SYNOPSIS
of
Application to PHARMAC for the subsidisation of

Dexcom G6™ Mobile Continuous Glucose Monitoring System

April 2019

Applicant:

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Withheld under section 9(2)(a)

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G6™ Mobile Continuous Glucose Monitoring System
PHARMAC Submission

IMPORTANT INFORMATION

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INTRODUCTION

Real Time Continuous Glucose Monitoring (RT CGM) is expected to reduce the short and long-term complications associated with diabetes by decreasing average blood glucose levels, glycaemic variability, and the incidence of hypoglycaemia A strong body of evidence has demonstrated the efficacy of RT-CGM for reducing HbA1c levels and glycaemic variability in children and adults with T1DM, and a recently published RCT showed that RT CGM significantly reduces HbA1c in adults with poorly-controlled insulin-treated T2DM. In addition, data show that RT-CGM reduces the incidence of severe hypoglycaemia by 64% in particularly vulnerable T1DM patients (those with a history of severe hypoglycaemia or IAH).[26] RT-CGM is estimated to confer cost savings over 1 year by reducing the incidence of costly emergency treatment of severe hypoglycaemia in insulin-treated patients with IAH Additional cost savings would be expected to accrue over a patient's lifetime as RT-CGM has been shown to significantly reduce HbA1c, which is strongly associated with the risk for developing long-term microvascular and neuropathic complications of diabetes.

RT CGM is an evolving technology that is becoming the standard of care for insulin treated patients with poorly controlled diabetes. Initial FDA approval of the Dexcom G5™ Mobile RT-CGM system as a replacement of SMBG for therapeutic decision making was made based on the recommendations of a full FDA panel hearing.[34] In addition, results from the REPLACE-BG study,[35] a multicentre, randomized, non-inferiority clinical trial, confirmed that the use of CGM without confirmatory blood glucose monitoring measurements is as safe and effective as using CGM adjunctive to blood glucose monitoring in well-controlled adults with T1DM. Subsequent FDA approval for the new Dexcom G6™ Mobile RT-CGM system as a replacement for SMBG with no calibration and for integration with compatible medical devices demonstrates the rapid evolution in this technology.

A recent study found that the G5 has better overall accuracy than many blood glucose meters The overall accuracy of 17 point-of-care SMBG blood glucose meters, as measured by the mean average relative difference (MARD), which represents the difference between RT CGM readings and contemporaneous blood glucose values assessed by a laboratory standard, ranged from 5.6% to 20 8%, with 9 of the 17 meters having a MARD exceeding 10% [36] In assessing the safety of insulin dosing based on RT-CGM data, the threshold for accuracy has been recognized at less than 10%.[37] The G5 and G6 have an overall MARD of 9 0% The high accuracy of these devices may enhance patients' confidence in the device's blood glucose readings and encourage patients to take more aggressive actions in response to this information.[38]

The new Dexcom G6™ is as accurate as the G5 while offering improved usability due to its improved sensor membrane technology, 30% thinner and contoured wearable sensor, improved applicator, no calibration requirement, 10-day sensor duration, and acetaminophen blocking capability.

1. PRODUCT INFORMATION

The Dexcom G6™ Mobile Continuous Glucose Monitoring System (G6) is indicated for the management of diabetes in persons aged 2 years and older

The G6 system is intended to replace fingerstick blood glucose testing for diabetes treatment decisions Interpretation of the G6 results should be based on the glucose trends and several sequential readings over time. The G6 also aids in the detection of episodes of hyperglycaemia and hypoglycaemia, facilitating both acute and long-term therapy adjustments

The G6 is also able to autonomously communicate with digitally connected devices, including automated insulin dosing systems The G6 can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

The G6 consists of three major components:

1. Sensor: The sensor is a flexible, round, miniature wire that is placed just under the skin to read glucose levels The Sensor is inside the applicator and can be inserted with the push of a button The sensor attaches to the skin with its adhesive patch.

2 Transmitter: The transmitter wirelessly sends glucose information to the smart device The transmitter snaps into the transmitter holder on the sensor.

3 Display Device: Data collected by the sensor is processed and displayed using a smart device (iOS or android) running the G6™ Mobile Application.

The sensor wire, transmitter holder, and transmitter are all that remain on the patient's skin during each sensor wear period.

Dexcom Share® in the Dexcom G6 Mobile Application allows patients to share their data with up to five people ("followers"). After being invited by the "sharer," and downloading the Dexcom Follow® App, an individual becomes a "follower " The user determines what a follower can see, including the user's sensor glucose readings, trends, alarm/alerts when the user's glucose is low or high, and messages

Dexcom Clarity® is a data management software program that allows the transfer of glucose data from the Dexcom G6™ System to remote servers for data management The cloud based Dexcom Clarity® software is intended for use by both home users and healthcare professionals to assist people with diabetes in the review, analysis, and evaluation of historical CGM data to support effective diabetes management. The software provides summary reports, which include average glucose, frequency of calibrations, and patterns of low and high glucose Healthcare professionals can use the retrospective information presented in Dexcom Clarity® to modify their recommendations for a patient's diabetes management plan.

