

6.3 DAPAGLIFLOZIN, 10 mg tablet, Forxiga[®], AstraZeneca Pty Ltd

1 Purpose of Application

- 1.1 To request amendments to the current restriction for dapagliflozin for use in diabetes mellitus type 2 (T2DM) to provide prescribers with clarity regarding the eligible PBS population.

2 Requested listing

- 2.1 The submission proposed the following changes to the restriction:

Authority Required

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Option 1: The ~~condition~~ disease must not be able to be adequately ~~controlled~~ managed by treatment with metformin and a sulfonylurea, irrespective of reason,

Option 2: The ~~condition~~ disease must not be able to be adequately ~~controlled~~ managed by treatment with metformin and a sulfonylurea,

AND

Wording continues as per current restriction

For more detail on PBAC's view, see section 7 "PBAC outcome"

3 Background

- 3.1 At its July 2013 meeting, the PBAC recommended the listing of dapagliflozin on the PBS on a cost minimisation basis with sitagliptin. The PBAC agreed that the restriction proposed by the submission appropriately limited use to the third line setting in combination with metformin or a sulfonylurea in patients whose diabetes, as measured by HbA1c, is not controlled on treatment with metformin and a sulfonylurea. However, the Committee recommended the restriction wording be modified to better reflect clinical practice in patients whose diabetes cannot be successfully managed with a combination of metformin and a sulfonylurea, irrespective of reason, are moved to dual therapy with metformin or a sulfonylurea, and a sodium glucose transporter 2 inhibitor, a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1. (Ratified Minutes July 2013, paragraph 2.2)

Listing was effective from 1 December 2013.

4 PBAC Outcome

- 4.1 The PBAC rejected the requested restriction changes of dapagliflozin.
- 4.2 The PBAC acknowledged the sponsor's concern about the current restrictions for dapagliflozin, specifically the interpretation of the words "condition" and "control" in the clinical criteria of the restriction and description of patient eligibility for PBS-

subsidised treatment. Specifically, the PBAC noted the sponsor's claim that the word 'condition' can be interpreted as type 2 diabetes in its entirety, or, to the level of blood glucose, and that the interpretation of the word 'control' is also directly related to the interpretation of the word 'condition'.

- 4.3 The PBAC noted that the listings data system used by the Department to give effect to PBS listings requires use of defined wording for clinical, treatment and population criteria used in PBS restrictions. For clinical criteria these wording options are:
- The condition must... / The condition must not...
 - Patient must... / Patient must not...
 - The treatment must... / The treatment must not...

Therefore, the PBAC considered that with the current data system it is not possible to change "condition" to "disease" in the clinical criteria as requested by the sponsor. The PBAC clarified that the term condition in the clinical criteria refers to type 2 diabetes mellitus.

- 4.4 The PBAC further noted that all submissions seeking PBS-listing of medicines for treatment of type 2 diabetes mellitus, including dapagliflozin, have used the surrogate outcome of change from baseline in HbA1c in support of their clinical claims. For purposes of clarity, the PBAC was of mind to amend the clinical criteria to "the condition must not be able to be adequately controlled, as measured by HbA1c...", noting that further consideration is required following the recommendations made for the Department's proposed amendments to the restrictions for PBS-subsidised third-line treatments for type 2 diabetes, considered in a separate item on this agenda.

Outcome:

Rejected

5 Recommended listing

- 5.1 No change to the existing listing.

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

7 Sponsor's Comment

The sponsor had no comment