

Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee

Briefing Paper for APC

NICE Guideline NG18: Diabetes (type 1 and type 2) in children and young people: diagnosis and management – Continuous Glucose Monitoring in Type 2 diabetes

Recommendations for local implementation

Terminology:

Continuous glucose monitoring (real-time continuous glucose monitoring) - rtCGM

Flash glucose monitoring (intermittently scanned continuous glucose monitoring) - isCGM

Intermittent capillary blood glucose monitoring (self-monitoring of blood glucose) - SMBG

Scope of guidance – Children and young people (younger than 18 years) with Type 1 or Type 2 Diabetes

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| **NICE Guideline** | *Diabetes (type 1 and type 2) in children and young people: diagnosis and management*  *NG 18*  Recommendations  Continuous Glucose Monitoring in Type 2 diabetes | |
| **Available at** | <https://www.nice.org.uk/guidance/ng18> | |
| **Date of issue** | 31st March 2022 |  |

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| **Description of technology** |
| **Self-monitoring of blood glucose by capillary blood glucose devices**  Self-monitoring of blood glucose is an integral part of therapy in diabetes treated with insulin, it involves the measurement of blood glucose concentration by people with diabetes or their carer using self-monitoring devices such as test strips. Capillary blood glucose monitoring involves pricking the finger with a lancet device to obtain a small blood sample at certain times of the day. The drop of blood is then applied to a test strip which is inserted into a blood glucose meter for automated determination of the glucose concentration in the blood sample at the time of the test.  This method of measuring blood glucose control of diabetes is inexpensive compared to newer technologies, but is more inconvenient for the user, and provides limited information on blood glucose levels providing “fixed” data points during the day, and frequency is dependent on the person. NICE recommend testing 4 times a day before each meal and bed, plus before driving. Some patients may need to test more frequently than this.  **Real time Continuous glucose monitoring (rtCGM)**  This involves measuring interstitial fluid glucose levels throughout the day and night. A continuous glucose monitor typically comprises a disposable sensor with a tiny cannula inserted into the skin to measure glucose levels, and a transmitter connected to the sensor that sends real time readings wirelessly to a receiver or a smart device that displays results. The user can obtain real-time data as well as trends, they can then analyse data and respond to changes in real-time or can make changes to insulin delivery, dose or timing based on retrospective data or trends. Some systems allow sharing of the data with their family/carers and health care professionals. Calibration is required for some continuous glucose monitors; hence they are used in conjunction with capillary blood testing. Most monitors can send alerts for high or low glucose levels and rapid rate of change of glucose levels.  Continuous glucose monitoring provides the user access to hundreds to thousands of data points per day, together with data trends and analysis and glucose level predictions. It also allows the user access to glucose level ‘alerts’ for out-or-range low and high glucose levels.  **Intermittently scanned glucose monitoring (isCGM)**  Intermittently scanned continuous glucose monitoring, also known as flash glucose monitoring, involves wearing a sensor just under the skin (usually in the upper arm) that automatically monitors interstitial fluid glucose levels. A sensor can be used for up to 2 weeks. A reader or a mobile device with the appropriate app installed can be used to scan the sensor to obtain real-time data as well as trends by scanning the sensor with a reader device (including smart phones). The information provided gives a glucose level and information regarding the rate of change of glucose levels glucose readings. A reader or smart phone with the appropriate app installed can be used to scan the sensor to obtain real time data as well as glucose trends. The information provided gives a sensor glucose level and information regarding direction of glucose level including its rate of change. This rate is indicated as an upward, downward, or oblique arrow. The Freestyle Libre 2 does not have a predictive low or high alarm, but it can be set to alert on high or low glucose settings.  The only currently available isCGM is Freestyle Libre 2 and costs **REDACTED** per patient per year on FP10 prescription. **This device is now used as a *rtCGM* if used with a smartphone but if used with a reader it functions as a *isCGM.***  **Role of SMBG in patients on CGM**  Historically, CGM was used as an adjunct to fingerstick blood glucose testing. Now, most systems (intermittent and real-time) are more accurate and “non-adjunctive,” enabling treatment decisions without finger stick blood glucose confirmation if symptoms match glucose levels. However, patients still need access to blood glucose meters and test strips during CGM start-up (the first 30-120 minutes when glucose data are not available) and for when symptoms do not match CGM-reported glucose levels, so competency in managing the diabetes without CGM, and access to finger stick test strips and a blood glucose meter is still advised.  A summary table of available rtCGM and isCGM, age group that that they are licensed for, and current traffic light status is attached. |
| **Type 2 diabetes** |
| Management of blood glucose is a core component of diabetes care.  **Complications of Type 2 diabetes**  If type 2 diabetes is not well controlled, patients are at risk of long-term complications of hyperglycaemia including microvascular damage such as retinopathy and blindness, nephropathy, neuropathy and are at increased risk of macrovascular complications such as ischaemic heart disease, stroke, and peripheral vascular disease.  Data from the TODAY study, suggests early and rapid deterioration of β-cell function occurs in CYP with type 2 diabetes(T2DM) compared with data published on adult individuals. This suggests the need to intervene aggressively and early in children and young people with type2 diabetes.  <https://diabetesjournals.org/care/article/36/6/1775/33309/The-TODAY-Study-An-NIH-Perspective-on-Its>  Acute short-term complications include diabetic ketoacidosis or which can be life-threatening and often requires admission to hospital.  Hypoglycaemia is a common complication in the treatment of type 2 diabetes in which a person’s blood glucose is usually below 4 millimoles per litre. In severe hypoglycaemia (defined as having low blood glucose levels that requires assistance from another person to treat.) symptoms can be life threatening and may require emergency treatment and admission to hospital.  In children, severe hypoglycaemia can cause long-term cognitive impairment.  People who have had type 2 diabetes for several years or who have frequent hypos may experience hypoglycaemia unawareness, a situation in which symptoms of hypoglycaemia are not noticed. Loss of hypo awareness is dangerous because people can go into severe hypoglycaemia without recognizing early warning signs. Fear of hypos also contributes to patients underdosing on insulin, erring on the higher blood glucose levels to avoid further hypos. |

