From: Alishba Ali
Sent: Friday, 15 January 2021 11:16 am
To: Kirstin Brown
Subject: RE: Weekly Update (15 January 2021)

Good morning Kirstin,

Thank you for the update.

I am still waiting on advice from the Therapeutic Group Manager around your queries. She will be joining us on the call next week and can talk to some of the points that you have raised.

Ngā mihi,

Alishba Ali | Contract Manager
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From: Kirstin Brown <Withheld under section >
Sent: Thursday, 14 January 2021 9:29 pm
To: Alishba Ali <Withheld under section 9(2)(a) >

Subject: Weekly Update (15 January 2021)

Hi Alishba,

I hope this finds you well.

Withheld under section 9(2)(ba)(i)

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Basal IQ Features will be available for all Tandem Pumpers, via a firmware upgrade as of January 25th, 2021.

Like any modern device such as smartphones, keeping the Tandem pump updated with the latest software is important to ensure that our Patients have access to all the latest enhancements, so that they can get the most out of their pumping experience. Later this month NZMS will offer **all** New Zealand Tandem customers, with in-warranty pumps, the opportunity to upgrade their Pump to the latest Basal IQ version.

Launch plans are in place for Control IQ software in NZ.

NZMS will trial 5 patients on Control IQ from January 27th with a trial review set for the 8th of March. All going well from the 15th of March we will run a pre-launch to a select group of patients by the HCP's with a plan for a broader market launch May 3rd.

Questions for Pharmac

Wondering if you have had any responses from your colleagues around the questions I asked late last year… 1) NZMS's next steps for our submission for reimbursement of the Dexcom G6 CGM and also, Withheld under section 9(2)(b)(ii)

Withheld under section 9(2)(b)(ii)

Withheld under section 9(2)(b)(ii)

Withheld under section 9(2)(b)(ii)

Withheld under section 9(2)(b)(ii)

Look forward to discussing these things with you next week Alishba. Keep well!

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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nzms diagnostic & point of care

nzms diabetes

nzms allergy

From: Kirstin Brown <Withheld under section>
Sent: Friday, 22 January 2021 9:10 am
To: Alishba Ali
Subject: Weekly Update (22 January 2021)

Good Morning Alishba,

I hope this finds you well.

Withheld under section 9(2)(ba)(i)

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Withheld under section 9(2)(ba)(i)

On the 25th of January NZMS will offer all NZ Tandem customers with in-warranty pumps the opportunity to upgrade to the latest Basal IQ version software. An email will be sent to customers on the 25th advising them of the upgrade and giving them instruction on how to do it. Upgrades are managed for safety and compliance by NZMS through Asset Management and Learning Management Systems. NZMS records the current software and available software for each in-warranty pump by serial number, along with all affiliated patient education required and completed.

Look forward to talking to you soon.

Many Thanks &
Kind Regards,

Kirstin Brown11th
Division Manager

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FILE NOTE

Subject:	Tandem pump
Event Type:	Phone Call
Author:	Alishba Ali (AA)
Attendees:	Alishba Ali (AA), Elena Saunders (ES) – PHARMAC Kirstin Brown (KB) – NZMS
Location:	Phone call
Date event took place:	22 January 2021

Basal IQ:

- ES noted in response to NZMS query about Basal IQ: Offering the upgrade to Basal IQ is all fine from PHARMAC perspective.

Control IQ:

- ES noted in response to NZMS query about Control IQ:
    - NZMS need to do a full funding application and a waiver type situation won't work. If NZMS want to offer this as an option upgrade and patients want to pay for it privately, then it is a commercial decision for them to make and we cannot make any recommendations on this as long as there is no undue pressure on patients to upgrade.
    - In a scenario where PHARMAC consideration for funding would be required, NZMS need to provide a full funding application through the PHARMconnect website with a justification around clinical value associated with the upgrade. ES noted that we would normally require clinical data to support this and KB advised that they have clinical data available to support this.
    - ES noted that we normally look at clinical advice, cost utility perspective and ranking against other investment options with any applications.
    - Diabetes SC meeting Q2/Q3 this year and if NZMS do intend to progress with Control IQ, it would be good to have the application before the meeting.
    - No objection to doing both.

Dexcom CGM

- Advice around CGM in the next diabetes SC meeting (last year's meeting got cancelled). Planning to take Dexcom as part of wider discussion. Dexcom application in process of being uploaded to application tracker – had considered this as a commercial proposal, but now view is we would consider this a funding application.

- ES advised that NZMS welcome to come and present if there is more information available – record of meeting is published publicly and we would normally send it to you prior to it being made available publicly to check if there is anything commercially sensitive etc.

- Goes to PTAC after that but possible there would be no further recommendation from PTAC as this Committee has previously noted that it may not be best placed to provide advice to PHARMAC on devices.

Withheld under section 9(2)(b)(ii)

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Feedback from clinicians

- ES mentioned feedback from clinician around offer of free pumps to users before their SA expires.

- KB noted it is something that NZMS do not wish to do, KB noted that in her time she has done one-off approval to loan them a pump until they could finish off their script, not something that they are commercially doing and no programs of this nature are being offered.

Withheld under section 9(2)(b)(ii)

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Withheld under section 9(2)(b)(ii)

From: Kirstin Brown <Withheld under section>
Sent: Wednesday, 27 January 2021 10:23 am
To: Elena Saunders
Cc: Alishba Ali
Subject: RE: PHARMAC: phone call follow-up

Fantastic, thank you Elena.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Wednesday, 27 January 2021 9:26 a.m.
To: Kirstin Brown <Withheld under section>
Cc: Alishba Ali <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC: phone call follow-up

Kia ora Kirstin,

Until the process has been announced I can't confirm anything, but based on the information available I think it's likely it would be just for community meters.

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager
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From: Kirstin Brown <Withheld under section>
Sent: Monday, 25 January 2021 10:54 am

To: Elena Saunders <[redacted]>
Cc: Alishba Ali <[redacted]>
Subject: RE: PHARMAC: phone call follow-up

Hi Elena,

Thank you so much for this information, greatly appreciated.

Do you know if Hospital Meters will also be in scope for this coming blood glucose monitor tender, or if it will just be Community Meters?

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Elena Saunders <[redacted]>
Sent: Friday, 22 January 2021 11:02 a.m.
To: Kirstin Brown <[redacted]>
Cc: Alishba Ali <[redacted]>
Subject: PHARMAC: phone call follow-up

Kia ora Kirstin,

Further to our phone call today – here are some links that may be of use to you.

For a new investment of Combined Pharmaceutical Budget (CPB) funds, we generally need a funding application to consider how the option ranks against other options for investment. From what we have discussed, my view is that the Control IQ would fall in scope. More information about making a funding application is available here.

With respect to blood glucose monitors, the current arrangement includes sole supply until 30 June 2022. You can read more about that here. As discussed, the procurement process that led to the current arrangement was a lengthy one – you may be interested to read more about it at the following links;

EOI: https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/invitation-for-expressions-of-interest-for-the-supply-of-diabetes-management-products/

RFP: https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/request-for-proposals-supply-of-funded-diabetes-management-products/

Consultation: https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/diabetes-management-products-amended-4-august/

Decision notification: https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/diabetes-management-products/

I hope this is helpful.

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

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From: Kirstin Brown <Withheld under section>
Sent: Thursday, 4 February 2021 8:30 pm
To: Alishba Ali
Cc: Igor Obradovic
Subject: Weekly Update (4 January 2021)

Hi Alishba,

I hope this finds you well.

Withheld under section 9(2)(ba)(i)

I am taking annual leave from the 8th to the 20th. Withheld under section 9(2)(ba)(i)

Withheld under section 9(2)(ba)(i)

If you have any concerns you can also contact our Product Manager, Igor Obradovic (copy to this email) who will be able to get any information you require. Of course, you can also reach me over this period on my mobile.

Look forward to catching up with you tomorrow.

Many Thanks &
Kind Regards,

Kirstin Brown

Division Manager

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nzms diagnostic & point of care

nzms diabetes

nzms allergy

From: Kirstin Brown <[redacted]>
Sent: Friday, 19 March 2021 8:56 am
To: Alishba Ali
Subject: Weekly Update (19 March 2021)

Morning Alishba,

I hope this finds you well.

Just to let you know... there have been no further updates this week [redacted].

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Kirstin Brown <Withheld under section>
Sent: Friday, 5 March 2021 9:00 am
To: Alishba Ali
Subject: RE: Weekly Update (05 March 2021)

Morning Alishba,

I hope this finds you well.

Just to let you know that I have no further updates for you this week Withheld under section 9(2)(ba)(i)).

Look forward to talking to you later this morning.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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From: Kirstin Brown
Sent: Thursday, 25 February 2021 6:28 PM
To: 'Alishba Ali' <Withheld under section 9(2)(a)>
Subject: Weekly Update (26 February 2021)

Hi Alishba,

I hope this finds you well.

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Withheld under section 9(2)(ba)(i)

Withheld under section 9(2)(ba)(i)

Look forward to talking to you tomorrow.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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From: Alishba Ali
Sent: Friday, 26 February 2021 12:12 pm
To: Alishba Ali
Subject: 2021-02-26 file note RE: phone call with Kirstin Brown NZMS - Tandem pump

In late January 2021, NZMS offered an upgrade to [redacted], including a free trial for the Dexcom G6 as part of the upgrade offer.
Approx. [redacted] have taken up the Dexcom G6 offer.
Approx [redacted].
[redacted]
[redacted]
Kirstin also noted that their application for Dexcom G6, submitted in April 2019 is not showing on the Application Tracker – I advised that I can check and get in touch with the right person at PHARMAC.

