Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1385 – Shared Medical Appointments (SMAs) for Type 2 Diabetes Management

Applicant: **Australian Lifestyle Medicine Association (ALMA) Southern Cross University**

Date of MSAC consideration: **MSAC 66th Meeting, 30-31 March 2016**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au.

1. Purpose of application and links to other applications

An application requesting Medicare Benefits Schedule (MBS) listing of Shared Medical Appointments (SMAs) for patients with Type 2 diabetes was received by the Department of Health from the Australasian Society of Lifestyle Medicine.

The Department received the evidence for the submission on 13 January 2016.

2. MSAC's advice to the Minister

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC did not support the use of SMAs for patients with type 2 diabetes due to a lack of evidence that they were clinically effective or cost-effective. There was uncertainty about the exact nature of SMAs and their place in the Australian health care setting was poorly defined. MSAC also had concerns about patient confidentiality.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that the application defined SMAs as group medical appointments involving 6–12 consenting patients with type 2 diabetes, a GP, a group facilitator and a documenter (who may be the same person as the facilitator). The facilitator, who is proposed to be a practice nurse or allied health professional, takes vital signs and bloods, manages group dynamics and updates the patient's medical record (if a separate documenter is not used). The GP conducts sequential standard medical consultations while all the patients are in the room.

MSAC noted that that are already a number of dedicated MBS items available to Australian patients and GPs for group allied health sessions, for people with type 2 diabetes. All require that the patient is being managed under a GP Management Plan, or if they are an aged care

resident, a multidisciplinary care plan. All require written reports back to the referring GP, usually after the initial and final session or consultation. The relevant items include:

- items 81100, 81110 or 81120 for 45 minute individual assessments by a diabetes educator, an exercise physiologist or a dietician to determine a patient's suitability for an allied health group session program.
- items 81105, 81115 and 81125 for up to eight attendances per year at 60 minute allied health group sessions involving 2–12 patients and conducted by a diabetes educator, exercise physiologist or dietician.
- Items 10950 to 10970 for a maximum of five individual allied health appointments per calendar year for eligible patients with a chronic condition.

In addition, MSAC noted the recent Commonwealth *Healthier Medicare* announcement which will trial 'Health Care Homes' to co-ordinate all of the medical, allied health and out-of-hospital services as part of a tailored care plan for patients with chronic diseases. It is possible that some patients with type 2 diabetes will be able to participate in the initial trial of this service. MSAC were uncertain what benefit SMAs would provide in addition to these services.

MSAC indicated that the exact nature of the SMAs was poorly defined in the application and considered it would be informative if the structure/co-ordination of items was more clearly defined:

- How patients are identified as being eligible for an SMA, i.e. appropriate patient characteristics.
- How SMAs fit into the current diabetes cycle of care, GP Management Plans and Team Care Arrangements.
- The duration of the SMA. It was suggested that the SMA could last up to 120 minutes but this was not fixed.
- The training and accreditation of the facilitator.
- The amount of time for which the GP would be present. It was proposed that the GP enter the room after the facilitator has taken the vital signs of the individual patients and after an undefined 'group discussion'.
- What the 'standard medical consultation' entailed in the context of a group appointment. Does it include physical examination, pathology testing or management of medicines (prescribing, dose adjustment)? Does the GP review each patient's medical notes prior to the SMA?
- The number and type of health professionals present. While the GP was a constant, the facilitator could be either a practice nurse or an allied health professional. It was also unclear whether additional allied health professionals could be present.
- Whether SMAs were expected to replace allied health professional group sessions and, if so, which allied health professional group sessions they were most likely to replace.
- Whether the same patients would attend each SMA or whether the patient group would be different each time.
- Whether any structured patient education is delivered during the group sessions and, if so, the theoretical underpinnings for this education.
- To what extent SMAs are intended to replace individual GP consultations or allied health professional consultations.
- The logistics of SMAs. This included a lack of clarity around how the MBS fee would be divided between the various health professionals (GP, practice nurse, allied health professional) involved in the delivery of the SMA.

In addition to uncertainty about the exact nature of SMAs, MSAC noted that the eight randomised controlled trials (RCTs) comparing group medical appointments with individual GP consultations ± allied health consultations/group sessions were primarily from the United States and from jurisdictions with limited applicability to Australian primary health care. There were differences in the composition and structure of the group medical appointments, such as duration and frequency of sessions and the types of health professionals involved, which also made it difficult to extrapolate the trial results to the proposed SMAs. No Australian RCTs were available and only limited, supportive evidence investigating SMAs in Australian diabetes patients have been published.
MSAC considered it would be informative to provide the anticipated benefits from a critical review of the available literature interpreted from an Australian perspective and what was the anticipated Allied Health input it would replace.

