National Diabetes Services Scheme

An Australian Government Initiative

NDSS Helpline 1800 637 700
ndss.com.au

Continuous and flash glucose monitoring devices

Information for health professionals about subsidised continuous glucose monitoring (CGM) and flash glucose monitoring (Flash GM) devices through the National Diabetes Services Scheme (NDSS).

Find this resource at ndss.com.au

diabetes australia

The NDSS is administered by Diabetes Australia

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Contents

Acronyms or terminology used in this document

ADA	American Diabetes Association
CGM	continuous glucose monitoring
CGM devices	continuous glucose monitoring devices
DHS	Department of Human Services
DVA	Department of Veterans' Affairs
Flash GM device	flash glucose monitoring device (FreeStyle Libre 2)
Flash GM	flash glucose monitoring
IAH	impaired awareness of hypoglycaemia
CSII	insulin pump therapy
isCGM	Intermittently scanned CGM also known as Flash GM
MDI	multiple daily injections
NDSS	National Diabetes Services Scheme
RCTs	randomised controlled trials
rtCGM	real-time CGM
SMBG	self-monitoring blood glucose
SNCC	Safety Net Concession card
SNEC	Safety Net Entitlement card

CGM and Flash GM devices

Continuous glucose monitoring uses small wearable devices that measure glucose levels in the interstitial fluid throughout the day and night. The device reader or receiver displays the user's current glucose level, trend arrows (to show how slow or fast the glucose levels are rising or falling, or if steady) and recent glucose level history.

There are two main types of continuous glucose monitoring devices:

- Continuous glucose monitoring (CGM) devices measure glucose levels continuously and can be programmed to sound alarms and send warnings. For example, if glucose levels are outside an individualised target range or are rising or falling rapidly. CGM is also known as real-time CGM (rtCGM). In this booklet, we refer to rtCGM when using the term CGM.
- Flash glucose monitoring (Flash GM) devices measure glucose levels continuously but only display glucose values when scanned by a reader, a smartphone or smart device that reveals glucose levels. Flash GM is as also known as intermittently scanned CGM (isCGM). In Australia, this technology is available in the FreeStyle Libre 2. The FreeStyle Libre 2 has optional alarms for high or low glucose levels and signal loss.

How do CGM and Flash GM devices work?

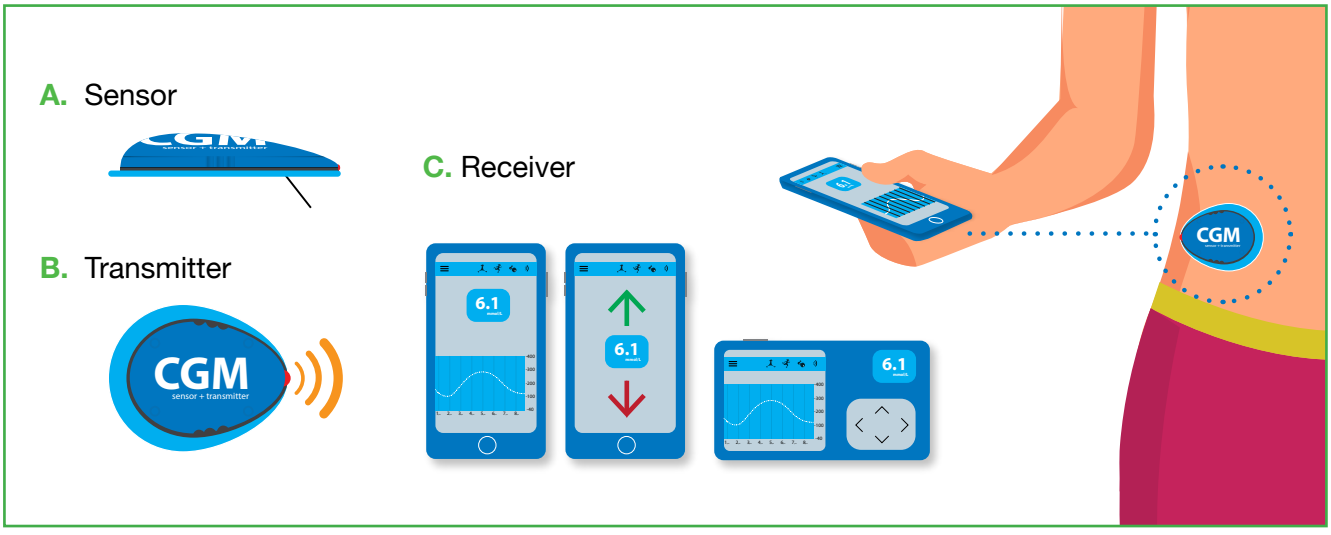
CGM devices have three main parts:

A. The **sensor** is a very small electrode inserted in the subcutaneous tissue. It measures the level of glucose in the interstitial fluid. A new sensor needs to be inserted every 6–7 days, depending on the device. Insertion sites are rotated around the abdominal area or upper, outer aspect of the arm.

B. The small **transmitter** is attached to the sensor and sends glucose readings to a wireless receiver or smart phone. Transmitters are reusable but depending on the device, need to be replaced every 3–12 months.

C. The **receiver** allows the user to view their glucose data. The receiver may be a standalone device, an insulin pump or compatible smartphone/device. The receiver also stores glucose data, which can be uploaded for the user and their diabetes health care team, to review. This can help in making decisions about changes to insulin doses or pump settings as well as food choices and physical activity.

CGM devices may need to be calibrated with self-monitoring blood glucose (SMBG) results at least every twelve hours.



