ATTACHMENT A

SCHEDULE OF DOCUMENTS - FOI 2351

Document no.	Date	Pages	Description	Decision on access[1]	Exemption/s
1	10/03/2020	3	Letter from AMSL to the department regarding Dexcom G6	REI	s 22 (irrelevant information) s 47 (commercially sensitive) s 47F (personal privacy)
2	24/07/2020	2	Letter from the department to AMSL regarding Dexcom G6	REI	s 22 (irrelevant information) s 47 (commercially sensitive) s 47F (personal privacy)
3	31/07/2020	2	Meeting record of teleconference between AMSL and the department regarding Dexcom G6	REI	s 22 (irrelevant information) s 47 (commercially sensitive)
4	09/09/2020	7	Email between departmental officers attaching meeting brief regarding CGM and Dexcom G6	REI	s 22 (irrelevant information) s 47 (commercially sensitive) s 47F (personal privacy) s 47C (deliberative process)
5	23/10/2020	4	Ministerial submission - CGM and Dexcom G6	REI	s 22 (irrelevant information) s 47 (commercially sensitive) s 47F (personal privacy) s 47C (deliberative process) s 47E (certain operations of agencies)
6	26/10/2020	2	Letter from the department to AMSL regarding Dexcom G6	REI	s 22 (irrelevant information) s 47 (commercially sensitive)

[1] RI = Release with irrelevant information removed, REI exempt and irrelevant information removed

Document no.	Date	Pages	Description	Decision on access[1]	Exemption/s
7	2/11/2020	4	Email between departmental officers attaching a minute regarding Dexcom G6 and Guardian Link 3	REI	s 22 (irrelevant information) s 47 (commercially sensitive) s 47C (deliberative process)
8	1/12/2020	4	Minute regarding Dexcom G6 and Guardian Link 3	REI	s 22 (irrelevant information) s 47 (commercially sensitive) s 47C (deliberative process)

March 10, 2020
Department of Health
GPO Box 9848
Canberra ACT 2601

Sent via email: s22 & s22

Dear s22 and s22 ,

Proposal to Include Dexcom G6 on the CGM Initiative

On 27th February, AMSL (Australasian Medical & Scientific Ltd) received notification from the TGA (Therapeutics Goods Administration) that the Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) has been approved and listed on the ARTG (Australian Register of Therapeutic Goods).

During negotiation for reimbursement of Dexcom G4 and G5 Continuous Glucose Monitoring System via the CGM initiative AMSL brought to the Departments attention, under section 4.26.1 of the invitation to offer, new CGM technologies that were in the pipeline. It was further discussed specifically in an email dated 12 December 2016 Subject: Updated Applicant Response to the Invitation to Apply for the Inclusion of CGM Products to the NDSS.

AMSL would like to formally request addition of the Dexcom G6 System to the CGM Initiative with the intention to supply on 1st July 2020.

Dexcom G6 Continuous Glucose Monitoring System

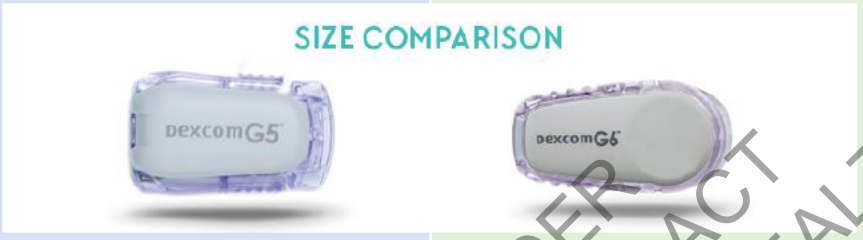
The Dexcom G6 System is indicated for persons with type 1 diabetes age 2 years and older. It is designed to replace finger stick blood glucose (BG) testing for treatment decisions. Interpretation of the Dexcom G6 System results should be based on the glucose trends and several sequential readings over time. The Dexcom G6 System also aids in the detection of episodes of hyperglycaemia and hypoglycaemia, facilitating both acute and long-term therapy adjustments. The Dexcom G6 System is also intended for use by patients at home and in healthcare facilities.

How the Dexcom G6 System works:

1. Simple auto-applicator – a one-touch applicator that easily inserts a small Sensor just beneath the skin.
2. Sensor and Transmitter – a slim Sensor which continuously measures glucose levels just beneath the skin and sends data wirelessly to a display device through a Transmitter.
3. Display device – a small touch screen receiver or compatible smart device displays real-time glucose data.