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| **NICE recommendations1** |
| **Recommendations in Children and Young People (CYP) with Type 2 Diabetes** |
| Offer real-time continuous glucose monitoring (rtCGM) to children and young people with type 2 diabetes if any of the following apply. 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. * would otherwise be advised to self-monitor at least 8 times a day. * have recurrent or severe hypoglycaemia. **[2023]**   1.3.39Consider rtCGM for children and young people with type 2 diabetes who are on insulin therapy.**[2023]**  1.3.40Consider intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') for children and young people with type 2 diabetes aged 4 years and over who are on insulin therapy if:   * rtCGM is contraindicated for them or * they express a clear preference for isCGM.  In May 2023, use of isCGM for children aged 3 years and under was off-licence. **[2023]**   1.3.41When offering CGM to children and young people with type 2 diabetes, choose the appropriate device with them, based on their individual preferences, needs, characteristics, and the functionality of the devices available. See [box 1](https://www.nice.org.uk/guidance/ng18/chapter/recommendations#continuous-glucose-monitoring) below for factors to consider as part of this discussion. **[2023]**  1.3.42When choosing a CGM device, if multiple devices meet the person's needs and preferences, offer the device with the lowest cost. **[2023]**  1.3.43CGM should be provided by a team with expertise in its use to support children and young people to self-manage their type 2 diabetes. **[2023]**  1.3.44Advise children and young people with type 2 diabetes who are using CGM, and their families or carers, that they will still need to take capillary blood glucose measurements, but they can do this less often. Explain that this is because they will need the capillary blood glucose measurements:   * to check the accuracy of their CGM device * as a back-up (for example, if the device stops working). **[2023]**   1.3.45Monitor and review the child or young person's use of CGM when reviewing their diabetes care plan and explain to them the importance of continuously wearing the device. **[2023]**  1.3.46If the child or young person is not using their CGM device at least 70% of the time:   * ask if they are having problems with their device. * look at ways to address any problems or concerns to improve their use of the device, including further education and emotional and psychological support. **[2023]**   1.3.47Commissioners, providers and healthcare professionals should address inequalities in CGM access and uptake by:   * monitoring who is using CGM * identifying groups who are eligible but have a lower uptake. * making plans to engage with these groups to encourage them to consider CGM. [2023]   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 (for children and young people: taking into account the age and abilities of the child or young person and also whether the device needs to be used by others)*  *• Fear, frequency, awareness, and severity of hypoglycaemia*  *• Psychosocial factors*  *• The person's insulin regimen if they are using insulin*  *• 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*  *• Whether the device will affect the person's ability to do their job. For children and young people: Whether the choice of device will impact on the child or young person's ability to attend school or education.*  *• How unpredictable the person's activity and blood glucose levels are and whether erratic blood glucose is affecting their quality of life*  *• Whether the person has situations when symptoms of hypoglycaemia cannot be communicated or can be confused (for example, during exercise)*  *• For children and young people: Whether the child or young person takes part in sports or exercise when glucose levels will need additional management*  *• Clinical factors that may make devices easier or harder to use*  *• Frequency of sensor replacement*  *Whether a real time or intermittently scanned device would be appropriate.*  *• Sensitivities to the device, for example local skin reactions*  *• Body image concerns* |

