-effectiveness has not been proven.

Key factor(s) influencing the recommendation:

- The applicant company did not present sufficiently robust clinical and economic analyses to gain approval by AWMSG.

Additional note(s):

- AWMSG considered that human alpha1-proteinase inhibitor (Respreeza[®]) satisfied the AWMSG criteria for a medicine developed specifically to treat a rare disease.
- Patients who are currently being treated with human alpha1-proteinase inhibitor (Respreeza[®]) for the indication stated above should have the option to continue their therapy until they and their clinicians consider it appropriate to stop.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 47), 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.

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