P 02 9882 3666 | W amsl.com.au | E amsl@amsl.com.au
A 2 McCabe Place, Chatswood NSW 2067

Comparison of Dexcom G6 and Dexcom G5 CGM

	Dexcom G5	Dexcom G6
Indicated Age	2 years +	2 years +
Dimensions Transmitter/Sensor	3.8cm x 2.3cm x 1.3cm (L x W x H)	**4.57cm x 3.05cm x 1.52cm (L x W x H) 30% Smaller**
		
Treatment decisions (Ability to administer insulin without confirming BG level via SMBG measurement)	Yes	Yes
Calibration (Calibrating, via SMBG device measurement being entered into the CGM device, to ensure ongoing accuracy of the Sensor)	Calibration via 2 SMBG measurements is required when initially applying the Sensor and every 12 hours thereafter.	**No**
Sensor Life	7 days	**10 days**
Transmitter Life	3 months	3 months
Stand-alone unit (no insulin pump required)	Yes	Yes
Insulin Pump Compatibility	Tandem t:slim X2 Insulin Pump	**Tandem t:slim X2 with Basal-IQ Technology** **Tandem t:slim X2 with Control Technology**
Receiving Device Compatibility	Android & Apple Compatible Mobile Devices. Dexcom G5 Mobile Receiver (sold separately).	Android & Apple Compatible Mobile Devices. Dexcom G6 Receiver (sold separately)
Waterproof	Sensor/Transmitter: when submerged for up to 2.4m and up to 24 hours	Sensor/Transmitter: when submerged for up to 2.4m and up to 24 hours
Customer Service	24/7 Australian based customer care	24/7 Australian based customer care
Alerts/Alarms	Customisable High and Low Alerts Fall and Rise Rate Alerts Mandatory 3.1mmol/L Urgent Low Alarm	Customisable High and Low Alerts Fall and Rise Rate Alerts **NEW Urgent Low Soon & Alert Schedules Feature** Mandatory 3.1mmol/L Urgent Low Alarm
Sensor	Manual Sensor applicator	**New automatic push button 'auto' Sensor applicator**
Paracetamol Interferences	Yes (not recommended to take paracetamol during use)	**No**
Compatible Data Software	Diasend by Glooko Dexcom CLARITY web version Dexcom CLARITY mobile app	Diasend by Glooko Dexcom CLARITY web version Dexcom CLARITY mobile app

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A 2 McCabe Place, Chatswood NSW 2067

Benefits of Dexcom G6 vs Dexcom G5 CGM

The Dexcom G6 System offers a longer duration of Sensor life (10 days) and better usability due to its improved Sensor membrane technology, 30% thinner and contoured wearable Sensor, improved applicator, no calibration requirement, and ability to provide accurate readings during use of acetaminophen.

For these reasons, the health outcomes demonstrated for the Dexcom G4 and G5 with 505 software are expected to be improved in Dexcom G6 System.

NDSS Pricing Model

	Annual Cost	Sensor Life	Cost / Box	Sensors / Box	Daily Cost
Dexcom G4/G5 Sensor	s47	7 Days	s47	4	s47
Dexcom G6 Sensor Proposal	s47	10 Days	s47	3	s47

AMSL acknowledges the Departments intention to maintain existing pricing arrangements. The proposed pricing maintains the annual cost on the CGM Initiative at s47 regardless of the added clinical benefits provided by the Dexcom G6 System.

Dexcom G4/G5 Sensors are currently supplied via the NDSS at s47 per box equating to a total annual cost of s47 . The Sensor life for G4/G5 is 7 days with 4 Sensors included in each box. Both Dexcom G4 and Dexcom G5 Transmitters are currently supplied at s47 .

Dexcom G6 Sensors are requested to be supplied via the NDSS at s47 per box equating to a total annual cost of s47 . The Sensor life for Dexcom G6 System is 10 days with 3 Sensors included in each box supplied to the end user. Dexcom G6 Transmitter will still be supplied at s47

Summary of Proposal

AMSL proposes that the Dexcom G6 System Sensor and Transmitter be listed at an annual reimbursement of s47 (Daily cost s47 , Per box cost s47).

This proposal is made in line with the Departments intention to provide greater value to end users who access products via the CGM initiative. AMSL will not be pursuing a price premium based on any added clinical benefit or cost saving when compared to other products on the CGM initiative.