2. WAND NOTIFICATION and FDA APPROVED INDICATIONS

DEXCOM DEVICE WAND NOTIFICATION STATUS

Product	Class	GMDN	WAND	Date of Registration
G6 Sensor	IIa	44611	180705-WAND-6QMVJ2	05/07/2018
G6 Transmitter	IIa	44611	180705 WAND-6QMVJJ	05/07/2018
G6 Mobile App	IIa	60702	180705-WAND-6QMVJV	05/07/2018

A De Novo 510(k) application for the G6™ Mobile CGM System was approved by the FDA for the management of diabetes in individuals aged 2 years and older on March 27, 2018. The G6 is intended to replace fingerstick blood glucose testing for diabetes treatment decisions

The G5™ Mobile CGM System is the only RT-CGM device on the market that meets the USA Centers for Medicaid & Medicare definition of therapeutic CGM The G6 is currently under review by the CMS and is expected to receive the same classification.

3. PROPOSED SCHEDULE LISTING AND CRITERIA

It is proposed the Dexcom G6™ System be listed in Section B of the Pharmaceutical Schedule within the Alimentary Tract & Metabolism / Blood Glucose Testing section It is suggested the G6 System would be subsidised by endorsement as follows:

The Dexcom G6 should be considered as replacement to conventional SMBG in people aged ≥2 years with diabetes and is particularly appropriate for insulin treated patients who meet any of the following criteria:

- *Frequent hypoglycaemia including all episodes of an abnormally low plasma glucose concentration that expose the individual to potential harm All episodes of hypoglycaemia substantially increase the risk of subsequent hypoglycaemia.*
- *Severe hypoglycaemia defined as an event requiring assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*
- *Nocturnal hypoglycaemia*
- *Impaired Awareness of Hypoglycaemia (IAH) defined as the inability to detect the early neurogenic warning symptoms of hypoglycaemia The presence of IAH increases the risk of severe hypoglycaemia by 3-10 times in patients with T1DM1.*

4. DOSING and ADMINISTRATION

As detailed in Section 1 above the G6 RT-CGM system consists of three major components: a sensor, a transmitter, and a display smart device (iOS or android).

The sensor attaches to the skin with its adhesive patch and is replaced every 10 days. The sensor is applied to the abdomen using a unique applicator; patients 2 to 17 years old can also choose to site the sensor on their upper buttocks. Users receive three notifications before each sensor session ends: 6 hours before, 2 hours before, and 30 minutes before The unique code for each new sensor is entered into the receiver smart device to calibrate the sensor.

The transmitter snaps into the transmitter holder on the sensor. The transmitter has a battery life of 90 days, so can be reused for approximately nine sensor sessions. Users receive notifications as the transmitter nears the end of its battery life. Each new transmitter is paired to the display device.

The smart display devices provide the information needed to make treatment decisions including:

- Dexcom Share (Share): allows users glucose information to be sent to others
- Alert Schedule: allows alarm/alerts to sound different during different times of the day.
- Always Sounds: allows phone settings to be overridden so alarm/alerts will always sound, even when the device is on mute/Do Not Disturb.
- Smart watch: sends G6 sensor information to a smart watch.
- Events: records events on the app and displays how they impact the user's trend graph.

The G6 system updates CGM readings every 5 minutes and does not require fingerstick calibration, however the app allows calibration if the user prefers it.

Complete product details are training are available in a variety of resources including the appended User Guide. Two guides are included in the G6 package; a *Start Here* guide and a more detailed *Using Your G6* booklet. A tutorial video is included on a USB stick with each system, and is available in the app. All training resources are also available online at dexcom.com/Support.