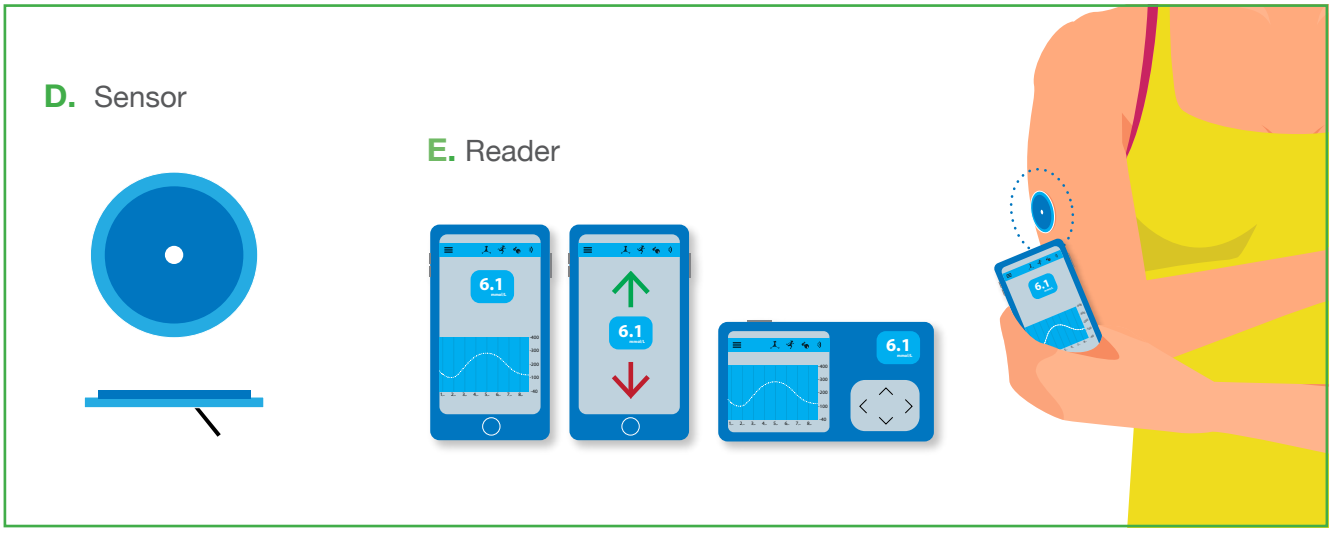
Flash GM devices have two main parts:

D. The **sensor** sits on the skin, usually on the upper, outer aspect of the arm, with a small electrode inserted just under the skin. It measures the level of glucose in interstitial fluid. A new sensor needs to be inserted every 14 days.

Unlike CGM, Flash GM does not use a transmitter. To see glucose levels data, you need to scan the sensor with the reader.

E. The **reader** allows the user to view their glucose data when the sensor is scanned. The reader may be either a handheld device, which is also a blood glucose and blood ketone meter, or smartphone or smartdevice via the FreeStyle LibreLink app.

Similar to CGM, the reader also stores glucose data—which can be uploaded for the user and their diabetes health care team to review—to help in making decisions about changes to insulin doses or pump settings as well a food choices and physical activity. The FreeStyle Libre 2 is a Flash GM device. The FreeStyle Libre 2 Reader works with the FreeStyle Libre 2 device. The FreeStyle LibreLink app is compatible with the FreeStyle Libre 2 device.



Why use CGM and Flash GM? Benefits and barriers

Benefits of CGM and Flash GM

CGM and Flash GM may have a number of benefits:

» **24/7 readings.** CGM and Flash GM allows the user to see glucose levels across the day and night, rather than just at a single point in time. The graphs on the receiver or reader can show patterns and may help identify how certain factors, such as food and exercise, affect glucose levels.

» **Trend arrows.** Besides showing glucose levels at any point in time, CGM and Flash GM shows if glucose levels are rising, falling or stable and how quickly they are changing. However, any clinical decisions informed by trends must consider the time lag between interstitial and blood glucose levels.

» **An easier way to monitor.** Flash GM and CGM make it much easier to check glucose levels, particularly those who might find SMBG difficult to do. It is also easier for carers, particularly for those in childcare, school or an aged care facility.

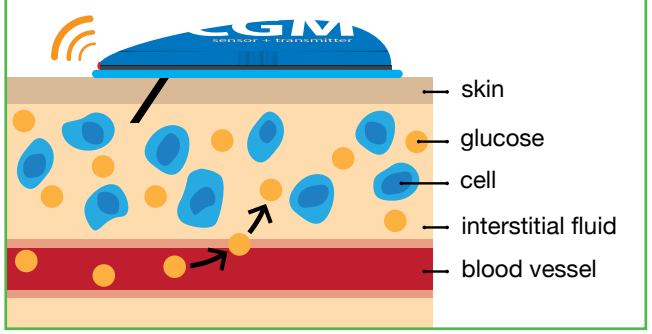
» **Alarms.** CGM devices can be set to sound an alarm if glucose levels go above or below individually set target levels. The FreeStyle Libre 2 device has optional alarms for high and low glucose levels and signal loss. Alarms can be especially useful for people with impaired awareness of hypoglycaemia (IAH).

» **Overnight monitoring.** CGM devices measure glucose levels throughout the night. With CGM, alarms can be set to alert the user to glucose levels above or below their target. There may still be a need for SMBG levels overnight, if the user has specific concerns or is advised by their diabetes health professional. The diabetes health professional can support the user to time calibrations that may be required overnight.

To assess patterns and evidence of hypoglycaemia, the Flash GM user can scan and view their overnight readings on waking. However, they must scan at least every 8 hours to see all their data.

» **Reduced need for SMBG.** CGM and Flash GM does not completely replace the need for SMBG, but it may reduce the frequency of SMBG required.