We thank you for your support and look forward to hearing from you.

Yours sincerely,

s47F

s47F
Australasian Medical & Scientific Ltd.

Enclosed - Using Your G6 Instructions

P 02 9882 3666 | W amsl.com.au | E amsl@amsl.com.au
A 2 McCabe Place, Chatswood NSW 2067

From: ndss products <ndss.products@health.gov.au>
Sent: Friday, 24 July 2020 9:35 AM
To:
Cc: >; s22
ndss products <ndss.products@health.gov.au>
Subject: Advice re proposed listing of Dexcom G6 [SEC=OFFICIAL]

Dear

Please find attached correspondence from Ben Sladic regarding the proposed listing of the Dexcom G6 on the CGM Initiative.

Kind regards,

s22

s22

Assistant Director
Diabetes Products Section
Pharmacy Branch

Technology Assessment and Access Division | Health Benefits Group
Australian Government Department of Health
s22

GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

Australian Government
Department of Health

Division Manager – Diabetes and Medical
Australasian Medical and Scientific Ltd
2 McCabe Place
CHATSWOOD NSW 2067

Dear

Re: Proposal to Include Dexcom G6 in the CGM Initiative

Thank you for your correspondence to the Department dated 10 March 2020, and subsequent discussions between the Department, and yourself, proposing the inclusion of the Dexcom G6 continuous glucose monitoring (CGM) device in the CGM Initiative.

In considering this request, the Department has identified a need to review the current operating arrangements for this program to ensure procedural fairness and consistency in considering new products for subsidisation under the scheme.

A review of the CGM Initiative was planned to commence later this year, however this review will now be brought forward and commence shortly. We expect the review to be completed within three months. While this review is undertaken the listing of any new products within the CGM Initiative will be suspended.

However, your request to include the Dexcom G6 system within the CGM Initiative will be considered as part of this review. You will be advised of the outcome of this request when the review is finalised.

Undertaking this review will support the long-term sustainability of the program and streamline future administrative arrangements for managing changes to the CGM Initiative and ensure all requests for subsidisation are dealt with on an equitable basis.

We appreciate your patience in this matter and thank you for your continued support of the CGM Initiative.

If you have any queries please contact s22 or at ndss.products@health.gov.au.

Yours sincerely

Ben Sladic
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
24 July 2020

Meeting Record

Teleconference with Australasian Medical and Scientific Ltd (AMSL) - Listing of Dexcom G6 on the CGM Initiative

Time: **3.00 pm to 3.45 pm**
Date: **Friday 31 July 2020**

Attendees:

Department	***AMSL***
s22	s47F

Apologies – Ben Sladic

Purpose of Meeting

AMSL requested the meeting to discuss the response letter from DoH regarding the delay of consideration of the Dexcom G6 (G6) device for listing as a subsidised product under the CGM Initiative.

- s22 commenced the teleconference and opened the floor to AMSL
- s47F noted the letter from DoH and indicated that AMSL was seeking a reversal of the decision to defer consideration or listing of the G6 device through the CGM Initiative.
- s47F commented that inclusion of the G6 would only bring further benefits and superior health outcomes for the CGM Initiative, as it had improved technology and compatibility with a range on Tandem® Insulin Pumps. s47F noted that these features had been a prime aspect of consideration for CGM since its implementation in 2017.
- s47F advised that there might be health ramifications for Tandem® Insulin Pump users, as software for these is being updated that will impact the insulin suspend functionality, and that this would only continue to function with the G6 platform (i.e. G4 and G5 devices will not interact with the updated software).
- s47F commented that DoH would like to have further information about the suggested Tandem® software upgrade provided and that he was surprised that it was being suggested that users of the G4 and G5 CGM devices would be impacted. s47F advised that AMSL could provide further information by Monday (3/8).
- s47F commented that since providing the AMSL proposal for the listing of the G6, all indications were that there would be an imminent listing of the product. s47F noted however, that DoH had not indicated this formally.
- In response to the G6's imminent listing, AMSL had moved to have sufficient stock on-hand to enable supply to commence immediately. s47F noted that the G6, with its superior technology, was being offered to DoH at the same price as the G4/G5 devices.
- s47F commented that he believed that DoH had set a precedent by listing the Medtronic Guardian Sensor (3) on the CGM, when the measure was expanded in March 2019.
- s47F acknowledged the good working relationship that was in place between AMSL and DoH and s22 commented that AMSL had always been very proactive in working with DoH.

