NHS
Derby and Derbyshire
Clinical Commissioning Group

CLINICAL POLICY ADVISORY GROUP (CPAG)

Continuous Glucose Monitoring Policy

Statement

Derby and Derbyshire CCG, in line with its principles for procedures of limited clinical value, has deemed Continuous Glucose Monitoring to be not routinely commissioned unless specific criterions are met.

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by Derby and Derbyshire CCG.

1. Introduction

The purpose of this policy is to support Derby and Derbyshire CCG (DDCCG) in funding clinically and cost effective treatment for adults and children with type 1 diabetes. It provides criteria for the commissioning of Continuous Glucose Monitoring (CGM) and Sensor-Augmented Pump therapy for patients with type 1 diabetes.

Since 1st April 2017, CGM and Sensor-augmented Pump therapy for both adults and children is the commissioning responsibility of the CCG.

This policy has been developed to support decision making for the equitable and ethical allocation of resources.

2. Background

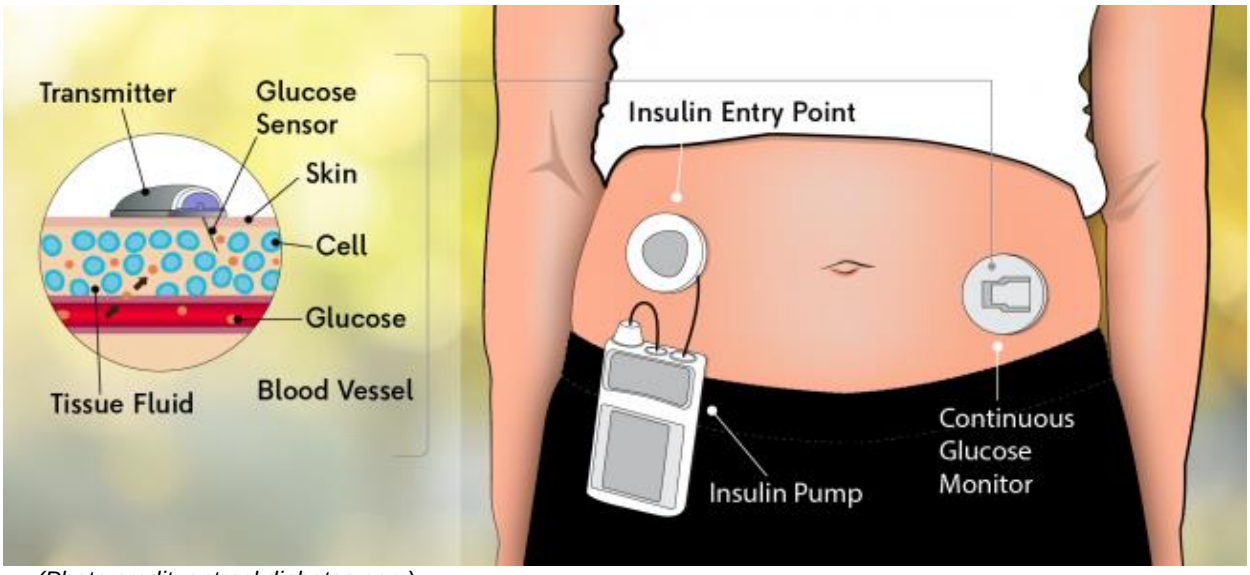
Most people with type 1 diabetes manage their blood glucose levels through regular daily self-monitoring of blood glucose (SMBG) and insulin injections. However, a small number of people have problems maintaining optimal blood glucose levels by self-administration of insulin therapy and are at risk of the severe complications associated with diabetes. Short-term complications of type 1 diabetes are hypoglycaemia and diabetic ketoacidosis. The

longer-term complications of type 1 diabetes include neuropathy, nephropathy, retinopathy and cardiovascular events, which are all related to hyperglycaemia.

Although many people effectively self-manage their diabetes with conventional insulin therapy or insulin pumps, there is a specific minority group of patients who have hypoglycaemic unawareness and/or recurrent disabling hypoglycaemia. This group meets the NICE criteria both for an insulin pump and for continuous glucose monitoring.