CGM sensors measure glucose levels in the interstitial fluid and not the blood.



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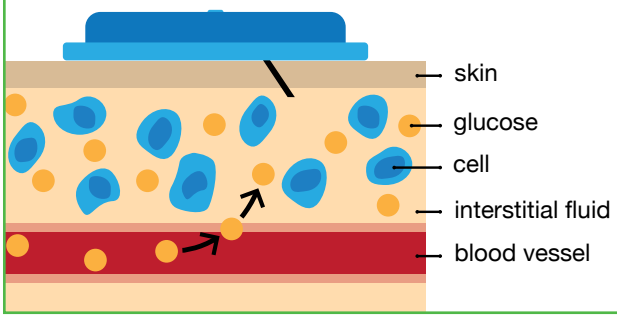
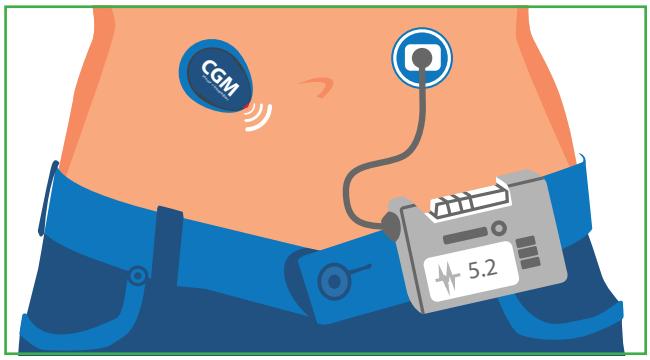


- **Peace of mind**. Being able to discreetly monitor glucose levels at any time can provide reassurance and reduce anxiety. With the added benefit of CGM and the Flash GM FreeStyle Libre 2 devices receiving alerts if glucose levels go outside the user's set target range.
- **Data sharing**. Some CGM devices and the Flash GM device provide the option of sharing glucose data with other people via an app on their smartphone/device, or via SMS messages to notify them of alerts and alarms. This can be particularly useful for parents or carers. Data can also be downloaded to share with the user's parent(s)/carer(s) and diabetes health care team.
- **Insulin pump integration to help with keeping glucose levels within a set target range**. Some CGM devices work with a compatible insulin pump and can temporarily stop insulin delivery from the pump if glucose levels drop below the set target range (or if the sensor predicts that the glucose level will become too low). This may help prevent hypoglycaemia or make episodes easier to manage. One device, when used with a pump, helps to keep glucose levels within the target range by delivering more or less insulin depending on the sensor readings.

  Flash GM devices are not compatible with insulin pumps.



Barriers to CGM and Flash GM

While CGM and Flash GM offer many benefits, there are also some disadvantages that should be discussed with anyone considering its use:

- **Accuracy**. After a meal or drink, glucose travels to the bloodstream and then to the interstitial fluid between cells. As CGM and Flash GM devices measure the glucose levels in the interstitial fluid, there may be a lag time between the glucose level measured by a CGM or Flash GM device and the actual blood glucose level. Studies have shown lag times ranging from 4-50 minutes, although most of these are with older devices[1]. Recent studies have found mean lag times between 4.5 and 9.5 minutes[2,3]. There is evidence that lag time may vary between individuals[2].
  A recent study in adults with type 1 diabetes found a longer lag time during prolonged aerobic exercise[4].
- **Does not replace SMBG**. While using CGM or Flash GM devices can reduce the frequency at which SMBG needs to be undertaken, it is not necessarily a replacement for SMBG. Calibration with SMBG may be necessary according to the manufacturer's specification for the particular CGM device. Similarly, SMBG may also be necessary to confirm hypoglycemia and for informing bolus insulin dosing depending on individual person's needs and according to the manufacturer's specification.
- **Self-adjustment of insulin**. Depending on the individual person's needs and according to the manufacturer's specification for the particular device, SMBG may be necessary to confirm sensor reading when symptoms do not match sensor reading and to inform self-adjustment of insulin and other self-management decisions.

- **Being attached**. Some people may not like wearing the sensor, particularly if they are using an insulin pump, as then they will have two different devices attached to their body. Some people do not like wearing devices that others may notice.
- **Staying attached**. It can be difficult for some people to keep the sensor attached, particularly if they spend a lot of time in water and/or sweat a lot during exercise. The sensor might also get displaced while playing or during sport. Tape or specifically designed protective patches can be used to help prevent this from occurring. Once a sensor comes off it cannot be reused.
- **Skin reactions**. Some people may experience allergic reactions, skin rashes, itching, bleeding or bruising in the area where the sensor is inserted.
- **Discomfort**. Some people may also experience mild pain or discomfort during insertion.
- **Information overload**. The additional information that CGM and Flash GM provide has many benefits, but it can also be overwhelming for the user (or their parent/carer) to see what their glucose levels are doing all the time.
- **Alarm fatigue**. Alarms can be very helpful, but if they occur often, some people may find them annoying and disruptive and may even start to ignore some of the alarms or disable them. Health professionals should discuss with the user which alarms may be useful.
- **Data sharing**. While it may be beneficial to share CGM and Flash GM readings with family, carers, friends or health professionals, the user's privacy and security should be considered before sharing data. This is a personal choice and should not deter people from using CGM or Flash GM. Any potential psychosocial impact on the person with diabetes from sharing data should be considered. Any potential impacts from data sharing should be discussed and consent addressed. People receiving data need to identify rules about how to discuss the information and the action to be taken and by whom. For instance, if a child is already responding to a reading, it may not be helpful to receive many text messages from others who receive the data and could lead to diabetes burnout or distress.

