

Enclosure No:	5/AWMSG/1116
Agenda Item No:	9 – Review of existing AWMSG advice: insulin detemir (Levemir®)
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Action for AWMSG:

Endorse the updated Final Appraisal Recommendation for insulin detemir (Levemir®) following a review of the recommendation.

Background:

Insulin detemir is licensed for treatment of diabetes mellitus, for which marketing authorisation was first granted in 2004. In 2011, the licence was extended to allow treatment of children aged 2 to 5 years. This licence extension was appraised by AWMSG using the limited submission process, and the following recommendation issued:

Insulin detemir (Levemir®) is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 2–5 years.

On 25 June 2015, the age group covered by the licensed indication was amended to allow treatment of children aged 1 year and above. Therefore the current licensed indication is:

Insulin detemir (Levemir) is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

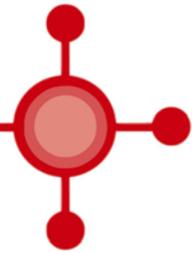
AWMSG advice on insulin detemir is undergoing 3-year review, and as part of this, it is proposed that the recommendation is updated to:

Insulin detemir (Levemir®) is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 1–5 years.

Consideration:

All AWMSG final appraisal recommendations are periodically reviewed. The review of the existing AWMSG advice on insulin detemir highlighted that the licensed indication has been amended to include children aged 1 year and above.

It is estimated that no more than four patients aged 1–2 years would be eligible for treatment with insulin detemir each year, at an estimated cost per patient of £75.50 per year. The maximum budget impact resulting from the use of insulin detemir in 1-2 year olds would therefore be £302.00 per year. This figure assumes that all eligible patients are treated with insulin detemir, and does not account for the savings from displacement of existing insulin treatment options. Therefore, the true budget impact is likely to be lower.



Final Appraisal Recommendation

Advice No: 3912 – November 2012

Insulin detemir (Levemir®) 100 U/ml solution for injection

Limited submission by Novo Nordisk Ltd

Recommendation of AWMSG

Insulin detemir (Levemir®) is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 1–5 years.

Additional notes:

- AWMSG is of the opinion that insulin detemir (Levemir®) may be appropriate for use within NHS Wales prescribed under specialist recommendation for the indication under consideration.
- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of 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:	Novo Nordisk Ltd
Date of first issue	November 2012
Last reviewed	November 2016

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All Wales Medicines Strategy Group. Final Appraisal Recommendation – 3912:
Insulin detemir (Levemir®) 100 U/ml solution for injection. November 2012.



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.

For full details on our accreditation visit: www.nice.org.uk/accreditation.