In addition to the above issues, MSAC noted that there was insufficient evidence to support the claim that SMAs were better than usual care. Seven of the above trials measured the effectiveness of group medical appointments via differences in HbA_{1c} levels. Only two reported statistically and clinically significant differences in HbA_{1c} between the intervention and the control groups. No study reported a clinically significant improvement in blood pressure between groups.

MSAC were concerned about maintaining patient confidentiality in the SMA setting. The application noted that SMAs would be voluntary and patients would be required to sign a confidentiality agreement that they would not disclose other patient's private medical details. However, it was uncertain whether this would be enough to eliminate psychological harm should the patient regret disclosing their own medical information and their loss of privacy.

MSAC considered that as there was no clear evidence that SMAs were better than individual GP consultations ± allied health consultations/group sessions, a cost-minimisation analysis was appropriate. However, MSAC noted that there was a great deal of uncertainty in the model which relied upon the unproven assumption that a SMA was no worse than an individual GP visit, no worse than an allied health group session and no worse than one individual GP visit plus one allied health group session.

The modelling presented suggested that if SMAs replaced group allied health sessions but not individual GP consultations, the additional MBS cost per patient would be $27.40 to $82.20 dependent on whether the SMAs replaced one, two, three or four allied health sessions. If SMAs replaced both group allied health sessions and individual GP consultations, there was a possibility that SMAs could be cost saving dependent upon how many GP consultations and group allied health sessions were replaced. However, this was reliant upon the unproven assumption that a single SMA would be as clinically effective as an individual GP visit and an allied health session. Given the considerable uncertainty as to the effectiveness of SMAs, MSAC was not convinced that this would be the case.

MSAC noted that the total cost to the Australian healthcare system, including the MBS, for SMAs was not able to be accurately estimated due to high uncertainty as to:

- how SMAs would fit into current diabetes cycle of care, GP Management Plan and Team Care Arrangements.
- what extent SMAs would substitute for individual GP consultations.
- what extent SMAs would substitute for allied health services and which allied health services were most likely to be replaced.

4. Background

MSAC has not previously considered an application for shared medical appointments.

Type 2 diabetes assessment and group treatment services are currently available under Medicare on referral from a GP for a patient who has a GP Management Plan (GPMP item 721), or on referral from a GP who has contributed to a care plan prepared by an aged care facility. These are in addition to the five individual Medicare subsidised allied health services available each calendar year through a GPMP/Team Care Arrangements (TCA item 723). These allied health services may include individual services from a diabetes educator, an exercise physiologist and a dietician through MBS items 10951, 10953 and 10954 respectively.

The existing MBS items 81100, 81110 or 81120 fund 45 minute individual assessments by a diabetes educator, an exercise physiologist or dietician for suitability to a group services program.

The existing MBS items 81105, 81115 and 81125 fund 60 minute group services for 2-12 persons, up to eight times a year. Diabetes educators, exercise physiologists and dieticians are encouraged to deliver multidisciplinary programs to allow patients to benefit from a range of interventions in the management of their Type 2 diabetes. Allied health providers and patients regularly report back to the referring GPs.

5. Prerequisites to implementation of any funding advice

Shared Medical Appointments do not require Therapeutic Goods Administration registration.

Facilitator training in the particularities of SMAs including group dynamics will be a prerequisite for implementation. The facilitator is expected to have knowledge of T2DM in the course of their professional duties and is most likely to be a practice nurse. Training for the facilitators has been developed by the applicant.

6. Proposal for public funding

Proposed MBS item descriptor

Category 1 – Professional Attendances
MBS XX SHARED MEDICAL APPOINTMENTS Service provided to a person with type 2 diabetes mellitus if: 1. The person has been assessed as suitable for group consultation 2. The person has agreed to attend group consultation in writing and have signed a confidentiality agreement about the sharing of personal information 3. The service is provided by at least two medical professionals, a GP and an accredited Group Facilitator 4. The service is provided on behalf and under the supervision of a medical practitioner by a health professional with group facilitator accreditation 5. Professional Attendance at the Shared medical appointment is compulsory and not less than 80 minutes 6. The location of the shared medical appointment is a consulting room (or an approved location)* 7. The person is not an admitted patient of a hospital or residential aged care facility 8. The service is provided to a person who is part of a group of between 6 and 12 patients 9. The person has a GP Management Plan, 10. The service is consistent with the GP Management Plan 11. All attendance in the group is maintained by the GP -to a MAXIMUM of SIX SHARED MEDICAL APPOINTMENTS per calendar year
Fee: $47.30 per patient *Approved location is a location other than consulting rooms that has been approved by the Department

