Midlands and Lancashire
Commissioning Support Unit

Equality Impact and Risk Assessment Stage 2 for Policies

Title of Policy / Strategy:

Policy for Continuous Glucose Monitors (CGM) and Policy for Continuous Sub-Cutaneous Insulin Infusion (CSII) Therapy (Insulin Pump Therapy) updated 10/09/2019

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Midlands and Lancashire Commissioning Support Unit

EQUALITY IMPACT AND RISK ASSESSMENT STAGE 2 ALL SECTIONS MUST BE COMPLETED Guidance is provided in appendix 3 SECTION 1 – DETAILS OF POLICY
Organisation: CCG's that are part of this review: NHS Halton Clinical Commissioning Group NHS Liverpool Clinical Commissioning Group NHS St Helens Clinical Commissioning Group NHS South Sefton Clinical Commissioning Group NHS Southport and Formby Clinical Commissioning Group NHS Warrington Clinical Commissioning Group
Policy Assessment Lead and Contact Details: Michael O'Brien – Project Manager
Directorate/Team: Commissioning
Responsible Director / CCG Board Member for the assessment: Various as policy will be ratified within each CCG.
Policy implementation Date: 2019
Who is involved in undertaking this assessment? Jennifer Mulloy – Equality and Inclusion Business Partner MLCSU Clinical Policy Development and Implementation Group (CPDIG) Virtual Clinical Forum Medicines Management team Communications and Engagement team
Date of commencing the assessment: 18/04/19
Date for completing the assessment: 10/09/2019
EQUALITY IMPACT ASSESSMENT Section 1

Please tick which group(s) this policy will or may impact upon?	Yes	No	Indirectly
Patients, Service Users	x		
Carers or Family			x
General Public		x	
Staff			x
Partner Organisations			x

How was the need for the policy identified? (is it part of a workstream / strategy?)

The policies are part of a suite of policies are being reviewed collaboratively across Merseyside CCGs and Warrington CCG as part of the Clinical Policy Development and Implementation Group (CPDIG). The policies have been identified as low clinical priority. The CCGs have a limited funding resource and therefore has to prioritise services that are commissioned. The CCGs currently give greater priority to life threatening and chronic ill health. The CPDIG are working to identify areas of impact through the changes they make balanced with the need to align eligibility for treatments with best clinical evidence and balancing health resources for the whole population.

The policies are for:

- Continuous Glucose Monitors (CGM)
- Continuous Sub-Cutaneous Insulin Infusion (CSII) Therapy (Insulin Pump Therapy)

Diabetes mellitus is a chronic metabolic disorder caused by insufficient activity of the hormone insulin and a subsequent loss of control of blood glucose levels. There may be a lack of the hormone itself or resistance to its action, or both. Insulin is produced by the beta cells of the pancreas in response to rising blood glucose levels and primarily regulates the metabolism of carbohydrates, but also that of proteins and fats. There are two main types of diabetes mellitus; Type 1 diabetes mellitus is caused by the destruction of insulin-producing cells, leading to an absolute lack of the hormone and requires life-long insulin treatment. Within the policy for Continuous Sub-Cutaneous Insulin Infusion (CSII) Therapy (Insulin Pump Therapy), patients who have had a pancreatectomy and therefore have an absence of insulin are subject to the same eligibility criteria as patients with Type 1 diabetes. Type 2 diabetes mellitus is characterised by insulin resistance and is often associated with obesity.

A number of patients with cystic fibrosis also develop diabetes as a result of build-up of secretions surrounding the pancreas and delayed/blunted 1st phase insulin release.

In Type 1 Diabetes or after pancreatectomy, insulin is administered subcutaneously as injections, or it may be given via an insulin pump as a ‘continuous subcutaneous insulin infusion’ (CSII). 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 is programmed to deliver a continuous ‘background’ insulin infusion to

cover basal insulin requirements, with higher infusion rates triggered by the push of a button at meal times or to correct high blood glucose levels. Basal insulin requirements often vary throughout the 24-hour period and are individualised according to patient need. Insulin boluses may be administered 'immediately', or over a longer period of time according to factors including meal composition.

Insulin pump therapy is recommended by NICE TA151 as a treatment option for some patients with Type 1 Diabetes with the following objectives:

- Improved glycaemic control (reduced HbA1c)
- Reduced rate of hypoglycaemia

Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer.

Regarding Continuous Glucose Monitors (CGM), a patient can see their blood glucose level every few minutes with a CGM. It lets patients see patterns in their levels and warns them if their glucose is too high or low.