- s22 advised that on receipt of the AMSL G6 proposal, DoH had commenced considering this on the basis of being a 'me too' listing – i.e. the product had functional and financial equivalence to the existing CGM products listed. However, the G6 exhibits some differences from other CGM products; particularly the fact that it does not require calibration.
- s22 commented that when the Guardian Sensor (3) was approved by the Minister for inclusion, this was on the basis that its functionality was the same as the other CGM sensors listed. FreeStyle Libre has been approved for listing but it is noted that its functionality is different (i.e. Flash GM).
- s22 also pointed out that Freestyle Libre went through an extensive assessment process and scrutiny prior to it being approved for listing through the CGM Initiative.
- s22 advised that DoH needs to establish a clear framework for considering new products for listing to ensure product assessment is equitable and consistent, and that it is important that DoH does not establish a precedent that would be problematic in relation to potential future consideration of new CGM products.
- s22 commented that in an effort to expedite the consideration of the G6 sensor, the G6 will be considered as part of the review of CGM. The timing for the review is expected to be approximately three months.
- s47F commented that as part of the process in preparing for the implementation of CGM in 2017, advice was sought from product sponsors as to what new technology may be available in the near future - AMSL had indicated that the G6 was in the pipeline.
- Whilst s47F noted that the G6 has a 10 day sensor life and an absence of calibration, he still could not see why the Guardian Sensor (3) was listed but G6 has not been.
- s22 responded by advising that DoH sees the products as being different and that it needs to assess these differences on their merits.
- s22 commented that the CGM Review was more about the subsidisation pathway and ensuring consistency, rather than a concern about a particular product.
- s22 again asked about the changes through the Tandem® software upgrade. s47F advised that the update will affect the blood glucose suspend functionality and will involve all Tandem® insulin pumps.
- s47F reiterated that the software update will means that the G4 and G5 CGM devices will not work with Tandem® insulin pumps.
- s22 commented that he was concerned that this might mean that safety issues would occur for G4/G5 users, and was interested in what level of control users would have in not accepting the software upgrades for their pumps.
- s47F asked whether DoH is looking to renegotiate the pricing structure of CGM devices as an outcome of the Review. s22 advised that this was not the purpose of the review but that being said, the Government must always have pricing and costs at the forefront of their program management strategies.

Meeting ended at 3.35 pm

From: s22
Sent: Wednesday, 9 September 2020 11:51 AM
To: Platona, Adriana
Cc: Sladic, Ben ; s22
Subject: Meeting Brief - CGM Review/G6 Listing [SEC=OFFICIAL]

Hi Adriana,

Please find attached a brief for your meeting with Ben and I at 9.15am tomorrow (via telco). This meeting is to discuss the HTA process for the CGM Initiative and the requested listing of the Dexcom G6 product.

Thanks

s22

Director
Diabetes Products Section
Pharmacy Branch
Technology Assessment and Access Division
s22

MEETING BRIEF

With: Adriana Platona
Date and Time: **Thursday, 10 September 2020, 9.15am-9.45am**

Participants (via Telco):
Adriana Platona, First Assistant Secretary, TAAD
Ben Sladic, Assistant Secretary, Pharmacy Branch
s22 , Director, Diabetes Products Section

Dial-in Details
Phone: (02) 8016 6192
Participant code: s22

Purpose:
To discuss the proposed approach for the CGM Review and arrangements for managing the request to list the G6 sensor from AMSL.

Key Issues:
1. Proposed Arrangements for the CGM Review – particularly timing – based on advice from MSAC Secretariat.
2. Handling arrangements for the G6 sensor.

Discussion

1. Proposed CGM Review Following MSAC Advice

- Based on advice from the MSAC Secretariat, MSAC will not be able to consider this matter this year – it will potentially be able to consider it at its March 2021 meeting or later.
- We are currently working with the MSAC secretariat to clarify how this review will work.
- Currently, the key questions to be resolved are:
    - should the product sponsors be involved in this review (recommend that they are as this supports a transparent process and allows them to comment on the information prepared); and
    - where should funding come from (MSAC appropriation or NDSS Appropriation) – cost is estimated at up to s47 .
- The MSAC will be asked to provide advice on the following matters:
    - the cost effective price of each of the products currently listed on the CGM Initiative (individually or by category) – this will also include the G6 and FreeStyle Libre 2; and
    - commentary on the eligibility criteria and whether individual product selection should be restricted or whether there should be a first line/second line approach to access (eg should access default to the cheapest product unless there is a clinical reason to use a more expensive option).
- The longer than anticipated timing doesn't create problems for the CGM Initiative except in relation to the request to list the G6 sensor – this is addressed below.