The SMA session details are as follows:

- The Facilitator is responsible for group dynamics and encourages group discussion throughout the appointment. They will use 20-30 minutes/per group to take vital signs and blood if necessary. Any results can be put on a white board (with the patient's permission).
- The GP enters the room after the group meeting has commenced, approximately 20 minutes in, and conducts a standard medical consultation with patients sequentially. GP leaves the room before the end of the group discussion, maybe up to 20 minutes prior.
- Documenter or Facilitator (usually the same person) will detail medical records in real time. This typically would involve taking required chart notes as care is being delivered.
- A minimum of 6 and maximum of 12 patients is proposed.
- SMA duration is not fixed. The Final Protocol describes it as expected to last up to 120 minutes. In publicly available literature, typical SMAs are described as lasting 90 minutes.
- The GP is not necessarily present for the entire appointment, but is in attendance for up to 80 minutes. A minimum GP attendance time is not stated. From the description this appears to equate to 6.7 minutes per patient if each is seen individually, and the maximum of 12 patients is present. A breakout room or screen may be available for patients who require a place for a physical medical or a private discussion.
- The group could stay the same, that is, the same group of patients with T2DM would continue to meet, or each SMA could involve a different mix of patients with T2DM.
- Patients can have between one up to a maximum of 6 appointments per year.

7. Summary of Public Consultation Feedback/Consumer Issues

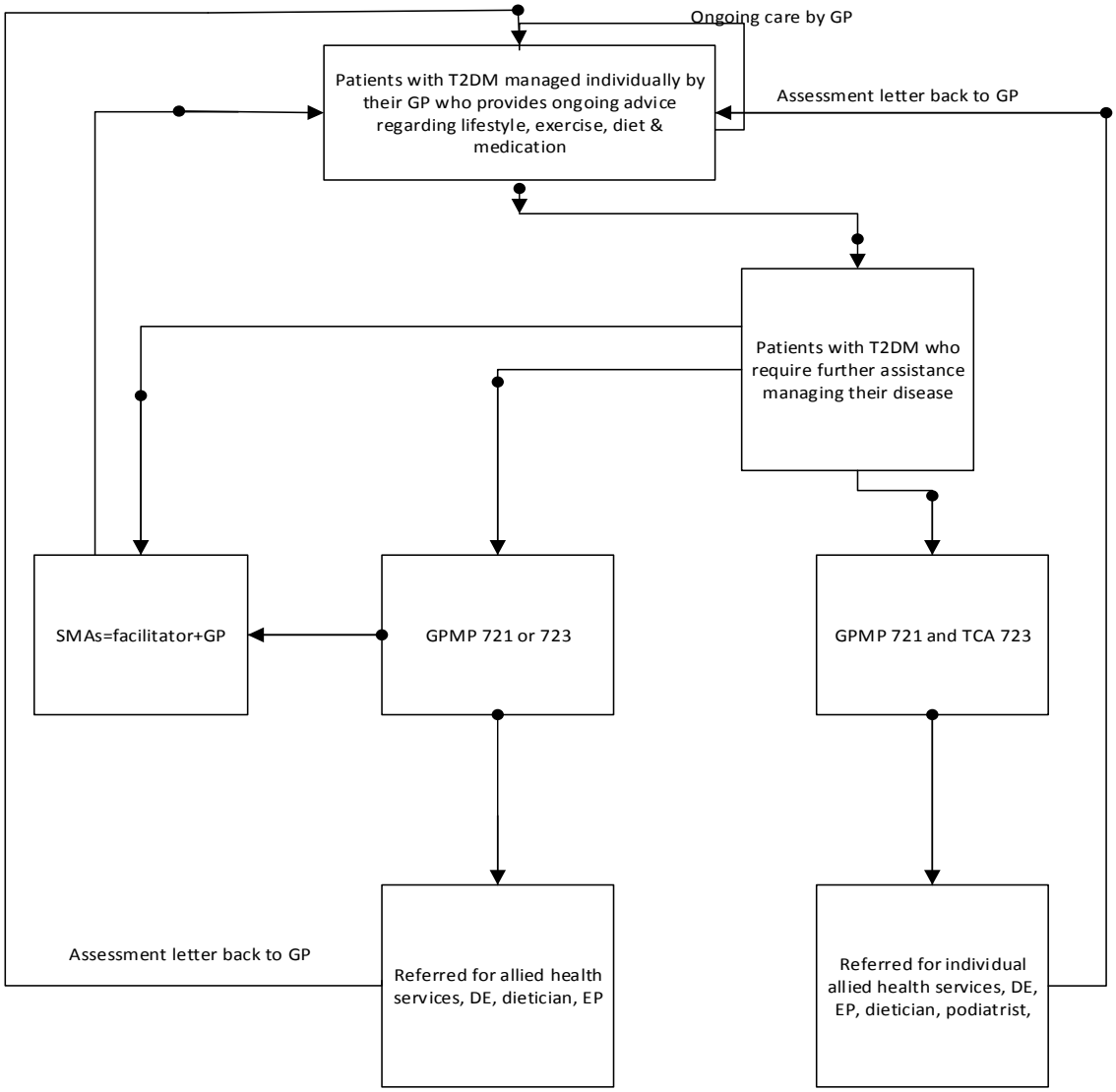
The peak consumer body associated with this application is Diabetes Australia, which provided feedback on the Consultation Protocol. It welcomed any opportunity to explore