A CGM is made up of:

- a sensor – a small device attached to the abdomen – it senses how much glucose is in the fluid under the skin
- a transmitter – attached to the sensor – it sends results to a receiver
- a receiver – a small box that displays your blood glucose level – people can carry this on their belt or in their bag

A sensor usually lasts for 14 days. Some are implanted and worn for 6 months.

The National Institute for Health and Care Excellence (NICE) states there isn't enough evidence to show CGMs are cost-effective enough for everyone with type 1 diabetes.

What are the aims and objectives of the policies?

To provide clinicians and the public with updated policies in line with clinical guidance. To provide consistency across the Merseyside and Warrington area.

To provide clear eligibility criteria across all policies of low clinical priority.

- **Policy for Continuous Sub-Cutaneous Insulin Infusion (CSII) Therapy (Insulin Pump Therapy**

There is currently no policy in place for Continuous Sub-Cutaneous Insulin Infusion.

The future policy contains the proposed criteria:

Minimum eligibility criteria

NICE technology appraisal TA151 on insulin pump therapy states that continuous

subcutaneous insulin pump therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:

- Attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. NICE guidance defines disabling hypoglycaemia as 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.

or

- HbA1c levels have remained high (that is, at 8.5% (69 mmol/mol) or above on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

Insulin pump therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:

- MDI therapy is considered to be impractical or inappropriate, and
- Children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.

Insulin pump therapy is also recommended as a treatment option for patients who have had a pancreatectomy and meet the criteria in NICE TA151.

Insulin pump therapy is also recommended for a small cohort of patients with cystic fibrosis-related diabetes (CFRD), as identified by the Advanced Nurse Practitioner for CFRD / CF specialist team at Liverpool Heart and Chest Hospital. These would be patients whose diabetes is not controlled despite carefully managed multiple daily injections and carbohydrate awareness.

and/or

- At least two hypoglycaemic episodes per day

and/or

- A complete loss of hypoglycaemia awareness

HbA1c is an unreliable measure of glycaemia in patients with CFRD owing to their increased red cell destruction. Guidelines recommend that decisions are not based on HbA1c but are based on glycaemic variability, especially hypoglycaemia.

Insulin pump therapy is not recommended for the treatment of people with type 2 diabetes mellitus.

This policy proposes that all currently available insulin pumps should be available for eligible patients defined above (see table):

Name of Pump	CGM Enabled?	Cost of Pump	Annual Consumables	4-year cost
Roche Accu-Chek insight	No	£2,495	£1,514.64	£8,553.56
Roche Accu-Chek Combo	No	£2,495	£1,300.32	£8,443.27
Medtronic 640G	Yes	£2,995	£1,746	£9,979
Cellnovo	No	Starter kit £1,100	£2,040	£9,430
Omnipod	No	1st year £2,558.20	£2,373.20	£9,677.80
DANA RS	No	£2,595	£1,605.63 (approx.)	£9,083.03
YpsoPump	No	£1,900	£1,068	£6,172
Animas Vibe*	Yes	£2,800	£1,464	£8,656

Table: Commonly used insulin pumps across Merseyside Pump Centres (2018). Insulin pump costs excluding VAT - 2018 financial data provided by UK insulin pump company representatives for (1) & (2) Roche Diabetes Care Ltd, (3) Medtronic Ltd, (4) Cellnovo Ltd, (5) Insulet corporation), (6) Advanced Therapeutics (UK) Ltd and (7) Ypsomed Ltd. Animas data (8) historical (Amimas UK & Ireland) – 2017.

*NB ANIMAS Vibe pumps are being withdrawn so no new patients are to be started on these pumps. Existing patients will be supported until they transfer to an alternative system.

This service will only provide pumps from the agreed list in this policy. Any amendments to this list will need to be approved by the respective CCGs prior to any changes being made. Where one of these pumps is not suitable and the service wishes to use an alternative pump a request must be made via the individual patient commissioning route.

This policy is to be reviewed in conjunction with the Insulin Pump – Service Specification document attached below:

- **Policy for Continuous Glucose Monitors (CGM)**

The current policy from 2014/15:

Not routinely commissioned and only considered if ALL of the following criteria are met:

Type 1 diabetes.

AND

Currently on a sensor augmented continuous subcutaneous insulin pump in strict accordance with NICE appraisal TAG 151.

AND

HbA1c which is equal to or greater than 69 (8.5%) mmol/OR experiencing severe hypoglycaemic attacks which require intervention by a carer.

AND

Selected to use an approved sensor augmented pump system of high specification with a low Mean Absolute Relative Difference (MARD) value.

AND

Managed by a recognised centre of excellence in diabetes (currently using a minimum of 20 continuous infusion pumps per annum).

AND

Motivated to comply with the requirements.