5. SUMMARY OF MAIN THERAPEUTIC CLAIMS and PROPOSED USE

The G6™Mobile CGM System is a real time, continuous glucose monitoring (RT CGM) device indicated for the management of diabetes in persons aged 2 years and older. The G6 is intended to replace fingerstick blood glucose testing for diabetes treatment decisions Interpretation of the G6 results should accordingly be based on the glucose trends and several sequential readings over time. The G6 also aids in the detection of episodes of hyperglycaemia and hypoglycaemia, facilitating both acute and long-term therapy adjustments, which may minimise these excursions and their associated adverse health consequences

The G6 is also able to autonomously communicate with digitally connected devices, including automated insulin dosing) systems The G6 can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

The G6 RT CGM technology represents a significant advance over SMBG alone because this technology reports glucose every 5 minutes, which facilitates the detection of impending low or high glucose levels that may otherwise be missed with intermittent data captured by SMGB or flash glucose monitoring.[162] Nocturnal hypoglycaemia, which accounts for half of all severe hypoglycaemia events,[163] is the primary concern motivating prescription of RT CGM in two thirds of cases [164] Most of these hypoglycaemic episodes are asymptomatic and remain undetected by standard SMBG, as fingerstick glucose or flash glucose measurements are rarely performed at night [18] For patients with impaired awareness of hypoglycaemia (IAH), the alarm function of RT-CGM devices may be their only warning of emerging hypoglycaemia

RT-CGM technology provides information on the direction, rate, and trend in glycaemic activity, thereby offering additional data to guide disease management decisions (eg., insulin dosage adjustments, changes in diet), which enables patients to reduce glycaemic variability and increase the time spent in the target glucose range [17,18]

Dexcom G5 and G6 are the only continuous RT-CGM devices approved in the United States for making treatment decisions and the replacement of confirmatory SMBG Although the FreeStyle Libre™ is approved for treatment decisions without confirmatory SMBG, the device only provides glucose readings when patients scan their sensors with the reader; thus, the intermittent patient activated glucose data provided by the FreeStyle Libre cannot alert individuals to potentially dangerous glucose excursions when they are asleep or otherwise not actively checking their sensor readings. A randomized trial comparing the G5 (n=20) and FreeStyle Libre (n=20) in patients with T1DM and IAH found that patients treated with G5 spent significantly less time in hypoglycaemia (<3 9 mmol/L: 6.2% vs. 11.0%, p=0.01; <3.5 mmol/L: 3.5% vs. 8.2%, p=0.004; <3.3 mmol/L: 2.4% vs. 6.8%, p=0 006; <2 8 mmol/L: 0 9% vs 3 8%, p=0 003) and had significantly less fear of hypoglycaemia (p=0.02) than patients treated with intermittent flash glucose monitoring.[165]

Evidence from REPLACE BG, a multicentre, randomized, noninferiority, clinical trial, demonstrated that the use of the earlier Dexcom G4 CGM device with 505 software (which has equivalent accuracy to the G5) without confirmatory BGM is as safe and effective as using RT CGM adjunctive to BGM in well-controlled adults with T1DM.[35] Mean time in 3.9-10.0 mmol/L (primary endpoint) was 63 ±13% at both baseline and 26 weeks in the RT CGM-only group and 65 ± 13% and 65 ±11% in the RT CGM + BGM group (adjusted difference 0%; one-sided 95% CI 22%). No severe hypoglycaemic events occurred in the RT CGM-only group, and one occurred in the RT CGM + BGM group These results indicate that patients using the G5 and G6 devices can reduce their burden of multiple daily finger sticks when using RT-CGM without loss of efficacy or safety, and that the cost of RT CGM may be lowered by reducing the number of BGM test strips required.

The Dexcom Share® feature allows users to select up to five designated recipients or "followers" who can remotely monitor the user's glucose information and receive alert notifications for added protection and peace of mind, particularly for parents of children and for loved ones of elderly individuals who may not be able to reliably measure their own blood glucose values and make insulin dosing decisions on their own. Children and elderly diabetes patients who use the G5 and have at least 1 follower have significantly better adherence to RT-CGM, lower mean blood glucose levels, and less exposure to hypoglycaemia than patients without any followers [20 22]

Three recently completed RCTs (the DIAMOND, GOLD, and HypoDE trials) have shown that RT-CGM in conjunction with MDI therapy significantly improves glycaemic control in T1DM and insulin treated T2DM patients compared to MDI,[23-25] and reduces the incidence of hypoglycaemic events in T1DM individuals with IAH or severe hypoglycaemia,[26] compared with conventional blood glucose monitoring. The DIAMOND RCT evaluated the effectiveness of RT-CGM in patients with poorly-controlled T1DM (n=158) or insulin treated T2DM (n=158) who were treated with MDI [23,24] After 24 weeks, RT-CGM reduced HbA1c by 0.6% (p<0.001) in patients with T1DM and by 0.3% in patients with insulin-treated T2DM compared with patients who received conventional blood glucose monitoring. T1DM patients who received RT-CGM also spent significantly less time in hypoglycaemia (p=0 002), had less diabetes distress (p<0 001) and hypoglycaemic fear (p=0 02), and had better hypoglycaemic confidence (p<0.001) and well-being (p=0.01), compared with conventionally-monitored patients [23,166]

The GOLD trial, a 26-week, multicentre, randomized, open-label, crossover study conducted in 161 patients with poorly-controlled T1DM treated with MDI, evaluated the impact of RT CGM on glycaemic outcomes, well-being, diabetes distress, and hypoglycaemic fear and confidence.[25,27] Mean HbA1c was 0 43% lower (p<0 001), and time spent in daytime and nocturnal hypoglycaemia significantly less (p<0.001), during RT-CGM use than during conventional blood glucose monitoring. In addition, during treatment with RT CGM, patients reported better well being (p=0 02) and hypoglycaemia confidence (p<0.001) compared to when treated with conventional SMBG.