Automated continuous glucose monitoring and sensor augmented pump therapy have the potential to reduce the incidence of complications associated with hypoglycaemia for these patients.

What is Continuous Glucose Monitoring?
A continuous glucose monitor is a device worn on the skin, comprising a sensor inserted under the skin to measure glucose levels in interstitial fluid. The sensor is connected to a transmitter, which sends the information via a wireless radiofrequency signal to a receiver, or more commonly, a smartphone application. Newer insulin pumps are designed to integrate with the CGM technology. The pumps automatically suspend the delivery of basal insulin should blood glucose levels drop below a pre-defined limit, thereby avoiding hypoglycaemic episodes.



(Photo credit: ontrackdiabetes.com)

3. Definitions

Continuous subcutaneous insulin infusion **(CSII)** therapy makes use of an external pump that delivers insulin continuously from a refillable storage reservoir by means of a subcutaneously placed cannula. The pump can be programmed to deliver a basal rate of insulin throughout the day, with a bolus of insulin triggered by the push of a button at meal times.

Continuous glucose monitoring **(CGM)** involves a device which is attached to the skin and provides a continuous reading of glucose levels. The CGM system alarms if the glucose

levels are falling or have entered the hypoglycaemic range, alerting the patient to the need to take corrective action. CGM can be combined with either a multiple daily injection insulin regime or an insulin pump.

Sensor augmented pump therapy **(SAPT)** refers to the use of CGM which is integrated with an insulin pump and glucose data is displayed on the insulin pump.

The predictive low glucose management **(PLGM)** system incorporates continuous glucose sensor data into an algorithm and suspends basal insulin before the occurrence of hypoglycaemia. This suspension of insulin delivery stops the glucose from falling and can help prevent hypoglycaemia. The insulin pump resumes insulin delivery when the glucose level has recovered.

Hypoglycaemia is defined as blood glucose <4.0 mmol/L (72mg/dL).

Severe hypoglycaemia (SH) is defined in adults as hypoglycaemia requiring third party assistance for recovery.

In a **child**, SH is defined as an event with severe cognitive impairment (including coma and convulsions) requiring external assistance by another person to actively administer carbohydrates, glucagon or take other corrective actions.
Severe hypoglycaemic coma is defined as a subgroup of severe hypoglycaemia, as an event associated with a seizure or loss of consciousness.

Disabling hypoglycaemia refers to the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.

DAFNE: Dose Adjustment for Normal Eating. A structured education programme that improves a diabetic person's skills in carbohydrate management.

IAH: impaired awareness of hypoglycaemia (Gold score ≥4)

MDI: Multiple daily insulin (injections)

Problems with daily living – defined as:

- Potential/ actual loss of driving licence
- Potential/ actual loss of employment
- Inability to care for dependents safely
- Significant disruption to ability to live independently.

SMBG: Self-monitoring of blood glucose refers to home blood glucose testing for people with diabetes

4. Full Details of Policy

a) Epidemiology

There are approximately 200,000 patients with type 1 diabetes in England. Patients experience between 36 and 106 episodes of hypoglycaemia (all severities) each year. Between 52–84% of individuals with Type 1 diabetes develop biochemical hypoglycaemia (usually asymptomatic) during sleep. Severe hypoglycaemia (requiring help for recovery) has an annual prevalence of 30–40% and an annual incidence of 1.0 – 1.7 episodes per patient per year[i].

Around 44% of patients are reported to reduce their insulin intake following a severe hypoglycaemic episode, in order to avoid another episode[ii]. This can result in uncontrolled, consistently high HbA1c and associated complications.

