2013

# Post Market Review of Medicines Used in the Treatment of Type 2 Diabetes

## Submission to the Pharmaceutical Benefits Scheme, Department of Health and Ageing

**Australian Diabetes Educators Association**

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Please forward any inquiries to the ADEA National Office.

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## About the ADEA

The Australian Diabetes Educators association (ADEA) is the leading organisation for all health care professionals providing diabetes education and care and actively promotes evidence-based best practice diabetes education for all people, affected by, and at risk, of diabetes.

The overarching goals of diabetes education are to attain optimal:

- adjustment to living with diabetes
- health outcomes
- cost effectiveness (public and personal)

through achieving knowledge and understanding, self-determination, psychological adjustment and effective self-management.[1] The ADEA sets the guidelines, standards and expected competencies for diabetes self management education and has registered the trade mark – Credentialled Diabetes Educator ®.

## Background

Credentialled Diabetes Educators (CDE) are mainstream healthcare professionals with registration to practice in a primary discipline of dietetics, exercise physiology, medicine, nursing, pharmacy or podiatry followed by post-graduate qualifications in diabetes management and education. To achieve credentialled status through the ADEA the following additional requirements must be completed:

- 1800 hours of practice in diabetes education, including a referee's report addressing core competencies and practice in accordance with the ADEA's Code of Conduct and Standards of Practice.
- A mentoring partnership.
- Evidence of undertaking continuing professional development.

To maintain currency of the credential CDEs apply for re-credentialling every three years. This credential is the hallmark of a commitment to the ongoing study of diabetes and its management, and the implementation of best practice in a clinical area of considerable and continuing change.

CDEs are best placed to provide holistic education to support and empower people to manage their diabetes and to prevent or delay the development of diabetes complications across type 1, type 2, gestational diabetes and pre-diabetes.

CDEs are the recognised providers of choice for diabetes self-management education for Medicare and the Department of Veterans Affairs. In addition, CDEs are recognised by the National Diabetes Services Scheme for authorisation of NDSS registrations and authorisation to access insulin pump consumables.

[1] Eigenmann C, Colagiuri R. (2007) Outcomes and Indicators for Diabetes Education - A National Consensus Position. Diabetes Australia: Canberra.



## Introduction

The Pharmaceutical Benefits Advisory Committee (PBAC) has completed Stage 1 and 2 of the planned post-market review "to examine and characterise the complexity and heterogeneity of PBS listings for drugs used in type 2 diabetes mellitus (T2DM); and to review self-monitored blood glucose testing for people with T2DM and insulin pumps for people with type 1 diabetes mellitus (T1DM) to inform an assessment of their effectiveness in terms of clinical outcomes and cost".

The purpose of this paper is to address Stage 3 of the post market review: Utilisation and patterns of treatment of PBS listed T2DM medicines in current clinical practice, including consideration of the range of treatment options available to manage T2DM and how these are being used.

| |
|---|
| 1. Information from prescribers and consumers on their current experiences with these T2DM medicines in terms of their health outcomes, efficacy, safety, particular combinations of medicines used, satisfaction with treatment, and other insights into T2DM drug management; |
| 2. Whether prescribers and consumers consider these medicines are used effectively, including benefit and cost; and |
| 3. Any information about preferred medicines for specific sub-populations of patients with T2DM. |

In addition, the diabetes related issues raised at the October 2012 and February 2013 DUSC meetings were mentioned.

A survey of diabetes educators (n=52) was undertaken to help inform the ADEA response (see Appendix 1). The practice of diabetes educators is grounded in a strong emphasis on providing patient/client centred care and holistic diabetes management through the health care team. The level of confidence and expertise around managing diabetes in primary care varies amongst GPs and generalist health care providers. Many people with diabetes do not currently access team based diabetes care, specialist supports or have a care plan to address their complex health needs. This influences the appropriate use of diabetes medicines and the ability of the person with diabetes to fully participate in the decision-making and self-management aspects of their health.



## Individualised treatment and use of algorithms

Diabetes educators see individualised treatment as highly important to quality care and a strong influence on likelihood of client adherence to prescribed medicines and diabetes therapy generally.