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| **Decision making framework (DMF)** |
| **National guidance and priorities** |
| Whilst there is not a legal obligation to fund the recommendations in NICE guidelines in the same way as a NICE Technology Appraisal (TA) or Highly Specialised Technologies Evaluation (HST), healthcare professionals are expected to NICE guidelines fully into account, alongside the individual needs, preferences, and values of their patients. Each published NICE guideline includes the summary of responsibilities for professionals, practitioners, commissioners, and providers of healthcare relating to the guideline.  The ICS is still expected to have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and considering their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.  Enabling people with type 2 diabetes access to CGM is a target in the NHS Long Term plan. Diabetes UK consider implementation of NICE CGM recommendations as an important priority for people with diabetes.  Reducing hospital admissions from the long-term complications from diabetes, and acute problems from diabetes is an important benefit for the ICS. |
| **Clinical effectiveness** |
| **rtCGM**  The evidence on real-time continuous glucose monitoring (rtCGM) showed it leads to:   * a decrease in HbA1c **and** * an increase in time in range.   This reflected the committee's experience in clinical practice. They highlighted that the continuous nature of rtCGM, and the fact that it can be connected to the phone or device of a parent or carer so they can track the data, were particularly important components for children and young people. Although some outcomes showed no meaningful difference, or could not differentiate between rtCGM or SMBG, where there was an effect, it consistently favoured the use of rtCGM.  **isCGM**  Intermittently scanned CGM (isCGM) had no clinically meaningful effect on any of the outcomes that were looked at in the evidence or could not differentiate between isCGM and SMBG. In the committee's experience, the intermittent nature of isCGM can affect adherence in children and young people.  CGM is already recommended for everyone with type 1 diabetes and in some adults with type 2 diabetes, and the committee agreed that children and young people with type 2 diabetes should be offered the same.  The committee's decision to include these recommendations was also based on the following:   * Type 2 diabetes in children and young people is the most aggressive form of the disease, and this population will live with the condition for longer than adults with type 2 diabetes, so timely intervention is important to reduce the risk of developing severe long-term (and possibly life-threatening) complications, such as peripheral neuropathy. * Many children and young people experience health inequalities because of comorbidities (for example, special educational needs or learning disabilities), which can make it difficult for them to conduct capillary blood glucose measurements. * Capillary blood glucose monitoring often requires several finger-prick tests a day, which can be tiring, stressful and have a negative psychological impact on the person. CGM provides another, less invasive way for children and young people with diabetes to manage their blood glucose levels. * Some CGM devices allow glucose data to be shared electronically. * Using CGM, even in the short term, is likely to improve the child or young person's understanding of their own blood glucose patterns because of the continuous and visual way CGM allows glucose data to be presented.   The evidence base for the effectiveness of CGM in this population is limited, mostly because of the small number of children and young people with type 2 diabetes. As a result, the committee based recommendations on CGM for this population on the [recommendations about CGM for children and young people with type 1 diabetes](https://www.nice.org.uk/guidance/ng18/chapter/recommendations#continuous-glucose-monitoring), in this guideline, and on the [recommendations about CGM for adults in NICE's guideline on type 2 diabetes in adults](https://www.nice.org.uk/guidance/ng28/chapter/Recommendations#blood-glucose-management).  The [2022 evidence review](https://www.nice.org.uk/guidance/ng18/evidence/b-continuous-glucose-monitoring-in-children-and-young-people-with-type-1-diabetes-pdf-11011942190) on the effectiveness of CGM to improve blood glucose level management in children and young people with type 1 diabetes concluded that:   * rtCGM is more effective than capillary blood glucose monitoring. * isCGM is no more effective than capillary blood glucose monitoring.   