The HypoDE study, a 6 month, multicentre, open label, parallel, randomized controlled trial, was conducted to determine whether RT-CGM reduces the incidence of hypoglycaemic events compared with SMBG in 149 high risk adults (history of IAH or severe hypoglycaemia) with T1DM treated by MDI.[26] Compared with SMBG, RT-CGM reduced the incidence of hypoglycaemic events by 72% (incidence rate ratio [IRR] 0 28, 95% CI 0 20 0 39, p<0 0001) and the incidence of nocturnal hypoglycaemic events by 65% (IRR 0.35, 95% CI 0.22-0.56, p<0.0001). RT-CGM also significantly reduced glycaemic variability, hypoglycaemia related distress, and satisfaction with glucose monitoring compared with SMBG.

Data from three recently published clinical studies show that RT-CGM used in conjunction with MDI is as effective as the combination of RT-CGM and insulin pump therapy for improving glycaemic control [28-30]

The results of these recent RCTs and real-world studies support the findings of earlier RCTs, including the landmark JDRF studies, which established the efficacy of RT CGM in T1DM patients treated with either MDI or insulin pump therapy.[167 171,33,172,173] These studies have shown that, compared to SMBG, RT CGM significantly reduces HbA1c, glycaemic excursions, and glycaemic variability without increasing hypoglycaemic episodes in children and adults with poorly-controlled T1DM and in adults with well controlled T1DM who are receiving MDI or insulin pump therapy.[167,171,33,172,173] Similar improvements in glycaemic control are seen when RT-CGM is continued or initiated in a routine clinical practice environment [169,170,33] The greatest reductions in HbA1c occur in patients who consistently use RT-CGM.[167,174,23,170,171,33,25]

The majority of RCTs conducted to date have not been designed or powered to detect significant changes in the rate of severe hypoglycaemic events, have often excluded individuals with recurrent severe hypoglycaemia from the study samples, and have not robustly measured hypoglycaemic episodes.[31] An exception was the recently published HypoDE RCT which demonstrated that RT-CGM reduced the incidence of severe hypoglycaemia events by 64% in high risk patients who were treated with MDI.[26] Additional evidence that RT-CGM can substantially reduce the incidence of severe hypoglycaemia is provided by the IN CONTROL trial and extension phase of the Juvenile Diabetes Research Foundation (JDRF) clinical trial. The IN CONTROL trial was a randomised, open-label, crossover study conducted in adults with poorly-controlled T1DM and IAH [32] In this study, RT CGM reduced the incidence of severe hypoglycaemia by 59% compared with SMBG. In a 6-month, open-label, extension study of the JDRF clinical trial, children and adults with poorly-controlled T1DM receiving intensive insulin treatment who were initiated on RT-CGM experienced a 46% reduction in the incidence of severe hypoglycaemia [33]

Thus, a strong body of evidence supports the efficacy of highly accurate RT-CGM, used in conjunction with MDI or insulin pump therapy, to significantly reduce HbA1c, time spent in hypoglycaemia and fear of hypoglycaemia and improve well-being and quality of life in patients with insulin-treated diabetes. Burgeoning data also suggest that this technology can significantly reduce the incidence of dangerous and costly severe hypoglycaemic events in high-risk patients.

6. COMPARISON WITH OTHER CGM PRODUCTS

A comparison of the attributes and performance of the G6 and other commercially available standalone RT CGM and flash glucose monitoring devices follows