Table 1: Importance of individualised treatment

| How important is individualised treatment for type 2 diabetes? | | | | | |
|---|---|---|---|---|---|
| Answer Options | Not important | Slightly important | Important | Very important | Extremely important |
| | 0 | 0 | 1.9% | 17.3% | 80.8% |

Among the specific issues to be considered were:

- Psychosocial - life stage; care preferences; perceptions; diabetes knowledge; self-management skills; supports
- Physical – HbA1c; co-morbidities; biometrics (weight, renal function etc); disabilities

Current clinical treatment algorithms are designed to meet PBS criteria for restrictive arrangements around prescribing that may not reflect optimum medicine use for individuals. While diabetes educators see value in having access to treatment algorithms, some problems were identified.

Using the treatment algorithm from 'Diabetes Management in General Practice'[2] as an example, diabetes educators were asked if the use of clinical treatment algorithms supports individualised management. Although algorithms were seen as a useful basic guideline for management, the perception of some respondents was that the clinical needs of individuals are not always met by adhering to the PBS restrictions and there were issues with having an algorithm that was not keeping pace with updated practice and options. There was strong support from respondents to consider the use of DPP4 and GLP 1 inhibitors earlier on the treatment algorithm tree, as a second line option. For example, the algorithm pathway recommends addition of a sulphonylurea as second line therapy, when earlier use of GLP 1 therapies in overweight people with diabetes may be preferred.

A smaller number of diabetes educators advocated a more conservative approach, stating that new medicines on the market need to be proven in their management use and should not be prescribed until other older proven medicines are utilised or are demonstrated as not suitable in that individual.

Diabetes educators with autonomous prescribing privileges (endorsed Nurse Practitioners -NP) were approached for their insights. Concerns were expressed regarding the NHMRC type2 diabetes medications information being out of date, the confusion for GPs with increasing treatment options and a range of prescribing restrictions and issues to consider, and that more emphasis on shared decision-making with the person with diabetes was needed.

[2] Harris P, Mann L, Bolger-Harris H, Phillips P, Webster C. Diabetes Management in General Practice: Guidelines for type 2 diabetes. Canberra: Diabetes Australia.

With access to online information the variance in use of medicines across international boundaries was more apparent. Some diabetes educators questioned why the prescription of insulin / exenatide with or without metformin was found in comparable health systems elsewhere but was not available through PBS to Australians.

To address the issues raised by diabetes educators regarding treatment algorithms the ADEA makes the following suggestions:

- Algorithms needed to be updated to include newer therapy options
- A selection of algorithms may be needed rather than one algorithm to address differing individual profiles (e.g; overweight vs optimal weight, existing CVD vs no complications present). The new algorithms and guidelines from the American Association of Clinical Endocrinologists (AACE) were mentioned as an example of this approach
- Shared decision-making on medicine use was highlighted and the Mayo Clinic examples used to demonstrate a useful guideline[3]
- An online library of guidelines and PBS related information would be helpful.
- Algorithms could be made more interactive to provide more clinically appropriate information.
- PBS criteria were important but should not 'drive' the structure of treatment algorithms
- There needs to be more focus on harm minimisation in terms of medication choice and hypos, weight gain, fluid retention which is not taken into consideration with the current algorithm/s
- It is essential to consider young people diagnosed with type 2 diabetes and whether the algorithms address their specific needs. For example, risk of pregnancy for younger women on metformin and contraception / pre-pregnancy counselling needs.

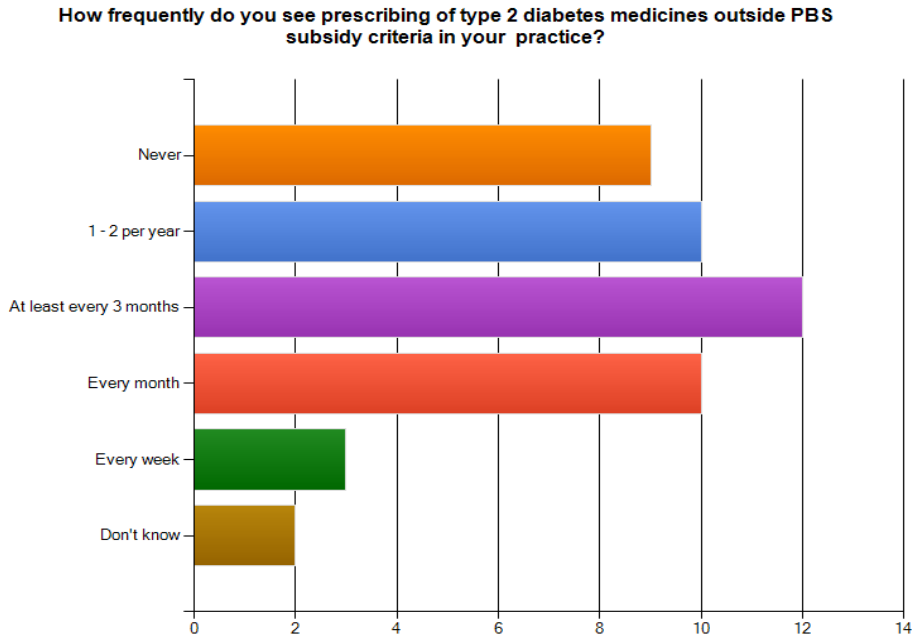
## Description of issues for diabetes educators and for patients regarding prescription outside of PBS restrictions