2. Handling Arrangements for the Dexcom G6 Sensor

AMSL has previously been advised that the review of the CGM Initiative would take approximately 3 months and that this would include consideration of the Dexcom G6 (Attachment A).

As the timeframe is now significantly longer than initially anticipated we will need to advise AMSL of our revised approach.

Three options have been identified for dealing with the request to list the G6 product: do not list until the MSAC review and any subsequent action is complete; list now and revisit following completion of the CGM Review; or provide limited or restricted access to the G6 product. These options are addressed below:

Option 1: Take no action until the review of CGM products is complete.

Under this option, we would advise AMSL that the G6 product will not be listed until MSAC has provided advice on cost-effectiveness. Following this advice we may also need to seek direction from the Minister and/or open new negotiations with CGM suppliers around pricing. Consequently, any action in relation to the G6 sensor may not occur until mid to late 2021.

Issues:

- People using the Tandem insulin pump may choose not to upgrade the existing software and miss out on the additional safety technology provided by the update (low glucose suspend which suspends delivery of insulin – this can be a life-saving feature).
- People using Dexcom products will not have access to a product that removes the need for blood glucose test strips (BGTS) which provides significant life-style benefits for users.
- s47C

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- AMSL has already raised concern that it has stock that it will be unable to sell if the product is not listed (however it has acknowledged that the Department has never given a commitment that the product would be listed).

Option 2: List the G6 product now and revisit arrangements following MSAC advice

The G6 product could be considered a 'me too' product and listed for use. AMSL would be advised that once MSAC has provided advice in relation to CGM products that the Department may seek to take further action on that advice such as revisiting commercial arrangements or eligibility criteria.

Issues:

- s47

- Any resultant increase in the cost of the CGM Initiative this year is expected to be able to be accommodated within the existing CGM budget.s47C

- If the G6 is listed, users of the Tandem insulin pump may consequently apply a recommended software upgrade to their pumps which will result in the pump only being compatible with the G6 sensor. In the event that the sensor was subsequently removed from the scheme, users would not be able to reverse this update and consequently would not be able to access subsidised CGM sensors for use with their pump.
- s22

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Option 3: List the G6 with restrictionss47

Under this option, the G6 would be listed but with restricted access. These restrictions could be one or more of the following criteria for allowing people to choose to use the G6:

- people currently using Dexcom products (ie G4/G5);
- new participants signing up to the scheme;
- only allow people to use G6 where they currently use a compatible pump; or
- only allow people to switch from FSL where they can demonstrate a clear clinical need for the features of full CGM products.

Two significant problems with this approach are:

- there would be significant IT and administrative work to support these arrangements (and they would likely change again following completion of the CGM Review); and

- we could be accused of unfairly limiting the market for the G6 as we're imposing restrictions on one product that do not apply to any other products in the scheme.

Recommendation
That we select Option 2, list the G6 as effectively a 'me too' listing and then revisit CGM product arrangements once the MSAC review is complete. This ensures people are able to benefit from the enhanced functionality of the G6 sensor and the flow-on improvements for Tandem pump users, avoids significant IT and administrative costs, and allows the matter to be further considered after the MSAC review.

Note that we would need to consider whether a 'me too' listing is appropriate, noting the requirement for a 'nil' financial impact, or whether Ministerial approval is required. s22

s22, s47E

Australian Government
Department of Health

s47F
Division Manager – Diabetes and Medical
Australasian Medical and Scientific Ltd
2 McCabe Place
CHATSWOOD NSW 2067

Dear s47F

Re: Proposal to Include Dexcom G6 in the CGM Initiative

Thank you for your correspondence to the Department dated 10 March 2020, and subsequent discussions between the Department, s47F and yourself, proposing the inclusion of the Dexcom G6 continuous glucose monitoring (CGM) device in the CGM Initiative.

In considering this request, the Department has identified a need to review the current operating arrangements for this program to ensure procedural fairness and consistency in considering new products for subsidisation under the scheme.

A review of the CGM Initiative was planned to commence later this year, however this review will now be brought forward and commence shortly. We expect the review to be completed within three months. While this review is undertaken the listing of any new products within the CGM Initiative will be suspended.