Ngā mihi,

Alishba Ali | Contract Manager

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From: Alishba Ali
Sent: Thursday, 8 April 2021 2:01 pm
To: Adam McRae
Cc: Joshua Cronin-Lampe; Gillian Anderson
Subject: NZMS Tandem pump
Attachments: 2021-04-08 from Kirstin Brown RE_ Update_ Tandem & Dexcom.obr

Hi Adam,

Withheld under section 9(2)(ba)(i)

They are planning to re-submit the Dexcom application and have asked when this would be considered. If there's anything we can share from a timing perspective, do let me know.

Ngā mihi,

Alishba Ali | Contract Manager

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From: Kirstin Brown <Withheld under section>
Sent: Thursday, 8 April 2021 1:19 pm
To: Alishba Ali
Subject: Update: Tandem & Dexcom

Hi Alishba,

I hope this finds you well.

Two quick notes for you…

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Regarding Dexcom
We are working with the Dexcom Market Access Team and are aiming to have the 2018 Submission updated and re-submitted to you by the 31st of May. Elena mentioned back in January that the Diabetes Sub-Committee Meeting to discuss this submission was likely to be scheduled in Q3 or Q4. Alishba, can you please keep me updated on the timings for this as they come to hand?

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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From: Joshua Cronin-Lampe
Sent: Tuesday, 25 May 2021 2:07 pm
To: Alishba Ali
Subject: RE: Update: CGM Dexcom submission / community meter tender

Hi Alishba,

Thank you for forwarding this on. I'll contact Kirsten and let them know about our plans regarding a Diabetes SC meeting.

Josh

From: Alishba Ali <Withheld under section 9(2)(a)>
Sent: Tuesday, 25 May 2021 9:11 am
To: Joshua Cronin-Lampe <Withheld under section 9(2)(a)>
Subject: FW: Update: CGM Dexcom submission / community meter tender

Hi Josh,

Please see email from NZMS below.

For context, I have attached the file note of the conversation Elena and I had with them earlier this year plus their email to us about the Dexcom submission.

Any questions, please let me know.

Ngā mihi,

Alishba Ali | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
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From: Kirstin Brown <[redacted]>
Sent: Monday, 24 May 2021 5:19 pm
To: Alishba Ali <[redacted]>
Subject: Update: CGM Dexcom submission / community meter tender

Hi Alishba,

I hope this finds you well.

I'm contacting you for a couple of quick catch ups;

1. I wanted to check in with you to see if there was any further update on the Dexcom CGM submission. You may recall, due to a technical glitch, this isn't showing up on your website and Elena had advised earlier this year that it was pencilled for review with the Diabetes Sub-committee in Q3 or Q4 of this year. Has there been a meeting set for this? I am in the process of updating the submission which was first made in 2018/2019 and am looking for timing to advise as to when this updated submission will be required by.

2. I also wanted to ask if there was any updates on the timing for the pending Community Glucose / Ketone

Meter Tender. From Elena's last this was scheduled for Q3 and Q4 also.

Look forward to hearing from you.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

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From: Kirstin Brown <[redacted]>
Sent: Friday, 9 July 2021 6:52 am
To: Joshua Cronin-Lampe; Adam McRae
Cc: Donald Rentoul; [redacted]
Subject: RE: Discussion: Dexcom Submission - Pharmac / THEMA / Dexcom / NZMS - 10am NZT Friday 9th July
Attachments: NICE G6 Medical Innovation Briefing.pdf

Good Morning Josh and Adam,

Please find attached a product briefing document in preparation for this morning call. The thought was that this might offer some frame and reference for the conversation later this morning.

Catch you soon,

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Kirstin Brown
Sent: Thursday, 8 July 2021 4:07 p.m.
To: Joshua Cronin-Lampe <[redacted]>; Adam McRae <[redacted]>
Cc: Donald Rentoul <[redacted]>; [redacted]
Subject: Discussion: Dexcom Submission - Pharmac / THEMA / Dexcom / NZMS - 10am NZT Friday 9th July

Good Afternoon Josh and Adam,

Looking forward to meeting with you both tomorrow morning.

We thought we'd send through a brief agenda, to give us a framework for tomorrows chat. We also, wanted to give you a heads up on the type of questions we were hoping you might be able to offer us some guidance on.

On the call will be;
Donald Rentoul - Market Access Manager EMEA / APAC – Dexcom

Greg Cogswell - Senior Manager Health Economics Outcomes Research - Dexcom
Dominic Tilden – Director – Thema Consulting
Nimita Arora – Senior Partner - Thema Consulting
Kirstin Brown – Diabetes Division Manager - NZMS

Suggested Agenda:

1. General introductions
2. Dexcom Team: A brief overview of Dexcom and its cost-effectiveness position
   - Information on population (all T1D)
   - Clinical and economic value
   - Methods
   - Reimbursement status in different countries
3. Pharmac Team: A 10 minute overview of the reimbursement application process as it relates to the CGM funding application.
   - Beginning to end process flows and timeline expectations
   - Ultimate funding arrangement / pricing
   - Question: We are looking to understand what information is required from us, at various points in the timeline.
4. Questions
   - Guidance and direction on the overall timeline to prepare materials, as appropriate.
   - What contents in particular do Pharmac want to see in the Dossier for the Diabetes Subcommittee's consideration.
   - Are we able to submit economics later which might better suit the Committees review? Guidance on this… i.e) any particular subpopulation focus?
   - Do Pharmac want a NZ model or will minor adaptations to Australia's model be acceptable?
   - Can we get an understanding of the budget perspective and how CGM will be positioned. Is it clear how this might be being funded – Pharmaceutical portfolio positioning guidance for a Medical Device?
   - At what point in the process is it appropriate to outlay comparison data with Flash CGM?

Thank you Gents, let me know if you have anything you would like to add in preparation for tomorrow.
Otherwise… look forward to speaking to you soon.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

NICE advice

Dexcom G6 for real-time continuous glucose monitoring

Medtech innovation briefing
Published: 3 November 2020
www.nice.org.uk/guidance/mib233

Summary

- The **technology** described in this briefing is the Dexcom G6 real-time continuous glucose monitoring system. It measures interstitial fluid glucose levels in people with type 1 or type 2 diabetes.
- The **innovative aspects** are that the Dexcom G6 continuously measures glucose levels using a sensor inserted under the skin instead of routine finger-prick blood glucose testing. Glucose measurements can be shared remotely with carers and family members through the connected app. Alerts sound if glucose levels fall outside of a target range. The sensor can be left in place for 10 days.
- The intended **place in therapy** is as an alternative to routine blood glucose monitoring in people (over 2 years old), including pregnant women, with type 1 or type 2 diabetes, who use multiple daily insulin injections or use insulin pumps and are self-managing their diabetes.
- The **main points from the evidence** summarised in this briefing are from 6 studies: 4 randomised controlled trials, 1 prospective multicentre cohort study and 1 retrospective cohort study, including a total of 10,967 people in diabetes clinics. They suggest that using the Dexcom G6 reduces interstitial fluid glucose levels and the time spent in hypoglycaemia compared with self-monitoring of blood glucose using finger-prick testing.

- **Key uncertainties** around the evidence or technology are that there is variable access to continuous glucose monitors, such as Dexcom G6, across clinical commissioning groups.
- The **cost** of Dexcom G6 is between £1,850 and £2,645 per person per year (excluding VAT) depending on the quantity of units bought. One economic study concluded that over each person's lifetime, the total costs of the Dexcom G6 device were £14,234 higher than finger-prick blood glucose testing (£102,468 compared with £88,234). However, improving blood glucose control could lead to cost savings by avoiding the costs of both short-term and long-term clinical outcomes of poorly managed diabetes.

The technology

The Dexcom G6 continuous monitoring system (Dexcom Inc) measures interstitial fluid glucose levels. The G6 system consists of 3 key parts: the sensor wire, a transmitter, and a display device. The display device can be either the Dexcom receiver or an app that can be used on a compatible Android or iOS smart device.

The sensor comprises a water-resistant sensor pod that is worn on the skin, and the sensor wire that is inserted under the skin using the single-use applicator. The sensor can be worn for 10 days and continuously measures glucose levels. All users may wear the sensor on their abdomen or on the back of their upper arm. Children aged 2 to 17 years can also choose to wear it on their upper buttocks.

The transmitter is a multiple-use device that attaches to the sensor pod and sends glucose information to the display device (a smart device or dedicated receiver) using Bluetooth. The transmitter must be discarded after 3 months of use. During normal use, interstitial glucose concentration estimates are sent from the transmitter to the receiving device at 5-minute intervals and can be checked at any time. Alerts can be set to respond when glucose levels or rates of change go outside of the healthy range. This is to help people manage both hyperglycaemia and hypoglycaemia.

The G6 software app is downloaded onto the compatible smart device, which must be paired with the transmitter before use. The app continuously and automatically sends data to the Dexcom remote server, where the data are processed for reporting by the CLARITY diabetes management software. To display the data, the smart device needs to be connected to the transmitter by Bluetooth and have the Dexcom G6 app running. Dexcom receivers store 30 days of readings and need connection to a computer to upload the data to the server periodically.

The user can choose to share glucose levels, trend information and alerts with others such as carers or family members who can view data by downloading the Dexcom Follow app. The Follow app can receive alerts, for example, if the user's glucose level falls outside of the healthy range. The user can also email data reports to healthcare providers or allow them to view their data through the CLARITY software. The Dexcom CLARITY mobile app can send a weekly push notification summarising weekly time-in-range, how the user's current week compares with the previous week, and any high or low glucose patterns.

Innovations

The Dexcom G6 has an alert function. The 'urgent low' alert cannot be deactivated. This alert notifies the user when the glucose level falls to 55 mg/dl or below (defined as a severe hypoglycaemic event). An 'urgent low soon' alert notifies the user if the glucose level is predicted to drop to 55 mg/dl within 20 minutes. This alert can be turned off.