Therefore, the committee agreed that rtCGM should be considered when children and young people with type 2 diabetes are on insulin therapy because of:   * the increased risk of hypoglycaemia * comorbidities associated with type 2 diabetes in children and young people and * the decreasing costs over time of available and appropriate devices.   As for adults, the committee agreed that CGM should not be considered for all children and young people with type 2 diabetes because some will be able to maintain their blood glucose levels within the target range using glucose-lowering agents that do not increase the risk of hypoglycaemia (such as metformin monotherapy).  The option to consider isCGM for people over 4 years old was provided because:   * some children and young people with type 2 diabetes have difficulties using rtCGM or may prefer isCGM to rtCGM. * in May 2023, isCGM was licensed for children aged 4 years and over.   The committee agreed that a stronger recommendation to offer rtCGM to 3 specific groups was justified, regardless of whether they are having insulin therapy, because of the child or young person's individual needs and the treatment burden associated with capillary blood glucose monitoring.  Regardless of the reason the child or young person with type 2 diabetes is offered CGM, the committee agreed that it should be provided by a team with expertise in its use, so that support can be provided and any issues with it can be quickly resolved.  The committee agreed that CGM should not replace capillary blood glucose monitoring because it is still needed both for checking the CGM device and as a back-up. They made some further recommendations about choosing and using a CGM device to encourage adherence and provide support.  Finally, the committee agreed, in line with the recommendations for children and young people with type 1 diabetes, that inequalities in access and uptake of CGM may still occur for those with type 2 diabetes, so they added a recommendation to address this. For example, obesity and type 2 diabetes are also closely associated, as are childhood obesity and socioeconomic status (it is highest among children living in the most deprived areas)  As the evidence showed key outcomes favoured rtCGM over SMBG, the committee recommended rtCGM use first in all children and young people with type 2 diabetes, only offering isCGM if rtCGM is not preferred or contraindicated. The committee highlighted that the active component of isCGM, of having to “swipe to take a reading” although easier than doing a blood test may be part of the reason adherence may not be as good in some young people more than adults as it requires them to undertake an action.  The committee highlighted that it was important to use the device consistently to ensure a more positive effect. They therefore made a recommendation for the device to be worn 70% of the time, and for education and support to be provided if this wasn’t the case. This recommendation was also made to avoid ongoing prescription of devices that aren’t being used, and to give providers an opportunity to address any barriers that may be reducing someone’s ability to use the device effectively. |
| **Patient safety** |
| * Users may have difficulties inserting the CGM, discomfort wearing it, alarm fatigue and a mismatch of expectations in terms of accuracy or performance. * Irritation and complications of the skin (degrees of allergic contact dermatitis) may occur from the use of adhesive on the skin with CGM devices. * NICE notes that one barrier to adherence to CGM that is a particular area of concern for children and young people is that some children develop skin reactions when wearing a CGM device due to the sensor adhesive * The frequency of skin problems in adults and CYP was one per 8 weeks of CGM wear time in one systematic review, most problems were mild and only 1.5% severe2. * In July 2023 an urgent [Field Safety Notice](https://www.freestyle.abbott/uk-en/freestyle-librelink-android-version-2-10-0.html) was issued by Abbott for their Freestyle Libre 2 and Freestyle Libre 3 CGM, related to the use of their CGM Apps on Android and smartphones. |
| **Patient factors** |