It is important for health professionals to discuss in detail, the potential benefits and barriers with people interested in using CGM or Flash GM.

Research into the use of CGM and Flash GM

Research has shown that regular use of CGM can reduce HbA1c and mean glucose levels, lower the risk of and time spent in hypoglycaemia and hyperglycaemia, reduce glycaemic variability, and improve quality of life[5–7]. Benefits have been seen in children and adults, pregnant women, and in those using multiple daily injections (MDI) and insulin pump therapy (CSII). Greater improvements in glycaemic management are seen with frequent as close to daily as possible and ongoing use of the CGM device[6,7].

While less research has been published on Flash GM, there is evidence from two randomised controlled trials (RCTs) and several observational studies in both adults and children to show reductions in hypoglycaemia and improvements in time in range, glycaemic variability, and user satisfaction[6–9].

The currently available Flash GM device, the FreeStyle Libre 2, appears to have similar accuracy to current CGM systems[8,9]. Alarms are particularly important for those with IAH. Alarms can reduce the time spent in hypoglycaemia in those with IAH[10,11].

A systematic review of the efficacy of technology in type 1 diabetes undertaken in 2019 concluded that integrated insulin pump and CGM systems with low glucose suspend or hybrid closed loop capability appear to be the best option for reducing HbA1c levels and the risk of severe hypoglycaemia[12].

The 2020 Standards of Medical Care in Diabetes by the American Diabetes Association (ADA) make the following recommendations regarding the use of CGM[7]:

- When used properly, CGM in conjunction with insulin therapy is a useful tool to lower HbA1c levels and/or reduce hypoglycaemia in adults with type 1 diabetes who are not meeting glycaemic targets, have IAH and/or have episodes of hypoglycaemia.
- CGM should be considered for children and adolescents with type 1 diabetes as an additional tool to help improve glycaemic management[7].
- CGM may be used effectively in pregnant women with type 1 diabetes to improve HbA1c levels, time in range and neonatal outcomes[7].

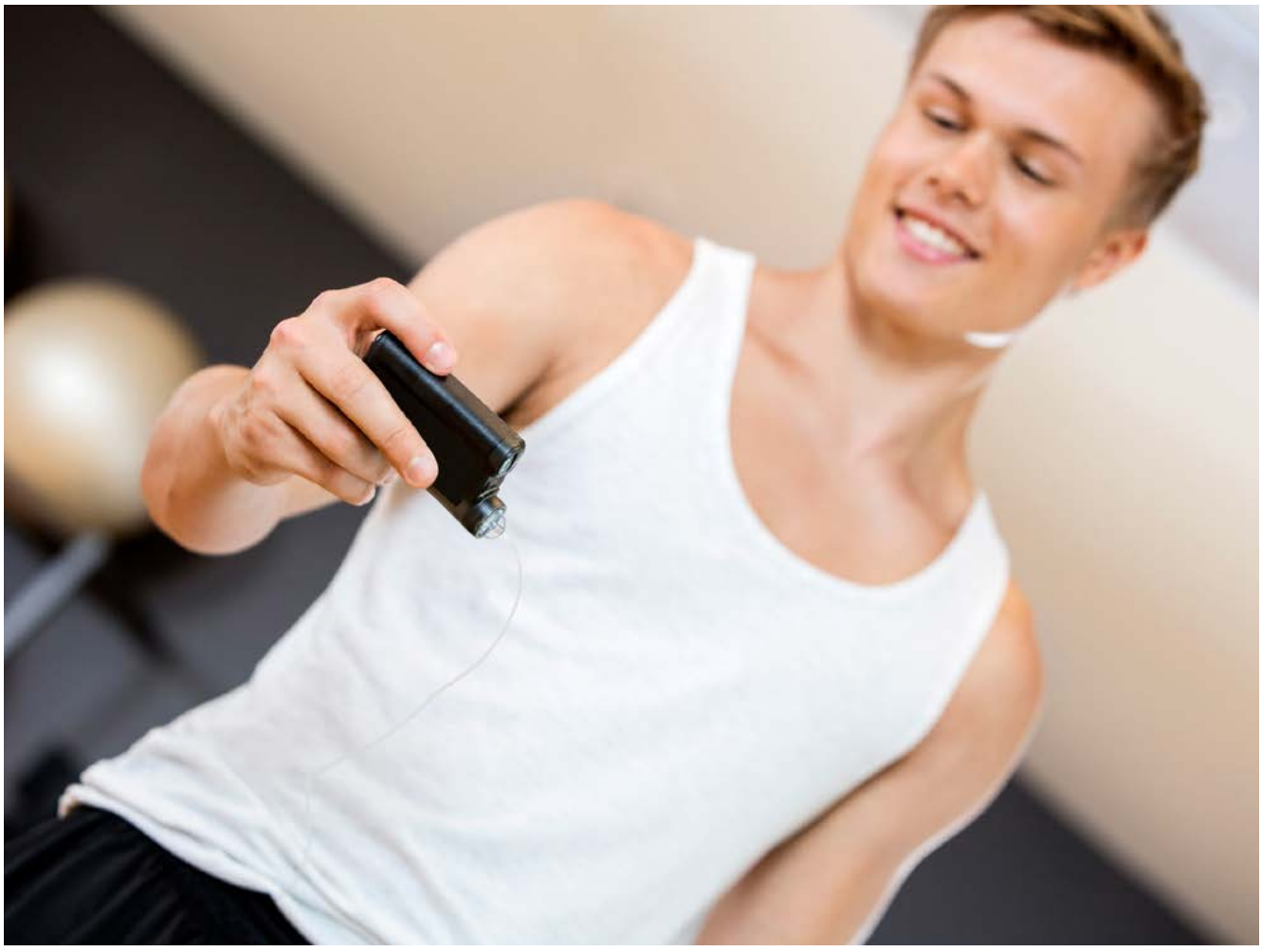
The ADA also highlights the importance of education and training in the use of CGM and recommends daily use as possible for maximal benefit[7].