However, your request to include the Dexcom G6 system within the CGM Initiative will be considered as part of this review. You will be advised of the outcome of this request when the review is finalised.

Undertaking this review will support the long-term sustainability of the program and streamline future administrative arrangements for managing changes to the CGM Initiative and ensure all requests for subsidisation are dealt with on an equitable basis.

We appreciate your patience in this matter and thank you for your continued support of the CGM Initiative.

If you have any queries please contact s22 or at ndss.products@health.gov.au.

Yours sincerely

Ben Sladic
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
24 July 2020

Australian Government
Department of Health

Ministerial Submission – Standard
MS20-001114 Version (1)
Date sent to MO:21/10/20

To: **Minister Hunt**

Subject: **Medical Services Advisory Committee (MSAC) Review of Products Subsidised Under the Continuous Glucose Monitoring (CGM) Initiative**

Critical date: 4 November 2020

Recommendations:

1.	**Agree** to a Health Technology Assessment (HTA) process being undertaken by MSAC for all products currently subsidised under the Continuous Glucose Monitoring (CGM) Initiative.	**1. Agreed / Not Agreed**
2.	**Note** that the results of this review and any subsequent recommended action will be provided to you for consideration.	**2. Noted**
3.	**Note** that the new Dexcom G6 CGM system will be assessed as part of this process, to inform any future listing.	**3. Noted**
4.	**Note** that pending the outcome of the MSAC review the Department may list the Dexcom G6 for a small cohort of people, who may be disadvantaged if it is not listed, due to connectivity issues with a specific brand of insulin pump.	**4. Noted**
5.	**Agree** to the Department establishing MSAC as the standard HTA pathway for new listings and technical matters for the National Diabetes Services Scheme (NDSS).	**5. Agreed / Not Agreed**

Signature ..... **Date:** 23/10/2020

Media Release required? YES/ NO

Comments:

Contact Officer:	*Adriana Platona*	*First Assistant Secretary, Technology Assessment & Access Division*	Ph: (02) 6289 1886 s22
Clearance Officer:	*Penny Shakespeare*	*Deputy Secretary, Health Resourcing Group*	Ph: (02) 6289 3348 s22

Issues:

1. The CGM Initiative currently provides fully subsidised access to a range of CGM products. When the CGM Initiative was established, there were only two suppliers of this technology in Australia. At the time, pricing was established through a competitive process which achieved significant savings compared to retail prices.

2. However, more suppliers have now entered the Australian market with further entrants expected in the near future. There is significant innovation in this sector with a range of new or enhanced CGM products emerging.

3. The Department has received a request from AMSL Pty Ltd to list the new Dexcom G6 product within the CGM Initiative, s47

4. To ensure the Department can appropriately assess and consider funding requests in relation to these products, it is essential that all products seeking subsidisation under the CGM Initiative – including those already subsidised – are evaluated through a formal HTA process. The appropriate HTA body to undertake this work is the MSAC. This would include the Dexcom G6 product.

5. This will ensure that all products are considered in a fair and equitable manner through a process that is robust and transparent. It will also formally establish the safety, efficacy, clinical effectiveness and cost effectiveness of these products, providing a sound basis on which future policy decisions in relation to this program can be made.

6. The MSAC review process is expected to be completed in mid-2021. Any future requests for product subsidisation under the CGM Initiative would be directed to MSAC for assessment.

7. A similar approach is proposed for products subsidised under the National Diabetes Services Scheme (NDSS). While existing products would not be subject to this review, any request to subsidise a new product may be directed to MSAC for assessment.

8. Note that MSAC is a technical body that advises on technical matters associated with evidence-based assessment of clinical effectiveness and cost effectiveness. A decision to fund, or not fund, a new product would remain a matter for Government.

9. Pending the results of the MSAC assessment, the Department may also approve a limited listing of the Dexcom G6 product within the CGM Initiative. This would be to support a small cohort of people using a model of insulin pump that may become incompatible with currently funded CGM sensors due to a software update for the pump. s47

s47

s47 This arrangement would be approved by the Departmental delegate.

