West Yorkshire and Harrogate Health and Care Partnership

West Yorkshire & Harrogate
Joint Committee of Clinical Commissioning Groups

Summary report			
Date of meeting: 12th January 2021		Agenda item: 08/21	
Report title:	**Amendment to Flash Glucose Monitoring Commissioning Policy**		
Joint Committee sponsor:	Jo Webster		
Clinical Lead:	James Thomas		
Author:	Kirsty Shuttleworth		
Presenter:	Catherine Thompson		
Purpose of report: (why is this being brought to the Committee?)			
Decision	✓	Comment	✓
Assurance			

Executive summary

The West Yorkshire and Harrogate Improving Planned Care programme addresses clinical thresholds and criteria for clinical procedures, as well as efficient prescribing. The purpose of the clinical thresholds workstream is to review and standardise the clinical thresholds for these procedures across the Clinical Commissioning Groups. We present here an amendment to the Flash Glucose Monitoring commissioning policy for adoption by the Joint Committee, to include those patients with Learning Disabilities, as advised by NHS England.

Recommendations and next steps

The Joint Committee is asked to adopt the amendments to the WY&H Flash Glucose Monitoring policy on behalf of the West Yorkshire Clinical Commissioning Groups with immediate effect.

Delivering outcomes: describe how the amendments support the delivery of outcomes (Health and wellbeing, care and quality, finance and efficiency)

Health and Wellbeing: The programme adopts a 'right care, right place, right time' approach to the planning and delivery of planned care services.
Care and Quality: The clinical thresholds and criteria are for procedures which provide benefit to only a limited number of people, or which should only be offered after other treatment options have been tried. Amending this policy will ensure that those people in vulnerable groups who will benefit from this device are offered it, and that the criteria are applied equitably across the region. The original roll out of Flash only applied to select patients with Type 1 Diabetes and so the amendment to the policy will reduce the variation in treatment offered to people across the West Yorkshire and Harrogate region.
Finance and Efficiency: The increased financial impact of including Learning Disabilities and Autism to the Flash Glucose Monitoring policy will vary between places. It is difficult to quantify but there will be some increase in spend. Some of this will be offset by the additional funding being provided by NHSE until March 2021, separate to the 2 years funding provided by NHSE in the initial implementation of the Flash policy but it will not cover the whole cost of implementing the amendment.

Impact assessment (please provide a brief description, or refer to the main body of the report)	
Clinical outcomes:	See paragraph 6-11
Public involvement:	See paragraph 12
Finance:	See paragraph 15-18 and Table 1
Risk:	See paragraph 13-14
Conflicts of interest:	Dr James Thomas: GP Chair of NHS Bradford, District and Craven CCG; partner of Modality GP partnership; Dr Kate Thomas (spouse) is also a partner of Modality GP partnership. Jo Webster: Chief Officer of NHS Wakefield CCG Catherine Thompson: none declared

West Yorkshire and Harrogate Health and Care Partnership
Improving Planned Care Programme

Introduction

1. The West Yorkshire and Harrogate Improving planned care programme addresses clinical thresholds and criteria for clinical procedures and prescribing. The purpose of the Prescribing workstream is to review and standardise the prescribing criteria for some medicines and prescribable devices across the Clinical Commissioning Groups of West Yorkshire. This will reduce variation in access to care across WY&H and ensure that care is evidence based.

2. The Improving Planned Care programme of the West Yorkshire and Harrogate Health and Care Partnership (WY&H HCP) has considered the current Flash Glucose Monitoring amendment from NHSE to include those patients with Learning Disabilities to be included within the policy. The policy is included at appendix 1. The amendment will form point 9 in the policy. The WY&H Flash Glucose Monitoring policy is to contain the following amendments to its own policy:

   "People with Type 1 diabetes or insulin treated Type 2 Diabetes who are living with a learning disability and recorded on their GP Learning Disability register"

3. The WY&H HCP improving planned care programme recommends the use of the amendment to policy with immediate effect across all CCGs within WY. This is presented here for consideration and decision by the WY&H Joint Committee of CCGs.

4. In order to ensure the treatments offered are equitable across the population of WY&H, vulnerable groups must be considered and included within the policy.