Impaired awareness of hypoglycaemia affects around a quarter of patients with established type 1 diabetes[iiiiv]. These patients have a six fold higher risk of severe hypoglycaemia[v] and higher incidence of biochemical hypoglycaemia compared with normal awareness.

b) Exceptional Circumstances

DDCCG will consider individual cases for funding outside this commissioning policy in accordance with the Individual Funding Request Policy which defines exceptionality and sets out a decision making framework for determining these cases.

c) Eligibility Criteria for Adults and Children

- Treatment is recommended by a consultant diabetologist for patients registered with a General Practitioner in Derbyshire.
- CGM should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes.
- The CGM system selected should be the most cost-effective option available at the time.
- Patient has Type 1 diabetes.
- The patient is appropriately engaged with diabetes care, including attending regular specialist diabetes follow-ups as recommended by the specialist diabetes team.
- The patient is adherent to dietary advice.
- The patient understands:
  - how to,
  - is motivated to,
  - is physically capable of,

  using the CGM device at least 70% of the time and to calibrating the device as needed.

d) Inclusion Criteria

Adults:
CGM may be funded, where the patient meets these criteria:

- Patients have been offered and are usually expected to complete a diabetes structured education course (e.g. DAFNE)

AND

- Experience more than one episode a year of severe hypoglycaemia (see 'Definitions') with no obvious preventable cause

Or

- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily living (see 'Definitions') or performance impairment.
    - Precipitating causes must be excluded
    - This assessment must be made using Freestyle Libre data OR a diagnostic CGM
    - Hypoglycaemia defined as being <4mmols/L (21.5mmols/mol)

AND (only where criteria are met for Freestyle Libre eligibility)

- Have trialled a Freestyle Libre device, after being given appropriate education and support, without improvement in hypoglycaemia (awareness of hypoglycaemia and/or frequency of hypoglycaemia)

AND at least ONE of the following criteria

- Complete loss of awareness of hypoglycaemia (as indicated by a Gold Score of 7)

- Extreme fear of hypoglycaemia:
    - Using the 18 HFS-W questions, with Likert scale of 1 – 6
        - Max score 108.
          A score of 80+ as a working definition of 'extreme fear' of hypoglycaemia

Offer continuous glucose monitoring (CGM) to all **pregnant women** with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes.

Consider continuous glucose monitoring for pregnant women who are on insulin therapy but do not have type 1 diabetes, if:

- they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia)

Or

- they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control.

(CGM should be offered to all women with Type 1 diabetes who are pregnant, for a period of 12 months.)

Children:

Offer ongoing CGM with alarms to children and young people with type 1 diabetes who have:

- frequent severe hypoglycaemia
  or
- impaired awareness of hypoglycaemia associated with adverse consequences such as seizures or anxiety
- **or**
- inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities

And, consider for those who fall into one of the following groups:

- neonates, infants and pre-school children
- children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level)
- children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult.

Transition from Child to Adult Services

The criterion for CGM differs in adults compared to children. As such it is anticipated that as children transition to adult services, there will be ample opportunity to trial without CGM, to enable the child to take responsibility for monitoring blood glucose levels independently, and have much improved hypoglycaemia awareness.

Continued funding of CGM as patients transition into adult services will be assessed on the merits of each case. As part of this assessment the clinician should consider the inclusion criteria for adults and balance the risk of hypoglycaemia with stopping CGM.

e) Exclusion and Withdrawal Criteria

Exclusion Criteria:

- Do not offer real-time continuous glucose monitoring **routinely** to adults or children with type 1 diabetes.
- **Patients with type 2 diabetes are excluded from using CGM**

Adults:

Treatment with CGM should be **discontinued** after six months (or before) if any one of the criteria below applies:

- the patient has failed to use the device for at least 70% of the time

or

- the patient has failed to achieve a clinically significant and sustained reduction in the number of hypoglycaemic episodes

or

- The patient's awareness of hypoglycaemia has improved (Gold score <4)

or

- There is no significant change in the patient's fear of hypoglycaemia (as measured by the clinical threshold set by the Consultant)

Children:

Barriers to accessing structured education sessions should be considered (e.g. language, timings of sessions, venues etc.) and attempts made to facilitate. This should include liaison with other services involved in working with and supporting the family.