Background:

<u>Dexcom G6 Product</u>

The Dexcom G6 CGM product is similar to the Dexcom G4 and Dexcom G5 with some notable differences: it has a longer sensor-life and does not require the use of blood glucose test strips (BGTS) to calibrate the device. s47

s47

While the product performs a similar role to the currently subsidised Dexcom products, and is offered s47

s47

s22

s47

CGM Initiative

The CGM Initiative commenced on 1 April 2017 and currently provides fully subsidised (ie no patient co-payment) CGM products to the following groups of people:

- children and young people, under 21 years of age, with type 1 diabetes
- children and young people with conditions very similar to type 1 diabetes, such as cystic fibrosis related diabetes and neonatal diabetes, who require insulin
- women with type 1 diabetes who are planning for pregnancy, pregnant or immediately post-pregnancy
- people with type 1 diabetes aged 21 years or older who have concessional status.

Products currently subsidised under the CGM Initiative are supplied by Medtronic Pty Ltd, AMSL Pty Ltd, and Abbott Diabetes Care Pty Ltd.

National Diabetes Services Scheme (NDSS)

The National Diabetes Services Scheme (NDSS) was established in 1987 to provide subsidised products and services needed for the effective self-management of diabetes. It delivers subsidised syringes and needles, blood glucose test strips, urine ketone test strips, insulin pump consumables and continuous glucose monitors to people with diabetes. In addition, NDSS also provides education and information to assist with the best use of products and diabetes self-management.

Changes to the products subsidised under the Scheme have only occurred on a small number of occasions. These include the addition of insulin pump consumables in 2004 and more recently the addition of Continuous Glucose Monitoring (CGM) products. 47E

47E

Medical Services Advisory Committee (MSAC)

The Medical Services Advisory Committee (MSAC) is an independent non-statutory committee established by the Australian Government Minister for Health in 1998. MSAC appraises new medical services proposed for public funding, and provides advice to Government on whether a new medical service should be publicly funded (and if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence. Amendments and reviews of existing services funded on the Medical Benefits Schedule (MBS) or other programmes (for example, high cost therapies under the NHRA, blood products or screening programs) are also considered by MSAC.

Budget/Financial Implications: Undertaking the review of CGM products would not result in products being added or removed from the CGM Initiative at this stage and consequently does not change the cost of the program.

s47C

s22

47E

Regulatory Burden Implications and/or Deregulation Opportunities: Nil

Communication/Media Activities: There are no community awareness opportunities relating to this submission.

Impact on Rural and Regional Australians: People living in rural and regional areas will not be impacted differently to those in metropolitan areas.

Australian Government
Department of Health

s47F
General Manager
Australasian Medical and Scientific Ltd
2 McCabe Place
CHATSWOOD NSW 206

Continuous Glucose Monitoring (CGM) Initiative – Requested Listing of Dexcom G6

Dear s47F

I am writing in relation to the request from Australasian Medical and Scientific Ltd (AMSL) to list the Dexcom G6 continuous glucose monitoring system within the CGM Initiative.

As outlined in my earlier correspondence of 24 July 2020, it was the Department's intention to undertake a review of the CGM Initiative to ensure that any future product listings – such as the Dexcom G6 – were managed in a consistent and transparent manner that ensured procedural fairness for all product suppliers and the best outcomes for NDSS registrants and Australian tax-payers.

In considering the current arrangements in place for the CGM Initiative, the Department has determined that all current CGM products subsidised under the CGM Initiative, and those for which subsidisation is sought, should be formally evaluated through a health technology assessment (HTA) process.

To facilitate this process, the Medical Services Advisory Committee (MSAC) has been appointed as the formal HTA pathway for new products seeking subsidisation under the CGM Initiative.

A formal review of these products, sponsored by the Department, has commenced and product suppliers (including AMSL) will shortly be invited to make a submission to this review.

The impact of this decision is that the Dexcom G6 will not be considered for listing within the CGM Initiative until the HTA process has been completed. The timing for this process is still being finalised but it is expected to be finalised mid next year.

In the interim, we understand that some NDSS registrants may be directly impacted by this decision where they are using an insulin pump that will become incompatible with the currently listed Dexcom G5 sensor, following a software update to the pump.

To address this issue, the Department may approve a limited listing of this sensor for use by NDSS registrants in this situation. Officers from my branch will be in contact to arrange a meeting later this week to discuss this matter.

While I understand that this may be unwelcome news for your organisation, I appreciate your continued support of the CGM Initiative and look forward to working productively with you in relation to this matter.

If you have any queries please contact s22 or at ndss.products@health.gov.au.