West Yorkshire and Harrogate Policy Development Process

5. The improving planned care programme has developed a governance process to support decision making through the Joint Committee of WY&H CCGs as set out in the scheme of delegation appended to the WY&H Memorandum of Understanding. This has been discussed during presentations of the improving planned care programme at the WY&H Clinical Forum and Joint Committee meetings and agreed as an acceptable approach. The process is detailed here for clarity;

- Each policy or pathway is developed in the relevant working group using the 'do once and share' approach i.e. one place / CCG leads the development of the policy or pathway.
- Clinical involvement is secured by the place leading the pathway / policy development, and the draft policy / pathway shared for comment and development with relevant clinicians across WY&H.
- The developed policy or pathway is shared with members of the working group to ensure agreement of all working group members.
- Mapping of the differences between the proposed pathway and the current pathway and policies in each of the CCGs and an assessment of issues and risks.
- Mapping of engagement findings from across the CCGs and assessment of the need for consultation or further engagement
- Completion of the WY&H Quality and Equalities Impact Assessment (agreed at the January 2019 Joint Committee).
- The policy or pathway is presented at the Planned Care Alliance board to ensure representation and agreement from all CCGs prior to recommendation to the Joint Committee.
- Development and discussion at Joint Committee and / or WY&H Area prescribing committee.
- Decision at Joint Committee.

West Yorkshire and Harrogate Flash Glucose Monitoring

6. Flash Glucose Monitors are small sensors worn on the skin for monitoring the glucose (sugar) levels of people with diabetes. This information is monitored using a mobile app. This information helps the user and their clinical team to identify what changes are needed to insulin administration to achieve optimal glucose control, and therefore reducing the risk of adverse outcomes. Due to the sensor not measuring levels of sugar in the blood, it is sometimes necessary to use traditional finger-prick testing of blood glucose levels in addition to the use of Flash Glucose Monitor.

7. There are a number of elements to the products used to support Flash Glucose Monitoring: the monitoring device itself, a sensor which is usually worn on the person's arm, to which the monitor is applied to take a glucose reading and an 'introducer' which is used to apply the sensor to the body. The sensors last up to 14 days and need replacing after that time. The monitor gives the glucose level at the time of reading but also show the trend in sugar levels over time for up to 8 hours previous

8. The additional blood sugar trend information can help people with diabetes to better manage their condition and if used effectively may lead to longer term improvements in health outcomes for people with diabetes. The reduction in finger-prick testing for blood glucose monitoring can provide a psychosocial advantage to people with diabetes.

9. A third of deaths of people with a learning disability were shown to have been due to treatable causes, compared with 8% in the general population. A recommendation specific to diabetes from the Learning Disabilities Mortality Review (LeDeR) Programme reviews related to appropriate provision of support for people with diabetes, particularly in community settings.

10. This self-management of the diabetes condition for patients with Learning Disabilities will promote and enhance their independence and reduce their health inequalities. The technology should help people with a Learning Disability achieve better health outcomes. The benefits include;

    - Not having to do finger-prick checks
    - Making it easier to check glucose levels, so action can be taken earlier
    - Giving patients, their families and carers more confidence in managing the condition

11. There is currently only one brand of Flash Glucose Monitor available (Freestyle Libre, supplied by Abbott) and this is only licenced for use by children over four years of age and adults with Type 1 Diabetes.

Engagement and Consultation

12. There has been no further engagement and/or consultation for this policy amendment as it follows NHSE guidance to increase access to the Flash device for patients with Learning Disabilities, ensuring fair and equitable access to the device across WY&H. The amendment is in response to the finding of the LeDeR review.

Quality and Equality Impact Assessment

13. The following considerations are to be made with regards to patients with Learning Disabilities and Flash;

    - Training to be needs appropriate to the needs of the individual.

- More non face to face / digital consultations and training are currently being delivered due to the impact of covid-19. Care providers will need to ensure this addresses the accessibility needs of people with a learning disability

Many people with Learning Disabilities are managed in primary care, however specialist services are in secondary care so a linking up, shared care approach and referral to secondary care for these patients will be needed.

14. For all other considerations please see original QEIA for the Flash Glucose policy.

Financial Impact and Risks

15. The average cost of Flash per patient, per year is £910, with approximately 20% of that cost currently being reimbursed by NHS England and NHS Improvement. With the inclusion of those patients with a Learning Disability to be given access to Flash, across the six CCGs there will be an approximate increase of;
    - Calderdale – 40 patients
    - Huddersfield – 36 patients
    - Bradford – 60 patients
    - Leeds – 115 patients
    - North Kirklees – 28 patients
    - Wakefield – 51 patients

    A table of approximate figures and costs can be found below in Table 1, including a column for costs for the remaining quarter of this financial year. Appendix 2 shows population data and how the estimates were arrived at based on definite figures gained in the two areas of Bradford and Calderdale.