The Dexcom G6 has been designed to communicate with other digitally connected devices (interoperable), including automated insulin pumps. This allows 'hybrid artificial pancreas' systems to be created from separate devices. The Dexcom G6 can work with either the Diabecare R (DANA) insulin pump or the Tandem t:slim X2 (Tandem) insulin pump.

The company states that unlike previous versions of the technology, the Dexcom G6 factory-calibrated sensor does not need daily calibration with finger-prick blood samples. Also, unlike earlier-generation Dexcom systems, G6 readings remain unaffected by routine doses of paracetamol (a maximum of 1,000-mg dose of paracetamol every 6 hours).

Current care pathway

NICE guidelines state that people with diabetes should be empowered to self-monitor their blood glucose, and be educated about how to measure it and interpret the results. Routine blood glucose testing is typically done using a finger-prick capillary blood sample. Currently, continuous monitoring of interstitial fluid glucose levels using a continuous glucose monitor is not recommended for routine use but can be considered for some people.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on type 1 diabetes in adults: diagnosis and management
- NICE's guideline on diabetes (type 1 and 2) in children and young people: diagnosis and management

- NICE's guideline on diabetes in pregnancy: management from preconception to the postnatal period
- NICE's guideline on type 2 diabetes in adults: management.

Population, setting and intended user

Dexcom G6 is intended to be an alternative to routine finger-prick blood glucose monitoring for people aged 2 and over, including pregnant women, who have type 1 or type 2 diabetes, have multiple daily injections of insulin or use insulin pumps and are self-managing their diabetes. Dexcom G6 is not indicated for people who are on dialysis or critically ill. Finger-prick blood glucose testing may still be needed if the user's symptoms do not match Dexcom G6 readings or if the user is taking hydroxyurea. The company notes that because the effect of airport scanners on the G6 is unknown, finger-prick blood glucose testing should be used when the user is walking through airport security screening areas. The Dexcom G6 should not be used during MRI, CT or high-frequency electrical heat (diathermy) treatment.

The Dexcom G6 is primarily for people at home as they go about their normal daily activities. Healthcare professionals can review data from the Dexcom G6 remotely using the CLARITY software.

The company provides free access to online training videos, documents and a telephone support service for users. Training and education are also provided free of charge to healthcare professionals, including supplying appropriate supporting materials if needed.

Costs

Technology costs

The company has provided a tiered pricing model for Dexcom G6, based on number of new patients per payer. These costs include all of the sensors and applicators needed for each patient. They do not include the optional Dexcom receiver, which costs £290. In the UK, 6% people using Dexcom G6 use the receiver. Unit costs were not provided.

Dexcom G6 pricing model:

- 1 to 4 new patients: standard price per patient per year £2,645
- 5 to 19 new patients: £2,500 per patient per year (5.5% discount on standard cost)

- 20 to 49 new patients: £2,200 per patient per year (16.8% discount on standard cost)
- more than 50 new patients: £2,000 per patient per year (24.4% discount on standard cost)
- more than 250 new patients: £1,850 per patient per year (30.06% discount on standard cost).

People using the Dexcom G6 may also need occasional use of a blood glucose monitor, with test strips and lancets. The costs for blood glucose monitoring starter kits available through the NHS range from £14.93 for 1 blood glucose meter and 10 glucose strips, lancets and a lancing device, to £107.85 for 1 blood glucose meter and 900 glucose strips and lancets. Blood glucose meters are generally provided to the patient at no cost, whereas test strips and lancets are available on prescription at various tariff prices. Costs of blood glucose test strips to the NHS vary according to the meter used but are typically between £7 and £16 for a pack of 50, with bulk-buy savings available and total cost depending on the meter chosen.

Costs of standard care

Currently, standard blood glucose meters and test strips are used to manage blood glucose levels. Flash glucose monitoring is another technology that is intended as an alternative to routine blood glucose monitoring. As an example of flash glucose monitoring, the company's website for Freestyle Libre advises that FreeStyle Libre costs £48.29 for the reader. It has a 3-year lifespan, and costs £48.29 for each sensor, which must be replaced every 14 days (equalling £1,271.64 per year). Diabetes UK advises that the current retail cost for FreeStyle Optium blood glucose test strips is £17.10 for 50 strips. FreeStyle Optium blood ketone test strips cost £21.90 for 10 strips. The FreeStyle lancets for taking finger-prick blood cost 3.9p each. Costs are excluding VAT.

Resource consequences

The company states that over 10,000 adults and children across the UK have received NHS funding for Dexcom continuous glucose monitors, and over 5,000 others pay for Dexcom monitors themselves. Access to continuous glucose monitoring (CGM) systems can vary significantly between clinical commissioning groups (Perera et al. 2018).

Resource consequences of the Dexcom G6 device have been reported by Roze et al. (2020). An economic analysis with an NHS perspective was done using the IQVIA CORE Diabetes Model to ascertain the cost effectiveness of real-time CGM with Dexcom G6 compared with self-monitoring of blood glucose alone. Clinical input data were sourced from the DIAMOND trial (Beck et al. 2017) for adults with type 1 diabetes.

Relative to self-monitoring of blood glucose, the use of Dexcom G6 resulted in 1.49 quality-adjusted life years (QALYs) incrementally, and total costs were £14,234 higher than self-monitoring of blood glucose (mean £102,468 compared with £88,234). This gave an incremental cost-effectiveness ratio of £9,558 per QALY gained.

There are no practical difficulties or changes in facilities and infrastructure associated with adopting the technology.

Regulatory information

The Dexcom G6 continuous glucose monitoring system (including the applicator and the app) is a CE-marked class IIb medical device.

The following manufacturer field safety notices or medical device alerts for this technology (Dexcom G5 or G6) have been identified.

- Users of the Dexcom G6 iOS App with versions before 1.54 were alerted that they may not receive their scheduled alerts. Dexcom advised users to update their apps. If the app was not updated, it was blocked from use (on 9 December 2019). Medicine and Healthcare products Regulatory Agency field safety notice (December 2019).
- The notice advised users of Dexcom G5 that the alert about sensor glucose readings not being received did not have an audible prompt. The company advised users to periodically check the app for the status of their sensor glucose readings. Medicines and Healthcare products Regulatory Agency field safety notice (June 2019).

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Pregnant women may particularly benefit from Dexcom G6. People with certain skin conditions or allergies may be unable to wear the sensor. The company notes there may be inequity in access to continuous glucose monitoring (CGM) technologies for people with type 1 diabetes. Type 1 diabetes is classed as a disability under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with NICE's interim process and methods statement for the production of medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Six studies are summarised in this briefing, including up to 10,967 people. The total number of people in the studies is not clear because some of the trials included overlapping populations. These studies were selected because they were the most relevant, had the highest-quality evidence and included the largest patient populations.

One UK randomised controlled trial (RCT) assessed time in target blood glucose range when using Dexcom G6 compared with self-monitoring of blood glucose (SMBG). Three RCTs using the previous version of the technology, Dexcom G5, were included because they are high-quality studies into relevant clinical outcomes (effect on blood glucose levels and incidence of hypoglycaemic events). Experts suggested that the results from RCTs into Dexcom G5 are generalisable to the G6 version. Welsh et al. (2016) suggested there may be some differences in terms of accuracy, utilisation and number of hypoglycaemic events, with the G6 outperforming the G5 overall. In addition to the 4 RCTs, 1 prospective multicentre cohort study and 1 retrospective cohort study into the Dexcom G6 were included.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

There is an extensive evidence base for Dexcom G5 and G6. This briefing presents a selection of the studies available. Six studies are summarised, including 4 RCTs. In addition, a published economic study was identified, which is reported in the resource consequences section. The evidence base suggests that results provided by the Dexcom G6 are consistent with laboratory-based glucose testing.

Most studies were done in the US, which may affect generalisability of results, but there was 1 RCT done in the UK and economic evidence from a UK NHS perspective. The UK RCT found Dexcom G6

increased the time spent in target blood glucose range compared with SMBG. Several studies suggest that using the Dexcom G6 reduces interstitial fluid glucose levels and the time spent in hypoglycaemia compared with routine SMBG, especially if alerts are turned on. All studies included in this briefing were funded by the company.

There is evidence in different populations including type 1 and type 2 diabetes, young adults and people with limited hypoglycaemia awareness. Other high-quality UK-based studies into other patient subgroups, including children, would further improve the impact of the evidence base.

Thabit et al. (2020)

Study size, design and location

A randomised, controlled crossover trial at 2 UK hospitals of 31 people with type 1 diabetes aged 16 to 24 years old being treated with multiple daily injections or insulin pump therapy. The study ran for 8 weeks and compared time in target blood glucose range (haemoglobin A1c [HbA1c] levels between 3.9 mmol/litre and 10 mmol/litre) using Dexcom G6 compared with SMBG. Measuring HbA1c is a commonly used way to understand a person's blood glucose levels over time. Elevated HbA1c levels are associated with diabetes-related complications.

Intervention and comparator

Intervention: Dexcom G6 (n=31).

Comparator: routine SMBG (n=31). People in the study acted as their own controls.

Reference standard: laboratory blood glucose test.

Key outcomes

Time in target blood glucose range (defined as 70 mg/dl to 180 mg/dl) was significantly higher during Dexcom G6 use compared with control (35.7% plus or minus 13.5% compared with 24.6% plus or minus 9.3%; $p<0.001$). Times spent below range (below 70 mg/dl and below 54 mg/dl) were low and not significantly different during both study periods. The Dexcom G6 was worn 84% of the study period. People reported significantly higher satisfaction levels using Dexcom G6 compared with SMBG.

Strengths and limitations

This was a UK RCT that was adequately powered (at the 80% level) to detect the primary outcome.

The sample size of the study limited any subgroup analyses such as glycemic outcomes in multiple daily injections and pump users. The amount of sensor data available for analysis was not equal between the Dexcom G6 and control periods. The study was funded by the company.