A 2017 international statement on the use of both CGM and Flash GM recommends that it should be considered in conjunction with HbA1c for glycaemic status assessment and therapy adjustment in all individuals with type 1 diabetes who are not achieving glucose targets, especially if they are experiencing problematic hypoglycemia[6]. The consensus recommends that all individuals should receive training in how to interpret and respond to their glucose data.

Health professionals may find a systematic review evaluating the impact of CGM on the physical, emotional and relational lives of people with type 1 diabetes is useful reading[13]. Themes explored in the article include interacting with CGM, the burden of living with CGM, feeling different from others, feeling empowered, and the impact on relationships[13]. While some users of CGM feel more empowered, there can also be many physical and emotional burdens associated with CGM use[13]. These include the pain and discomfort of wearing CGM, the impact on sleep, dealing with alarms and the constant nature of CGM feedback[8].

For children and young people, supportive parental behaviours are important, particularly being non-judgemental and avoiding making the child feel like their device is 'spying' on them[13].

All these factors need to be taken into account when assessing the suitability of a person for CGM and Flash GM, and in setting realistic goals and expectations for use of CGM and Flash GM.



Eligibility for subsidised products through the NDSS

The Australian Government provides access to subsidised CGM and Flash GM products through the NDSS. People are eligible to access CGM if in the following groups:

- **Type 1 Diabetes; Age Under 21 Years.** Children and young people with type 1 diabetes aged under 21 years
- **Type 1 Diabetes.** People with type 1 diabetes
- **Type 1 Diabetes; Pre-Pregnancy/Pregnancy/Post-Pregnancy.** Women with type 1 diabetes who are actively planning pregnancy, pregnant or immediately post-pregnancy
- **Other Eligible Conditions; Age Under 21 Years.** Children and young people aged under 21 years with conditions very similar to type 1 diabetes who require insulin

Go to **ndss.com.au/cgm** to find out more about the eligibility criteria and how to access subsidised CGM and Flash GM supplies through the NDSS. An authorised health professional can assess, confirm and certify eligibility, and ensure that the use of CGM or Flash GM will help as part of the person's diabetes management.

The health professionals who can perform these assessments and are authorised to certify eligibility are listed on the Continuous and Flash Glucose Monitoring Access forms for the different eligibility cohorts.

The authorising health professional will need to complete the appropriate Continuous and Flash Glucose Monitoring Access Form, which can be found on the NDSS website at **ndss.com.au/forms#cgm** and submit this according to the details outlined on the page and on the form.

The subsidised access is **only** available for CGM and Flash GM devices that are specified on the Continuous and Flash Glucose Monitoring Access Forms. The subsidy covers the cost of CGM sensors and transmitters, but the cost of the CGM receiver needs to be paid by the person with diabetes (or their family) if they choose to use a receiver rather than using an insulin pump or smartphone/device. The subsidy also covers the cost of Flash GM sensors, and people eligible to receive subsidised sensors can access a complimentary reader from the manufacturer should they choose to not use a smartphone/device as a reader.

How is overall eligibility determined for subsidised access to CGM land Flash GM supplies through the NDSS?

Confirmation of eligibility for access to subsidised CGM or Flash GM products through the NDSS will require an authorising health professional, in consultation with the person or their parent/carer, to determine whether:

- the person is expected to benefit clinically from the use of CGM or Flash GM; and
- the person or family/carer has the willingness and capability to use CGM or Flash GM; and
- the person or family/carer has the commitment to actively participate in a diabetes management plan which incorporates CGM or Flash GM.

Eligibility criteria

To be eligible to access subsidised CGM and Flash GM products through the CGM Initiative, as part of the NDSS, the person must meet the criteria in one of the following categories.

Type 1 Diabetes; Age Under 21 Years

The eligibility criteria are outlined on the Continuous and Flash Glucose Monitoring Access Form for Type 1 Diabetes; Age Under 21 Years.

The health professionals authorised to certify access are listed on the Continuous and Flash Glucose Monitoring Access Form for Type 1 Diabetes; Age Under 21 Years.

Children and young people with type 1 diabetes under the age of 21 years can access fully subsidised CGM and Flash GM supplies.

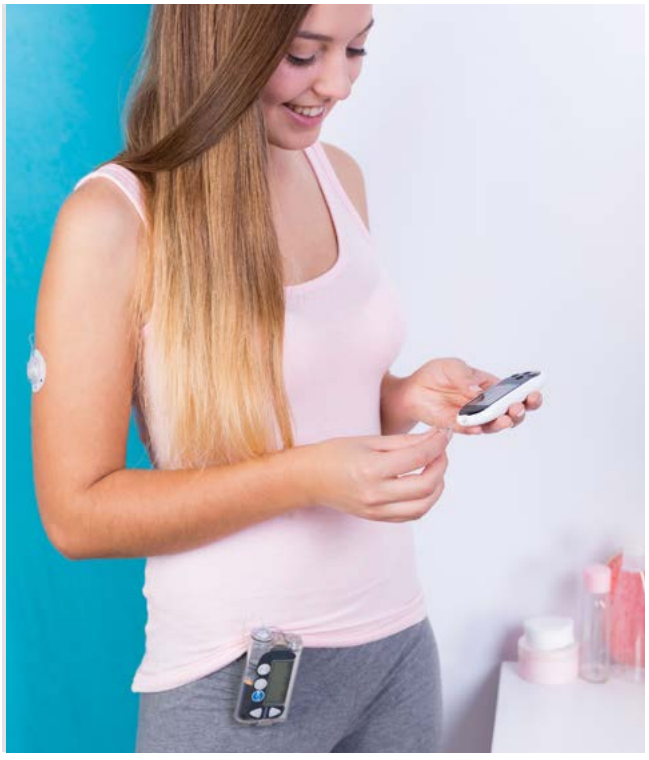
At the age of 21 years and over, subsidised CGM and Flash GM supplies can be accessed with a co-payment.