Withdraw CGM after 1 month if:

SAPT has not been used 60-70% of the time – 5 days a week minimum

Withdraw CGM at 3 months OR **second main review after initiation** if:

- Child / young person does not wear the device for at least 5 days a week
- No improvement in scores on fear of hypoglycaemia scales (where SAPT was introduced for anxiety)
- No improvement in hypoglycaemia unawareness if introduced for hypoglycaemia unawareness (based on Clarke or Gold score)
- No reduction in frequency of hypoglycaemia – particularly nocturnal hypoglycaemia (assessed from CGM download)
- CGM use for sport/ exercise is not being optimised

The device does not need to be reviewed for withdrawal if it was introduced following hypoglycaemic seizures, provided it is being used > 5 days per week or in younger children providing it is in regular use.

5. Monitoring and Review

DDCCG has deemed commissioning of continuous glucose monitoring and sensor-augmented pump therapy to be a clinical and cost-effective intervention for this defined cohort of patients.

In order to ensure value, represented by clinical outcomes and costs, this policy will be subject to individual patient audit.

Further detail regarding how this policy will be monitored is outlined in the Appendices

6. Appendices/Relevant Web Links

Clinical effectiveness

A Cochrane systematic review[vi] and NICE systematic reviews (NG17[vii] and NG18[viii]) form the basis of the evidence for CGM. These and subsequent small, low quality studies show that CGM is associated with a modest improvement in HbA1c (0.3% reduction). This difference is statistically significant but is of marginal clinical significance. Few studies have addressed the impact of CGM on quality of life.

Since the publication of the above reviews, the Association of Children's Diabetes Clinicians (ACDC) has developed a comprehensive guideline, based on recent reviews of the literature and consultation.[ix]

A systematic review and meta-analysis (based on evidence up to January 2015) found that improvements in HbA1c in patients using CGM were primarily seen in individuals over the age of 15 years. The authors were unable to identify a statistically significant difference in time spent in hypoglycaemia or the number of hypoglycaemic episodes, although these analyses were imprecise and warrant lower confidence[x].

The clinical efficacy of SAPT with PLGM has been demonstrated in two landmark randomised controlled trials[xixii]. SAPT with PLGM is associated with a significant ($p<0.05$) reduction in:

- frequency, duration and severity of hypoglycaemia
- seizure and coma events in patients with impaired hypoglycaemic awareness
- improves awareness of hypoglycaemia and can eradicate severe hypoglycaemia in patients with reduced hypoglycaemic awareness.

An Australian clinical trial based economic evaluation found that after 6 months, the use of SAPT with PLGM significantly reduced the incidence of severe hypoglycaemia compared

with standard pump therapy with SMBG (incident rate difference 1.85 [0.17–3.53]; P=0.037)[xiii].

In an RCT of 160 diabetic patients, the use of CGM reduced time spent outside glucose targets compared with self-monitoring of blood glucose, especially among users of insulin pumps.[xiv]

In a non-randomised 52 week follow-up study of 65 type 1 diabetic patients, those patients using CGM with MDI showed similar improvement to those using CGM with insulin pump.[xv]

A recent retrospective longitudinal study found that use of CGM in type 1 diabetes patients facilitated greater HbA1c improvements and reduced health care system utilization compared with traditional SMBG use regardless of insulin administration method. Treatment with CGM in conjunction with MDI conferred similar or greater glycaemic benefits without the additional costs associated with insulin pump therapy[xvi].

An open label multicentre parallel randomised control trial (HypoDE) demonstrated a significant reduction in the mean number of hypoglycaemic events per month, when compared to patients on standard blood glucose monitoring.

Cost effectiveness

A NICE review of the economic evidence[xvii] for CGM identified the following:
Two cost–utility analyses found that CGM was not cost effective compared with SMBG in people with type 1 diabetes (ICERs: £29,029 per QALY gained and £63,828 per QALY gained respectively). These analyses were assessed as partially applicable with potentially serious limitations.
One original cost-utility analysis found that in people with type 1 diabetes SMBG (8 times a day) was dominant (less costly and more effective) compared with CGM. This analysis was assessed as directly applicable with potentially serious limitations.

