Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 0322 – February 2022

Ravulizumab (Ultomiris®) 300 mg/3mL and 1100 mg/11mL concentrate for solution for infusion

Licence extension for paediatric use submission by Alexion Pharmaceuticals.

Recommendation of AWMSG

Ravulizumab (Ultomiris®) is recommended as an option for use within NHS Wales for the treatment of paroxysmal nocturnal haemoglobinuria in paediatric patients with a body weight of 10 kg or above:

- **in patients with haemolysis with clinical symptom(s) indicative of high disease activity**
- **in patients who are clinically stable after having been treated with eculizumab for at least the past 6 months**

This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent or lower than the PAS price.

Additional note(s):

- See NICE guidance for ravulizumab (Ultomiris®) for the treatment of paroxysmal nocturnal haemoglobinuria in adults (TA698, originally published May 2021).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 4869), which includes the All Wales Therapeutics and Toxicology Centre (AWTTC) assessment, 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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NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendations. Accreditation is valid for 5 years from October 2016. More information on accreditation can be viewed at http://www.nice.org.uk/about/what-we-do/accreditation