Guidance for Continuous Glucose Monitoring (CGM) in Adults and Children with Type 1 and Type 2 Diabetes

Guidance Statement

South Yorkshire ICB commissions Continuous Glucose Monitoring (CGM) for people living with diabetes (type 1 and type 2) who meet the criteria as set out in this document.

Purpose

This guidance has been developed to clearly indicate to clinicians and patients the criteria that SY ICB supports for the prescribing of CGM. It covers children, young people, and adults living with diabetes in the South Yorkshire ICB

This guidance is based on the following four NICE Guidelines:

NG17 Type 1 Diabetes in Adults: Diagnosis and Management
NG18 Diabetes (Type 1 and Type 2) in Children: Diagnosis and Management
NG3 Diabetes in Pregnancy: Management from Preconception to the Post-natal period
NG28 Type 2 Diabetes in Adults: Management

Type 1 diabetes

Adults with Type 1 Diabetes

All adults with type 1 diabetes should be given a choice of intermittently scanned continuous glucose monitoring (isCGM, also known as flash glucose monitoring) **or** real-time continuous glucose monitoring (rtCGM) as their primary tool for monitoring blood glucose levels based on preferences, needs, characteristics and functionality of the devices available. See South Yorkshire ICB Guideline to Support the Prescribing of CGM Document for device options and characteristics (Link to be added once IMOC approved). If multiple devices meet their needs and preferences, they should be offered the device with the lowest cost.

Advanced rtCGM is a more expensive technology and is not currently available on FP10 so can't be prescribed in primary care. All prescribing of advanced CGM is therefore initiated and continued by secondary care. It has other features which may include predictive alarms, and the capability to be used with an insulin pump as part of a hybrid closed loop system.

Adults (aged 19 and over) with Type 1 Diabetes and problematic hypoglycaemia, as defined below, should be referred to secondary care to consider advanced rtCGM:

- Recurrent episodes of severe hypoglycaemia – at least two events in 12 months, or
- Impaired hypoglycaemia awareness – GOLD score ≥ 4, or
- High volume of hypoglycaemia on Libre or Dexcom One, defined as > 7% time below range < 4 mmol/L, or >1% time below range < 3 mmol/L

In addition, other criteria for consideration of advanced rtCGM / insulin pump therapy include:

- HbA1c measurements >69 mmol/mol
- Worsening complications of diabetes

These recommendations also apply to adults with other forms of diabetes caused by severe insulin deficiency.

Pregnancy

All pregnant women living with type 1 diabetes should be offered *advanced **rtCGM in line with evidence used to support NICE guideline NG3. Where possible rtCGM should be considered during pre-conception.

The criteria for access at this point would be the same as in the non-pregnant population.

In those people living with diabetes who DO NOT have type 1 diabetes (i.e. those with pre-existing type 2 Diabetes and Gestational Diabetes) who are pregnant consider **rtCGM if they are on insulin (any number of doses/day), and there is the expertise within the joint diabetes/antenatal to provide education and support (including advising on out of hours support) if the criteria below are met:

- problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) OR
- unstable blood glucose levels that are causing concern despite efforts to optimise

These guidelines are recommendations for 12 months during pregnancy. This should be made clear to people living with Type 2 Diabetes or other types of diabetes before commencing the technology in pregnancy. They must fulfil the criteria for eligibility when not pregnant to continue past 12 months.

*Note NICE NG3 guideline refers to offering rtCGM, however at the time of publication **advanced** rtCGM were the only rtCGM available and hence what the evidence, cost analysis and recommendations within NG3 are based. Advanced rtCGM have additional features, such as 'urgent low alerts'.
**If rtCGM is unable to be used or a person expressed a preference for isCGM then this can be offered.

Children and Young People (CYP) with Type 1 Diabetes

All CYP with type 1 diabetes should be offered rtCGM as recommended by NICE guideline NG18 (Diabetes (type 1 and type 2) in children and young people). The choice of CGM should be made through shared decision making and taking into account the young person's needs and preferences (See appendix 1 – Factors to consider when choosing CGM). If multiple devices meet their needs and preferences, offer the device with the lowest cost. isCGM can also be used for CYP older than four years who express a clear preference for it or who are unable to use rtCGM.

