All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Final Appraisal Recommendation

Advice No: 3113 - November 2013

Lixisenatide (Lyxumia®▼)
10 micrograms and 20 micrograms solution for injection

Submission by Sanofi

Recommendation of AWMSG

Lixisenatide (Lyxumia®▼) is recommended as an option for restricted use within NHS Wales.

Lixisenatide (Lyxumia®▼) should be restricted for use in the following circumstances within its licensed indication for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control:

- **In combination with basal insulin, with or without oral glucose-lowering medicinal products, in patients uncontrolled on basal insulin;**
- **In combination with oral glucose-lowering medicinal products in patients uncontrolled on two or more oral glucose-lowering medicinal products.**

Lixisenatide (Lyxumia®▼) is not recommended for use within NHS Wales outside of these circumstances.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 863), 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:	Sanofi-Aventis Ltd
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