

## Enc 7 Appx 3

### Clinical Expert Summary Saxagliptin (Onglyza®) 2.5 mg and 5 mg film-coated tablets

Saxagliptin (Onglyza®) is indicated in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as triple oral therapy in combination with metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.

#### 1. Existing guidelines

The following guidelines were identified:

- National Institute for Health and Clinical Effectiveness (NICE). Type 2 diabetes – newer agents: Guidelines on the management of type 2 diabetes (clinical guideline 87 (2009). NICE guidelines for the management of type 2 diabetes are currently being revised with further guidance expected to be published in 2014.
- The All Wales Consensus Group. Designed for the management of adults with diabetes mellitus across Wales (2008). This guideline is consistent with NICE Clinical Guideline 87.

#### 2. Disease prevalence/incidence

Clinical experts referred to the publication 'Together for Health - the diabetes delivery plan up to 2016 for NHS Wales and its partners' (September 2013), which states that around 6% of the population of Wales are being treated for diabetes; 14% of which are over 65 years of age. They explain that the incidence of diabetes is increasing rapidly as the prevalence of obesity rises with the prevalence of diabetes amongst adults expecting to rise to 8.5% in 2020 and by 9.5% by 2030.

#### 3. Current treatment options

The options for third-line triple therapy (after metformin and a sulphonylurea) highlighted by clinical experts included the other gliptins (sitagliptin and vildagliptin) and other classes of hypoglycaemic drugs (pioglitazone, acarbose [rarely used in the UK], GLP-1RA injectables and insulin). Clinical expert opinion was that the most likely treatment in Wales would be gliptin due to the advantages in terms of side effect profile (low risk of hypoglycaemia, weight gain and gastro-intestinal upset) and the fact that they are oral agents.

#### 4. Unmet needs

Clinical experts highlighted that as type 2 diabetes is a progressive disease, lifestyle and then mono- and dual- therapies tend to fail, leading to the need for add-on treatments (triple therapy) over time. Experts also acknowledged that the licence extension under consideration is consistent with that of other approved drugs of the same class.

It was also highlighted that in a recent study, saxagliptin was demonstrated to have no significant effect on cardiovascular ischaemic events [NEJM 2013] while cardiac end point data on the other gliptins are awaited.

#### 5. Knowledge of product in given indication

Clinical expert opinion is that saxagliptin would provide an additional option for triple oral therapy, predominately replacing other drugs in the gliptin class, which are similarly priced. It was also noted that saxagliptin can be used in patients with mild to moderate renal impairment, a common problem in the elderly population.

**It should be noted that experts involved in compiling this response declared personal and non-personal, specific and non-specific interests in relation to saxagliptin for the indication under consideration.**