Post Market Review of Products Used in the Management of Diabetes

Stage 3 – Medicines used in the treatment of type 2 diabetes

Australian Diabetes Council

Contents

Acronyms and Abbreviations

AIHW	Australian Institute of Health and Welfare
DUSC	Drug Utilisation Sub-Committee
NDSS	National Diabetes Services Scheme
NHMRC	National Medical Research Council
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefit Scheme
Type 2	Type 2 diabetes

Executive Summary

Australian Diabetes Council is Australia's first, oldest and largest diabetes consumer organisation and welcomes the opportunity to participate in the review for Medicines used in the treatment of type 2 in Australia. We support the Government's efforts to ensure that clinical evidence underpins all aspects of diabetes management and care.

Australian Diabetes Council promotes evidence based, effective and sustainable health care delivery. As the peak Australian consumer body for people with and at risk of diabetes, Australian Diabetes Council advocates on behalf of our members as well as the wider community with and at risk of diabetes, and their families to ensure their voices are heard and their views well represented.

- Australian Diabetes Council recommends that the Expert Advisory Group considers experience, opinions and end-point outcomes of people living with the condition central to any review of compliance with PBS restriction and utilization patterns PBS approved diabetes pharmacological options for the treatment of type 2.

- Australian Diabetes Councils recommends that the person with type 2, their circumstance and individual needs remains central to any clinical decision. The possibility for long-term cost-efficiencies from individualised therapy options should not be compromised by an attempt to achieve short-term cost-efficiencies with a 'one-size-fits-all' model of access to pharmacological therapies.

- Australian Diabetes Council recommends that the Australian Government invests in a regular review and up-date of the national best-practice guidelines for type 2 to inform the PBAC, clinicians, people with diabetes, industry and other stakeholders.

- Australian Diabetes Council welcomes a review that has a broader view than short-term cost-efficiencies and only HbA1c lowering when considering pharmaceutical therapies for improving outcome for people with type 2.

- Australian Diabetes Council recommends introduction of time-frames that encourages inclusion of a wide scope of information and evidence that can contribute to improving health outcomes for people with diabetes and/or a significant difference to the quality of life people affected by the condition.

Introduction

Australian Diabetes Council

Formed in 1938 ADC is Australia's oldest and largest not-for-profit organisation focused on providing support and services nationally and internationally to people living with and at risk of diabetes, their families, carers, friends and health practitioners.

As the peak consumer body for diabetes, the first diabetes organisation in Australia and the third oldest diabetes association in the world, we have a long history of successfully working with our members to create a powerful shared voice for diabetes, now and in the future. We also play a vital role in informing the whole community about diabetes and its complications.

Australian Diabetes Council makes a positive difference to the everyday lives of those living with and at risk of diabetes and their carers. We do this by ensuring decisions in areas of policy, research, delivery of services and programs are made in the best interest of those living with and at risk of diabetes.

Australian Diabetes Council raises funds and awareness to promote diabetes prevention and management, education and research through community events, corporate and individual membership, fundraising events and activities. We also co-ordinate, run and manage community and health-professional education programs, lifestyle programs, fundraising activities and events, corporate and individual membership as well as sponsorship.

Australian Diabetes Council provides its 180,000 members and the wider diabetes community with the strength of a shared voice. We consult with and act on behalf of our members to ensure that decisions on policy, research, and program and service delivery make a positive difference to the everyday lives of people living with or at risk of diabetes.

Type 2 Diabetes in Australia

Prevalence and incidence

The prevalence of diabetes in Australia has more than doubled from 1.5% in 1989 to 4.1% in 2008[1]. According to the National Diabetes Services Scheme (NDSS) as of 31 October 2012, 1,057,731 Australians have already been diagnosed with diabetes[2] and at least another 500,000 have a silent and yet to be diagnosed type 2 diabetes (type 2)[3]. Every day 280 Australians are diagnosed with diabetes and approximately 100,000 have developed the disease in the past 12 months[3].

Diabetes is the fastest growing chronic disease in Australia. Within five (5) years, diabetes will become Australia's number one disease burden. By 2025, an estimated 3 million Australians over the age of 25 years is predicted to have the disease if diabetes continues to rise at the current rates. Type 2 accounts currently accounts for 80-90% of all diabetes in Australia and continuing rise of obesity, the ageing population, dietary changes and sedentary lifestyles will be the major contributors to ongoing increase of its prevalence and incidence[4].

Impact and burden

Type 2 diabetes is a complex metabolic condition. The seriousness of the condition is often underestimated. Similarly, the impact and burden of type 2 on the individual person with the condition, their family and Australia at large is also often underestimated.