Product Attributes and Performance	G6™ CGM System (Dexcom)	G5™ Mobile CGM System (Dexcom)*	FreeStyle Libre Flash Glucose Monitoring System (Abbott)[39]	Guardian™ Connect (Medtronic)
Indication	≥2 years[40]	≥2 years[41]	≥4 years[39] (Children 4-17 years of age must be supervised by a caregiver ≥18 years.)	≥14 years[42]
Treatment decisions can be made without confirmatory SMBG	Yes[40]	Yes[41]	Yes except: * During times of rapidly changing glucose levels, as reported interstitial glucose levels may not accurately reflect blood glucose levels. • existing or impending hypoglycaemia as reported by the Sensor. • If symptoms do not match the reading.[39]	No[42]
Sensor & Transmitter Specifications				
Sensor/Transmitter dimensions	3.8 x 3.0 x 1.5 cm[40]	3.8 x 2.3 x 1.3 cm[41]	3.6 x 2.5 x 0.5 cm[39]	1.9 x 1.1 x 0.7cm[43]‖
Sensor/Transmitter weight	11.9 gm.[40]	11.3 gm.[41]	5.1 gm[39]	2.8 gm.[43]
Sensor duration	10 days[40]	7 days[41]	10 days[39]	7 days[42]
Sensor start-up time	2 h[40]	2 h[41]	12 h[39]	2 h[42]
Moisture protection	Water resistant < 2.4 metres for 24 hrs[40]	Water resistant < 2.4 metres for 24 hrs[41]	Water resistant < 0.9 metres for 30 min[39]	Waterproof < 2.4 metres for 30 min[42]
Transmitter power	Non-rechargeable; silver oxide batteries[40]	Non-rechargeable; silver oxide batteries[41]	Non rechargeable; silver oxide battery[39]	Rechargeable (charge lasts 14 days)[44]
Communication range	6 metres[40]	6 metres[41]	3 8 cm[39]	1 8 metres[42]
Receiver/Reader Specifications				
Smartphone display option	Yes[40]	Yes[41]	No[39]	Yes[45]
Receiver dimensions	NA	10 0 x 4 6 x 1 3 cm[41]	9 4 x 6 1 x 1 5 cm[39]	No dedicated receiver[45]
Receiver weight	NA	68 gm.[41]	65 gm.[39]	
Memory storage	NA	30 days of glucose data, 7 days of tech support data[41]	90 days of glucose data; reader only collects data when sensor is scanned[39]	
Receiver power	NA	Rechargeable (full charge lasts 3 days)[41]	Rechargeable (full-charge lasts 7 days)[39]	
Calibration				
Minimum calibration	No calibration required[40]	2 h after sensor insertion, then every 12 h[41]	No calibration required [39]	2 and 6 h after sensor insertion, then every 12 h[42]
Range	2.2-22.2 mmol/L[40]	2.2-22.2 mmol/L[41]	2.2-27.8 mmol/L[39]	2.2-22.2 mmol/L[42]
Restrictions	N/A[40]	Do not calibrate when glucose levels are rapidly changing (>0.1 mmol/L per minute)[41]	N/A	None[42]

Interaction with BG meter	Manually enter reading from any meter[40]	Manually enter reading from any meter[41]	Reader incorporates a glucose meter[39]	Reading is manually entered from any meter, or wirelessly uploaded using Bayer Contour® Next Link meter[42]
Alarms				
Hypoglycaemia fixed alarm	Set at 3 1 mmol/L; cannot be adjusted or disabled[40]	Set at 3 1 mmol/L; cannot be adjusted or disabled[41]	No alarms or alerts[39]	Not available[42]
Customisable alarms	Optional; set by user[40]	Optional; set by user[41]	Not applicable[39]	Optional; set by user[42]
Performance Characteristics				
Overall Accuracy MARD (average % discrepancy between CGM and reference YSI, 2.2 22.2 mg/dL)	9.0% (overall) 9.8% (adults) 7.7% (paeds)[40]	9 0% (adults) 10.4% (paeds)[41]	9.7%[39]	10.6%[46]
Accuracy dependent on acetaminophen exposure	No[40]	Yes[41]	No[39]	Yes[46]
Hypoglycaemia Accuracy (% of CGM readings within ±20%/1.1 mmol/L of reference YSI, 2 2 4 4 mmol/L)	Adults: <3 0 mmol/L: 91% 3.0-3.8 mmol/L: 95% Children: <3.0 mg/dL: 62% 3 0 3 8 mmol/L: 89% [41]	Adults: 2 2 3 3 mmol/L: 94% 3.4-4.4 mmol/L: 96% Children: 2.2-3.3 mmol/L: 74% 3.4-4.4 mmol/L: 82% [41]	2.2-2.8 mmol/L: 58% 2 8-4.4 mmol/L: 81%[39]	≥2 2 3 3 mmol/L: 97% >3 3-4 4 mmol/L: 88%[46]
Hypoglycaemia Detection Rate (% of time BG level was ≤ alert setting of 3.7 mmol/L and alert sounded)	Adults: 86% Children 6 17 yrs: 82% [40]	Adults: 91% Children 2-5 yrs: 100% Children 6-17 yrs: 75%[41]	85%[39]†	88%[46]
Hyperglycaemia Detection Rate (% of time BG level was ≥ alert setting 13.3 mmol/L and alert sounded)	Adults: 98% Children 2-5 yrs: 93% Children 6 17 yrs 97%[41]	Adults: 95% Children 2-5 yrs: 98% Children 6-17 yrs: 94%[41]	95%[39]†	100%[46]
Accuracy Over Time MARD (average % discrepancy between CGM and reference YSI, 2.2-22.2 mmol/L)	Days 1 & 2: Adults 10.9% Children 10.9% Days 4 &5: Adults 9.2% Children 9 2% Day 7 &10: Adults 9 6% Children 9.6%[41]	Day 1: Adults 10.7% Children 14.8% Day 4: Adults 8.0% Children 10 7% Day 7: Adults 8 5% Children 11.3% [41]	Day 1: 10 7%[39] Day 4: 9.6%[39] Day 7: 9.1%[39] Day 10: 9 3%[39]	Day 1: 12.4% Day 3: 8.7% Day 7: 10.1%[43]
Sensor Life (% Sensors working at end of maximum indicated use)	Adults: 94% @ 10 days Children: 77% @ 10 days [41]	Adults: 98% @ 7 days Children: 94% @ 7 days [41]	77% @ 10 days[39]	72.3% @ 7 days[46]