The device should be withdrawn from patients who fail to achieve clinically significant response after 6 months.

All cases will be subject to individual approval by the IFR Team.

The revised, future policy contains the proposed criteria:

Minimum eligibility criteria

Adults with type 1 diabetes

CGM is not routinely commissioned.

CGM will only be considered for patients when the following criteria are met:

Currently using a continuous subcutaneous insulin pump of high specification in strict accordance with NICE appraisal TAG 151 and the local insulin pump policy.

AND

Managed by a recognised adult specialist centre of expertise. This will have a multidisciplinary team comprising a trained diabetes nurse specialist, physician and dietician with all patients trained to

count carbohydrates.

AND

Willing to commit to using CGM at least 70% of the time and to calibrate it as needed.

PLUS

HbA1c ≥75 mmol/mol (9%) that persists despite blood glucose testing at least 10 times a day**

OR

Experiencing more than one severe hypoglycaemic episode a year with no obviously preventable precipitating cause. (Severe hypoglycaemia is generally recognised as hypoglycaemia involving convulsions/ unconsciousness)

OR

Experiencing more than 2 episodes of hypoglycaemia per week that the patient has been unable to manage themselves and are causing problems with daily activities.

OR

Complete loss of awareness of hypoglycaemia

OR

Inability to recognise or communicate about symptoms of hypoglycaemia e.g. because of cognitive or neurological disabilities where other forms of glucose monitoring are not appropriate.

Pregnancy

CGM is not routinely commissioned in pregnancy unless all criteria for CGM in adults are met. Where CGM in pregnancy is used, funding is **only** for the duration of the pregnancy. Insulin doses are reduced to pre-pregnancy levels as soon as the baby is delivered and CGM should not be continued beyond this point.

FOR ALL PATIENTS

A CGM system with a low Mean Absolute Relative Difference (MARD) value should be chosen.

Where there is a CGM system with alarm function that will integrate and communicate directly with the patient's established insulin pump, then this CGM system should generally be used. However, an appropriate real-time Dexcom CGM system with alarm function may be considered for patients using other insulin pumps, or those individuals where the integrated system is not the most clinically appropriate CGM system.

The device should be withdrawn from patients who fail to achieve a clinically significant response after 6 months*.

There should also be an annual review to assure the clinically significant response is

maintained and that CGM is still the most appropriate method of glucose monitoring for the patient.

Consideration should be given to switching to an integrated insulin pump/CGM system when seeking to replace the insulin pump at warranty expiry, if appropriate.

Children and young people with type 1 diabetes

CGM is not routinely commissioned.

CGM will only be considered for patients when the following criteria are met:

Currently using a continuous subcutaneous insulin pump of high specification, in strict accordance with NICE appraisal TAG 151 and the local insulin pump policy.

AND

When provided by a specialist centre with a multidisciplinary team including an active member who attends at least 67% (2/3) of the North West children and young people's diabetes network meetings. In addition, the specialist centre is achieving best practice tariff in paediatric diabetes and is also engaged with the national peer review programme in paediatric diabetes, to monitor the quality of its service.

AND

Willing to commit to using CGM at least 70% of the time and to calibrate it as needed.

PLUS

Experiencing more than 2 episodes per week of severe hypoglycaemia. This is defined as having low blood glucose levels that require assistance from another person to treat and that are happening often enough to have a significant impact on school work or quality of life.

OR

Inability to recognise or communicate about symptoms of hypoglycaemia e.g. because of cognitive or neurological disabilities, or less than 4 years of age.

OR

Impaired awareness of hypoglycaemia which is associated with significant adverse consequences e.g. seizures or severe anxiety.

Prior to transition to adult services, the child should be counselled on the transition process and advised that their CGM will be reviewed as part of the transition and their ongoing adult diabetes care. On transition to adult services there should be a review to assure there is still a clinically significant response* and that CGM is still the most appropriate method of glucose monitoring for the patient.

Ongoing continuation of CGM

* A clinically significant response is considered to be:

- When the patient demonstrates wearing the sensor for at least 70% of the time.

PLUS

- A reduction in the frequency and/or severity of hypoglycaemic episodes.

OR

- A reduction in the need for third party intervention during hypoglycaemic episodes.

AND/OR

- Achievement of a clinically significant reduction in HbA1c, that demonstrates the patient is moving towards their individually agreed HbA1c target.

**Where CGM is initiated due to hyperglycaemia in adults, it should only be continued longer-term if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more, in accordance with NICE CG17

Update following meeting on 2/9/2019:

Revision proposed regarding time of using *3 months with an insulin pump to have lapsed with supporting clinical assessment to determine that a CGM device is appropriate.* This change is a deviation from the previous policy wording that was subject to engagement work.