Having diabetes contributes to significant morbidity, mortality and reduced quality of life. Early diagnosis, appropriate treatment and ongoing management and support reduces the risk of developing serious health problems from the condition, but duration of diabetes is also a significant contributor to diabetes related complications. People with diabetes are up to four (4) times more likely to have a heart attack or a stroke and 15 times more likely to have an amputation. Diabetes is the leading cause of preventable blindness in

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[1] Australian Institute of Health and Welfare (AIHW) 2011, *Diabetes prevalence in Australia: detailed estimates for 2007-08*, Diabetes series no. 17, Cat. No. CVD 56, Canberra, AIHW, Viewed 7 November 2012, < http://www.aihw.gov.au/publication-detail/?id=10737419311>.

[2] National Diabetes Services Scheme (NDSS) 2012, *NDSS Database*, NDSS, October 31 2012, Canberra.

[3] Diabetes Australia National Expert Advisory Group, 2013, *A National Diabetes Strategy and Action Plan*, Diabetes Australia, Canberra.

[4] Shaw J, Tanamas S 2012, *Diabetes: The silent pandemic and its impact on Australia*. Baker IDI Heart and Diabetes Institute, Diabetes Australia and Juvenile Diabetes Research Foundation. 2012: Canberra.

adults and kidney failure is three (3) times more common in people with the condition. Up to 30% of people with diabetes report experiencing depression, anxiety and distress[5].

For every person living with the impact of diabetes, there is also a carer and/or a family member living with the social impact and responsibility of providing day-to-day support and encouragement. Carers and families frequently have to share in the financial burden through diabetes and it complications limiting their own or the sufferers ability to participate in the workforce and other constraints on disposable income e.g. from purchasing medicines, contributing to medical and allied health consultation fees.

Similarly, the economic and social cost on the Australian community and economy is continuing to grow. Thirty-percentage of all hospital admissions in Australia are reported to be related to diabetes[5]. Currently, the total cost of diabetes is reported to be at least $14.6 billion every year and estimated to increase to $30 billion by 2025[6]. In addition, the increasing rates of type 2 may have other economic consequences such as arrested economic growth and prosperity caused by, for example, reduced workforce participation due to morbidity associated with diabetes or the need to care for a family member with the condition, reduced workforce health affecting productivity.

The type 2 diabetes journey

Beta-cells capacity for insulin secretion declines with age and duration of diabetes[7]. As people with type 2 progress along their diabetes journey, pharmacological initiation, multi – pharmacological combinations and intensification of diabetes therapy is required to achieve glycaemic targets[7].

Research findings suggest that between 30-50% of all people with type 2 progress to secondary failure and will require insulin to manage their condition within 10 years of diagnosis[8]. In the period 2000 to 2009, 172,246 Australians with type 2 started to use insulin to manage their condition. Moreover, 77% of all people using insulin were diagnosed with type 2[9]. According to the National Diabetes Services Scheme(31/05/13)

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[5] Diabetes Australia National Expert Advisory Group, 2013, *A National Diabetes Strategy and Action Plan*, Diabetes Australia, Canberra.

[6] Lee CM, Colagiuri R,, Magilioano DJ, Cameron AJ, Shaw J, Zimmet P, Colagiuri S 2013, The cost of diabetes in adults in Australia, *Diabetes Res Clin Pract*, vol. 99, nr. 3, pp. 385-390.

[7] Ramlo-Halsted BA, Edelman SV 2000, The Natural History of Type 2 Diabetes: Practical Points to Consider in Developing Prevention and Treatment Strategies. *Clinical Diabetes*. Spring 2000, vol. 18, nr. 2.

[8] UKPDS Study Group 1998, Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33), *Lancet.* 1998, vol. 352, pp. 837-853.

[9] AIHW 2012, *Insulin treated diabetes in Australia 2000 -2009*, March 2012, viewed 7 November 2012, <http://www.aihw.gov.au/diabetes/incidence/ >.

(NDSS) database, 212,357 (23%) of the 932,425 of its registrants with type 2 diabetes use insulin to treat their condition[10].

[10] NDSS 2012, *NDSS Database*. NDSS: October 31 2012; Canberra.

Review of medicines used in the treatment of type 2 diabetes

Australian Diabetes Council promotes timely and equitable access to evidence based best-practice diabetes treatment, management and support for all Australians living with diabetes. Australian Diabetes Council, we subscribe to sustainable health care delivery. In light of the current and predicted future rise of type 2, we recognise the importance of and support the government' efforts to invest in the most cost-efficient, effective and safe therapies, management and use products.

However, Australian Diabetes Council urges careful consideration of the need to balance short-term cost efficiencies with the possibilities of achieving long-term cost efficiencies from a reduction in morbidity and mortality from diabetes and an increased quality of life and work force participation by people living with the condition and their carers. The views and long-term health interests of people living with type 2 and their lived experiences through their own diabetes journey must be at the centre of the decision making process. At Australian Diabetes Council, the interest and views of our members inform our position on public health policy decisions.