Beck et al. (2017a)

Study size, design and location

A multicentre, randomised controlled trial at 24 endocrinology centres in the US of 158 adults with type 1 diabetes and elevated HbA1c treated with multiple daily insulin injections. The study ran for 6 months and assessed if using the Dexcom G5 reduced HbA1c levels compared with standard methods.

Intervention and comparator

Intervention: Dexcom G5 (n=105).

Comparator: routine SMBG (n=53).

Reference standard: laboratory blood glucose test.

Key outcomes

HbA1c levels were significantly reduced in the Dexcom G5 group compared with SMBG (1.1% at 12 weeks and 1.0% at 24 weeks compared with 0.5% and 0.4%, respectively, p <0.001). Median duration of hypoglycaemia (defined as below 70 mg/dl) was 43 minutes per day in the Dexcom G5 group compared with 80 minutes per day in the SMBG group (p=0.002). There were severe hypoglycaemic events in 2 people in each group (p=0.67). In 102 people in the Dexcom G5 group who completed the trial, median sensor use was 7 days per week at 4, 12, and 24 weeks.

Strengths and limitations

This multicentre RCT was adequately powered to detect a difference in mean blood glucose level between treatment groups (randomised 2:1). The study had a low dropout rate (3 people).

People in the study were unblinded to the group to which they had been assigned (but this is expected with interventions such as Dexcom, which are designed to encourage behaviour change). The study was funded by the company.

Beck et al. (2017b)

Study size, design and location

A multicentre, randomised controlled trial at 25 endocrinology centres in the US of 158 adults with type 2 diabetes treated with multiple daily insulin injections. The study ran for 6 months and assessed if using the Dexcom G5 reduced HbA1c levels compared with standard methods.

Intervention and comparator

Intervention: Dexcom G5 (n=79).

Comparator: routine SMBG (n=79).

Reference standard: laboratory blood glucose test.

Key outcomes

Mean HbA1c levels, which at baseline were 8.5% in both groups. HbA1c levels were significantly reduced in the Dexcom G5 group compared with SMBG (1.0% at 12 weeks and 0.8% at 24 weeks compared with 0.6% and 0.5%, respectively, $p<0.05$). The amount of hypoglycemia was extremely low at baseline (defined as below 70 mg/dl), limiting any assessment of differences in the 2 groups. In 77 people in the Dexcom G5 group who completed the trial, median sensor use was 6.9, 6.7, 6.7 days per week at 4, 12, and 24 weeks, respectively.

Strengths and limitations

This multicentre RCT was adequately powered to detect a difference in mean blood glucose level between treatment groups. The study had a low dropout rate (6 people).

People in the study were unblinded to the group to which they had been assigned (but, as noted above, this is expected with interventions such as Dexcom that are designed to encourage behaviour change). The study was funded by the company.

Heinemann et al. (2018)

Study size, design and location

A multicentre, randomised controlled trial at 12 diabetes centres in Germany of 149 adults with type 1 diabetes treated with multiple daily insulin injections. People who were eligible for the study

had a history of impaired hypoglycaemia awareness or severe hypoglycaemia during the previous year. The study duration was 6 months.

Intervention and comparator

Intervention: Dexcom G5.

Comparator: routine SMBG.

Reference standard: laboratory blood glucose test.

Key outcomes

A hypoglycaemic event was defined as glucose values of 3.0 mmol/litre (54 mg/dl) or lower for at least 20 minutes, preceded by a minimum of 30 minutes with glucose values greater than 3.0 mmol/litre (54 mg/dl). The mean number of hypoglycaemic events in the Dexcom G5 group was significantly reduced over 28 days (10.8 at 4-week baseline to 3.5 events at 4-week follow up). There was no significant reduction in the SMBG group. The incidence of all severe hypoglycaemia events among control group participants during follow up was about twice the incidence seen in the Dexcom G5 group (standardised as 1.18 compared with 0.64 events per patient-year). Variability in blood glucose levels fell in the Dexcom G5 group to a greater extent than in the SMBG group. Severe hypoglycaemia events needing third-party assistance without medical assistance for recovery were also less frequent in the Dexcom G5 group than in the control group (19 events compared with 36 events).

Strengths and limitations

This multicentre RCT was adequately powered for the primary outcome of assessing the effect of Dexcom G5 on the number of hypoglycaemic events compared with SMBG. The glucose value in this study is defined as a severe hypoglycaemic event according to experts (below 4.0 mmol/litre defined as hypoglycaemia or a severe hypoglycaemic event).

People were unblinded to the group to which they had been assigned. The study was funded by the company.

Wadwa et al. (2018)

Study size, design and location

A prospective multicentre study of 262 people 6 years or older with type 1 diabetes or insulin-

treated type 2 diabetes from 11 sites in the US. The study duration was 10 days.

Intervention and comparator

Intervention: Dexcom G6.

No comparator.

Reference standard: laboratory blood glucose test (Yellow Springs Instrument, YSI).

Key outcomes

There was 10% mean absolute relative difference (MARD) between Dexcom G6 and reference blood glucose measurements. Matched pairs from 134 adults and 128 children and young people aged 6 to 17 years were similar. Dexcom G6 values were within 20% of paired blood glucose values in 92.4% and 91.9% of instances in adults and children and young people. Similarly, MARD was 9.9% and 10.1% respectively. The hypoglycaemia alert was correctly activated in 84.4% of instances within 30 minutes of a hypoglycaemic event (defined as below 70 mg/dl). The corresponding false alert rate was 15.6% and missed detection rate was 15.0%. The 10-day sensor survival rate was 87%.

Strengths and limitations

This is a prospective multicentre site study. There were 28 people excluded from an initial 290 people. This was primarily because of a lack of corresponding blood glucose test data. This was study with a short duration (10 days) in a chronic condition. Larger long-term studies could provide more generalisable results. The study was funded by the company.

Welsh et al. (2019)

Study size, design and location

A study retrospectively comparing the accuracy of Dexcom G5 (n=50) compared with Dexcom G6 (n=159) in people with type 1 or type 2 diabetes from 3 previous separate prospective studies (compared with laboratory tested blood glucose values). The study also compared the clinical outcomes in 10,000 people who switched from the G5 to the G6 system. The location was not reported.

Intervention and comparator

Intervention: Dexcom G6.

Comparator: Dexcom G5.

Reference standard: laboratory blood glucose test.

Key outcomes

The G5 system showed slightly better accuracy than the G6 system in terms of MARD compared with the laboratory blood test, but the statistical significance of this result was not tested. The G6 system had a higher utilisation rates over 30 days compared with the G5 system (95.3% compared with 93.8% respectively, p<0.001). Using G6 system was associated with fewer recorded hypoglycaemic glucose values, defined as below 55 mg/dl (3.1 mmol/litre; 0.7% compared with 1.1%, p<0.001).

Strengths and limitations

The accuracy of the Dexcom G6 was assessed using data from previous studies (including Wadwa et al. 2018), so there is population overlap. The patient groups were from different studies, so the performance differences may be because of differences in study design. Propensity score matching was used to adjust for differences between G5 and G6 study populations, but it is unclear whether the method was appropriate. The study did not collect data about changes in diabetes treatment, diet, or exercise patterns. The extent to which the switch from G5 to G6 accounted for the changes is therefore uncertain. The glucose value in this study is defined as a severe hypoglycaemic event. The study was funded by the company.

Sustainability

The company suggested that Dexcom G6 could support sustainability by reducing the materials used in the manufacturing of self-monitoring blood glucose test strips and lancets and the use of sharps bins to discard the waste material. There is no published evidence to support these claims.

Recent and ongoing studies

There were 13 recent and ongoing studies identified in the development of this briefing. These included the following 5 UK studies:

- Automated insulin delivery among pregnant women with type 1 diabetes. ISRCTN56898625. Status: recruiting. Indication: pregnant women with type 1 diabetes. Devices: Dexcom G6 continuous glucose monitoring as part of automated closed-loop insulin delivery. Date: January 2022.

- Assessment of the accuracy of continuous glucose sensors in people with diabetes undergoing haemodialysis (ALPHA). ClinicalTrials.gov identifier: NCT03885362. Status: recruiting. Indication: type 1 diabetes. Devices: Dexcom G6 continuous glucose monitoring sensor system compared with FreeStyle Libre. Date: September 2020.

- Assessment of the impact of real-time continuous glucose monitoring on people presenting with severe hypoglycaemia (AIR-CGM). ClinicalTrials.gov identifier: NCT03748433. Status: active, not recruiting. Indication: type 1 diabetes. Devices: Dexcom G6 continuous glucose monitoring as part of automated closed-loop insulin delivery. Date: September 2020.

- Real-time continuous glucose monitoring in young adults at risk of diabetic ketoacidosis (YODA). ClinicalTrials.gov identifier: NCT04039763. Status: suspended because of COVID-19. Indication: diabetes, type 1 diabetes, glucose metabolism disorders, metabolic disease, autoimmune diseases, and endocrine system diseases. Devices: Dexcom G6 continuous glucose monitoring sensor system compared with self-monitored blood glucose. Date: 5 March 2021.

- The impact of a predictive hypoglycaemia alert function in physical activity for people with type 1 diabetes (PACE). ClinicalTrials.gov identifier: NCT04142944. Status: active, not recruiting. Indication: type 1 diabetes. Devices: Dexcom G6 with alert compared with Dexcom G6 without alert. Date: 31 August 2020.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 clinical experts were familiar with the Dexcom G6 device and use it with patients. None felt it had been superseded.