What evidence have you considered as part of the Equality Impact Assessment?

- Demographic profile information on the areas is available.
- https://www.nhs.uk/conditions/diabetes/
- https://www.nhs.uk/conditions/type-1-diabetes/insulin-pumps/
- https://www.nhs.uk/conditions/type-1-diabetes/continuous-glucose-monitoring-cgms/
- https://www.diabetes.org.uk/ramadan
- NHS England guidance on monitoring devices: https://www.england.nhs.uk/wp-content/uploads/2019/03/flash-glucose-monitoring-national-arrangements-funding.pdf
- Local data on diabetes and sugar levels at GP level:

http://fingertips.phe.org.uk/profile/general-practice

Clinical guidance:

- NICE guidance on Type 1 diabetes in adults – diagnosis and management: https://www.nice.org.uk/guidance/ng17
- NICE guidance on Type 2 diabetes in adults - management: https://www.nice.org.uk/guidance/ng28

Are there any identified health inequalities relating to this decision? If so, please summarise these:

No health inequalities identified specific to this policy.

SECTION 2

In this section you will need to consider:

What activities you currently do that help you to comply with the Public-Sector Equality Duty (three aims).

Will your policy affect your ability to meet the Public-Sector Equality Duty?

How you will mitigate any adverse impact?

- Eliminate, unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Act;
- Advance equality of opportunity between people who share a protected characteristic and those who do not;
- Foster good relations between people who share a protected characteristic and those who do not.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Does the policy provide an opportunity to eliminate discrimination, harassment and victimisation? What do we mean? Unlawful discrimination takes place when people are treated 'less favourably' as a result of having a protected characteristic. Harassment is unwanted conduct (including a wide range of behaviours) because of or connected to a protected characteristic. Victimisation is where one-person subjects another to a detriment because they have acted to protect someone under the act. (e.g. bullied for reporting discrimination / harassment for a work colleague with a protected characteristic)	x	

Explanation:

The CPDIG considers any impact of change on different patient groups (considering those in protected groups).

The policy group are aligning policies to create improved consistency across decision making within the area.

A range of information has been used within this assessment and engagement with the public is being conducted to help identify any potential impact on patients / staff.

The ingredients of insulin products have been queried with the Medicines Management team. The majority of insulin products are now synthetic. Where ingredients would cause a cultural / religious concern, this would be discussed.

Update following meeting on 2/9/2019:

Proposed change to introduce a 3 month period with an insulin pump to have lapsed with supporting clinical assessment to determine that a CGM device is appropriate may delay (and not stop) access to CGM. This assessment would recommend that this change is subject to engagement work to assess the impact.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Does the policy provide an opportunity to advance equality of opportunity between people who share a protected group and those who don't share it? What do we mean? Equality of opportunity is about making sure that people are treated fairly and given equal access to opportunities and resources. Promoting is about: • Encouraging people/services to make specific arrangements • Take action to widen participation • Marketing services effectively • Remove or minimise disadvantages • Take steps to meet different needs • Securing special resources for those who may need them	x	

Explanation:

Equality of opportunity has been considered as part of the equality impact assessment process.

Due to some changes in the criteria of this policy, it has been shared with the public and engagement feedback has been sought through a questionnaire- on line and paper version alongside focus groups. This has been carried out in order to understand any potential impact from the revised criteria.

The policy has undergone engagement with providers and clinicians to ensure that criteria is based on best clinical advice and guidance.

Update following meeting on 2/9/2019:

Proposed change to introduce a 3 month period with an insulin pump to have lapsed with supporting clinical assessment to determine that a CGM device is appropriate may delay (and not stop) access to CGM. This assessment would recommend that this change is subject to engagement work to assess the impact.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Does the policy provide an opportunity to Foster Good Relations between people who share a protected characteristic and those who don't share it? What do we mean? Foster Good Relations between people: This is about bringing people from different backgrounds together by trying to create a cohesive and inclusive environment for all. This often includes tackling prejudice and promoting understanding of difference. • Tackle prejudice • Promote understanding • Could the policy create any issues for Community cohesion (will it impact certain communities compared to others and how this be managed?)	x	

Explanation:

The revised policy has been subject to engagement and the communication and communication plan has included sharing the policy with different parts of the community.

Update following meeting on 2/9/2019:

This assessment would recommend that this change is subject to engagement work to assess the impact of changes to introduce a 3 month period that a patient should be on an insulin pump before GCM is considered.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Has engagement/involvement or consultation been carried out with people who will be affected by the policy?	x	

Explanation:

Engagement work is having been carried out on this policy as part of a suite of 6 polices. For this policy, for Insulin Pump policy, there was 37 responses. For CGM devices where were also 37 responses.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Has the engagement/involvement or consultation highlighted any inequalities?		x

Explanation:

The engagement did not highlight any inequalities.