The majority of diabetes educators (86.7%) had been approached to discuss medication options for clients with medical specialists and GPs, as part of their practice. In terms of clinical experience with diabetes medicines, most diabetes educators (76.1%) reported contact with prescribing that does not fit the current PBS criteria and restrictions. The frequency varied, with occurrences in clinical practice mainly 1-3monthly. A small number of educators interacted weekly with people taking diabetes medicines prescribed outside of current PBS criteria.

[3] Mayo Clinic - http://diabetesdecisionaid.mayoclinic.org/index.php/site/decide



Figure 1: Clinical experience with prescribing outside PBS criteria




The key issues that arose for diabetes educators were:

- Reviewing medications with prescriber in case PBS criteria was misinterpreted
- Risk of confusion between health professionals involved in the diabetes care team (for example, individual started on diabetes medicines outside PBS restrictions while under hospital care and then returns to community for GP management or home nursing support with medicine management)
- Need to provide detailed explanation to client so they understand the possible rationale for the prescribing approach and the potential for increased cost
- Encouraging regular review to assess the clinical effects of the prescribing. Several mentioned the positive benefits identified from earlier use of some medicines
- Some indications of prescribers seeking to improve glycaemic management with prescribing outside of restrictions, where the addition of insulin was refused by the person with diabetes.

Diabetes educators indicated that the key issues for people with diabetes prescribing outside PBS restrictions were:

- Increased cost of prescriptions, especially for concession card holders
- Increased risk of non-adherence to therapy due to number of medicines prescribed

- Risk of concern and misunderstanding if not carefully explained, especially where care is transferred from one prescriber to another
- Positive effects relating to improved glycaemic management and less weight gain

## DUSC

The data on utilisation of medicines for newly diagnosed type 2 diabetes suggests that in the first 3.5 years of therapy the majority of prescribing is in accordance with clinical guidelines and PBS restrictions. The proportion of use outside of the restriction is growing over time, appears to occur more frequently with fixed dose combination products, and is likely to be far more extensive in patients who have been treated for diabetes for a period longer than 3.5 years.

A large proportion of prescriptions supplied through the PBS for the dipeptidyl peptidase-4 inhibitors ('gliptins') do not meet the criteria for PBS subsidy.

Some prescribing of exenatide, rosiglitazone and pioglitazone is outside of the PBS restrictions.

PBS restrictions do not align with recent clinical guidelines and the perceived place of newer medicines for type 2 diabetes in practice. The data suggests that gliptins may be viewed as an alternate therapy to sulfonylureas, rather than being reserved for patients who cannot take a sulphonylurea. As gliptins are much more costly than sulphonylureas, use outside of the current PBS restrictions is unlikely to be cost-effective at the current prices.

Type 2 diabetes is a progressive disorder that requires adjustment to therapy over time. Issues remain with adherence to therapy, especially in the setting of the polypharmacy that is usual for diabetes management. The proportion of Australians with type 2 diabetes achieving optimal glucose levels is less than 60%[4] and the current approach to management is one of increased use of diabetes medications when glycaemic targets are not met[5].

Some examination of the wider issues as to why the patterns identified by DUSC are emerging should consider health professional and client based factors. For example, does the person have access to culturally appropriate and health literacy level appropriate diabetes self-management education, what is their adherence to therapy, can they afford the prescribed medicines? For the prescriber, easier access to information on PBS restrictions, support from diabetes specialist health professionals and a wider health care team, algorithms that are updated to reflect current clinical recommendations. Progressive beta cell failure means that around 50% of those with type 2

[4] Si, D., Bailie, R., Wang, Z., & Weeramanthri, T. (2010). Comparison of diabetes management in five countries for general and indigenous populations: an internet-based review. *BMC Health Services Research, 10*, 169.