new, innovative and cost-effective models of care that are evidence-based. However, it went on to state that SMAs are a relatively new concept and remain largely untested in an Australian context. It was noted that there had been limited consultation by the Applicant with the diabetes sector, including Diabetes Australia, allied health practitioners and credentialed diabetes educators who are important providers of Medicare-funded services to people with diabetes. Diabetes Australia concluded that the SMA model outlined in the MSAC Application appears to have little focus on diabetes self-management and is delivered by GPs and Practice Nurses, who may have limited training and expertise in diabetes self-management education or behaviour change tools.

Other consumer input stated that this application appears to attempt to provide peer support, which can assist self-management, but lacks the evidence and business case at this time to offer value to consumers. There were also concerns about confidentiality for participating patients.

8. Proposed intervention's place in clinical management

The proposed population is patients diagnosed with Type 2 diabetes mellitus (T2DM), either recently diagnosed or with long standing disease, whom the GP determines will benefit from a SMA. Patients will be volunteers and assessed by their GP to be able to self-manage their condition, albeit with additional support and education.



9. Comparator

The Final Protocol stated that the proposed service, is expected to partially substitute for usual GP care and group allied health services for type 2 diabetes (MBS items 81100 to 81125)

The application nominated the partial substitution of group allied health services as one of the comparators, requiring a visit to a GP and a referral to access group allied health services. Therefore, the comparator is 'Usual GP care" described as standard care and applied to individual face-to-face consultations with or without referral to and attendance at group allied health services for type 2 diabetes**.**

To access group allied health services, patients must be referred by their GP to an eligible allied health provider for an initial assessment. Before referring patients, the GP must develop a GP Management Plan (GPMP – item 721) or Team Care Arrangement (TCA – item 723)

81100/81110/81120: initial assessment for Group Services by:

- diabetes educator/exercise physiologist/dietician,
- Fee: $79.85 Benefit: 85% = $67.90

81105/81115/81125: Group Service by:

- diabetes educator/exercise physiologist/dietician,
- Fee: $19.90 Benefit: 85% = $16.95 (maximum 8 per year)

10. Comparative safety

Only one of the identified RCTs examined the risk of hypoglycaemic events associated with group medical visits (Edelman 2010). A hypoglycaemic episode was defined as a recorded blood glucose level less than 3.33 mmol/L (<60 mg/dL) or a self-report of symptomatic hypoglycaemia and defined serious hypoglycaemia as any such episode that required medical assistance. There was no statistically significant difference in relation to hypoglycaemia or other adverse events; however the study is likely to be underpowered to detect a statistically significant difference in these outcomes.

The reported quality of life outcomes, including mental health subscale of the SF-12, did not detect any significant difference between the intervention and control groups, but the instrument is not sensitive to privacy issue

11. Comparative effectiveness

The assessment report noted that the identified RCTs had limited applicability and generalisability to Australian primary health care because of large heterogeneity in population, settings, research questions, composition of the SMA, theoretical foundations and other characteristics of the various types of SMAs presented in the Assessment.

The proposed model of care appeared to be successful, but MSAC noted that making this model work on a fee-for-service-basis would be difficult.

The assessment report found inconsistent evidence supporting the claim of superiority of SMA in reducing of glycated haemoglobin (HbA1c), blood pressure or other outcomes (lipid levels, changes in body mass index [BMI], quality of life, medication adherence, diabetes

knowledge/confidence) in patients with T2DM when compared with regular medical consultations alone or in combination with some DM education.