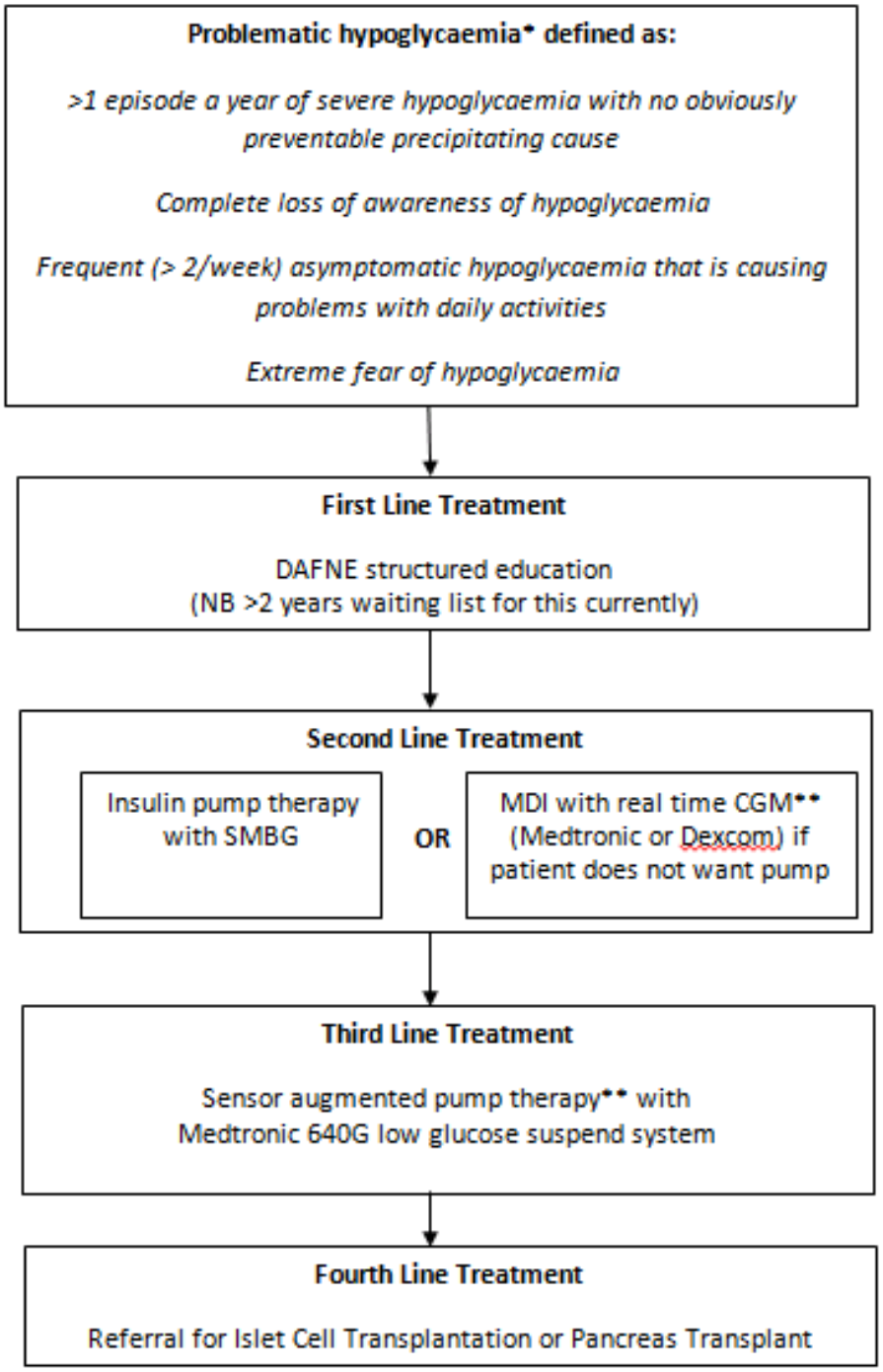
A cost-effectiveness analysis of SAPT with PLGM vs. insulin pump plus SMBG was performed to determine the health economic benefits in type 1 diabetes patients using insulin pumps in the UK[xviii]. Projected outcomes in this study showed that SAPT with PLGM was associated with higher QALYs and higher life expectancy (23.8 vs. 21.9 years) but higher mean lifetime direct costs (£125,559 vs. £88,991), leading to an incremental cost-effectiveness ratio (ICER) of £12,233 per QALY gained for SAPT with PLGM vs. insulin pump in this patient group.