Update following meeting on 2/9/2019:

This assessment would recommend that this change is subject to engagement work to assess the impact of changes to introduce a 3 month period that a patient should be on an insulin pump before GCM is considered.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Have you added an Equality Statement to the Policy? Example statement: Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have given regard to the need to • eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and • reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities • make reasonable adjustments when necessary	x	

Explanation:

The policy introduction section contains reference to equality legislation.

All the policy review meetings contain an 'equality and inclusion' agenda item where any issues can be raised and discussed.

Ongoing EIA content is shared and discussed with the CPDIG group.

SECTION 3

Does the 'policy' have the potential to:

- Have a positive impact (benefit) on any of the equality groups?
- Have a negative impact / exclude / discriminate against any person or equality groups?
- Have a neutral / potential indirect effect on any equality groups?
- Explain how this was identified? Evidence/Consultation?
- Who is most likely to be affected by the proposal and how (think about barriers, access, effects, outcomes etc.)

Guidance document available on Equality Groups and their issues. This document may help and support your thinking around barriers for the equality groups.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Age	x		

Explanation:

Approximately 400,000 people are currently living with type 1 diabetes in the UK, of this figure, over 29,000 are children. Although it used to be referred to as 'juvenile diabetes', around half of newly diagnosed cases are in people over the age of 18. A person with type 1 diabetes will have around 65,000 injections and measure their blood glucose over 80,000 times in their lifetime.

Insulin pumps are small devices that send insulin through a fine plastic tube that runs from the pump to a cannula inserted underneath the skin - therefore removing the need for self-injection. As the need for self-injection is removed, insulin pumps prevent bruising and associated rashes and spots that can affect injection sites. Feedback from young people on a Diabetes UK forum notes that insulin pumps were helpful in controlling blood sugars throughout the school day, and were particularly useful during school exam periods.

Similarly, continuous glucose monitoring could be positive for patients across age groups who are not managing their glucose levels well – this may be particularly beneficial for young people due to lifestyle (for example during a school day) and older age groups, who may experience age-related memory loss and therefore possibly struggle to manage glucose monitoring.

In respect to children, the insulin pump policy states: Insulin pump therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:

- MDI therapy is considered to be impractical or inappropriate, and

- Children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.

Engagement responses were collated for the suite of policies. Monitoring responses of 87 people disclosing age, shows that largest age group giving responses are aged over 45.

Engagement work did not highlight any impacts regarding this group.

Update following meeting on 2/9/2019:

This assessment would recommend that this change is subject to engagement work to assess the impact of changes to introduce a 3 month period that a patient should be on an insulin pump before GCM is considered.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Disability	x		

Explanation:

Type 1 diabetes is a long-term condition that requires ongoing monitoring and treatment.

Access to insulin pump therapy and continuous glucose monitoring may have positive effects for people living with type 1 diabetes as it will help them manage their condition – for example, management of diabetes will no longer require relying on memory to test and record glucose level.

Poor management of diabetes can be life threatening. Effective monitoring and management of type 1 diabetes will help to mitigate health complications that are linked to the condition, such as eye sight loss, podiatry problems, nerve damage, kidney problems, heart problems, and circulation problems.

The insulin pump therapy policy notes that patients with cystic fibrosis are at risk of developing diabetes as a result of build-up of secretions surrounding the pancreas and delayed 1st phase insulin release. Effective diabetes monitoring will have a positive impact for this cohort of patients.

The policy – for Insulin Pumps is aligned to the NICE TAG 151 and also includes criteria for patients with pancreatectomy and cystic fibrosis.

Additional support may be required to assist people experiencing physical, sensory or cognitive impairment in the use of insulin pump therapy / continuous glucose monitors.

The pumps are not be available to patients with type 2 diabetes. Type 2 diabetes is not included as a criteria due to the current NICE technology appraisal TA151 on insulin pump therapy states that continuous subcutaneous insulin pump therapy is recommended as a

treatment option for adults and children 12 years and older with type 1 diabetes mellitus.

Engagement feedback has been received from a significant number of people disclosing a disability 42.6%.

Engagement feedback did not raise any significant concerns in regards to disability. There is some feedback where 4 people don't feel that the policy is aligned to NICE and that the decision should not be via a policy but through a consultant – as previously determined before the policy was developed. This issue refers to NG17 – extreme fear of hypoglycaemia and including wording of the NICE guidance.