Level of innovation

Three experts agreed that the Dexcom G6 is an innovative technology. One noted that providing a

24-hour glucose profile with hypoglycaemia alerts without the need for calibration represented a unique and significant change. Another noted that while continuous glucose monitoring (CGM) itself is not new, it is significantly different to capillary glucose testing which is the current standard of care. One expert suggested the technology 'shifts the paradigm from invasive monitoring with finger sticks to non-invasive monitoring' with added benefits of alarms at low levels of blood glucose readings. All experts noted that there are alternative companies providing CGM within the UK. Other similar technologies mentioned were the Medtronic Guardian RT and the FreeStyle Libre. Experts noted that, unlike the Dexcom G6, the Medtronic Guardian RT requires finger-prick calibration and the FreeStyle Libre does not have alarms and provides intermittent flash-monitoring rather than continuous monitoring.

Potential patient impact

All 3 experts felt that this technology could offer benefits to people. Benefits included reducing the frequency and severity of hypoglycaemia and better glucose control. One expert highlighted that continuous monitoring of a person's glucose profile can support treatment decisions and enable appropriate adjustments to medication, which would improve clinical outcomes and quality-of-life indicators. Another expert noted that the device's ability to connect to insulin pumps to provide a closed-loop artificial pancreas system may significantly aid monitoring and management.

Two experts felt it was particularly beneficial for people with type 1 diabetes at risk of hypoglycaemia, with 1 expert suggesting children or people operating heavy machinery as specific examples of groups that may benefit. One noted that people who would benefit should include those who need carer support to manage their diabetes. A third expert highlighted that pregnant women and people who have been unable to achieve target glucose control (after structured education, multiple dose insulin or insulin pump therapy) may benefit.

All experts felt that the technology could change current pathways and clinical outcomes. All experts suggested that the technology could help prevent the need for clinical intervention. For example, 1 expert suggested that recognition and prevention of hypoglycaemia could prevent admission to hospital for severe hypoglycaemia. All experts noted that overall improvement in blood glucose levels could have a positive impact on the development of diabetes-related conditions needing hospital admission and intensive treatment (such as foot disease, diabetes-related eye disease, diabetes nephropathy and dialysis, and cardiovascular disease). One expert also highlighted the potential benefits to mental health.

Potential system impact

Three clinical experts felt that using Dexcom G6 could reduce costs and would benefit the healthcare system. This is because it could improve long-term outcomes, reducing the need for intensive treatment and, in the short term, reducing severe hypoglycaemic events leading to hospital admissions. Remote care may reduce the need for hospital visits.

One expert suggested that managing this technology (including patient support and potential data collection) would need an increase in number of clinicians. Two experts mentioned that training would be needed for staff working with the technology.

General comments

Two experts estimated that between 5% and 20% of people with type 1 diabetes would benefit from CGM.

One expert noted that clinicians working in specialist diabetes care will need training in data analysis and review to provide support to those using the technology. The competency of specialist diabetes centres to provide technologies such as CGM and insulin pump therapy should be standardised to ensure safety in delivering increasingly complex diabetes care.

More research into which subgroups of patients would benefit from this treatment would be valuable and this may allow greater access to the technology. All experts felt that NICE guidance on Dexcom G6 would be very relevant to support decision making and local implementation.

Patient organisation comments

Diabetes UK gave the following comments on the Dexcom G6.

In its experience, Diabetes UK stated that Dexcom represents a significant change from finger-prick blood glucose monitoring, which is presently the most common form of monitoring. It noted that the Dexcom G6 can be used in combination with either the Diabecare R insulin pump or the Tandem t:slim X2 insulin pump to produce a hybrid-closed-loop artificial pancreas system. This represents a significant change in diabetes management.

Diabetes UK noted that continuous glucose monitoring (CGM) devices, such as Dexcom, can improve patient experience and quality of life, particularly in diabetes-related quality-of-life measures such as diabetes distress. The size of the Dexcom sensor allows it to be worn in different

locations and this may allow greater flexibility for patients.

The Dexcom sensor alarm function may benefit parents and carers of children with diabetes by reducing the need for blood glucose testing in the middle of the night, and for people with limited hypo-awareness by allowed earlier detection of a hypoglycaemic event then by routine testing. Other groups who may particularly benefit from Dexcom G6 include people with elevated haemoglobin A1c (HbA1c), people who experience frequent hypoglycaemia, people who do regular intensive exercise, and children and young people.

Diabetes UK stated that clinical benefits of CGM for people with diabetes are well documented. This includes the lowering of HbA1c levels, improved neonatal outcomes in mothers with type 1 diabetes and decreasing the number of hypoglycaemic events. They noted that since 2019 the Driver and Vehicle Licensing Agency permits CGM for people with diabetes to establish they are fit to drive, in place of finger-prick monitoring.

Diabetes UK noted the potential benefits of Dexcom on family life because of reducing the diabetes-related anxieties that parents and carers may experience when away from their children. However, the charity also noted that some people using CGM may experience burnout because of alarms or the volume of data CGM can produce. Data from the Dexcom G6 could be used to offer more tailored, person-centred advice and support around steps to improve diabetes self-management. Training by the healthcare team would be needed and could be given remotely or face-to-face.

Expert commentators

The following clinicians contributed to this briefing:

- Ms Mel Curtis, diabetes specialist nurse, Swindon Integrated Diabetes Service.
- Professor Partha Kar, consultant endocrinologist, Portsmouth Hospitals NHS Trust.
- Dr Parth Narendran, reader in diabetes medicine, University of Birmingham, and consultant diabetologist, The Queen Elizabeth Hospital, Birmingham.

Representatives from Diabetes UK contributed to this briefing.

Development of this briefing

This briefing was developed for NICE by the King's Technology Evaluation Centre (KiTEC). NICE's interim process and methods statement for the production of medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-3904-6

From: Alishba Ali
Sent: Tuesday, 13 July 2021 1:14 pm
To: Alishba Ali
Subject: 2021-07-13 file note RE: Tandem Consumables Pharma Code Changes

TruSteel cannula line length change – phone call with Kirstin Brown (KB)

I advised KB that we normally need sufficient notice for product changes and discontinuations.
I noted that our concern would be a patient impact or pharmacies not getting enough notice for de-listing.
KB advised that the 80 cm and 81 cm are clinically appropriate alternatives, no clinical difference between the line lengths.
KB advised has not received feedback from HCPs and the 80 cm considered to be a full and complete substitute.
I queried if the 81 cm was ever sold and then transition to 80 cm, or has it been 80 cm since the beginning when the Animas to Tandem pump transition took place.
KB advised not sure but noted that no stock of the 81 cm has been available for the past year or so.
I asked KB to send NOPCs ASAP so that we can put the proposal forward within schedule change timeframes.

Ngā mihi,

Alishba Ali | Contract Manager

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PHARMAC
TE PĀTAKA WHAIORANGA

From: Kirstin Brown <[redacted]>
Sent: Monday, 12 July 2021 5:29 pm
To: Alishba Ali <[redacted]>
Subject: RE: Tandem Consumables: Pharma Code Changes

Hi Alishba,

Discontinuation is immediate, there is no stock transition. All current inventory in NZ is of the new codes and the 80cm line. The new code / product is a direct substitute for the prior.

It appears this has been a miscommunication from back during the transition of Animas to Tandem. We (NZMS) were under the assumption that the prior Pharma Codes (below) applied to the new product descriptions.
However, on recent inquiry with Lisa at Pharmacodes, we have learned she has different records.

As I wasn't at NZMS for the transition and am not aware of the history behind what's occurred here – I have applied for new codes to formally realign.

If this is a viable solution for you, I can make changes to our Tandem Prescription Form for HCP's and reach out to the Distributors to ensure they are looped in.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Alishba Ali <[redacted]>
Sent: Monday, 12 July 2021 4:10 p.m.
To: Kirstin Brown <[redacted]>
Subject: RE: Tandem Consumables: Pharma Code Changes

Hi Kirstin,

Thanks for your email. Hope you are doing well.

Just checking the timeframes as I have not heard of this change before.

Please let me know when the discontinuation is taking effect e.g., date NZMS would stop supplying the 81 cm presentations. We would also need to know how much stock is currently available in the distribution channels e.g., at wholesaler level. Please provide any information that you may have to this effect.

Please also share any plans for patient or market communications.

Ngā mihi,

Alishba Ali | Contract Manager

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PHARMAC
TE PĀTAKA WHAIORANGA

From: Kirstin Brown <[redacted]>
Sent: Monday, 12 July 2021 3:47 pm
To: Alishba Ali <[redacted]>
Subject: Tandem Consumables: Pharma Code Changes

Hi Alishba,

I hope this finds you well.

Can you please let me know how I go about updating the pharmaceutical schedule with Pharma Code changes?

We have had two minor product changes, which I have highlighted below.

Current Pharma Code	Discontinued Pharma Code	Description	Description Of Discontinued Product	Package Format
2598345		Tandem t:slim X2™ Insulin Pump With Basal IQ		1
2556790		Tandem t:slim X2™ Cartridge 300U		10/box
2556804		AutoSoft™ 90 Infusion Set 6mm cannula/60cm line		10/box
2556812		AutoSoft™ 90 Infusion Set 6mm cannula/110cm line		10/box
2556820		AutoSoft™ 90 Infusion Set 9mm cannula/60cm line		10/box
2556839		AutoSoft™ 90 Infusion Set 9mm cannula/110cm line		10/box
2556847		AutoSoft™ 30 Infusion Set 13mm cannula/60cm line		10/box
2556855		AutoSoft™ 30 Infusion Set 13mm cannula/110cm line		10/box
2556863		TruSteel™ Infusion Set 6mm cannula/60cm line		10/box
2616491	2556871	TruSteel™ Infusion Set 6mm cannula/80cm line	TruSteel™ Infusion Set 6mm cannula/**81cm** line	10/box
2556898		TruSteel™ Infusion Set 8mm cannula/60cm line		10/box
2612550	2556901	TruSteel™ Infusion Set 8mm cannula/80cm line	TruSteel™ Infusion Set 8mm cannula/**81cm** line	10/box

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Joshua Cronin-Lampe
Sent: Wednesday, 21 July 2021 7:26 pm
To: Kirstin Brown
Cc: Adam McRae; [redacted]; Greg Cogswell
Subject: RE: Dexcom Submission: NZ Specific Diabetes Complication Costs / Future product upgrades

Hi Kirstin

Apologies for not getting back to you sooner.