[5] Nathan, D., Buse, J., Davidson, M., Ferrannini, E., Holman, R., Sherwin, R., et al. (2009). Medical management of hyperglycaemia in type 2 diabetes mellitus: a consensus algorithm for the initiation and adjustment of therapy. Diabetologia, 52(1), 17-30.



diabetes will eventually require insulin to maintain their blood glucose levels[6]. The cost-effectiveness of diabetes medicines needs to be considered in terms of longer term health outcomes and overall associated costs, not just the PBS component of the cost.

An analysis of PBS prescription data showed that nearly all prescriptions of insulin are for the PBS maximum quantity of five packs, despite there being a wide range in the insulin dosing needs of individual patients. DUSC noted that it is essential that patients have an adequate supply of insulin, but quantities supplied may not always be appropriate and there may be some wastage. DUSC requested that the distribution of insulin doses be investigated from additional data sources. There may be a need for an education campaign if further analysis indicates that there is wastage is occurring.

ADEA has long argued that the processes around prescription, supply and education regarding the use of insulin could be further improved.

In 2001, subsequent to the reclassifying of insulin as an S4 medicine, NSW based Registered Nurse - CDEs successfully argued to able to provide a limited supply of already prescribed insulin to people who were newly commencing insulin therapy. This was addressed through an authority under the 'Poisons and Therapeutic Goods Act 1966' and published in the NSW Government Gazette dated 10 December 2001. Undertaking supply was limited to RN CDEs who were "educated and appropriately credentialed for the role" as nurses were health professionals already identified under the relevant regulations and had medicine management within their usual scope of practice. (see Appendix 2)

This now accepted practice in NSW allowed RN CDEs to assess individual needs, provide the appropriate insulin delivery device with the required education and then give a small supply of insulin to expedite the commencement of therapy. It also helped to avoid multiple GP visits to start insulin therapy and the common problem of the individual being prescribed insulin that did not suit the appropriate device, or insulin that was an unsuitable choice due to other concerns (such as irregular meals, shift work or erratic lifestyle patterns and so on).

Insulin is classified as a high-risk medicine because it can cause severe and adverse harm. Effective insulin initiation, education and management require the collaborative effort of an interdisciplinary team of health professionals working with the person with diabetes. In addition, the person with diabetes must have the relevant knowledge, skills and support to take responsibility for their day-to-day diabetes care.

The ADEA framework to guide insulin initiation in the ambulatory setting is based on the following:

1. The person with diabetes has a right to receive insulin-related education from health professionals accessing evidence based guidelines with relevant training in insulin initiation and self-management education and the ability to provide follow up advice and education.

[6] Wright, A., Burden, A. C. F., Paisey, R. B., Cull, C. A., & Holman, R. R. (2002). Sulfonylurea Inadequacy. *Diabetes Care, 25*(2), 330-336.



2. Insulin is a high risk Schedule 4 medicine. Health professionals should only undertake insulin management tasks that fall within the level of their knowledge, competence, education, role and scope of practice and the legislation/regulations governing their practice.
3. Health professionals should only delegate insulin initiation, education and ongoing dose management responsibility to another health professional that has the appropriate knowledge, education, competency and scope of practice.
4. Safety and quality use of medicine (QUM) are of paramount importance.
5. Insulin initiation, education, ongoing dose management and review should be encompassed within QUM.
6. The medicine management plan must be individualised to suit the person with diabetes, considering their capabilities, preferences and individual circumstances (for example, cultural or diversity considerations, co-morbidities, polypharmacy).
7. The insulin regimen should be developed in collaboration with the person with diabetes.
8. Education, support and evaluation at follow up are essential.
9. Maintaining an healthy diet and regular physical activity, individualised to the person's needs, is a key component of successful medicine management and prevention of complications.

ADEA representatives would be happy to provide further information to the PBAC if requested regarding the education needs and associated considerations for people newly commencing insulin therapy and how this may impact on appropriate levels of insulin supply.



## APPENDIX 1 - Survey demographics summary

ADEA members working in diabetes education responded to a brief survey regarding their experience with clients / patients and prescribers around the use of medicines for type 2 diabetes.

The majority of respondents were from nursing backgrounds, reflecting the spread of health professionals in the ADEA membership. Most were from Victoria, were Credentialled Diabetes Educators (>80%) and had worked in diabetes education for more than 10 years. Distribution across urban and regional centres was as follows:

Table 1. Distribution of ADEA respondents by population centre

| | |
|---|---|
| **Capital City** | **28.85%** |
| **Metropolitan centre (population > 100 000)** | **25%** |
| **Large rural centre (population 25 000 – 99 999)** | **19.23%** |
| **Small rural centre (population 10 000 – 24 999)** | **13.46%** |
| **Remote area (population < 10 000)** | **13.46%** |
| | **100%** |

Employment profile showed that just over 44% worked in major diabetes centres (public or private), with another 27% working in the community health sector. Approximately 22% were employed in general practice and/or private practice with the remaining respondents involved in home visiting nursing services.