Type 1 Diabetes

The eligibility criteria are outlined on the extract from the Continuous and Flash Glucose Monitoring Access Form for Type 1 Diabetes.

To be eligible to access subsidised CGM products through the NDSS:

- the person is expected to benefit clinically from the use of CGM or Flash GM; **AND**
- the person or family/carer has the willingness and capability to use CGM or Flash GM; **AND**
- the person or family/carer has the commitment to actively participate in a diabetes management plan which incorporates CGM or Flash GM.



Concessional Status

People with type 1 diabetes aged 21 years and over with the following valid concessional types are eligible to access fully subsidised CGM and Flash GM supplies through the NDSS:

Concession Types
Commonwealth Seniors Health Card (as issued by DHS or DVA)*
Commonwealth Pensioner Concession Card (as issued by DHS or DVA)*
Commonwealth Health Care Card (as issued by DHS or DVA)*
DVA* Gold Card
DVA* White Card
Safety Net Concession Card (SNCC)
Identifies as Aboriginal and/ or Torres Strait Islander person

* DHS = Department of Human Services,
DVA = Department of Veterans' Affairs

What happens when the person's concessional status expires? Do people lose eligibility?

No, people do not lose their eligibility. They will need to revalidate their concessional status every 12 months to continue to access fully subsidised products through the NDSS. We will remind them to revalidate their concessional status 4 weeks before the end of their 12-month access period.

If they no longer have a valid concessional status, subsidised CGM and Flash GM supplies can be accessed with a co-payment.

Concessional status can be updated at a NDSS Access Points (usually a community pharmacy), by going to **ndss.com.au/forms#cgm** or by calling the NDSS Helpline on **1800 637 700**.

Once the concessional status has been updated, they will be able to again access fully subsidised CGM and Flash GM supplies through the NDSS.

Type 1 diabetes; Pregnancy Planning, Pregnancy or Immediately Post Pregnancy

The eligibility criteria for women with type 1 diabetes are outlined on the extract from the Continuous and Flash Glucose Monitoring Access Form for Type 1 Diabetes; Pregnancy Planning, Pregnancy or Immediately Post Pregnancy.

To be eligible to access fully subsidised products through the NDSS:

- the person is expected to benefit clinically from the use of CGM or Flash GM; **AND**
- the person or family/carer has the willingness and capability to use CGM or Flash GM; **AND**
- the person or family/carer has the commitment to actively participate in a diabetes management plan which incorporates CGM or Flash GM.

In addition, the person must meet the criteria in one of the following categories:

Part A - Pregnancy planning

The woman with type 1 diabetes is actively and frequently engaging with a health professional to manage their diabetes and pregnancy planning. Ideally at least every 6-8 weeks or more frequently if required; AND

The authorised health professional is confirming eligibility for an initial 6-month period.

OR

Access to CGM or Flash GM for pregnancy planning care is to be continued, the authorising health professional is confirming eligibility for a further 6-month period. Access will continue from the expiry of the initial 6-month period, for a maximum period of 12 months in total.

Part B – Pregnant or Immediately Post-Pregnancy

The woman with type 1 diabetes is regularly engaging with a health professional to manage their diabetes and is pregnant or immediately post pregnancy.

When pregnancy is confirmed, an authorised health professional may now confirm eligibility. The eligibility period ends 3 months after the expected or actual date of birth provided above

After an initial 12 months eligibility—supporting documentation is required for an extension of access

In certain circumstances, extended access to fully subsidised products through the NDSS may be granted for women with type 1 diabetes who are continuing to actively plan pregnancy.

More information about applying for extended access to fully subsidised CGM and Flash GM products is available on the NDSS website at **ndss.com.au/resources-hp/cgm-extended-access**.

Eligibility period

Category A: Pre-pregnancy

Up to 12 months (initial period of 6 months with a subsequent period of an additional 6 months on confirmation that pre-pregnancy care is continuing).

Category B: Pregnancy/Post-pregnancy

From when the pregnancy is confirmed, until 3 months after the expected date of birth of the baby.

At least 1 month prior to the completion of either the 'pre-pregnancy' or 'post-pregnancy' periods, the person will receive a notification via SMS or email, advising them that their access period is ending soon and that they should consult their authorised health professional in relation to future access, or transitioning to alternative arrangements for SMBG.

NOTE: In the event of a pregnancy loss, or similar event, the currently approved period of fully subsidised access will continue unchanged. In this event, the individual may reapply for pre-pregnancy status at any time, and this would be considered a separate distinct application, not a continuation of previous access.

The health professionals authorised to certify access are listed on the Continuous and Flash Glucose Monitoring Access Form for Type 1 Diabetes; Pregnancy Planning, Pregnancy or Immediately Post Pregnancy.

If a person is planning pregnancy through other means, such as IVF, are they eligible?

If a person is planning pregnancy, they are eligible, irrespective of the pregnancy planning pathway they choose.

An authorised health professional may then certify eligibility for an initial 6-month period based on if a women seeking active pre-conception care and committing to regular engagement with the pre-conception care service provider.