Our Senior Health Economist, Tal, is away until tomorrow – but I will run your questions via her then as she will have a better idea of where to get up to date pricing information, as well as any workarounds that may ease the burden on your end.

As a first port of call, I know we include the costings of various services in our Cost Resource Manual, which we use to promote consistency in the costs and prices used in HTA. In terms of epidemiological data, the Virtual Diabetes Register is a good place to start.

I will get back to you in the next day or two with further information but hope this helps for the time being.

Kind regards,
Josh Cronin-Lampe | Therapeutic Group Manager

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From: Kirstin Brown <[redacted]>
Sent: Wednesday, 21 July 2021 10:19 am
To: Joshua Cronin-Lampe <[redacted]>
Cc: Adam McRae <[redacted]>; [redacted]; Greg Cogswell <[redacted]>
Subject: RE: Dexcom Submission: NZ Specific Diabetes Complication Costs / Future product upgrades

Hi Josh,

I hope this finds you well.

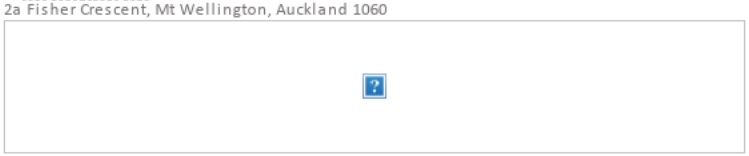
I'm sorry to chase you up on this… we are working to such a tight deadline.

Have you had a moment to consider Donald's questions below?

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060



From: Kirstin Brown
Sent: Friday, 16 July 2021 2:53 p.m.
To: Joshua Cronin-Lampe <Withheld under section>
Cc: Adam McRae <Withheld under>; Withheld under; Greg Cogswell <Withheld under>
Subject: Dexcom Submission: NZ Specific Diabetes Complication Costs / Future product upgrades

Hi Josh,

I hope this finds you well.

Josh, we have all hands to pump on our side to ready our Dexcom Dossier for the submission deadline of the 13th of August.

May I please request your attention to the below email from Donald Rentoul - Dexcom's Market Access Manager APAC, who you met the other day on our Telcon.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Donald Rentoul <[redacted]>
Sent: Thursday, July 15, 2021 10:21 AM
To: Kirstin Brown <[redacted]>
Cc: Greg Cogswell <[redacted]>
Subject: PHARMAC Email

Dear Josh,

Thank you for the opportunity to discuss Dexcom's upcoming submission. We would appreciate your advice on the following topics:

Sourcing New Zealand specific reference cost to inform the economic analysis
What is the mechanism for future product upgrades to be included under an existing reimbursement scheme?

In reference to the Cost-Utility Analysis, Dexcom has perused PHARMAC's Prescription for Pharmacoeconomic Analysis: Methods for Cost-Utility Analysis. Given PHARMAC's prescriptive requirements for the CUA, coupled with the upcoming submission date of August 13th, Dexcom has concerns which warrant a frank dialogue with PHARMAC:

New Zealand specific diabetes complication costs (annualized) are not readily available/accessible in published literature, or, currently compiled/available for sale from venders:

An initial query, performed both by Dexcom as well as by external experts, yielded no referenceable/published New Zealand specific diabetes CUAs and/or associated New Zealand diabetes complication costs.

A New Zealand specific diabetes complications datafile is not currently developed and available via venders.

Dexcom has approached many creative solutions to ascertaining the necessary data, however, none have resulted in access to the necessary data.

Without access to readily available New Zealand diabetes complication costs, this would require extensive work to properly research and/or survey to identify properly referenced/sourced costs, likely extending well beyond the currently established submission date.

With these considerations in mind, Dexcom cordially requests PHARMAC's support to optimally assist Dexcom in identifying the necessary diabetes complication costs necessary to execute the CUA (please see the attachment for the specific complication costs needed).

Can PHARMAC refer Dexcom to any healthcare system/governmental databases or data repositories which can provide Dexcom the necessary New Zealand specific diabetes complication cost data?

If New Zealand specific diabetes complication costs are not readily referenceable, would PHARMAC consider an index-based adjusted of diabetes complication costs from a proxy market (such as Australia) to inform the New Zealand complication costs?

If Dexcom must design and compile New Zealand specific diabetes complication costs, would PHARMAC consider extending the submission deadline to enable proper and effective sourcing efforts to inform the CUA?

[redacted]
Withheld under section 9(2)(b)(ii) and 9(2)(ba)(i))

Would PHARMAC require a full submission that follows the same format, process and timelines as the current CGM assessment? Or is there an opportunity for new product iterations to be included under an existing reimbursement scheme, if so what would be the method and nature of the assessment?

Dexcom greatly appreciates and welcomes PHARMAC's feedback and dialogue surrounding the inquiries listed above

Donald Rentoul
Market Access Manager APAC
Mobile: Withheld
Tel.: Withheld
Email: Withheld under

Annual costs needed for New Zealand

Costs for CDM (NZD)	Cost/patient/year	Year collected	Reference
c statins			
c aspirin			
c ACE			
c screening for MA			
c screening for GRP			
c stopping ACEs due to SE's			
c eye screening			
c foot screening program			
c non-standard ulcer treat (eg. Regranex)			
c anti-depression treatment			
c screening for depression			
DIRECT COSTS CVD COMPLICATIONS			
c MI 1st year			
c MI 2nd+ years			
c angina 1st year			
c angina 2nd+ years			
c CHF 1st year			
c CHF 2nd+ years			
c stroke 1st year			
c stroke 2nd+ years			
c stroke death within 30 days			
c PVD 1st year			
c PVD 2nd+ years			
DIRECT COSTS RENAL COMPLICATIONS			
HD costs 1st year			
annual costs HD 2+ years			
PD costs 1st year			
annual costs PD 2+ years			
RT costs 1st year			
annual costs RT 2+ years			
DIRECT COSTS ACUTE EVENTS			
c NHSE			
cSHE1 (Minor)			
cSHE2 (Major)			

c keto event				
c lactic acid event				
c edema onset (adv.ev.)				
c edema follow up (adv.ev.)				
DIRECT COSTS EYE DISEASE				
c laser treatment				
c cataract operation				
c following cataract operation				
c blindness - year of onset				
c blindness - following years				
DIRECT COSTS NEUROP/FOOT ULCER/AMP				
c Neurop 1st year				
c Neurop 2nd+ years				
c Amputation (event based)				
c Amp Prosthesis (event based)				
c Gangrene treatment				
c after healed ulcer				
c infected ulcer				
c standard uninfected ulcer				
c healed ulcer history of amputation				

Annual cost of intervention

	Unit cost	Units	Net cost
rtCGM cost	Need unit cost of rtCGM. Can be discounted list price but must be approved by Dexcom. (list source: xxx)		
FGM cost	Need current unit costs of FGM (also list source)		
SMBG cost Total annual cost/patient	Need unit cost of SMBG strips + lancet (list source: xxx)		

From: Joshua Cronin-Lampe
Sent: Thursday, 29 July 2021 12:28 pm
To: Kirstin Brown; Adam McRae
Cc: [redacted]; Greg Cogswell
Subject: RE: Follow up from todays meeting

Hi Kirstin,

Apologies for not getting back to you sooner.

Regarding the assessment of product upgrades, we are still working through what this looks like for diabetes technology. The level of due diligence required will likely depend on the nature of the upgrade and the potential impact on our budget.

We are hoping to secure enough clinical advice in the next few months on CGM's as a therapeutic category, such that for minor changes we would only need to seek very targeted clinical advice to determine safety and therapeutic equivalence. However, any substantive additional investment relating to newer models would need to be compared against other options for investment.

Subject to receiving a positive recommendation for funding, a lot of the issues above will depend on how we decide to contract for these products, which obviously still needs to be worked through.

Let me know if you have any further questions.

Kind regards,

Josh Cronin-Lampe | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | M: [redacted] | www.pharmac.govt.nz

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From: Kirstin Brown <[redacted]>
Sent: Wednesday, 28 July 2021 1:18 pm
To: Adam McRae <[redacted]>
Cc: Joshua Cronin-Lampe <[redacted]>; [redacted]; Greg Cogswell <[redacted]>
Subject: RE: Follow up from todays meeting

Hi Adam,

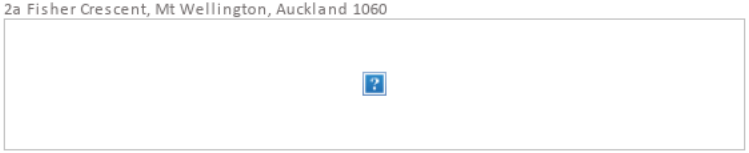
Thank you for this information.

Can I please draw your attention to the attached request? Additional to the Diabetes Specific Costings the team also had a query around how you would like to consider future product updates.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060



From: Adam McRae <[redacted]>
Sent: Wednesday, 28 July 2021 10:42 am
To: Kirstin Brown <[redacted]>
Cc: Joshua Cronin-Lampe <[redacted]>
Subject: RE: Follow up from todays meeting

Dear Kirstin

In Josh's absence I have followed up with our Health Economics team regarding provision detailed costs. This isn't something that we are in a position to help suppliers put together in detail. Generally, we would expect that suppliers engage with DHBs, clinicians or consultants to get an idea of costs at this granular level.

