SHIP8 Clinical Commissioning Groups Priorities Committee

Policy Recommendation: **Continuous Glucose Monitoring (CGM) for Adults with Type 1 Diabetes Mellitus**

Date of issue: **February 2016**

The Priorities Committee recommends that the routine use of continuous glucose monitoring without the use of a pump is considered a low priority.

However there is a place for CGM in the pathway for a specific subset of patients who meet the criteria set out below, as jointly agreed by all specialist diabetic units and ratified with the Priorities Committee. The choice of device will attempt to gain the lowest acquisition costs.

Clinicians will need to inform the Commissioning Support Unit (CSU) when they enter patients on the program and an ongoing audit of results will be supplied to the CSU.

Background

- Type 1 diabetes (T1DM) is characterised by deficient insulin production. Treatment requires daily administration of insulin in order to normalise glucose metabolism. Self-monitoring of blood glucose (SMBG) with fingerstick measurements is the cornerstone of T1DM self-management. The frequency and timing is dictated by the particular needs and goals of individual patients.

- T1DM is associated with reduced life expectancy; long term complications include cardiovascular disease, kidney disease, eye and nerve disease as well as acute hypoglycaemia or diabetic ketoacidosis. The risk of complications and comorbidities is reduced if blood glucose is strictly controlled.

- The continuous glucose monitor (CGM) continuously measures glucose levels in the interstitial fluid and wirelessly sends readings to a remote, portable monitor or to an insulin pump by radio. CGM requires a minimum of two calibrations per day using fingerstick blood glucose measurements.

- 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. Severe hypoglycaemia occurs at between 0.012 to 3.2 episodes per patient per year, commonly at night. 44% patients are reported to reduce their insulin intake following a severe hypoglycaemic episode, in order to avoid another episode. This can result in uncontrolled, consistently high HbA1c and associated complications.

Clinical effectiveness

- A Cochrane systematic review and NICE systematic review form the basis of the evidence for CGM. These, and subsequent small, low quality studies show that real-time CGM is associated with only a modest improvement in HbA1c (0.30% reduction).

Notes:

Exceptional circumstances may be considered where there is evidence of significant health impairment and there is also evidence of the intervention improving health status.

This policy may be reviewed in the light of new evidence or guidance from NICE.

- No clinical difference between real-time or retrospective CGM and SMBG has been shown for:
    - hypoglycaemia (episodes/day)
    - severe hypoglycaemia (per 100 patient years)
    - severe hypoglycaemia (annualised rate)
    - adverse events
    - QoL measures of physical health, mental health, Hypoglycemia Fear Survey (HFS) Problem Areas In Diabetes (PAID) and total score
    - HbA1c (retrospective CGM)
    - number of people experiencing episodes of severe hypoglycaemia.

- One RCT found that real-time-CGM with an alarm compared to SMBG was associated with:
    - Reduced time spent outside target (h/day): 9.6 vs 11.0 (95% CI -2.52 to-0.28, p=0.0149)
    - Reduced time in hypoglycaemia (h/day): 1.0 vs 1.6 (95% CI -1.2 to -0.1, p=0.030).

- It is not clear to what extent the reduced time outside target (1.4h/day) or reduced time in hypoglycaemia (0.6h/day) is clinically significant nor whether over time, the cumulative reduction in these events prevents the incidence of complications and comorbidities.

- There were no studies that included adherence and patient satisfaction.

Cost effectiveness

- Estimates of cost-effectiveness of CGM compared to SMBG are unreliable. None of the studies included found CGM to be cost-effective at the £20,000 per QALY threshold.

Pathway for the Controlled use of CGM (as an alternate to pump therapy, not in association with pump therapy) in Specialist Diabetes Clinics within the SHIP8 Catchment

Entry Criteria

1) Type 1 Diabetes
2) Have undergone previous "advanced insulin self-management education" (DAFNE / BERTIE / JIGSAW)
3) Utilising effective basal bolus insulin self-management with evidence of CHO counting and correction insulin use with an SMBG frequency of >4 tests daily
4) Problematic BG Control despite the above
    a. Variable SMBG control with episodic hypoglycaemia impacting on lifestyle
    b. Recurrent hypoglycaemia (> 3 episodes per week or >2 severe episodes in a year)
    c. Loss of hypoglycaemia Awareness Symptoms (Gold Score <3)
    d. Persistent Elevation of HbA1c despite insulin dose adjustments
5) Regular attendance at accredited intensive insulin clinic (e.g. pump-enabled services)

Action Pathway

Initial assessments
Full examination and biochemical assessment of potential confounders of control (e.g. thyroid / adrenal assessment)
Diagnostic (Professional) CGM (iPro or equivalent) on usual SMBG control as a baseline assessment
Provision of a CGM device for a 3-month trial period*

Minimum of monthly assessments (with regular data upload) whilst on trial to confirm

1) Use of sensor for at least 70% of the time
2) Effect of sensor use on reduction of BG variability and increase of percentage of time spent in target BG range (4-10mmol/L) compared to baseline professional CGM
3) Improvement in the initial problem triggering the trial

If all 3 criteria are achieved, then letter sent to Commissioning team for that patient informing them of the effect to approve continued use of sensors (reviewed annually) with expectation of ongoing regular contact and sensor upload by HCP team
If use is suboptimal or does not result in effective change then sensor supply withdrawn and alternative avenues for the assistance of the individual are assessed (e.g. possible pump pathway use)

Specialist Clinic Reporting to Commissioners

1) Annual report of numbers of patients assessed
2) Annual report of numbers of patients offered 3 month trials (and devices used)
3) Annual report of numbers of trial successful and numbers of established users continuing effective use (after year 1)

Device choice to be led by presenting problem – generally use of the Abbott FreeStyle Libre to be considered first (cost-led) but where a hypoglycaemia alarm is considered a key element then dexcom device to be trialled if initial benefit not achieved with Libre.