BG=blood glucose; MARD=mean average relative difference; YSI=Yellow Springs Instrument
*Performance data are for the G5™ Mobile CGM System with the 505 software. All G5™ Mobile CGM Systems use the 505 software. Unless otherwise specified, the age range for children is 2-17 years.
‖ The dimensions and weight reflect only that of the Guardian 3 sensor and do not include the Guardian Link 3 transmitter that is attached to the sensor.
†The FreeStyle Libre has no alarms or alerts. The hypoglycaemia and hyperglycaemia detection rates reflect the % of high glucose readings that were correct when the Reader was used to scan the Sensor

7. EXPECTED UPTAKE OF DEXCOM G6 SYSTEM IN NEW ZEALAND

The projected uptake of the G6 RT-CGM system in New Zealand consistent with the access criteria proposed in Section 2 1 is based on sales of the system in Australia, where it is reimbursed through the National Diabetes Services Scheme under the following eligibility criteria:

Children and young people with type 1 diabetes aged less than 21 years who:

- *Are expected to benefit clinically from the use of CGM;* ***and***
- *have the willingness and capability to use CGM;* ***and***
- *have the commitment to actively participate in a diabetes management plan which incorporates CGM*

And *fulfil one of more of the following criteria:*

- *frequent significant hypoglycaemia—more than one episode a year of significant hypoglycaemia requiring external, third party assistance;* ***and/or***
- *impaired awareness of hypoglycaemia;* ***and/or***
- *inability to recognise, or communicate about, symptoms of hypoglycaemia;* ***and/or***
- *significant fear of hypoglycaemia for the child/young person or a family member/ carer which is seriously affecting the health and wellbeing of the child or young person or contributing to hyperglycaemia as a reaction to this fear.*