| * rtCGM offers benefits to children and young people with T2DM in terms of improved diabetes control, reduction in fear of hypoglycaemia and ability to share their data on blood glucose control with their healthcare professional and parents/carers. * Feedback from a CGM device that is provided to both a child and their parents or carers can help to provide remote support and early identification of hypoglycaemia. * Use of CGM reduces the need for frequent finger prick testing for self-monitoring of blood glucose. * NICE recommends that the specific choice of CGM devices should be decided by the healthcare professional and CYP with T2DM and their parents or carers based on their preferences, needs and characteristics. They have suggested factors that should be considered when choosing a device, including some specific considerations for CYP. If multiple devices meet a patient’s needs, then the device with the lowest cost should be offered. A summary of key features of the devices that may be important when choosing a device is attached. * Education of children and young people and their parents or carers is important to help them understand how CGM works, how to use the CGM devices and associated Apps, sharing of data with healthcare professional, family and carers if needed, ordering the sensor and transmitter, and what to do if the sensor is faulty. * Younger children under the age of 7 do not have the cognition required for self-care and self-management of their diabetes particularly scanning of isCGM. * CGM devices can be purchased by members of the public directly from the manufacturers. The manufacturers of CGM provide comprehensive patient support helplines and on-line education for both NHS and private patients. * A receiver to read the CGM results is available for some devices for people who do not have a Smartphone. * A small number of devices are available via FP10 prescription in primary care. * The view of the paediatric specialist teams was that review of patients initiated on CGM should be determined by clinical need. CGM review can be included within the patient’s annual review, however some patients will be followed up more closely where the need arises. * Children and young people with type 2 diabetes will transition into adult services and stopping CGM would be detrimental to their management of diabetes. CYP should be allowed to continue use of CGM if needed into their adult lives. |
| **Equality & diversity** |
| NICE recommends that commissioners, providers and healthcare professionals should address inequalities in CGM access and uptake by:  • monitoring who is using CGM  • identifying groups who are eligible but who have a lower uptake  • making plans to engage with these groups to encourage them to consider CGM.  Most CGM devices are recommended for use in children, although the minimum age does differ between devices.  The National Paediatric Diabetes Audit 2021/22 found that the use of rtCGM was lower in CYP in the most deprived quintiles and was lower in CYP of Asian and Black origin5. |
| **NICE Cost-effectiveness assessment** |
| Overall, no relevant published economic evidence was identified for this guideline update and no original economic modelling was performed. Therefore, only the unit costs of the medications were presented to the committee. The committee acknowledged that this guideline had a different recommendation for continuous glucose monitoring (CGM) than for adults with diabetes.  There is no health economic evidence on whether CGM is cost effective in young people with type 2 diabetes; however, it was found to be cost effective in the adult population. Therefore, the committee felt that it was important to bring this in line and recommend CGM for patients on insulin or those with a condition or disability which would make finger pricking difficult.  The committee assumed that around 70% of patients would take up this option and therefore it would be approximately £330,000 for those on insulin and £258,000 for those with a condition or disability that makes finger pricking difficult. These cost estimates fall below NICE’s threshold of £1 million per recommendation and so are not deemed to have a significant resource impact. The committee also felt that introducing CGM to this population would help reduce health inequalities.  The guideline does not quantify the benefits of CGM in CYP with type 2 diabetes. The implementation of the guideline is expected to result in significant improvements to quality of life. CGM technologies offer an incremental improvement in preventing the long-term complications that may arise from poor control of blood glucose levels. They may reduce the risk of hospital admissions from acute complications of diabetes but will not eliminate this risk. |
| **Costs to health economy** |