Post-market stage three; terms of reference one to four

Terms of reference point one

Describe the utilisation and patterns of treatment of Pharmaceutical Benefit Scheme listed drugs for type 2 diabetes, and compare these with PBS restrictions

The Pharmaceutical Benefits Advisory Committee (PBAC) is currently charged with evaluating evidence and recommending restrictions around the use of diabetes medicines. Drug Utilisation Sub-Committee (DUSC) reports that diabetes medicines are prescribed outside restrictions the Pharmaceutical Benefit Scheme (PBS). Several factors must be taken into account when considering utilisation outside the restrictions recommended by the PBS:

- Reports into utilisation of diabetes medicines outside the recommended restrictions of the PBS should also include investigations into the potential benefits and improved outcomes as such prescriptions.

- Concerns for the individual person with diabetes health, welfare and personal circumstances may inform clinicians' decisions not to comply with PBS restrictions.
- PBS restrictions may limit the access to the most appropriate pharmacological therapies for people with diabetes who may already be economically disadvantaged.

Australian Diabetes Council recommends that the experience, opinions and end-point outcomes of people living with the condition central to any review of compliance with PBS restriction and utilization patterns PBS approved diabetes pharmacological options for the treatment of type 2.

Terms of reference point two

Consider if the utilisation of Pharmaceutical Benefit Scheme listed drugs in current clinical practice represents expected cost-effective use.

Short-term cost efficiencies are important to enable a sustainable health-care system. Whilst much more difficult to assess and map, potential for long-term cost-efficiencies from a reduction in morbidity and mortality from diabetes and an increased quality of life and work force participation by people living with the condition and their carers must also be considered. Moreover, clinical practice and the most appropriate use of pharmacological therapies are decisions that are best made by the person with type 2 and their carer and/or family in consultation with the treating medical practitioner.

Australian Diabetes Councils recommends that the person with type 2, their circumstance and individual needs remains central to any clinical decision. The possibility for long-term cost-efficiencies from individualised therapy options should not be compromised by an attempt to achieve short-term cost-efficiencies with a 'one-size-fits-all' model of access to pharmacological therapies.

Terms of reference point three and four

Consolidate the clinical trial evidence used to support Pharmaceutical Benefit Scheme listings of diabetes medicines listed since 2002.

Collate and evaluate any additional clinical studies or meta-analyses for drugs currently Pharmaceutical Benefit Scheme listed for type 2 diabetes that the Pharmaceutical Benefits Advisory Committee has not seen and that would inform their consideration.

Evidence from all aspects of research must inform all aspects of health delivery from policy decisions to clinical care and pharmaceutical therapies. However, it is important to note that obtaining scientific evidence to support listings of pharmacological therapies and use of best-practice treatment and management approaches require specific knowledge, skills and experience from the field of research and clinical practice.

It may be difficult to compare the long-term cost-efficiencies of emerging therapies and technologies to that of established therapies for the treatment and support of people with type 2. This presents particular risk if equitable access for Australians with type 2 to innovative new therapies is discounted as appropriate options on the grounds that long-term cost efficiencies cannot be demonstrated. Moreover, innovation that makes diabetes self-care easier may contribute to improved outcome for people, for example improved adherence to pharmacological therapies with newer medicines that combine 2 (two) different oral hypoglycaemic agents into one (1) tablet.

Australian Diabetes Council recommends that the Australian Government invests in a regular review and up-date of the national best-practice guidelines for type 2 to inform the PBAC, clinicians, people with diabetes, industry and other stakeholders.

Post-market review

Scope and time frames

Australian Diabetes Council understands that other aspects of diabetes treatment, management and support will be considered in the context of the overarching evaluation of diabetes management. This fragmented approach may result in overlooking key information. Similarly, the time-frames within which to consider the questions or make a significant contribution are unrealistic to the task at hand, particularly with respect to consolidating scientific evidence or inform the PBAC.

Australian Diabetes Council recommends introduction of time-frames that encourages inclusion of a wide scope of information and evidence that can contribute to improving health outcomes for people with diabetes and/or a significant difference to the quality of life people affected by the condition.

Terms of Reference

The Terms of Reference (ToR) for stage three (3) of the post-market review are specifically focused on whether medicines prescribed are meeting current PBS restrictions and their overall cost-effectiveness. This narrow ToR focus is not consistent with the overall health objectives as framed in the overall review.

Australian Diabetes Council welcomes a review that has a broader view than short-term cost-efficiencies when considering pharmaceutical therapies for improving outcome for people with type 2.