Table 1 of potential Financial Impact

CCG	Number of Patients	Cost per year (£)*	Final Quarter cost
Bradford	60	54,000	13,650
Calderdale	40	36,400	9,100
Huddersfield	36	32,760	8,190
Leeds	115	104,650	26,162.5
North Kirklees	28	25,480	6,370
Wakefield	51	46,410	11,602.5

*The total costs per year listed do not have NHS/I reimbursement or expected savings from testing strips included

16. The total cost per year as indicated in the table in Table 1 are estimate costs and do not take into consideration the current NHSE/I reimbursement or the expected savings from a reduction in providing testing strips, which is estimated to be £676.78 annually per patient.

17. These costs are estimated on device cost only and do not take into account the cost of training of patients and referral into specialist services.

18. The FGS reader is not available on prescription and is currently being provided by the manufacturer, free of charge, this may become a financial risk in the future if the manufacturer no longer provides this item free of charge.

19. The funding for this amendment has already been made available to CCGs in the baseline for this financial year.

Recommendations and Next Steps

20. The Joint Committee is asked to adopt the amendments to the WY&H Flash Glucose Monitoring policy on behalf of the West Yorkshire Clinical Commissioning Groups with immediate effect.

Flash Glucose Monitoring
Monitoring glucose levels in adults and children over 4 years of age with type 1 diabetes mellitus.
West Yorkshire and Harrogate Health and Care Partnership commissions the use of Flash Glucose Monitoring Systems (FGS) for: 1. People with type 1 diabetes OR with any form of diabetes on hemodialysis and on insulin treatment Who in either of the above, are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months OR with diabetes associated with cystic fibrosis on insulin treatment 2. Pregnant women with Type 1 diabetes -12 months in total inclusive of post-delivery period 3. People with type 1 diabetes unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management 4. People with type 1 diabetes for whom the specialist diabetes MDT determines have occupational (eg. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances that warrant a 6-month trial of flash glucose monitoring with appropriate adjunct support 5. Previous self-funders of flash glucose monitors with type 1 diabetes where those with responsibility for their diabetes care are satisfied that their clinical history suggests that they would have satisfied one or more of these criteria prior to them commencing use of flash glucose monitoring had these criteria been in place prior to April 2019 AND shown improvement in HbA1c since self-funding. 6. For those with type 1 diabetes and recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia, NICE suggests that Continuous Glucose Monitoring with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. However, if the person and their clinician consider that a Flash Glucose Monitoring System would be more appropriate for the individual's specific situation then this can be considered. 7. Pregnant women with type 2 diabetes on insulin requiring intensive monitoring more than 8 times a day – 12 months in total inclusive of total delivery period 8. Poorly controlled type 1 diabetic patients as part of pre-conception health care. Other requirements:

1. Education on Flash Glucose Monitoring has been provided by a suitably trained member of the diabetes team.
2. Agree to scan glucose levels no less than 8 times per day NB this should be spread over the day, and use the sensor >70% of the time.
3. Agree to regular reviews with the local clinical team
4. Previous attendance, or due consideration given to future attendance, at a type 1 diabetes structured education programme (DAFNE or equivalent) if available locally.

Diabetes Specialist Teams Responsibilities*

1. Assess type 1 diabetic patients for suitability for flash glucose monitoring and ensure any appropriate patients meet the criteria within the NHSE guidance before considering initiation. Record the criteria for initiation in patients' medical records.
2. Discuss use of flash glucose monitoring with patient and complete a patient contract form (appendices 1 &2) to ensure they are aware that continuation of supply beyond 6 months is contingent on achieving a demonstrable improvement and engagement with other diabetes care processes. The expected improvement or benefit from treatment should be recorded and agreed with the patient.
3. Patients need to sign up to share their scan data with the diabetes team on Libreview.com or other suitable platform.
4. Arrange training on the use of flash glucose monitoring products with a suitable trained member of the team or group training.
5. Supply a starter pack to patient (monitor and 1 sensor lasting 2 weeks)
6. Inform patient of safe disposal of sensors as clinical waste, supply clinical waste bags or large sharps bins as per local arrangement.
7. Inform GP practice in timely manner that patient has been initiated on flash glucose monitoring. For Cystic Fibrosis and Haemodialysis patients inform all relevant clinicians involved in their care.