I appreciate that it is a tight turnaround to meet the submission date. Please estimate as many of your model costs using PHARMAC's cost resource manual (on our website) and the MOH cost weights (https://www.health.govt.nz/nz-health-statistics/data-references/weighted-inlier-equivalent-separations/wiesnz21-cost-weights) as possible. You may need to aggregate several costs to build up the costs you had listed. Where it isn't possible for your to determine a New Zealand price, you could use Australian cost as surrogates as long as these are made explicit in the reporting.

Kind regards
Adam

From: Kirstin Brown <[redacted]>
Sent: Tuesday, 27 July 2021 1:03 pm
To: Joshua Cronin-Lampe <[redacted]>
Cc: Adam McRae <[redacted]>
Subject: RE: Follow up from todays meeting

Hi Josh,

I'm so sorry to be chasing you.

Our team has such a tight deadline to get our submission ready for August 13th.

Do you have any information at this stage on the below request, or the others Donald raised in the email on the 16th of July?

Any direction you can give us on these matters, gratefully received.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Kirstin Brown
Sent: Tuesday, 13 July 2021 4:12 p.m.
To: Joshua Cronin-Lampe <Withheld under section>
Cc: Adam McRae <Withheld under>
Subject: RE: Follow up from todays meeting

Hi Josh,

This is fabulous information – thank you.

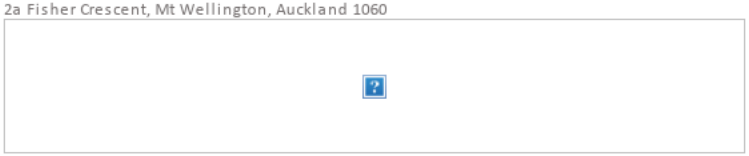
Can you please recommend the most accurate data source we should use to estimate current volumes for Diabetes Community Meters and associated consumables?
Also, has there been any change in patient eligibility criteria since the last Community Meter Tender?

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]

2a Fisher Crescent, Mt Wellington, Auckland 1060



From: Joshua Cronin-Lampe <Withheld under section>
Sent: Tuesday, 13 July 2021 9:19 a.m.
To: Kirstin Brown <Withheld>
Cc: Adam McRae <Withheld under>
Subject: RE: Follow up from todays meeting

Hi Kirstin,

Hope you had a great weekend.

Withheld under section 9(2)(b)(ii) and 9(2)(ba)(i)
Withheld under section 9(2)(b)(ii) and 9(2)(ba)(i)
Withheld under section 9(2)(b)

Regarding your previous submission, our IT team have managed to successfully fix the issue that we were having with the portal and you can now track the progress of your application here. I have all your current material on file and am happy to receive additional information via PDF. You can rest assured that your application will be included in the upcoming agenda.

Many thanks,

Josh Cronin-Lampe | Therapeutic Group Manager

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DDI: WWWWi | P: +64 4 460 4990 | M: WWWWi | www.pharmac.govt.nz

From: Kirstin Brown <Withheld>
Sent: Friday, 9 July 2021 5:15 pm
To: Joshua Cronin-Lampe <Withheld under section>

Subject: Follow up from todays meeting

Hi Josh,

Thank you very much for your time this morning.

Couple of things I wanted to follow up on.

[redacted] Withheld under section 9(2)(b)(ii)

I also wanted to align with you on the issues with this submission being outside the gateway, most likely because it was made back in 2018, I think. I had raised this prior with Alishba and understood that there was some kind of IT error that was causing the issue. As we have such a lot to get ready in time for the 13th we are grateful to be able to submit additional information via PDF. However, it would be good to insure we are not missed by being outside of your system. Can you please follow this up for me?

Again, thanks so much Josh.

Have a wonderful weekend!

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

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From: Ruth Hughes <Withheld under section>
Sent: Thursday, 5 August 2021 12:46 pm
To: Joanne McFadyen
Cc: Kirstin Brown; Ian Slater; Suhayl Khan
Subject: NZMS announcement
Attachments: AMSL, NZMS, Dexcom Announcement 1st August 2021.pdf

Follow Up Flag: Follow up
Flag Status: Completed

Dear Joanne,

I hope this finds you well.

I'm contacting you to advise of a Change of Ownership of NZMS, which will be announced later today.

I request that that the 4 NZMS Contracts are added to this same Change of Ownership Consent Request that my colleague Kirstin Brown , Division Manager for Diabetes, Allergy and POC communicated with Josh Wiles, Katie Brownless, Alishba Ali and Joshua Cronin-Lampe today.
NZMS has supply agreements for the following devices

Patient Warming and Cool Products

Urology , Ostomy and Continence Products

Feeding Devices and Accessories

Obstetrics and Gynaecology Devices and related products

There are to be no changes to the Legal Entity and the Change of Control will not in any way affect NZMS's ability to perform its obligations in full in accordance with the terms of the Contract.

Also, I would like to share with you an exciting change for our team at NZMS as of 1 August 2021 Ian Slater has become our Managing Director for both Australia (AMSL) and New Zealand (NZMS)

The NZMS Team are excited about the future and very much appreciate continuing our long partnership with Pharmac.

Please let me know if there are any requirements relating to the contracts.

Kind regards

Ruth

Ruth Hughes
Medical Division Manager

P +64 9 259 4062 | M [redacted] | F +64 9 259 4067
Email: [redacted]
Web: www.nzms.co.nz

2a Fisher Crescent, Mt Wellington, Auckland 1060
PO Box 132400, Sylvia Park, Auckland 1644, New Zealand

Press Release August 2021

Dexcom, Inc. acquires AMSL and NZMS

Richard Plowright, Managing Director and Owner of Australasian Medical & Scientific Limited (AMSL) and New Zealand Medical & Scientific (NZMS) has announced his retirement, after over 30 years of providing the Australasian market with access to leading edge healthcare solutions from all over the world. As of the 1st August 2021, Richard has sold all his shares in both companies to Dexcom, Inc., a leader in the medical technology industry and as such, Dexcom, Inc. has now acquired AMSL and NZMS. Dexcom, Inc., AMSL and NZMS will continue to provide high quality products and services across the Allergy, Diabetes, Medical, Point of Care/Diagnostics, Regenerative Medicine and Scientific divisions. We are driven by our vision to create positive healthcare outcomes for our customers by providing innovative technologies, supported by our team's expertise, professionalism, and commitment. This acquisition of AMSL and NZMS further strengthens Dexcom's position as a leading provider of medical technology. At the heart of this acquisition is a mission to form an even greater business together; to expand our footprint in the healthcare industry, to grow the careers of employees, and to change more lives. Our suppliers and customers will experience no difference in our day-to-day activities with all staff to be retained.

About Dexcom, Inc.

Dexcom, Inc. was founded in 1999 with the mission to empower people to take control of diabetes through innovative continuous glucose monitoring (CGM) systems. By listening to the needs of users, caregivers, and providers, Dexcom simplifies and improves diabetes management around the world.

Headquartered in San Diego, California, with additional offices in the U.S., Europe, and Asia Pacific, Dexcom employs more than 5,000 people worldwide. For more information on Dexcom, Inc. visit Dexcom.com.

For more information:

If you have any questions or feedback regarding this announcement, please contact our Customer Service Team, your local AMSL Territory Manager or alternatively contact AMSL at amsl@amsl.com.au or 02 9882 3666.

From: Joanne McFadyen
Sent: Thursday, 5 August 2021 1:32 pm
To: Alishba Ali
Subject: NZMS acquisition by Dexcom

Hi Alishba

As discussed NZMS has 1 Medical Device Listing Agreement dated **6 December 2018**.

Also if you could acknowledge receipt of NZMS's letter sent to me today 5 August 2021.

Thanks Alishba let me know how you get on.

Joanne

Joanne McFadyen | Contract Manager, Devices

PHARMAC Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | M: [redacted] | www.pharmac.govt.nz

From: Alishba Ali
Sent: Thursday, 5 August 2021 2:34 pm
To: Kirstin Brown
Subject: RE: Change of control acknowledgment for NZMS

Hi Kirstin,

Acknowledging receipt of your letter. As discussed, please note that there are other agreements between Pharmac and NZMS as well.

Ngā mihi,

Alishba Ali | Contract Manager

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DDI: [redacted] | P: +64 4 460 4990 | M: [redacted] | www.pharmac.govt.nz

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From: Kirstin Brown <[redacted]>
Sent: Thursday, 5 August 2021 12:26 pm
To: Josh Wiles <[redacted]>; Katie Brownless <[redacted]>
Cc: Ruth Hughes <[redacted]>; Igor Obradovic <[redacted]>; Alishba Ali <[redacted]>; Joshua Cronin-Lampe <[redacted]>
Subject: FW: Change of control acknowledgment for NZMS

Good Morning Josh and Katie,

I hope this finds you well.

I'm contacting you to advise of a Change of Ownership of NZMS, which will be announced later today.

I had preveiusly contacted Pharmac regarding our existing Insulin Pump Contract, as below to request consent for a change of ownership.

My colleague Ruth Hughes is contacting Joanne McFadden to add our other 4 NZMS Contracts to this same Change of Ownership Consent Request.

There are to be no changes to the Legal Entity and the Change of Control will not in any way affect NZMS's ability to perform its obligations in full in accordance with the terms of the Contract.

Please let me know if there are any requirements relating to the contract(s) currently under discussion with yourselves.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Kirstin Brown
Sent: Friday, 30 July 2021 11:48 a.m.
To: Joshua Cronin-Lampe <[redacted]>; Alishba Ali <[redacted]>
Cc: Adam McRae <[redacted]>; Hugh Plowright <[redacted]>
Subject: Change of control acknowledgment for NZMS

Good Morning Josh, Alishba and Adam,

Thank you for making the time to speak with me this morning.

As discussed, attached is a notice formally advising you of the proposed change of control for NZMS.