In a French cohort of type 1 patients at elevated risk for hypoglycaemic events, an economic evaluation of SAPT with PLGM vs. insulin pump plus SMBG resulted in an ICER of €22,005 (£19,200) per QALY gained[xix].

A similar Australian economic evaluation returned a cost per QALY of $40,803 (£25,300) for type 1 patients over 12 years of age using SAPT plus PLGM vs. standard insulin pump therapy[xx].

7. Appendices

Appendix 1: Local Type 1 Diabetes Hypoglycaemia Pathway (June 2016)



*Any patient with problematic hypoglycaemia should be frequently reviewed by the specialist diabetes team, at least every 4 months, in some instances weekly

**Those who meet the criteria for CGM or sensor augmented pump therapy must agree to use it at least 70% of the time and to calibrate it as needed. Treatment goals will be set and reviewed.

Review Process for CGM use In Derbyshire

1. Confirm patient meets clinical criteria for funding of a Continuous Blood Glucose Monitoring

ALL PATIENTS

- Patient has type I diabetes (or insulin dependent gestational diabetes)
- The patient is established on an insulin pump (or a pump is deemed clinically inappropriate)
- The patient is appropriately engaged with diabetes care, including attending follow-ups
- The patient is adherent to dietary advice
- The patient understands how to use the CGM device, will calibrate it as needed, and will use it at least 70% of the time.

ADULTS

- Patients have been offered (and are usually expected to complete) a diabetes structured education course (eg DAFNE)

AND

- More than one episode a year of severe hypoglycaemia (see 'Definitions') with no obvious preventable cause

Or

- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily living (see 'Definitions') or performance impairment.
  - Precipitating causes must be excluded
  - This assessment must be made using Freestyle Libre data OR a diagnostic CGM
  - Hypoglycaemia defined as being <4mmols/L (21.5mmols/mol)

AND (only where criteria are met for Freestyle Libre eligibility)

- Have trialled a Freestyle Libre device, after being given appropriate education and support, without improvement in hypoglycaemia (awareness of hypoglycaemia and/or frequency of hypoglycaemia)

AND at least ONE of the following criteria

- Complete loss of awareness of hypoglycaemia (as indicated by a Gold Score of 7)
- Extreme fear of hypoglycaemia
  Using the 18 HFS-W questions, with Likert scale of 1 – 6. Max score 108.

A score of 80+ as a working definition of 'extreme' hypoglycaemia

PREGNANCY

Offer continuous glucose monitoring (CGM) to all **pregnant women** with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes.

Consider continuous glucose monitoring for **pregnant women** who are on insulin therapy but **do not have type 1 diabetes**, if:

- they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia)

Or

- they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control.

(CGM should be offered to all women with Type 1 diabetes who are pregnant, for a period of 12 months.).

CHILDREN

Offer ongoing CGM with alarms to children and young people with type 1 diabetes who have:

- frequent severe hypoglycaemia **or**
- impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) **or**
- inability to recognise or communicate symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities)

And, consider for those who fall into one of the following groups:

- neonates, infants and pre-school children
- children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level)
- children and young people who have comorbidities (for example, anorexia nervosa) or who are receiving treatments that can make blood glucose control difficult (for example corticosteroids).