When a young person already using advanced rtCGM is transferred to adult services, advanced rtCGM should be continued.

Type 2 diabetes

Adults with Type 2 Diabetes

Those with multiple daily insulin injections (2 or more injections) should be offered isCGM or rtCGM (if it is available for the same or lower cost) if any of the following apply:

- Recurrent or severe hypoglycaemia
- Impaired hypoglycaemia awareness
- A condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring
- Advised to self-measure at least 8 times a day
- Need help from a care worker or healthcare professional to monitor their blood glucose

Currently either Freestyle Libre or Dexcom One are within the SY formularies and both can be prescribed via FP10 by primary care as advised by specialist teams trained in its use. Healthcare professionals initiating this technology should:

- Understand the differences between the systems
- Be able to support the user to adjust insulin doses appropriately basing their decisions on review of CGM data via device portals, for example, Libreview, Dexcom Clarity, Glooko

In cases where hypoglycaemia is the reason for CGM use in adults with Type 2 Diabetes, a trial period of three months is usually sufficient for healthcare practitioners to adjust insulin doses to resolve the issue.

Pregnancy

See above

Children and Young People with Type 2 Diabetes

CYP with type 2 diabetes should be offered rtCGM if any of the following apply as per NG18:

- they have a need, condition, or disability (including a mental health need, learning disability or cognitive impairment) that means they cannot engage in monitoring their glucose levels by capillary blood glucose monitoring
- they would otherwise be advised to self-monitor at least 8 times a day
- they have recurrent or severe hypoglycaemia

Consider rtCGM for CYP with type 2 diabetes who are on insulin therapy.

Dialysis

isCGM or rtCGM should be considered for people receiving dialysis who are on insulin or sulphonylureas

Other Considerations

It should be noted that patients who do not meet the NHSE criteria may purchase privately. Anyone already established on CGM either alone or as part of a closed loops system prior to the launch of this guidance will not be affected by this guidance. People using rtCGM outside of these recommendations may continue until they and their NHS clinician consider it appropriate to stop.

The ICB criteria for access to isCGM or rtCGM is contained in the South Yorkshire ICB Guideline to Support the Prescribing of CGM Document (link to be added once IMOC approved). How this is implemented will be left up to each place of the ICB. To reduce inequity of access in different localities the ICB is working to support implementation. Depending on where each place is starting

from and the resource disparities within each place to roll this out, there may be differences in roll out schedule.

People using CGM will still need to take capillary blood glucose measurements, for example if the readings do not match symptoms and sensor failure is suspected, and therefore will still need BG testing strips to be prescribed.

Appendix 1

Box 1 Factors to consider when choosing a continuous glucose monitoring device

- Accuracy of the device.
- Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else, for example a parent or carer.
- Whether using the device requires access to particular technologies (such as a smartphone and up-to-date phone software).
- How easy the device is to use and take readings from, including for people with limited dexterity (taking into account the age and abilities of the child or young person and whether the device needs to be used by others).
- Fear, frequency, awareness and severity of hypoglycaemia.
- Psychosocial factors.
- The child or young person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function).
- Whether, how often and how the device needs to be calibrated, and how easy it is for the person to do this themselves.
- How data can be collected, compatibility of the device with other technology, and whether data can be shared with the person's healthcare provider to help inform treatment.
- How unpredictable the child or young person's activity and blood glucose levels are and whether erratic blood glucose is affecting their quality of life.
- Whether the choice of device will impact on the child or young person's ability to attend school or education, or to do their job.
- Whether the child or young person takes part in sports or exercise when glucose levels will need additional management.
- Whether the child or young person has situations when symptoms of hypoglycaemia cannot be communicated or can be confused, for example during exercise.
- Clinical factors that may make devices easier or harder to use.
- Frequency of sensor replacement.
- Sensitivities to the device, for example local skin reactions.
- Body image concerns.

If multiple devices meet their needs and preferences, offer the device with the lowest cost