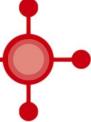
All Wales Medicines Strategy Group





AWMSG ADVICE SUPERSEDED BY NICE GUIDANCE (ID927)

NICE GUIDANCE ISSUED MAY 2018

(Refer to NICE website for full guidance on NICE recommendations, including any specific restrictions on the use of the technology)

Final Appraisal Recommendation Advice No: 1717 – September 2017

Afamelanotide (Scenesse®) 16 mg implant

Submission by Clinuvel Pharmaceuticals Ltd

Recommendation of AWMSG

Afamelanotide (Scenesse®) is not recommended for use within NHS Wales for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).

The case for cost-effectiveness has not been proven.

Key factor(s) influencing the recommendation:

 There are several uncertainties and limitations in the economic model provided in the company's submission.

Additional note(s):

- AWMSG considered that afamelanotide (Scenesse®) satisfied the AWMSG criteria for ultra-orphan status.
- Patients who are currently being treated with afamelanotide (Scenesse®) 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 634), 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.



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.

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

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All Wales Medicines Strategy Group Final Appraisal Recommendation – 1717: Afamelanotide (Scenesse®) 16 mg implant. September 2017