12. Economic evaluation

A cost-minimisation analysis was presented. Although none of the identified RCTs was designed to test non-inferiority of the SMAs vs the comparator, in the absence of sufficient evidence to establish superiority of SMA, the non-inferiority hypothesis could not be ruled out.

The assessment group conducted scenario analyses under different assumptions where a variable number of GP and/or allied health group visits were replaced by SMAs. The incremental costs that might be expected as a result of introducing SMAs into general practice for managing patients with T2DM were then calculated. It should be noted that the validity of the estimates depends on the assumption of clinical non-inferiority of:

a) an SMA vs individual GP visit;
b) an SMA vs AH group visits; and
c) an SMA vs one individual GP visit + one AH group visit.

The overall conclusion of the cost-minimisation analysis found that, given there is no definite provision in the Final Protocol for allied health professionals participating in the SMAs, it is unlikely that the SMAs would be a cost saving alternative without compromising the quality and clinical effectiveness outcomes of the current general practice.

13. Financial/budgetary impacts

No evidence was found of a reduction in health care resource utilisation as a result of SMAs. The following calculations were performed based on the potential costs to the MBS but are not supported by any available clinical evidence. Furthermore, the financial calculations are only presented for one financial year due to the lack of evidence of the likely degree of substitution, and the possibility that SMAs are not 'partial substitutes' for usual care but an adjunct model to usual care.

- It was estimated that there are 4.75 million GP encounters for patients with T2DM per year.
- Based on a conservative estimate of the population of patients with T2DM (847,000) and the number of GP encounters it was estimated that on average patients with T2DM see their GP six times per year.
- The estimated costs to the MBS of current usage of a Level B GP consultation (the most frequently claimed GP consultation item), by patients with T2DM was $175.9 million
- Medicare statistics indicate that only 8.8% of all patients who accessed allied health services accessed as a group (although it is not possible to accurately estimate the number of patients who used individual allied health and who had T2DM).
- The predominant reason a patient with T2DM is referred to group allied health services is for exercise physiology (75% of referrals).
- The proposed cost of an SMA was assumed ($47.30) and a maximum of six visits per year is allowed.
- The costings were performed for the following scenarios:
  - SMAs replace individual GP visits for patients with T2DM (1 to 6 visits)
  - SMAs replace an individual GP visit which includes a visit to a practice nurse (who delivers care under a GPMP (max 5 a year)

- SMA replaces individual GP visits for patients with T2DM and an SMA can only occur under a GPMP
- The current scenario of a patient seeing their GP and then being referred to group allied health is substituted by patients attending a SMA and being referred to group allied health services excluding exercise physiology services.

The table below, from the assessment report, provided different costs to the MBS for the 4 scenarios, depending on whether it is assumed that a SMA replaces an individual consultation, 1 time or 2 times or 3 times etc. Numbers in brackets represent savings.

Costs to Medicare if SMAs replace GP consultation under 4 scenarios-one year only

	1 visit	2 visits	3 visits	4 visits	5 visits	6 visits
GP only vs SMA	1,281,972	5,127,889	11,537,750	20,511,555	32,049,304	46,150,998
GP+PN vs SMA	(18,010,146)	(35,957,756)	(53,842,832)	(71,665,372)	(89,425,376)	(107,122,846)
GP+PN vs SMA+GPMP	31,268	125,070	281,409	500,282	781,690	1,125,634
Current+AH vs SMA+AH	(45,475)	(89,984)	(133,527)	(176,105)	(217,718)	(258,365)

The incremental costs will depend on actual GP and allied health practitioner involvement, and the degree of substitution for current standard care.

14. Key issues from ESC for MSAC

- The proposed intervention is poorly defined;
- The evidence base is characterised by marked heterogeneity in population, settings, research questions, composition of the SMA, theoretical foundations and other characteristics of the various models of SMAs evaluated;
- Incremental costs are unknown, as this will depend on the level of GP and allied health practitioner involvement;
- Shared medical appointments' place in current care is poorly defined;
- There are uncertainties about facilitator accreditation and mechanisms for allied health professional reimbursement; and
- There are concerns about the management of patient confidentiality.

15. Other significant factors

Nil.

16. Applicant's comments on MSAC's Public Summary Document

Overall, the MSAC response is a fair assessment of the current situation for SMAs (with the exception of some small points). However, as a new and innovative process for dealing with chronic diseases, the process offers huge potential and existing successes overseas, which cannot be dismissed, largely on the basis of lack of evidence (which cannot be accumulated while the process is unavailable for use).

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.