‘Other’ Eligible Conditions; Age Under 21 Years

‘Other’ Eligible Conditions are listed on the NDSS website at **ndss.com.au/other-eligible-conditions-age-under-21-years**. Children and young people under the age of 21 years with these eligible conditions can access fully subsidised CGM and Flash GM supplies.

For children and young people with ‘Other’ Eligible Conditions access to CGM and Flash GM products will cease once they reach 21 years of age.

The health professionals authorised to certify access are listed on the Continuous and Flash Glucose Monitoring Access Form for ‘Other’ Eligible Conditions; Age Under 21 Years.

Information on the eligibility criteria for all groups is available on the NDSS website at **ndss.com.au/cgm**.

For children and young people with ‘Other’ Eligible Conditions, subsidised access to CGM and Flash GM products will cease once they reach 21 years of age.

CGM and Flash GM devices

Available CGM and Flash GM devices

The choice of device for an individual will depend on a number of factors, including whether or not they:

- would like the device to integrate with an insulin pump
- have, or wish to purchase, a compatible smartphone/device
- require other features, such as data sharing or automated insulin pump suspension for low glucose levels
- would like and/or benefit from alerts to inform them when their blood glucose level rises above or drops below their individual target range
- are willing and able to perform daily calibrations of the device by entering a finger prick blood glucose level 2-3 times per day, depending on the device
- have other personal preference.

All CGM and Flash GM products made available through the NDSS are approved for use in Australia by the Therapeutic Goods Administration (TGA) and hold a current Australian Register of Therapeutic Goods (ARTG) certificate.

Selection of appropriate CGM and Flash GM products should be made by the authorised health professional (based on their clinical assessment) and in consultation with the person with diabetes and/or carer. This assessment should take into account the indicated uses for each CGM or Flash GM device. It is important to note that these products do not have identical indications and so not all products may be suitable for the individual user.

Authorising health professionals who help people to choose a device confirm, by certifying eligibility, that they have:

- considered available advice about the selected device, including the relevant ARTG listing (if unsure search the device at: **tga.gov.au/artg**) and any specific condition comments; **AND**
- **obtained informed consent from the person/family/carer for the specific device chosen for use.**

Available on the NDSS website at **ndss.com.au/cgm-device-chart** is a list of NDSS subsidised CGM and Flash GM devices, their compatibility with insulin pumps and smartphone and smart devices and links to guidelines about appropriate use.

Setup and ongoing access to CGM and Flash GM products

Once the applicant's Continuous and Flash Glucose Monitoring Access Form has been processed, they will be contacted by the NDSS to confirm their eligibility for access to subsidised CGM and Flash GM products.

CGM

If the person with diabetes is a new user of CGM or are changing to a different CGM device, a Starter Kit (including one box of sensors, one transmitter and related materials and product information) will be sent to the health professional nominated on the Continuous and Flash Glucose Monitoring Access Form. Alternatively, a Starter Kit can be sent directly to the person with diabetes or carer when requested by the authorising health professional.

This health professional will be responsible for helping the person (and/or their parents/carers) to set up and learn how to use their new CGM device. After the initial set up, ongoing access to CGM products will be available from any NDSS Access Point (usually a community pharmacy).

If the person is already using CGM and is continuing with the same device, access to CGM products are through any NDSS Access Point, usually a community pharmacy.

Both the sensor and the transmitters are subsidised through the NDSS. Sensors are supplied in boxes of four or five depending on the model. Transmitters are supplied individually.

Flash GM

FreeStyle Libre 2 sensors are available through pharmacies. If the person is using Flash GM for their diabetes management, there will be no Starter Kit provided to the authorised health professional.

All health professionals who recommend, provide support or certify access to Flash GM devices should provide the person with diabetes, or their parent/carer, with comprehensive diabetes self-management education. This includes how to use the new technology and how to interpret the results.

This education should be provided prior to, or in conjunction with, completing the Continuous and Flash Glucose Monitoring Access Form or the Continuous and Flash Glucose Monitoring Access Form - Update or Ceasing Access. If diabetes self-management education cannot be arranged at the time of completing the form, then a follow up appointment should be made for this to take place.

Whether the person is a new or existing user of Flash GM, they will be able to order sensors through any pharmacy.

To activate the FreeStyle Libre 2 sensor, participants in the CGM Initiative can either:

- download the FreeStyle LibreLink mobile app onto a compatible smartphone or smart device from **freestylelibre.com.au/glucose-monitoring-system/librelink-app**; OR
- once approved as an eligible registrant, they can order a free FreeStyle Libre 2 Reader by calling the product manufacturer directly via the Abbott Diabetes Care Helpline on **1800 801 478**, rather than through Access Points.

What happens if someone wants to change their device?

Based on the authorised health professional recommendation, if the device needs to be changed, a Continuous and Flash Glucose Monitoring Access Form - Update or Ceasing Access must be completed and submitted according to the details on the form.

If a CGM device is required, a Starter Kit will be sent either to the nominated authorised health professional who will be assisting the person with the setup and operation of the device, or directly to the person with diabetes if this has been requested by the authorising health professional.

There are no time restrictions on when a person can change their device. The change of device remains a decision of the health professional in consultation with the person (or their parent/carer).

Note: CGM and Flash GM devices are highly specialised products with a short shelf life. Pharmacies will not have products in stock and will have to order these for the person. It may take 24-48 hours for sensors to be delivered to the Access Point. Delivery times may be longer in rural areas.