2. Sign patient up to a clinical contract. Agree and establish treatment goals

3. Review the patient at one month (or first review)

- Record **HbA1c**, **number of severe hypos and % time in hypo,** track **compliance,** as appropriate from the CGM download.
- **Stop treatment** if the patient is not using the device at least 70% of the time OR
- The family have not attended all DAFNE sessions (children only)

4. Review the patient at three months (or second review)

- Record **HbA1c, number of severe hypos and % time in hypo,** track **compliance** as appropriate from the CGM download.
  - **Stop treatment** if the intended benefit has not been achieved e.g.
    - **Is not wearing the device a minimum of 70% of the time (from CGM download)**
    - **There is not a sustained reduction in frequency of hypos**
    - **There has not been an improvement in HbA_{1c}**
    - **Hypo awareness has not improved**
    - **There is no improvement in fear of hypoglycaemia** (as shown by 18 HFS-W)

5. Review the patient at six months

- Record **HbA1c, number of severe hypos and % time in hypo** and track **compliance** as appropriate from the CGM download.
- **Stop treatment** as previously outlined, if any of the factors at three month review are present **OR** outcomes have sufficiently improved **OR** goals at initiation of treatment are not otherwise met.
- **If patient has demonstrated improvement, set patient expectations about moving away from CGM, to encourage the patient to take responsibility for monitoring their own blood glucose levels and encourage recognition of hypoglycaemia symptoms.**

6. Review the patient at 12 months

- Record **HbA1c, number of severe hypos and % time in hypo**, track **compliance** as appropriate from the CGM download.
- **Stop treatment** if goals of CGM are no longer being met **OR** outcomes have sufficiently improved.
- Consider if patients needs could be met via other options; repeat steps 1 – 5.

Appendix 2: Consultation

Consultee	Date
Clinical Policy Advisory Committee	May 2019, July 2019
Public Health Input	Consultant in Public Health and Public Health Specialty Registrar
Derbyshire Affiliated Commissioning Committee	13/04/17; 08/06/17, Nov 18
Clinical engagement	Diabetes Consultants, UHDB and CRH
Local Maternity Services	November 2020
Clinical Policy Advisory Group	January 2021
Clinical Lay Commissioning Committee	February 2021

Appendix 3: Document Update

Document Update	Date Updated
First produced- Version 1	November 2018
Updated- Version 2	May 2019
Updated – Version 3	July 2019
Updated – Inclusion criteria modified for pregnancy- In line with NICE CG3 - Offer continuous glucose monitoring (CGM) to all **pregnant women** with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes. Consider continuous glucose monitoring for **pregnant women** who are on insulin therapy but **do not have type 1 diabetes**, if: • they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) Or • they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control. *(CGM should be offered to all women with Type 1 diabetes who are pregnant, for a period of 12 months.)*.	January 2021

8. References

[i] Frier BM. The incidence and impact of hypoglycemia in type 1 and type 2 diabetes. International Diabetes Monitor 2009;21:210–218

[ii] Leiter, Lawrence A., et al. "Assessment of the impact of fear of hypoglycemic episodes on glycemic and hypoglycemia management." *Can J Diabetes* 29.3 (2005): 186-192.

[iii] Little, Stuart A., et al. "Recovery of hypoglycemia awareness in long-standing type 1 diabetes: a multicenter 2× 2 factorial randomized controlled trial comparing insulin pump with multiple daily injections and continuous with conventional glucose self-monitoring (HypoCOMPaSS)." *Diabetes Care*37.8 (2014): 2114-2122.

[iv] Yeoh, Ester, et al. "Interventions that restore awareness of hypoglycemia in adults with type 1 diabetes: a systematic review and meta-analysis."*Diabetes Care* 38.8 (2015): 1592-1609.

[vi] Langendam M, Luijf YM, Hooft L, DeVries JH, Mudde AH, Scholten RJPM. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database of Systematic Reviews 2012, Issue 1. Art. No.: CD008101. DOI: 10.1002/14651858.CD008101.pub2.

[vii] Type 1 diabetes in adults: diagnosis and management; NICE guidline [NG17], August 2015

[viii] Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE guideline [NG18], August 2015.

[ix] Association of Children's Diabetes Clinicians "Clinical Guideline: A practical approach to the management of continuous glucose monitoring / real-time flash glucose scanning in type 1 Diabetes Mellitus in children and young people under 18 years"; January 2017

[x] Benkhadra, Khalid, et al. "Real Time Continuous Glucose Monitoring in type 1 diabetes: A Systematic review and Individual Patient Data Meta-Analysis."*Clinical Endocrinology* (2016).

