

**EXENATIDE PROLONGED-RELEASE FOR TYPE 2 DIABETES –  
RECOMMENDED FOR RESTRICTED USE**

Name of Treatment: generic (trade)	Indication	Date last revised	Status	NICE / SMC Guidance
Exenatide prolonged-release suspension for injection (Bydureon®)	Improve glycaemic control in type 2 diabetes	April 2012	Final	NICE – TA 248 – recommended for restricted use (Feb 2012) SMC – Recommended for restricted use (Jan 2012)

**HMMC RECOMMENDATION: Exenatide prolonged-release suspension for injection is **RECOMMENDED FOR RESTRICTED USE** as a treatment option for people with type 2 diabetes in accordance with the initiation and stopping criteria specified in the NICE guidance:**

#### Triple Therapy Regimes

- with metformin and a sulphonylurea, **or** metformin and pioglitazone as a treatment **option** when control of blood glucose remains or becomes inadequate ( $HbA_{1c} \geq 7.5\%$  [59 mmol/mol] **or other higher level agreed with the individual**), **AND** the person has:
  - a body mass index (BMI)  $\geq 35$  kg/m<sup>2</sup> in those of European family origin (with appropriate adjustment for other ethnic groups) and specific psychological or medical problems associated with high body weight **OR**
  - a BMI  $< 35$  kg/m<sup>2</sup>, and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related comorbidities.
- **Treatment should ONLY be continued if there is a reduction of at least 1 percentage point in HbA<sub>1c</sub> [11 mmol/mol] AND a weight loss of at least 3% of initial body weight at 6 months.**

#### Dual Therapy Regimes

- with metformin **or** a sulphonylurea as a treatment **option** if:
  - the person is intolerant of either metformin **or** a sulphonylurea, **or** treatment with metformin **or** a sulphonylurea is contraindicated, **AND**
  - the person is intolerant of pioglitazone **and** dipeptidyl peptidase-4 (DPP-4) inhibitors, **or** treatment with pioglitazone **and** DPP-4 inhibitors is contraindicated.
- **Treatment should ONLY be continued if there is a reduction of at least 1 percentage point in HbA<sub>1c</sub> [11 mmol/mol] at 6 months.**

#### Points for consideration from NICE Guidance:

- NICE concluded that the continuation rules in current NICE guidance are appropriate for weekly exenatide.
- NICE highlights that **there is currently no available evidence for cardiovascular outcomes with weekly exenatide (there is no cardiovascular outcome data for the other GLP-1 receptor agonists).**
- NICE concluded that there was **no evidence that a weekly injection would improve adherence or outcomes** in any patient group to justify differential recommendations for weekly exenatide.
- Most common adverse drug reactions with weekly exenatide are mainly gastrointestinal (nausea, vomiting, diarrhoea and constipation), injection site reactions, hypoglycaemia (with a sulphonylurea) and headache.

#### Cost impact from NICE Costing statement:

- Significant impact on resources is not anticipated as weekly exenatide is recommended for the same people as daily exenatide and liraglutide (1.2mg) from NICE CG 87 & TA 203 and has a comparable cost.

#### Further Information

- Recommended dose is 2 mg once weekly administered on the same day each week in the abdomen, thigh, or the back of the upper arm as a subcutaneous injection.

Refer to Summary of Product Characteristics for full details; [www.medicines.org.uk](http://www.medicines.org.uk)

**NICE TA248:** Exenatide prolonged-release suspension for injection in combination with oral antidiabetic therapy for the treatment of type 2 diabetes, February 2012 <http://guidance.nice.org.uk/TA248>