Communications should include the following information:

a) which criteria the patient meets for initiation of flash glucose monitoring
b) what is expected improvement or benefit at 6 months from flash glucose monitoring
c) what is frequency of ongoing need for patient to continue BGTS as well as flash glucose monitoring. State expected reduction in BGTS usage.
d) a copy of the patient contract form
e) next review appointment

8. Arrange to review the patient at an appropriate interval but no later than 6 months after initiation.
9. Review the patient at 6 months to determine whether they have achieved the expected improvement or benefit to continue flash glucose monitoring (see under 'Review') and record outcome on agreed audit tool as appropriate.
10. Inform GP practice in a timely manner whether the patient should continue on flash glucose monitoring following 6 month review. Communications should include the following information:

a) What improvement or benefit has been achieved from flash glucose monitoring in line with patient contract.
b) Whether patient is continuing on flash glucose monitoring or agreed to stop due to lack or benefit or patient choice.

c) What is frequency of ongoing need for patient to continue BGTS as well as flash glucose monitoring. Expected reduction in BGTS usage.
d) Next review appointment

* The definition of 'diabetes specialist' will be subject to local interpretation. This will be defined by each of the nine CCGs of WY&H. This may include Consultant Diabetologists and Endocrinologists, GPs with a specialist interest in Diabetes and Advanced Nurse Practitioners or Practice Nurses with skills in the management of diabetes. This will reflect current local service models and the knowledge and skills of local primary and community care clinicians.

Primary Care Prescribers Responsibilities

1. **Do not** initiate diabetic patients on flash glucose monitoring in primary care. Refer patients to discuss their eligibility with the diabetes team at their next planned review.
2. Patients who do not meet the NHSE criteria may purchase privately. Continue to prescribe sensors for patients who have been initiated by diabetes specialist team on flash glucose monitoring.
3. Following receipt of communication (letter/task) from the diabetes specialist team add Freestyle Libre sensors to the patients repeat prescription authorised for 6 months. Add a note so that all prescribers can see when the review date is due. NB. 2 sensors last for 28 days
   If the sensors fall off within 14 days the patient should contact Abbott Customer Care to obtain a replacement they should not be issued again on prescription.
4. Reduce the quantity of BGTS from the patient's prescription record in line with the diabetes team instructions regarding need for ongoing monitoring.
5. At the end of the initial 6 months' supply ensure the patient has been reviewed by the specialist team and has achieved the planned improvements or benefits before re-authorising further supply of sensors. NB the practice should receive communication following this specialist review to confirm success or failure of flash glucose monitoring
6. Ensure the patient receives an ongoing review of flash glucose monitoring as part of their regular diabetes reviews.

Review at 6 months by Specialist Diabetes Team

The following should take place 6 months after initiation

- Check patients are scanning glucose levels at least 8 times a day. NB this should be spread over the day. Libreview.com can be used for this purpose.
- Check patients have reduced the use of BGTS taking into account any defined need for continued use in some patients.
- Check patients have achieved the improvements or benefits stated in the patient contract and agreed at initiation of flash glucose monitoring. Where this was an improvement in HbA1c the following should be seen OR a clinically significant improvement in time in range:

Pre-FlashGM HbA1c (mmol/mol)	Goal HbA1c to continue FlashGM
>100	reduce by at least 15 mmol/mol
70-100	reduce by at least 10 mmol/mol
<70	reduce by at least 5 mmol/mol

- Check patients continue to engage with diabetes care processes including attendance at planned appointments, engagement with training and education, attendance for foot and eye care appointments and annual vaccination (where indicated).
- Record the outcome of the review in patients' medical records and update the agreed audit tool if appropriate. Communicate outcome of the review to the GP practice (see section 9 under specialist responsibilities)

Ongoing reviews by Specialist Diabetes Team or GP Practice (if patient no longer under specialist care) as part of regular planned diabetes review

- Check patients are scanning glucose levels at least 8 times a day. NB this should be spread over the day.
- Check patients have maintained a reduction in use of BGTS taking into account any defined need for continued use in some patients.
- Check patients have maintained the improvements or benefits stated in the patient contract and agreed at initiation of flash glucose monitoring.
- Check patients continue to engage with diabetes care processes including attendance at planned appointments, engagement with training and education, attendance for foot and eye care appointments and annual vaccination (where indicated).
- Record the outcome of the review in patients' medical records.
- Stop prescribing if the patient is no longer benefitting from flash glucose monitoring.