May I please request you kindly return this to me at your earliest convenience, with your signed acknowledgment of receipt.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

This email is intended only for the person or company to which it is addressed and may contain information that is privileged, confidential or otherwise protected from disclosure. Dissemination, distribution, or copying of this email or the information herein by anyone other than the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, is prohibited. If you have received this email in error, please notify the sender immediately.

From: Alishba Ali
Sent: Friday, 27 August 2021 5:10 pm
To: Alishba Ali
Subject: 2021-07-30 file note RE: phone call from NZMS

Phone call with Kirstin Brown (KB) at NZMS

KB called me to advise me of a change of ownership impacting NZMS; NZMS acquired by Dexcom.
KB advised NZMS will remain its own legal entity.
KB noted will be sending a letter confirming this via email.

Ngā mihi,

Alishba Ali | Contract Manager

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DDI: Withheld Wit Withheld Withheld under | P: +64 4 460 4990 | M: Withheld Wit hheld Withheld Withheld | www.pharmac.govt.nz

27 July 2021

To: PHARMAC
Level 9, 40 Mercer Street,
PO Box 10-254,
Wellington 6143
New Zealand

Dear Alishba Ali and Josh Cronin-Lampe,

Notice of Proposed Change of Control – Request for Consent

As you may be aware, DexCom (UK) Intermediate Holdings Ltd., a limited company incorporated in the United Kingdom (the **Buyer**) and a wholly-owned subsidiary of DexCom, Inc., a Delaware corporation (NASDAQ: DXCM) (**DexCom**), is planning to purchase all of the issued shares of Australasian Medical & Scientific Limited (**AMSL**) and New Zealand Medical and Scientific Limited (**NZMS**) following which AMSL and NZMS will both be a wholly-owned subsidiaries of the Buyer (the **Proposed Transaction**).

There have been discussions with DexCom about NZMS's relationship with PHARMAC. DexCom value this relationship and they are very keen on maintaining it on the terms of the agreement between PHARMAC and New Zealand Medical & Scientific Ltd (NZMS) dated 15 February 2012, as amended on 26 July 2012 and 16 October 2012 and 2 October 2018, relating to the terms of listing of an insulin pump and consumables in Section B of the Pharmaceutical Schedule (**Contract**).

The Contract states for NZMS: *24. Assignment. You will not permit this Agreement, or any part of this Agreement, to be transferred, assigned or sub-contracted (either directly or due to a change of ownership or control) without PHARMAC's prior written consent (such consent not to be unreasonably withheld). Any such consent may be given subject to such reasonable conditions as PHARMAC sees fit but no such consent will relieve you from any liability or obligation under the terms of the Agreement, and you will continue to be responsible for the acts, defaults and neglects of your transferee, assignee or sub-contractor.* The completion of the Proposed Transaction will result in a change of control in NZMS for the purposes of the Contract (**Change of Control**). We are therefore reaching out to you to request your consent, and an acknowledgment that you will not terminate the Contract, in relation to, specially, the Change of Control and, generally, the Proposed Transaction.

DexCom is a global provider of continuous glucose monitoring systems, with a mission to empower people to take control of diabetes. Headquartered in San Diego, California in the United States, Dexcom has emerged as a leader of diabetes care technology. For more information about Dexcom, including historical earnings information, please visit www.dexcom.com. Buyer is a wholly-owned subsidiary of Dexcom.

NZMS confirms that the Change of Control will not in any way affect its ability to perform its obligations in full in accordance with the terms of the Contract. We are retaining all our key staff and your primary point of contact for NZMS will still be Kirstin Brown.

Please indicate your consent and acknowledgment by returning a signed duplicate of this letter by email, as acknowledgment of receipt and agreement to its terms, as soon as reasonably practicable, and in any event by no later than Friday 30 July 2021, to Kirstin Brown (Withheld under).

This letter, and any dispute, controversy, proceedings or claim of any kind arising out of or in any way relating to this letter or any act performed or claimed to be performed under it, is governed by New Zealand law.

Yours faithfully

Richard Day Plowright
Managing Director
New Zealand Medical and Scientific Limited

P 09 259 4062 | **W** nzms.co.nz | **E** nzms@nzms.co.nz
A 2a Fisher Crescent, Mt Wellington, Auckland 1060
P.O. Box 132400, Sylvia Park, Auckland 1644

Acknowledgment of Receipt / Consent to Change of Control

I am a duly authorised representative of **PHARMAC** and hereby acknowledge receipt of the letter dated 27 July 2021, of which the above is a copy, and confirm for and on behalf of **PHARMAC**, that **PHARMAC** irrevocably consents to, and acknowledges that it will not terminate the Contract in relation to, the Change of Control and/or the Proposed Transaction, as set out in the letter, and that all arrangements pursuant to the Contract will continue unaffected by such Change of Control.

Yours faithfully

_____

Signature

Name:

Title:

Date:

P 09 259 4062 | **W** nzms.co.nz | **E** nzms@nzms.co.nz
A 2a Fisher Crescent, Mt Wellington, Auckland 1060
P.O. Box 132400, Sylvia Park, Auckland 1644

From: Joshua Cronin-Lampe
Sent: Monday, 9 August 2021 1:42 pm
To: Kirstin Brown; Adam McRae
Cc: Donald Rentoul; [redacted]
Subject: RE: Dexcom G6 Submission

Hi Kirstin,

Great to hear!

[redacted]

Thanks,
Josh Cronin-Lampe | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | M: [redacted] | www.pharmac.govt.nz

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From: Kirstin Brown <[redacted]>
Sent: Monday, 9 August 2021 11:32 am
To: Joshua Cronin-Lampe <[redacted]>; Adam McRae <[redacted]>
Cc: Donald Rentoul <[redacted]>; [redacted]
Subject: RE: Dexcom G6 Submission

Hi Josh,

I had a lovely weekend, thank you.

Josh, thanks for getting back to me so promptly.

[redacted] … do we need to highlight that in our submission or, does the process allow for a follow up discussion for such matters.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Joshua Cronin-Lampe <[redacted]>
Sent: Monday, 9 August 2021 10:58 a.m.
To: Kirstin Brown <[redacted]>; Adam McRae <[redacted]>
Cc: Donald Rentoul <[redacted]>; [redacted]
Subject: RE: Dexcom G6 Submission

Kia ora Kirstin

Hope you had a good weekend.

As previously discussed, I'm happy to receive a pdf submission to present to the Subcommittee and will ensure that the previous document is not considered.
I'll work with our IT team to see what we can do to formally withdraw the original submission. If this were to be withdrawn, we would need the new submission to be made via the portal but would be happy for this to occur separately at a later date.

[redacted]
Withheld under section 9(2)(b)(ii) and 9(2)(ba)(i))
Withheld under section 9(2)(b)(ii) and 9(2)(ba)(i))
Withheld under section 9(2)(b)(ii) and 9(2)(ba)(i))

Kind regards,
Josh Cronin-Lampe | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | M: [redacted] | www.pharmac.govt.nz

PHARMAC
TE PĀTAKA WHAIORANGA

From: Kirstin Brown <[redacted]>
Sent: Monday, 9 August 2021 8:15 am
To: Joshua Cronin-Lampe <[redacted]>; Adam McRae <[redacted]>
Cc: Donald Rentoul <[redacted]>; [redacted]
Subject: FW: Dexcom G6 Submission
Importance: High

Hi Josh and Adam,

May we please request your urgent attention to two remaining questions before we submit our dossier on Friday the 13th of August.

> As per the below thread… To avoid the wrong document being reviewed for consideration at any point, can we please **formally withdraw the submission made in 2019**. This will be replaced entirely by the submission you will be receiving this Friday.
>
> [redacted]
> [redacted]
> [redacted]
> [redacted]

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M [redacted]
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Kirstin Brown
Sent: Wednesday, 4 August 2021 4:35 p.m.
To: Joshua Cronin-Lampe <[redacted]>; Adam McRae <[redacted]>
Cc: Donald Rentoul <[redacted]>; [redacted]
Subject: Dexcom G6 Submission

Hi Josh and Adam,

I hope this finds you well.

I am seeking to clarify the process for submission of the new G6 Dossier.

The **new submission due 13th of August 2021** will replace the prior submission made back in 2018.

To avoid the wrong document being reviewed for consideration at any point, can we please withdraw the previous submission and start anew with the 2021 version.

You mentioned that you would be happy to receive this new submission via PDF, considering the above clarification, can you please confirm that this is still the best method to proceed.

Many Thanks &
Kind Regards,

Kirstin Brown
Division Manager

M
2a Fisher Crescent, Mt Wellington, Auckland 1060

From: Joanne McFadyen
Sent: Wednesday, 11 August 2021 8:03 am
To: Ruth Hughes
Subject: Proposed acquisition of New Zealand Medical and Scientific Limited
Attachments: NZMS Consent Letter.pdf

Hi Ruth

Please find attached a consent letter from Pharmac regarding the proposed acquisition of New Zealand Medical and Scientific Limited.

Kind regards
Joanne McFadyen

Joanne McFadyen | Contract Manager, Devices

PHARMAC Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
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www.pharmac.govt.nz

11 August 2021

Ruth Hughes
Medical Division Manager
New Zealand Medical and Scientific Limited
2a Fisher Crescent
Mt Wellington
Auckland 1060

Dear Ruth

NZMS Limited and Dexcom, Inc.

I refer to the agreement between Pharmac and New Zealand Medical & Scientific Limited (NZMS) dated 6 December 2018, for the listing of medical devices on the Pharmaceutical Schedule (the "Agreement").

Proposed Acquisition

I also acknowledge receipt of your letter dated 5 August 2021 in respect of the proposed acquisition of NZMS shares by Dexcom, Inc.

Consent

In accordance with Part 7, clause 51 of the Agreement, Pharmac consents to the proposed acquisition as stated in this letter, in the context of a change in control of NZMS upon completion of the acquisition.

Yours sincerely

Craig Butler
Manager, Procurement and Contracts