PROJECTED SALES OF DEXCOM G6 SYSTEM ASSUMING REIMBURSEMENT 1 JANUARY 2019 UNDER DESCRIBED SCENARIOS

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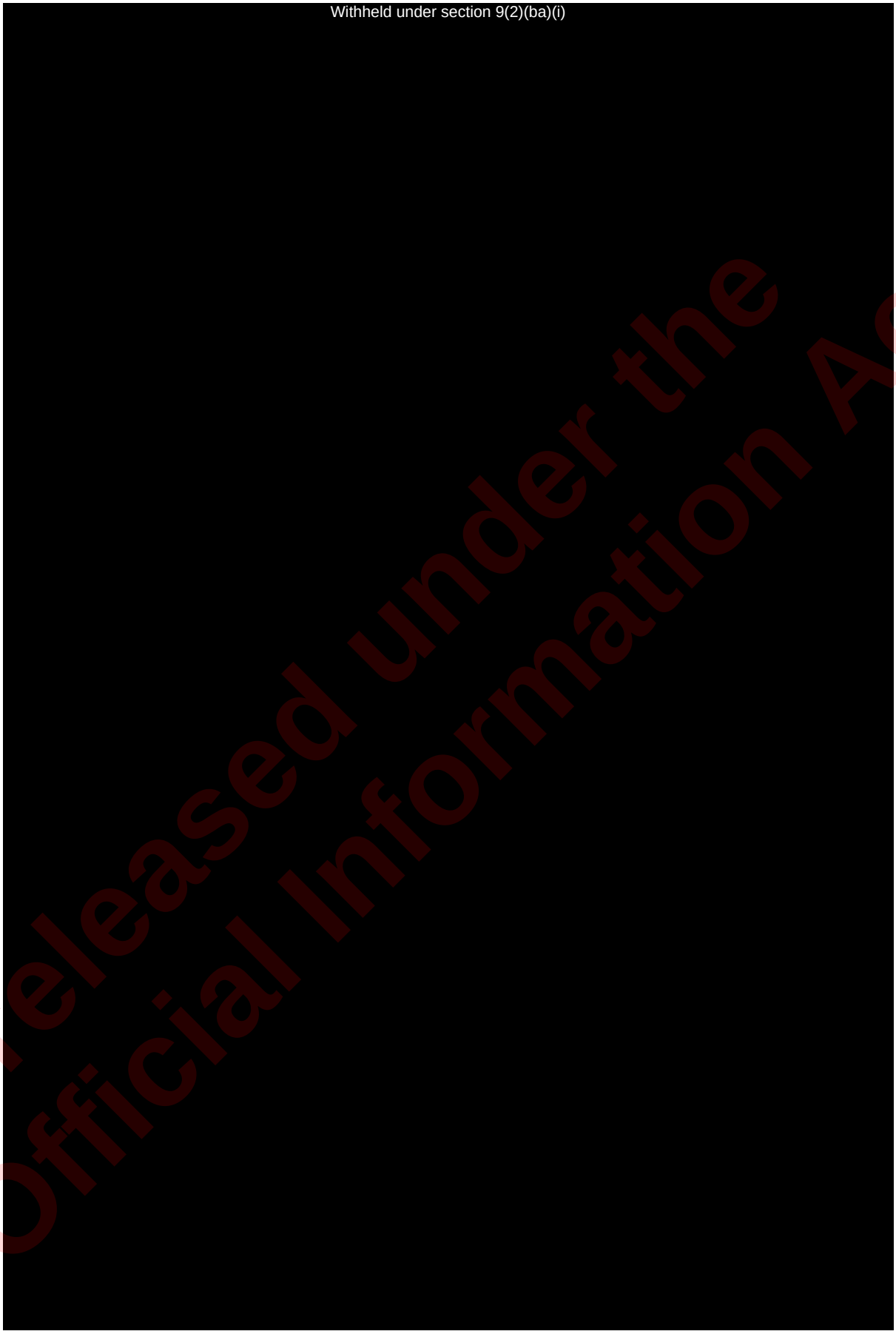

8. PRICE INFORMATION (PLACEHOLDER)

9. PATENT INFORMATION

Dexcom has no patents relating to the G6 System filed in New Zealand at the present time.

10. IMPACT ON THE WIDER HEALTH SECTOR (PLACEHOLDER)

11. CONTRAINDICATIONS/ WARNINGS/ PRECAUTIONS/ INTERACTIONS

Contraindication

No MRI/CT/Diathermy
Don't wear the G6 system for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high frequency electrical heat (diathermy) treatment as it hasn't been tested in those situations The magnetic fields and heat could damage the components of the G6, which may cause it to display inaccurate G6 sensor glucose readings (G6 readings) or may prevent alerts.

Warnings

- Read User Materials
- Don't Ignore Low/High Symptoms
- No Number, No Arrow, No CGM Treatment Decision
- Don't Use If:
  - you are pregnant
  - on dialysis
  - critically ill
- Use a meter to make treatment decisions during the 2-hour sensor warmup period.
- When a new sensor is started G6 readings or alarm/alerts commence until the sensor code is entered, or two calibrations.
- You must calibrate immediately when the G6 notifies you otherwise the G6 may not be accurate
- Use fingertips only to calibrate from your BG meter. Blood from other places may be less accurate and not as timely
- Don't ignore broken or detached sensor wires.
- **Sensor Insertion Risks:**
  It's uncommon, but inserting the sensor can cause infection, bleeding, or pain, and wearing the adhesive patch can irritate your skin Only a few patients in the G6 clinical studies got slight redness and swelling. No sensor wires broke in the clinical studies; however, there is a remote chance a sensor wire could break or detach and remain under your skin Sterile broken sensor wires usually don't pose a significant medical risk.
- Don't use a damaged or cracked transmitter A damaged transmitter could cause injuries from electrical shocks and may make the G6 not work correctly.
- **Check Smart Device Settings:**
  When using your smart device, you should confirm the volume is turned up, the device is not muted, and headphones are not plugged in Some notifications are silent during the first visual and vibrate notification and then make a sound on the second notification. If you don't clear the alert, it repeats at half volume after 5 minutes and at full volume after 10 minutes Your alarm and important alerts sound and display information even when your volume is low or muted. Specifically, if your smart device is on mute, only these notifications make a sound:
  - Glucose Alarm/Alerts:

    - Urgent Low
    - Low Glucose
    - Rise Rate
    - No Readings Alert
    - * Urgent Low Soon
    - * High Glucose
    - * Fall Rate
  - System Alerts:
    - Calibration Required
    - Sensor Expired
    - Transmitter (not working)
    - App Stopped.
    - Exceptions: On Apple® devices, Signal Loss doesn't sound when your volume is low or muted.
    - * Calibration Error
    - * Replace Sensor
    - * No Storage Error
  - *Bluetooth*: The transmitter talks to the app with *Bluetooth* Ensure the device *Bluetooth* is on
  - Notifications:
    - Make sure the smart device settings allow Dexcom app notifications to show on your Lock screen. This will allow you to see notifications without unlocking your phone.
    - Apple: During G6 setup, enable Dexcom app notifications or you won't get alarm/alerts.
  - Battery: The app must always be running in the background and may drain your smart device battery Keep the battery charged
  - Compatibility: Before upgrading your smart device or its operating system, check dexcom com/compatibility Automatic updates of the app or your device operating system can change settings or shut down the app. Always update manually and verify correct device settings afterward
  - Time: Let the date and time on your smart device automatically update when you travel across time zones or switch between standard and daylight saving times. Don't manually change your smart device time, because it can make the time on the trend screen wrong and the app may stop displaying data
- Use USB cable only as directed, and store safely.
- Use Your G6 to Make Treatment Decisions: Don't use Share information for treatment decisions, like treating for a low or dosing for a high. Use the sensor information on your G6 instead.
- Follow HCP Advice
- *Share* Followers Must Follow and You Must Share: User have to turn *Share* on to make it send your sensor information to Followers Followers have to download the Dexcom Follow app to see what is sent.

Precautions

- **Avoid Sunscreen and Insect Repellent**
- **Use Correct Sensor Code**
- **Be Accurate, Be Quick:** Enter the exact BG value displayed on the meter within five minutes of using the meter. Don't enter the G6 reading as a calibration.
- **Don't Use Sensors if Expired**
- **Check Sensor Package** to ensure it isn't damaged or opened.
- **Clean and Dry Skin** before inserting the sensor. Clean the insertion site with alcohol wipes to prevent infections. Don't insert the sensor until the skin is dry
- **Where to Insert Sensor:** sensor placement is important. Choose a site:
  - At least 8 centimetres from insulin pump infusion set or injection site
  - Away from waistband, scarring, tattoos, irritation, and bones
  - Unlikely to be bumped, pushed, or laid on while sleeping
- **Don't Throw Away the Transmitter:** the transmitter is reusable until the G6 notifies you that the transmitter battery is about to expire.
- **Use Correct Transmitter, Receiver Device, and Sensor:** G6 components are not compatible with any previous Dexcom products.
- **Going Through Security Check Point:** When wearing your G6 ask for hand-wanding or full-body pat-down and visual inspection instead of going through an Advanced Imaging Technology scanner (also called a millimetre wave scanner) or putting any part of the G6 in the baggage x-ray

machine. The G6 can be worn in a walk-through metal detector. If not, use a meter for treatment decisions while in the security area

- **Keep Transmitter Close to Display Device:** Keep the transmitter and display device within 6 metres with no obstacles between them Otherwise, they might not be able to communicate If water is between the transmitter and the display device (eg. if showering or swimming) keep them closer to each other The range is reduced because Bluetooth® doesn't work as well through water.
- **Get Alarm/Alerts on Display Device You Use:** To get your alarm/alerts, set them on the display device you use. Your receiver smart device won't get the alarm/alerts you set on your app. Likewise, your app won't get the alarm/alerts you set on your receiver device
- **Check *Followers*' Smart Devices to ensure:**
  - Sounds on:
  - Sharing gaps: *Followers* won't get sensor information when their smart device is off, not connected to the Internet, or in *Do Not Disturb* or *Airplane* mode When the *Followers* fix those issues, they'll start getting the current information but they won't get the information they missed
  - Cell carrier supports simultaneous voice and data: Most cell service carriers support using voice and data at the same time. Check yours and have *Followers* check theirs. If it's not supported, *Share* won't work during phone calls *Share* will send any waiting notifications when the call is over.
- **Customise *Share* So *Followers* Can Support You**
  - Customise *Share* to make sure *Followers* have the information they need
  - Delay feature: *Followers* won't get notified until after the delay time set by the system user
  - *Not Share* feature: You can stop sharing with a *Follower* any time by choosing *Not Share*.

- ***Interactions***

Paracetamol/Acetaminophen Blocking

A standard or maximum paracetamol/acetaminophen dose of 1 gram (1,000 mg) every 6 hours does not affect G6 readings for treatment decisions. Doses of paracetamol/acetaminophen >1000mg every 6 hours in adults may give elevated G6 readings.

12. ECONOMIC VALUE AND MODELING REPORT (PLACEHOLDER)

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