In regards to organisational responses, North West Adult and Paediatric Neuromuscular Network suggested changing 'neuromuscular diseases such as ALS' to 'muscle wasting disease.'

Engagement concerns were shared and discussed at the policy development group meeting on the 2/9/2019.

Update following meeting on 2/9/2019:

This assessment would recommend that this change is subject to engagement work to assess the impact of changes to introduce a 3 month period that a patient should be on an insulin pump before GCM is considered.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Sexual Orientation			x

Explanation:

Currently, no direct impact has been found on this group.

Engagement monitoring of responses show that the majority of people were heterosexual (83%) 2 % disclosed they were gay, and rest preferred not to say.

Further engagement work did not highlight any impacts on this group.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Gender Reassignment			x

Explanation:

Currently, no direct impact has been found on this group. There is no available data specifically regarding type 1 diabetes and gender reassignment.

Further engagement work did not highlight any impacts on this group.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Sex (Gender)			x

Explanation:

The policies do not restrict insulin pump therapy and continuous glucose monitoring on the basis of sex therefore no direct impact identified.

Monitoring of engagement work shows that 64.7% are female and 26% males. (rest did not disclose). Engagement work did not highlight any impacts on this group.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Race			x

Explanation:

JDRF advises that type 1 diabetes is an autoimmune condition, however currently there is no clear understanding of the precise causes of the condition (https://jdrf.org.uk/information-support/about-type-1-diabetes/causes-of-type-1-diabetes/).

Race has not been identified as a factor in the prevalence of type 1 diabetes (race is a risk factor for type 2 diabetes; however this is outside of the scope of the proposed policies), therefore, no direct impact has been found on this group.

In terms of using insulin pump therapy / continuous glucose monitoring, older patients from BME backgrounds may have language support needs when learning to use devices.

Monitoring of engagement work shows that 82.9% were white British. 12.5% are BME backgrounds. Engagement work did not highlight any impacts on this group.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Religion or Belief			x

Explanation:

No direct impact has been found regarding the use of insulin pump therapy and/or continuous glucose monitors – the policies do not restrict usage of these devices on religion or belief grounds.

Available research highlights that religious beliefs / practices can impact a patient with type 1 diabetes, such as during periods of fasting e.g. Ramadan. Health advice notes that patients with health conditions are exempt from fasting.

The ingredients used in insulin therapy products have been queried as part of this assessment as some insulin products were previously made from animal products would directly impact patients on basis of religion or belief. The response from the Medicines Management team confirms that with one exception they are all 'Human' insulins now i.e. derived synthetically. The only exception is Hypurin which has both a pork and beef version. This is unlikely that Hypurin is used much due to new human insulin alternatives which are much cheaper. It is likely to be ongoing for existing patients who don't want to change. New patients will never be put on it.

Monitoring of engagement work shows that 54% were Christian – representing the largest group. 12.5% are BME backgrounds. Engagement work did not highlight any impacts on this group.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Pregnancy and Maternity			x

Explanation:

No direct impact has been found on this group. Insulin pump therapy / continuous glucose monitoring is safe to use during pregnancy.

The policy for continuous glucose monitors states:

Pregnancy

*CGM is not routinely commissioned in pregnancy unless all criteria for CGM in adults are met. Where CGM in pregnancy is used, funding is **only** for the duration of the pregnancy. Insulin doses are reduced to pre-pregnancy levels as soon as the baby is delivered and CGM should not be continued beyond this point.*

Query made to Medicines Management team on the basis of this criteria of which sought advice from Consultant regarding use of CGM during Maternity period and rationale as to why funding is only for the duration of pregnancy due to information from Diabetes UK:

Diabetes and breastfeeding page on Diabetes.co.uk states that diabetes can affect the ability to produce milk, but if blood glucose is well controlled, there should not be any issue (https://www.diabetes.co.uk/pregnancy/diabetes-and-breastfeeding.html)

Response from Consultant:

"As soon as the baby is delivered, insulin doses are reduced to pre-pregnancy levels. Post-delivery we no longer aim for such strict control as this no longer impacts on the pregnancy. Glycaemic targets are the same as for non-pregnancy. It is true that breast feeding can interfere with blood glucose levels, but I do not ask for CGM to cover any breast feeding period when I complete the IFR requests (this could extend up to a year or more).

I think the reality is that women will likely have a few sensors left over at the end of pregnancy – they would usually be prepared in the weeks leading up to delivery and would order plenty of sensors to cover the last part of the pregnancy. I think this would be sensible and important in case sensors fell out or stopped working in labour, for example.

I would advise patients that they should not order any more sensors after the baby has been born and to use the remainder wisely. I think most patients would have a few spare to use up."