[xi] Ly TT, Nicholas JA, Retterath A, Lim EM, Davis EA, Jones TW. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycemia in patients with Type 1 Diabetes. A randomized clinical trial. JAMA 2013;310(12):1240-7.

[xii] Bergenstal RM, Klonoff DC, Garg SK, Bode BW, Meredith M, Slover RH, et al. Threshold-Based Insulin-Pump Interruption for Reduction of Hypoglycemia. N Engl J Med 2013 Jun 22.

[xiii] Ly, Trang T., et al. "A cost-effectiveness analysis of sensor-augmented insulin pump therapy and automated insulin suspension versus standard pump therapy for hypoglycemic unaware patients with type 1 diabetes."*Value in Health* 17.5 (2014): 561-569.

[xiv] New, J P,Ajjan, R,Pfeiffer, A F H,Freckmann, G. "Continuous glucose monitoring in people with diabetes: the randomized controlled Glucose Level Awareness in Diabetes Study (GLADIS)." *Diabetic Medicine* 32.5 (2015): 609-617.

[xv] Šoupal, Jan, et al. "Comparison of Different Treatment Modalities for Type 1 Diabetes, Including Sensor-Augmented Insulin Regimens, in 52 Weeks of Follow-Up: A COMISAIR Study." *Diabetes Technology & Therapeutics* 18.9 (2016): 532-538.

[xvi] Parkin, Christopher G., Claudia Graham, and John Smolskis. "Continuous Glucose Monitoring Use in Type 1 Diabetes: Longitudinal Analysis Demonstrates Meaningful Improvements in HbA1c and Reductions in Health Care Utilization." *Journal of Diabetes Science and Technology* (2017): 1932296817693253.

[xvii] Type 1 diabetes in adults: diagnosis and management; NICE guideline [NG17], August 2015

[xviii] Roze, Stéphane, et al. "Long-term health economic benefits of sensor-augmented pump therapy vs continuous subcutaneous insulin infusion alone in type 1 diabetes: a UK perspective." *Journal of medical economics* 19.3 (2016): 236-242.

[xix] Roze, Stéphane, et al. "Cost-Effectiveness of Sensor-Augmented Pump Therapy with Low Glucose Suspend Versus Standard Insulin Pump Therapy in Two Different Patient Populations with Type 1 Diabetes in France."*Diabetes technology & therapeutics* 18.2 (2016): 75-84.

[xxxxxx] Ly, Trang T., et al. "A cost-effectiveness analysis of sensor-augmented insulin pump therapy and automated insulin suspension versus standard pump therapy for hypoglycemic unaware patients with type 1 diabetes."*Value in Health* 17.5 (2014): 561-569.

[xxv] "Warning for parents as one hoax call costs public £2465 and diverts ambulance from real emergency call" 2017 News, East Midlands Ambulance Service NHS Trust, Accessed https://www.emas.nhs.uk/news/latest-news/2017-news/warning-for-parents-as-one-hoax-call-costs-public-2465-and-diverts-ambulance-from-real-emergency/ (accessed 27th September).

[xxvi] McEwan P, Thorsted B, Wolden M, Jacobsen J, Evans E. Healthcare resource implications of hypoglycaemia-related hospital admission and inpatient hypoglycaemia: retrospective record-linked cohort studies studies in England. BMJ Open Diabetes Research and Care **2015;**3e000057. Doi: 10.1136/bmjdrc-2014-000057

xxvii Feig DS, Donovan LE, Corcoy R, Murphy KE, Amiel SA, Hunt KF et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Lancet* **2017**; 390: 2347- 2359.

xxviii. Hex N, Bartless C, Wright D, Taylor M and Varley D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs, and indirect societal and productivity costs. *Diabet. Med*. **2012**; 29: 855 – 862

xxiv. Heinemann L, Freckmann G, Ehrmann D, Faber-Heinmann G, Guerra S, Waldenmaier D et al. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. *Lancet* **2018**; 391: 1367 – 77. xxx https://www.england.nhs.uk/wp-content/uploads/2020/10/C0770-dpp-and-cgm-letter.pdf accessed 08/10/20