## Appendix 2 – Excerpt from NSW Government Gazette 14 December 2001



SCHEDULE

Pilot (Pesticide Rating) Licence

| Name and address of Licensee | Date of Granting of Licence |
|---|---|
| Mr Patrick William PARKER, 11 Lignum Avenue, Dirranbandi, Qld 4486. | 6 December 2001. |

**POISONS AND THERAPEUTIC GOODS ACT 1966**

Authorisation to Supply Insulin on Medical Authority

PURSUANT to Clauses 147 and 148 of the Poisons and Therapeutic Goods Regulation 1994, I, JOHN LUMBY, Chief Pharmacist, a duly appointed delegate of the Director-General of the Department of Health, do hereby grant authority to registered nurses, hereby specified as a class of persons, to supply those restricted substances listed in the Schedule hereunder, for the purposes of Clause 56 of that Regulation, subject to the following conditions:

(1) the nurse supplies the substance in accordance with the prescription of a medical practitioner; and

(2) the nurse is credentialled by the Australian Diabetes Educators Association Limited as a Credentialled Diabetes Educator-RN; and

(3) the nurse supplies the substance in a quantity of no more than seven days supply; and

(4) the nurse supplies the substance in the manufacturer's original unit container which is labelled by the manufacturer in accordance with the requirements of the Commonwealth therapeutic goods laws.

SCHEDULE

Insulin.

Signed at Sydney, this 10th day of December 2001.

JOHN LUMBY,
Chief Pharmacist.

**PUBLIC WORKS ACT 1912**

Notification of Alteration of Rates of Interest

IN pursuance of the provisions of section 126A (5) of the Public Works Act 1912, I hereby determine that on and from the date of this notification, the rates of interest payable under section 126A (3) shall be:

(a) where the total amount of compensation is less than $50,000 — 4.32 per cent per annum.

(b) where the total amount of compensation is $50,000 or more and less than $250,000 — 4.22 per cent per annum.

(c) where the total compensation is $250,000 or more — 4.30 per cent per annum.

MICHAEL EGAN, M.L.C.,
Treasurer

**SPORTING INJURIES INSURANCE ACT 1978**

Order of Declaration under Section 5

IN pursuance of section 5 of the Sporting Injuries Insurance Act 1978, I declare by this Order the BYRON BAY TOUCH FOOTBALL ASSOCIATION to be a sporting organisation, for the purposes of the provisions of the Act, in respect of the activities of Touch Football.

JOHN GARBUTT,
Acting Chairperson.

Sporting Injuries Committee,
Sydney, 5 December 2001.

**SPORTING INJURIES INSURANCE ACT 1978**

Order of Declaration under Section 5

IN pursuance of section 5 of the Sporting Injuries Insurance Act 1978, I declare by this Order the WALKBALL NSW to be a sporting organisation, for the purposes of the provisions of the Act, in respect of the activities of Walkball.

JOHN GARBUTT,
Acting Chairperson.

Sporting Injuries Committee,
Sydney, 5 December 2001.

**THE SYDNEY WATER CATCHMENT MANAGEMENT ACT 1998**

Notice Under Section 38

IN accordance with section 36 of the Sydney Water Catchment Management Act 1998, the Sydney Catchment Authority has entered into Memoranda of Understanding with the Director-Generals of NSW Health and the Environment Protection Authority.

The purpose of these Memoranda is to form the basis for co-operative relationships between the signatories, including agreed areas of study and data exchange.

In July 2001 the Sydney Catchment Authority placed on public exhibition amended Memoranda of Understanding with the above agencies.

The Sydney Catchment Authority now provides notice of execution of the amended Memoranda of Understanding with the above agencies in accordance with section 38 (5) of the Sydney Water Catchment Management Act 1998.

The dates of execution for the amended Memoranda are 28 November 2001 for NSW Health and 4 December 2001 for the Environment Protection Authority.

Copies of the Memoranda can be obtained by telephoning the Sydney Catchment Authority on 4731 0213 or downloading from the Sydney Catchment Authority's website at www.sca.nsw.gov.au (in the Information and Reports section).