Yours sincerely

Ben Sladic
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
26 October 2020

From: s22
Sent: Tuesday, 1 December 2020 1:53 PM
To: CRANK, Mariana <Mariana.Crank@health.gov.au>
Cc: ndss products <ndss.products@health.gov.au>
Subject: FOR APPROVAL: Additions to the NDSS Product Schedule/CGM Initiative [SEC=OFFICIAL]

Hi Mariana,

Please find attached for your clearance a minute to Thea seeking approval for 3 new listings on the NDSS Product Schedule, as part of the CGM Initiative. Ben is aware of these listings and is comfortable with the approach.

Happy to discuss.

Cheers

s22
Director
Diabetes Products Section
Pharmacy Branch
Technology Assessment and Access Division
s22

Australian Government
Department of Health

To:	Thea Connolly A/g First Assistant Secretary Technology Assessment and Access Division	**Deadline:** Contact officer:	4 December 2020 s22
From:	Mariana Crank	Phone:	s22
Date:	1 December 2020	TRIM Ref:	

APPROVAL OF LISTINGS s47 ON THE NATIONAL DIABETES SERVICES SCHEME FROM 13 DECEMBER 2020

Purpose

To seek your approval to list three items s47 to Government under the Continuous Glucose Monitoring (CGM) Initiative through the National Diabetes Services Scheme (NDSS) from 13 December 2020.

Issue

The following three CGM products are recommended for listing on the NDSS Product Schedule, for registrants eligible to receive assistance through the CGM Initiative:

- Dexcom G6 Sensor;
- Dexcom G6 Transmitter; and
- s22

<u>Dexcom G6 Sensor and Transmitter</u>

The Dexcom G6 Sensor and Transmitter are the latest models in the Dexcom range. The Dexcom G4 and Dexcom G5 are currently subsidised under the CGM Initiative. s47

Consequently, a full listing of this product is not recommended until MSAC has assessed the cost-effectiveness of all products subsidised under the CGM Initiative.

However, as a result of a software update for a specific model of insulin pump – the Tandem t:slim X2 – the pump will no longer be compatible with the currently subsidised G5 sensors, and will only be compatible with G6 sensors. This means that current participants in the CGM Initiative, who also use this insulin pump, may be disadvantaged as they will not be able to access subsidised, compatible sensors.

Note that the software update was recommended by the Therapeutic Goods Administration and provides clinical benefits to the user.

To address this issue, a limited listing of the G6 product is recommended with eligibility restricted to current users of the Tandem t:slim X2 pump. By limiting access to this cohort – which will comprise current users of the G5 product – s47

s22

Timing

These products will be listed on the NDSS Product Schedule no earlier than 13 December 2020, with specific timing agreed in consultation with Diabetes Australia and product manufacturers.

47E

Delegation

You have the legal delegation to make arrangements for the availability of all NDSS equipment under Section 9A of the National Health Act 1953.

s47F

Recommendation

That you:

R1 **APPROVE** the three items at Attachment A for listing on the NDSS from 13 December 2020. **APPROVED / NOT APPROVED**

Mariana Crank
A/g Assistant Secretary
Pharmacy Branch
December 2020

Thea Connolly
A/g First Assistant Secretary
Technology Assessment and Access Division
December 2020

ATTACHMENTS:

A: NDSS listings

Attachment A

Proposed NDSS listings for 13 December 2020 with no financial impact for the NDSS

Type of listing	Product	Indication	Fiscal Impact over 5 years ($m)
NDSS recommendation: The NDSS program area recommends the listing of these products on the NDSS.	s22	For the management of **diabetes**	s47
	Dexcom G6 Sensor		s47
	Dexcom G6 Transmitter.		s47

These items are comparable and directly substitutable with products already listed on the NDSS s47

The Dexcom G6 Sensor and G6 transmitter will only be available to patients currently using the Tandem t:slim X2 insulin pump (due to technical compatibility with this system), and is comparable and directly substitutable with Dexcom G4 and Dexcom G5 sensors that are already listed on the National Diabetes Services Scheme (NDSS).

s47

s22

From: CONNOLLY, Thea <Thea.Connolly@health.gov.au>
Sent: Tuesday, 1 December 2020 5:16 PM
To: CRANK, Mariana <Mariana.Crank@health.gov.au>
Cc: s22 >; ndss products <ndss.products@health.gov.au>
Subject: RE: FOR APPROVAL: Additions to the NDSS Product Schedule/CGM Initiative [SEC=OFFICIAL]

Approved thanks Mariana and s22

Thea Connolly
A/g First Assistant Secretary
Technology Assessment and Access Division
Department of Health
s22

s22