Self-management education and training

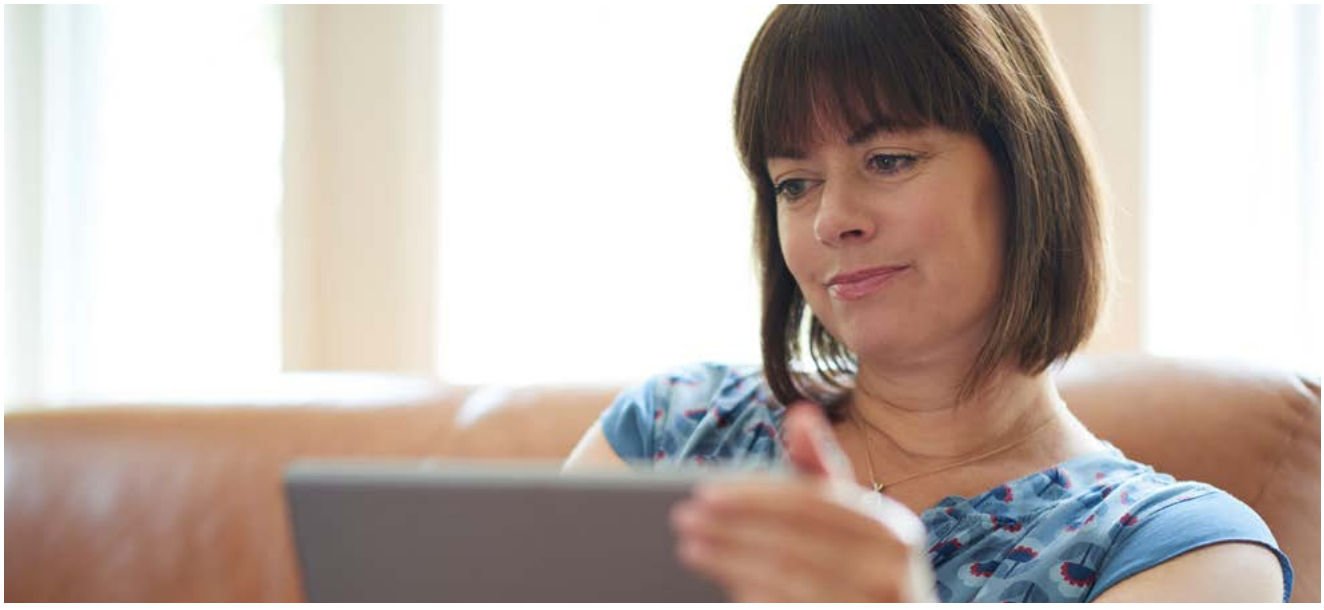
The ADA 2020 Standards of Medical Care in Diabetes related to diabetes technology, highlight the importance of thorough diabetes education, training, and support when prescribing CGM or Flash GM devices, to ensure optimal device implementation and ongoing use[7].

Authorised health professionals who help users set up and learn how to use their new CGM or Flash GM devices will need to provide comprehensive diabetes selfmanagement education and ensure the user's understanding of the following topics:

- How and where to insert a new sensor.
- How to remove and dispose of an old sensor.
- The lifespan of the products and the importance of regularly replacing the sensors to avoid the risk of infection.
- The use of additional tape and barrier creams to help keep the sensor attached, if required.
- The need to remove the device when undergoing procedures including an MRI, CT scan, x-ray or diathermy treatment.
- How to understand and interpret data.
- How to respond and interpret trend arrows.
- How to upload and share data with their health professional using the device's software programs.
- How to order products subsidised through the CGM Initiative as part of the NDSS.
- How to access support.
- Establish rules to prevent diabetes burnout from data and carer overload.

How to set and change high and low glucose alerts for CGM devices only:

- How and when to calibrate the device.
- How to respond to alerts and alarms.



Changing a device or ceasing use

A person, together with their certifying health professional, may submit the Continuous and Flash Glucose Monitoring Access Form - Update or Ceasing Access to change device or to opt-out of the CGM Initiative. To download this form, visit **ndss.com.au/forms#cgm**.

Product lifespan and access

Each of the CGM transmitters and sensors and the Flash GM sensors available through the NDSS has a product usage lifespan. This means the amount of time that each product can be used will vary according to manufacturer's user guidelines for the specific device.

As these products are more expensive than other NDSS supplies and have a relatively short expiry, only one box of sensors will be provided at a time through pharmacies (approximately one month's supply).

There are annual limits for products accessed through NDSS by eligible users to ensure products are used according to guidelines, including the manufacturer's product lifespans. Pharmacies receive alerts about the quantity and frequency of supply of products that users order through the NDSS. Alerts are calculated on the number of products accessed in the last 12 months from the present date and determine when the user will again be able to order more subsidised supplies.

It is important that the lifespan of products is understood by the user. If products are used and ordered according to the product's lifespan the user should not encounter any difficulties when accessing products through pharmacies.

Faulty devices

In the unlikely event that a person receives a faulty CGM sensor or transmitter, and Flash GM sensor, through pharmacy, they should contact:

- AMSL for Dexcom products (**1300 851 056**), or
- Medtronic for Medtronic products (**1800 777 808**) or
- Abbott Diabetes Care Helpline for FreeStyle Libre products (**1800 801 478**).

Contacting the supplier rather than ordering more supplies may mean they are able to receive a free replacement product from the manufacturer, without affecting their annual product supply limits.

More information

For more information about:

- CGM and Flash GM including the eligibility criteria and forms, go to **ndss.com.au/cgm** or call the NDSS Helpline on **1800 637 700**.
- Diabetes, go to the Diabetes Australia website **diabetesaustralia.com.au**
- CGM and Flash GM devices available through the NDSS, go to the supplier websites:
  - AMSL Diabetes (for Dexcom products) at **amsl.com.au**
  - Medtronic (for Medtronic products) at **medtronic.com.au**
  - Abbott (for FreeStyle Libre products) at **freestylelibre.com.au**.

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