NICE guidance advises that women with insulin-treated pre-existing diabetes "should reduce their insulin immediately after birth and monitor their blood glucose levels carefully to establish the appropriate dose".

NICE guidance also states that women with insulin-treated pre-existing diabetes are at increased risk of hypoglycaemia in the postnatal period, especially when breastfeeding (source: https://www.nice.org.uk/guidance/ng3/chapter/1-Recommendations#postnatal-care-2)

Monitoring of engagement work indicates a low number of people that had recently given birth / currently pregnant – 1%. Engagement work did not highlight any adverse impacts.

Update following meeting on 2/9/2019:

This assessment would recommend that this change is subject to engagement work to assess the impact of changes to introduce a 3 month period that a patient should be on an insulin pump before GCM is considered.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Marriage and Civil Partnership			x

Explanation:

No impact has been found on this group.

This group is protected in relation to employment – not service provision.

Engagement work did not highlight any adverse impacts in relation to this group.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Carers	x		

Explanation:

The proposed criteria may have a positive impact on carers as insulin pump therapy / continuous glucose monitors may remove stress associated with assisting patients to accurately monitor and record glucose levels. Compared to traditional monitoring methods involving strip testing, insulin pump therapy and continuous glucose monitoring may also reduce time that carers spend in assisting monitoring, which may also be a positive impact.

Carers should be supported in learning how to use monitoring devices in order to use them effectively with patients.

Engagement work did not highlight any adverse impacts in relation to this group.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Deprived Communities	X – possible (see explanation)		x

Explanation:

No direct impact currently identified. There is no clear understanding of the causes of type 1 diabetes, and no link of prevalence to deprivation.

Emerging research has highlighted that there is a link between the monitoring and management of type 1 diabetes and socio-economic status. A study has found that people with type 1 diabetes living in deprived areas were more likely to have higher blood glucose levels compared with people from more affluent areas (https://www.diabetes.co.uk/news/2019/mar/deprivation-linked-to-poor-blood-glucose-control-in-type-1-diabetes-97428963.html) Using this insight, for patients with poorly managed diabetes, this intervention would be positive.

Engagement work did not highlight any adverse impacts.

Update following meeting on 2/9/2019:

This assessment would recommend that this change is subject to engagement work to assess the impact of changes to introduce a 3 month period that a patient should be on an insulin pump before GCM is considered.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Vulnerable Groups e.g. Asylum Seekers,	x		x

Homeless, Sex Workers, Military Veterans, Rural communities **Driving occupations**			

Explanation:

Asylum seekers living with type 1 diabetes may have a poorly managed condition due to their background (e.g. travelling from countries where access to healthcare may have been compromised).

DVLA guidance published in March 2019 regarding assessing fitness to drive makes reference to diabetes monitoring:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/783444/assessing-fitness-to-drive-a-guide-for-medical-professionals.pdf

The guidance provides information on driving occupation groups where glucose monitoring systems are not permitted – such as bus / haulage driving roles. This guidance may impact some patients' choices in terms of available treatment.

Engagement work did not highlight any adverse impacts.

SECTION 5: HUMAN RIGHTS ASSESSMENT

How does this policy affect the rights of patients set out in the NHS Constitution or their Human Rights?

No Human Rights concerns identified.

SECTION 6: RISK ASSESSMENT

See guidance and table of risks in appendix 3 section 6 for step by step guidance for this section

RISK MATRIX

	Risk level				
Consequence level	**RARE 1**	**UNLIKELY 2**	**POSSIBLE 3**	**LIKELY 4**	**VERY LIKELY 5**
1. Negligible	**1**	**2**	**3**	**4**	**5**
2. Minor	**2**	**4**	**6**	**8**	**10**
3. Moderate	**3**	**6**	**9**	**12**	**15**
4. Major	**4**	**8**	**12**	**16**	**20**
5. Catastrophic	**5**	**10**	**15**	**20**	**25**

Consequence Score: **Likelihood Score:** **Risk score = consequence x likelihood**	**9**
Any comments / records of different risk scores over time (e.g. reason for any	**4 (July)**

change in scores over time): Increase in risk as change in policy to introduce a 3 month period that a patient should be on an insulin pump before GCM is considered. No engagement has been carried out on this criteria and this may effectively delay treatment of GCM device. Further clinical assurance for this change would be helpful in assessing the impact.	**12 (10/9/2019) N/A**

Important: If you have a risk score of 9 and above you should escalate to the organisations risk management procedures.

