

Statement of advice SMC2715

pegcetacoplan solution for infusion (Aspaveli®)

Swedish Orphan Biovitrum Ltd

09 August 2024

ADVICE: in the absence of a submission from the holder of the marketing authorisation **pegcetacoplan (Aspaveli®)** is not recommended for use within NHSScotland.

Indication under review: as monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have haemolytic anaemia.

This advice refers to use in treatment naive patients. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result, we cannot recommend its use within NHSScotland.

SMC has previously accepted pegcetacoplan (Aspaveli) for restricted use for treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months (SMC2451). This advice remains valid.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Chair Scottish Medicines Consortium