15 November 2012

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## Comment to the review of blood glucose monitoring strips – Stage 1 of the Diabetes Review by the Pharmaceutical Benefits Advisory Committee

AstraZeneca and Bristol-Myers Squibb are two companies with an expanding role and responsibility as stakeholders in diabetes management in Australia. This alliance continues to conduct substantial research, in Australia and globally, on the pharmacological management of high blood glucose, with studies ongoing involving:

- Saxagliptin: a PBS listed DPP-IV[1] inhibitor;
- Dapagliflozin: a SGLT-2[2] inhibitor;
- Exenatide: a PBS listed GLP-1[3] receptor agonist that has been recently acquired by the alliance;

These efforts are focussed on the best ways to use these medicines to secure a meaningful improvement in the health and long term outcomes for people with type 2 diabetes mellitus.

Stage 1 of the post market diabetes review is a call for submissions on the review of blood glucose test strips addressing terms of reference 5-7, detailed as follows:

5. Describe the utilisation and patterns of use of self-monitoring of blood glucose (SMBG) for people with type 2 diabetes;
6. Determine the clinical outcomes and benefits (e.g. HbA1C) of self-monitoring of blood glucose (SMBG) relative to HbA1C monitoring alone for people with type 2 diabetes not treated with insulin;
7. Consider the clinical criteria for eligibility for subsidised access to blood glucose test strips under the PBS and NDSS, accounting for clinical benefits offered through SMBG compared to regular HbA1C monitoring;

As an alliance, AstraZeneca and Bristol-Myers Squibb are well placed to provide data and insight into Stage 2 of the review, which centre on the medicines used to treat diabetes. However we would also like to provide brief commentary on SMBG gathered from our interactions with physicians and from the literature. Our comments are primarily related to the 6th and 7th terms of reference.

This submission to Stage 1 is consistent with the aim of the alliance – that is, providing the tools and evidence which enable physicians to provide the best outcomes for their patients with diabetes.

[1] Dipeptidyl peptidase-4
[2] Sodium glucose transport protein (subtype 2)
[3] Glucagon-like peptide-1

## Background

Australian Diabetes Guidelines on SMBG in people with T2DM state that "blood glucose control should be optimised because of its beneficial effects on the development and progression of microvascular complications", and that "self monitoring of blood glucose (SMBG) should be considered in all people with T2DM but the decision to perform SMBG, and the frequency and timing of testing, should be individualised." [4]

AstraZeneca and Bristol-Myers Squibb assert that:

- access to glucose strips is necessary when patients are on diabetes medications that have a high risk of hypoglycaemia (sulfonylureas and insulin)
- patients on sulfonylureas and insulin should measure their blood glucose levels regularly
- a reduction in the reliance of treatments that can cause hypoglycaemia may reduce the cost of SMBG
- SMBG can provide quality of life benefits to some patients through the reduction of anxiety and worry and an increase in compliance

In these cases, a physician may appropriately recommend no blood glucose testing for some patients, while for others some frequency of testing is appropriate and valuable. In all cases, AstraZeneca and Bristol-Myers Squibb recognise the clinician as the key decision maker.

## SMBG and the optimisation of the control of blood glucose

The mechanism by which SMBG can improve the control of blood glucose will vary by patient. A few of these mechanisms are briefly discussed below and, together, are relevant to the 6th and 7th terms of reference.

### *When hypoglycaemia is a risk due to use of specific drugs*

Some medicines are well recognised for their propensity to cause hypoglycaemia in some patients. The PBS schedule contains a caution that "sulfonylureas may cause hypoglycaemia, particularly in the elderly." [5] In a patient who has been identified as being at risk of hypoglycaemia because of the use of such a medicine either at initiation or when titration is necessary, a clear argument exists that there is value in SMBG.

However, the adverse event of hypoglycaemia, and the requirement for SMBG may be avoided in some patients if there is improved access to alternative treatments which have demonstrated lower rates of hypoglycaemia[6]. Similarly, avoidance of insulin will also remove the significant burden of SMBG on patients.

### *When hypoglycaemia is a risk due to patient characteristics*

[4] Colagiuri S, Dickinson S, Girgis S, Colagiuri R. National Evidence Based Guideline for Blood Glucose Control in Type 2 Diabetes. Diabetes Australia and the NHMRC, Canberra 2009

[5] Schedule of Pharmaceutical Benefits November 2012

[6] Resources and Activities on Type 2 Diabetes 2012, http://www.nps.org.au

Patient characteristics such as age and hepatic or renal insufficiency can increase the risk of hypoglycaemia[7]. In such cases, SMBG can represent a valuable safety tool for both patient and physician.

*Compliance*

The Australian Diabetes Education Association (ADEA) state that "*the availability of low cost blood glucose meters improves the ability of people with diabetes to intensively monitor and allows the person to become actively involved in the management of their disease. Self monitoring may contribute in several ways. Firstly, it can reinforce beneficial health behaviours and increase compliance with medication. The immediate feedback provided by self monitoring also helps to establish short term blood glucose patterns and, with appropriate education, assists people with diabetes to make day to day decisions regarding their therapy, such as appropriate insulin dose adjustment and management of hypoglycaemia and sick days*". [8]

Some people with diabetes, as in other chronic conditions, are naturally compliant while others require a tangible reminder or some other stimulus. As described by the ADEA, in some patients, a regular understanding of actual blood glucose levels assists compliance and can minimise anxiety and worry. The identification of these individuals is clearly best left to the physician.

## Conclusion and recommendation

In the experience of AstraZeneca and Bristol-Myers Squibb, physicians are almost invariably in the best position to identify patient risk and need, and act accordingly. Maintaining this system should be non-negotiable. In addition, increasing the access of treatments for T2DM that do not result in a requirement for SMBG is one option that may reduce the economic and clinical burden to both payers and patients.

[7] UKPDS Group. Lancet 1998;352:837–53

[8] Australian Diabetes Education Association Position Statement 2010