

## **Ratified Minutes August 2013 PBAC Special Meeting**

### **Item 15 - Post-market review of products used in the management of diabetes, Pharmaceutical Policy Branch**

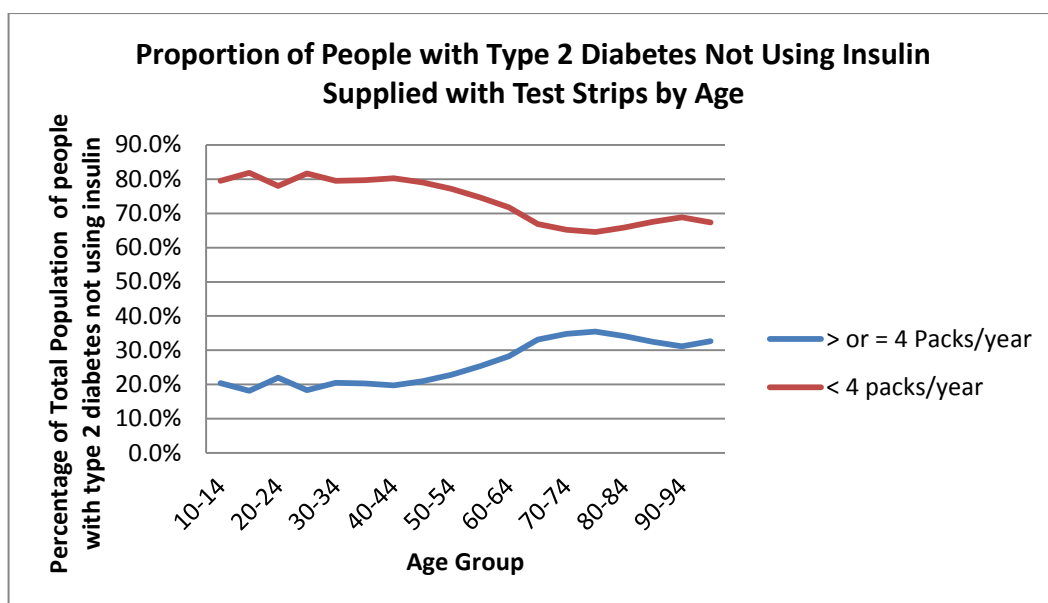
#### **Part 1: Blood Glucose Test Strips in People with Type 2 Diabetes Not Using Insulin**

##### **1 Purpose of Item**

- 1.1 The Department requested the PBAC to:
- i. Note the final Report for Stage 1 of the “Post-Market Review of Products Used in the Management of Diabetes”, which focused on the use of blood glucose test strips (BGTS) in people with type 2 diabetes not using insulin.
  - ii. Note the preference of the Diabetes Review Reference Group for Option 2, which provides up to 12 months access to test strips for people with type 2 diabetes not using insulin who are initiating or changing diabetes management, while maintaining ongoing access for a range of other sub-groups, such as people using insulin.
  - iii. Provide a recommendation considering the options provided in the Report to alter Pharmaceutical Benefits Scheme (PBS) restrictions for BGTS.

##### **2 Background**

- 2.1 In August 2012, the PBAC endorsed the following Terms of Reference (5-7) for the Diabetes Review:
- i. Describe the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) for people with type 2 diabetes;
  - ii. Determine the clinical outcomes and benefits (e.g. HbA1C) of SMBG relative to HbA1C monitoring alone for people with type 2 diabetes not treated with insulin; and
  - iii. Consider the clinical criteria for eligibility for subsidised access to BGTS under the PBS and National Diabetes Services Scheme (NDSS), accounting for clinical benefits offered through SMBG compared to regular HbA1C monitoring.
- 2.2 The PBAC noted the focus of this final Report was on the use of BGTS in people with type 2 diabetes, not using insulin. The PBAC noted a trend towards higher use of test strips in the older age groups, peaking at 75–79 year olds, where 35.5% had used four or more packs of test strips per year, as illustrated below:



- 2.3 The PBAC noted an increase in net growth of 6.3% per year of test strips, and the trends in the increasing supply from the NDSS and a declining use on the PBS. The average number of packs supplied per year per person with type 2 diabetes not using insulin was 3.06 in 2008–09, 3.08 in 2009–10, 3.09 in 2010–11 and 3.11 in 2011–12.
- 2.4 The PBAC acknowledged the stakeholders' feedback and input on the draft Report and noted they included: Diabetes Australia, the Australian Diabetes Educators Association, Roche Diagnostics, Abbott Diabetes Care, IVD Australia, the Consumers Health Forum of Australia, and the Australian Institute of Health and Welfare (AIHW).
- 2.5 The PBAC noted neither of the options proposed would change the current access arrangements for people with diabetes using insulin, people with gestational diabetes, people with inter-current illness, or those receiving treatment with a concomitant medicine that may adversely affect blood glucose control (e.g. corticosteroids, sulfonylureas).
- 2.6 The PBAC noted that access to BGTS for patients outside the categories above would be limited to those who are initiating, or have had a change in diabetes management (e.g. treatment or lifestyle change), to:
- Option 1: 3 months' access (100 strips, max qty 1, no. of repeats 2)
  - Option 2: 6 months' access (100 strips, max qty 1, no. of repeats 5), with an option for an additional 6 months access at the prescriber's discretion.
- 2.7 The PBAC noted the preference of the Diabetes Review Reference Group for Option 2, as it balanced the findings of the review with the clinical need for patients to access BGTS in a range of sub-groups such as patients on dietary management only or patients treated with oral medications only. It was noted that the Reference Group also preferred an Authority Required (STREAMLINED) restriction.

- 2.8 The PBAC noted Option 2 recommended an initial restriction where the patient will be able to access up to six months' supply. A 'continuing' supply for another six months would be available if the prescriber determines that the person would benefit from further monitoring. After 12 months' supply, only people requiring additional SMBG when further changes to diabetes management are made would be eligible to access test strips through the 'initial' restriction pathway. This recommendation was consistent with the findings of the Cochrane Review (2012) that indicate a minimal clinical benefit in improving blood glucose control at six months, which disappeared after 12 months' follow-up.

### **3 PBAC Outcomes**

- 3.1 The PBAC considered that Option 2 provided people with type 2 diabetes not using insulin who are initiating or require changes to existing diabetes management, access of up to 6 months' supply of test strips with the option to access an additional 6 months' supply under a continuing restriction at the prescriber's discretion if the patient will benefit from further monitoring. The PBAC therefore recommended Option 2 as it appropriately balances clinical need with the findings of the Diabetes Review.
- 3.2 The PBAC considered that given the volume of prescriptions, changing the restriction to 'Authority Required' and requiring prescribers to phone the Department of Human Services (DHS) for an authority approval number would create substantial administrative burden for DHS and prescribers. The PBAC recommended an Authority Required (STREAMLINED) restriction, to balance the need for compliance with administrative burden.
- 3.3 The PBAC recommended the possibility of making test strips available in smaller pack sizes (e.g. 50 strips) to reduce potential wastage and provide additional access for short-term use, such as during periods of inter-current illness. Overall, the proposed changes to the current PBS listing will remove the unrestricted listing for test strips and provide more guidance to the prescriber on the targeted use of the strips in specific groups of patients.
- 3.4 The PBAC suggested that changes to the current PBS restrictions should be reflected in the NDSS. The PBAC noted this restriction change may take longer to implement than other changes to the PBS because the NDSS operates on a different IT platform which does not include authorities or prescriptions. The NDSS would require system and IT changes.
- 3.5 The PBAC recommended that any changes to the PBS or NDSS should be communicated to stakeholders including NPS MedicineWise, Diabetes Australia and the Royal Australian College of General Practitioners (RACGP), the Australian College of Rural and Remote Medicine, Australian Diabetes Educators Association, Australian Diabetes Society and to Aboriginal and Torres Strait Islanders populations.