EQUALITY IMPACT AND RISK ASSESSMENT AND ACTION PLAN

Risk identified	Actions required to reduce / eliminate the negative impact	Resources required *(see guidance below)	Who will lead on the action?	Target date
Engagement	Pre engagement stage 2 assessment identifies that engagement work is required.		Comms and Engagement	July 2019 – working around Purdah.
Religion / belief query	Clarify whether CGM/Insulin Pump Therapy contains any animal products due to potential impact linked to religion / belief		E&I team	May 2019
Potential disadvantage relating to Maternity?	Query rationale why, when CGM funding is commissioned during pregnancy, funding is only for the duration of the pregnancy		E&I team	May 2019
Potential disadvantage for people with diabetes and fear of needles	Potential non alignment with NICE guidance – pregnancy / needle phobia – discussed 02/09/2019.		Development group	August 2019
02/09/2019 new policy amendment	Engagement and clinical justifications would help		Development	Before

to introduce a 3 month period that a patient should be on an insulin pump before GCM is considered.	assess the level of impact.		group	ratification

'Resources required' is asking for a summary of the costs that are needed to implement the changes to mitigate the negative impacts identified

SECTION 7 – EQUALITY DELIVERY SYSTEM 2 (EDS2)

Please go to Appendix 1 of the EIRA and tick the box appropriate EDS2 outcome(s) which this policy relates to. This will support your organisation with evidence for the Equality and Inclusion annual equality progress plan and provide supporting evidence for the annual Equality Delivery System 2 Grading

SECTION 8 – ONGOING MONITORING AND REVIEW OF EQUALITY IMPACT RISK ASSESSMENT AND ACTION PLAN

Please describe briefly, how the equality action plans will be monitored through internal governance processes?

CPDIG processes and regular meetings to ensure equality related information has been shared and informs decision making.

Internal governance processes within each CCG will oversee the implementation of the revised policy.

Date of the next review of the Equality Impact Risk Assessment section and action plan?

Review dates to be decided by individual CCG as part of their governance processes.

SECTION 9

FINAL SECTION

Date completed: 23/04/2019

Date received for quality check: 10/09/2019

Signature of person completing the assessment: *Gemma Aspinall and Jennifer Mulloy*

Date reviewed by Equality and Inclusion Team: 10/09/2019

Signature and Date quality check completed by Equality and Inclusion Team:

Jennifer Mulloy – 10/09/2019
Date signed off by CCG / CSU Committee: TBA

Appendix 1: Equality Delivery System 2:

APPENDIX 1: The Goals and Outcomes of the Equality Delivery System			Tick box(s) below
Objective	**Narrative**	**Outcome**	
1. Better health outcomes	The NHS should achieve improvements in patient health, public health and patient safety for all, based on comprehensive evidence of needs and results	**1.1** Services are commissioned, procured, designed and delivered to meet the health needs of local communities	**x**
		1.2 Individual people's health needs are assessed and met in appropriate and effective ways	**x**
		1.3 Transitions from one service to another, for people on care pathways, are made smoothly with everyone well-informed	
		1.4 When people use NHS services their safety is prioritised and they are free from mistakes, mistreatment and abuse	**x**
		1.5 Screening, vaccination and other health promotion services reach and benefit all local communities	
2. Improved patient access and experience	The NHS should improve accessibility and information, and deliver the right services that are targeted, useful, useable and used in order to improve patient experience	**2.1** People, carers and communities can readily access hospital, community health or primary care services and should not be denied access on unreasonable grounds	**x**
		2.2 People are informed and supported to be as involved as they wish to be in decisions about their care	**x**
		2.3 People report positive experiences of the NHS	
		2.4 People's complaints about services are handled respectfully and efficiently	
3. A representative	The NHS should increase the diversity	**3.1** Fair NHS recruitment and selection processes lead to a more representative workforce at all levels	

and supported workforce	and quality of the working lives of the paid and non-paid workforce, supporting all staff to better respond to patients' and communities' needs	**3.2** The NHS is committed to equal pay for work of equal value and expects employers to use equal pay audits to help fulfil their legal obligations	
		3.3 Training and development opportunities are taken up and positively evaluated by all staff	
		3.4 When at work, staff are free from abuse, harassment, bullying and violence from any source	
		3.5 Flexible working options are available to all staff consistent with the needs of the service and the way people lead their lives	
		3.6 Staff report positive experiences of their membership of the workforce	
4. Inclusive leadership	NHS organisations should ensure that equality is everyone's business, and everyone is expected to take an active part, supported by the work of specialist equality leaders and champions	**4.1** Boards and senior leaders routinely demonstrate their commitment to promoting equality within and beyond their organisations	**x**
		4.2 Papers that come before the Board and other major Committees identify equality-related impacts including risks, and say how these risks are managed	**x**
		4.3 Middle managers and other line managers support their staff to work in culturally competent ways within a work environment free from discrimination	