NHSE issued guidance in March 2019 on the national arrangements for the funding of flash glucose monitoring for relevant patients with type 1 diabetes. (https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/)

Prior to this guidance three commissioning policies have been in place since 2018 from the three Area Prescribing Committees in West Yorkshire which were similar but not identical in their criteria for accessing this technology.

The FGS consists of a sensor worn on the upper arm that measures interstitial glucose every minute and a reader device that is scanned over the sensor to get a result. It can produce a near continuous record of measurements which can be accessed on demand. It can also indicate glucose level trends over time.

The FGS is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. The product is classified as a device and received European CE mark certification in August 2014.

The sensors may also be read with an appropriate application on a Smart phone which has near-field communication.

This new technology helps to reduce the burden of finger prick blood tests but there is not any evidence available as yet as to whether it reduces complications and long-term outcomes for diabetic patients.
There is no NICE directive for CCGs to fund this new technology but NICE has undertaken a Medtech innovation briefing [1].

The main points from the evidence are from 5 studies involving 700 people [1]. This includes 2 randomised controlled trials; one that includes people with type 1 diabetes (n=241; the IMPACT study) and the other including people with type 2 diabetes (n=224; the REPLACE study) [1].

Three of the studies reported device accuracy compared with self-monitored blood glucose, with results ranging from 84% to 88% accuracy and from 99% to 100% clinical acceptability, using an error grid. One study reported device accuracy and acceptability of 97% to 99% compared with venous blood sampling [1].

Patients using FreeStyle Libre® experienced less time in hypoglycaemia than patients using SMBG, averaging 1.24 hours per day (SE 0.24) or 38% less time ($p<0.0001$) in hypoglycaemia and 1 hour more per day in euglycaemia ($p=0.0006$). The number of hypoglycaemic events per day reduced by mean of 0.45 (by over 25%; $p<0.0001$) [1].

The limited data available suggests that using FreeStyle Libre® for up to 12 months reduces time spent in hypoglycaemia compared with self-monitoring of blood glucose using finger-prick tests, and reduces the average number of finger-prick blood glucose tests needed [1].

There is limited safety data available on the use of the FGS. The only published study carried out by Bailey et al reported there were no unexpected adverse device effects reported during the clinical study. Finger prick capillary blood glucose monitoring is still advised during periods of rapidly changing levels of interstitial glucose when interstitial glucose levels may not accurately reflect blood glucose levels, if hypoglycaemia or impending hypoglycaemia is reported, or the patient's symptoms do not match the system readings. Three of the studies reported device accuracy compared with self-monitored blood glucose. The investigators concluded that interstitial glucose measurements via the FreeStyle Libre® system were accurate compared with capillary blood glucose reference values, and this accuracy was maintained over 14 days lifespan of the Freestyle Libre® sensor.

Cost effectiveness / resource impact:

There is currently no UK cost-effectiveness data available for FGS to be able to determine whether this new technology is cost-effective for the NHS.

The resource impact depends upon the extent to which improved glucose control through the adoption of FGS translates into fewer complications (hypoglycaemia and the longer term microvascular and macrovascular complications of hyperglycaemia), reduced admissions and reduced use of blood glucose test strips.

NHSE have agreed time limited national funding arrangements for 2019/20 and 2020/21. CCGs will be refunded at each quarter end on the basis of primary care prescribing data from NHSBSA.

In 2019/20 CCGs will be reimbursed £26.03 for each sensor prescribed, less than the actual cost of £35 taking into account the expected savings from reduced requirement to fund blood glucose testing strips. Annual reimbursement of £676.78 per patient. A year's cost of sensors is £910 per patient. The FGS reader is not available on prescription and will be provided free of charge by the manufacturer.

CCGs will be reimbursed up to a maximum of 20% of their type 1 diabetes population (as set out in 2017/18 National Diabetes Audit)

CCG Heads of Medicines Management/Optimisation

Appendix 2 Population Data with LD patients eligible for Flash

WY&H CCG	Mid 2019 ONS Population Estimates	Number of LD patients eligible for Flash	Rate per 1,000 Population
NHS Calderdale CCG	211,455	40	0.189
NHS Greater Huddersfield CCG	246,604	36	0.145
NHS North Kirklees CCG	193,183	28	0.145
NHS Wakefield CCG	348,312	51	0.145
NHS Leeds CCG	793,139	115	0.145
NHS Bradford District and Craven CCG	590,901	60	0.102

Estimated

Real Figures