| Section 1: Cost of the technology   |  |  | | --- | --- | | **Hospital only CGM** | | | Dexcom 6 | £3,174 | | Guardian 3 & 4 | £3,170 | | Dexcom 7 | £2,214 | | Freestyle Libre 3 | £1,121 | | A8 Touchcare Nano | £1,110 |  |  |  | | --- | --- | | **FP10 prescribed CGM** | | | Dexcom One | £912 | | Freestyle Libre 2 | £912 |   Section 2: Cost to the system  Currently, CGM is not availabe for CYP with T2 diabetes.  Potential cost impact if current CYP T2 Diabetes patients were to have access to CGM:     |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | No. of CYP with T2 diabetes 2023 | Cost per yr if started 50% on CGM (assuming cost is £912/yr) | Cost per yr if started 100% on CGM (assuming cost is £912/yr) | | Acute trust | RSFT | 5 | £2,280 | 4,560 | | ASPH | 6 | £2,736 | 5,472 | | SASH | 8 | £3,648 | 7,296 | | EsH | 5 | £2,280 | 4,560 | |  | Total | 24 | £10,944 | 21,888 |   The National Paediatric Diabetes Audit Annual Report 2020/21 showed there was a 14% rise in CYP with Type 2 diabetes in one year.  Taking this into account, in 5 years it is expected there may be around 44 CYP with T2 diabetes.  CYP with T2 diabetes are managed with oral hypoglycaemic medications as well as insulin. Not all the CYP T2 diabetes patients in Surrey Heartlands will fit the NICE criteria for CGM especially if they are not taking any medications that cause hypoglycaemia.  Section 3: Cost benefits  The NICE cost-effectiveness analysis was not able to demonstrate short term cost benefits to the health economy in terms of hospital admissions, ambulance call outs etc. |
| **Implications** |
| NICE guideline NG18 recommends widening the availability of CGM technology to all children and young people with T2DM.  The guidance from NICE does not recommend isCGM (unless person is unable to use rtCGM or who express a clear preference for isCGM) as there was no benefit shown of this technology compared to standard self-monitoring of blood glucose levels. Offering rtCGM, instead of isCGM, could offer greater clinical benefits for our population of children and young people with Type 2 diabetes.  The guideline has implications for the health economy in terms of costs and capacity of paediatric specialist teams to support assessment for and initiation of rtCGM in all CYP with T2DM.The implications to the health economy though are relatively low as the number of children and young people with type 2 diabetes who will be eligible for CGM is relatively low. Therefore, recommendations to consider or offer CGM to children and young people with type 2 diabetes is unlikely to have a significant resource impact. |
| **Implementation** |
| APC is asked to recommend that Surrey Heartlands ICB agree to the implementation of the CGM recommendation in NICE guideline NG18 and actions to ensure cost-effective use of CGM in children and young people with T2 DM.  Actions to support implementation (see accompanying papers):   * Agree cost-effective choice, and traffic light status of CGM devices to be available in Surrey Heartlands for CYP with T2DM. * Agree pathway, review criteria and accompanying table(s) to indicate cost-effective choice of device depending on patient characteristics. * Use Blueteq® form when informing ICB that hospital team are initiating specialist rtCGM. * Agree communication template (BLUE information sheet) to support transfer of prescribing to primary care for FP10 prescribable CGM.  1. Paediatric specialist teams  * Providers are within NHS hospital trusts. * Trusts to follow internal governance procedures to add to their formulary and ensure all rtCGM is purchased via most cost-effective route, usually NHS Supplies framework. * Initiation, supply, and on-going management is managed by secondary care. * Specialist teams will be required to notify the Medicines Resource Unit team of initiation of the specialist device using the Blueteq® system. This is a notification not a request for funding. * Following initiation of FP10 prescribable CGM, request ongoing prescribing by primary care. * Following initiation of FP10 prescribable CGM, ensure minimum dataset in Transfer of Care form is included in information provided to GP.  1. Primary care  * Record CGM in the patient’s notes. * Prescribe blood glucose test strips as per advice from specialist team and local guidance. * Note the frequency of sensor and transmitter (if applicable) prescribing intervals and be alert to patients under or over ordering CGM sensors. * Recommendations for APC; * Freestyle Libre 2, Dexcom G7 and Dexcom One to be recommended for use for children and young people with type 2 diabetes. * When a child or young person with type 2 diabetes is transferred to adult services, their CGM should be continued. |

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Declaration of Interest:

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