Insulin Pumps and Glucose Monitors in Adults, Children and Young People Policy

Version:	2017-20
Ratified by:	NHS Leeds West CCG Assurance Committee on; 16 November 2016 NHS Leeds North CCG Governance on Performance and Risk Committee on; 17 November 2016 NHS Leeds South and East CCG Governance and Risk Committee on 13 November 2016
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Date issued:	July 2017
Review date:	September 2020
Target audience:	Primary and secondary care clinicians, individual funding request panels, and the public
Document History:	Leeds CCGs Targeted Interventions Policy Feb 2014 Leeds insulin pumps and glucose monitors 2016 (adults)

Produced on behalf of NHS Leeds West Clinical Commissioning Group, NHS Leeds North Clinical Commissioning Group and NHS Leeds South and East Clinical Commissioning Group

Executive Summary

This policy applies to all Individual Funding Requests (IFR) for people registered with General Practitioners in the following three Clinical Commissioning Groups (CCGs), where the CCG is the responsible commissioner for this treatment or service:

- NHS Leeds West CCG
- NHS Leeds North CCG
- NHS Leeds South and East CCG

This policy does not apply where any one of the Leeds CCGs is not the responsible commissioner.

The policy updates all previous policies and must (where appropriate) be read in association with the other relevant Clinical Commissioning Groups in Leeds commissioning policies, which are to be applied across all three CCGs, including but not limited to policies on cosmetic exceptions and non-commissioned activity.

All IFR and associated policies will be publically available on the Internet for each CCG.

This policy relates specifically to insulin pumps and glucose monitors in adults, children and young people.

Contents

1 Introduction

The Clinical Commissioning Groups (CCGs) (NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG) were established on 1 April 2013 under the Health and Social Care Act 2012 as the statutory bodies responsible for commissioning services for the patients for whom they are responsible in accordance with s3 National Health Service Act 2006.

As part of these duties, there is a need to commission services that are evidence based, cost effective, improve health outcomes, reduce health inequalities and represent value for money for the taxpayer. The CCGs in Leeds are accountable to their constituent populations and Member Practices for funding decisions.

In relation to decisions on Individual Funding Requests (IFR), the CCGs in Leeds have a clear and transparent process and policy for decision-making. They have a clear CCG specific appeals process to allow patients and their clinicians to be reassured that due process has been followed in IFR decisions made by the Non Commissioned Activity Panel, Cosmetic Exclusions and Exceptions Panel, or Non NICE Non Tariff Drug Panel (the IFR panels).

Due consideration must be given to IFRs for services or treatments which do not form part of core commissioning arrangements, or need to be assessed as exceptions to Leeds CCGs Commissioning Policies. This process must be equitably applied to all IFRs.

All IFR and associated policies will be publically available on the Internet for each CCG. Specialist services that are commissioned by NHS England or Public Health England are not included in this policy.

2 Purpose

The purpose of the IFR policy is to enable officers of the Leeds CCGs to exercise their responsibilities properly and transparently in relation to IFRs, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions in relation to IFRs are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCGs.

The policy outlines the process for decision making with regard to services/treatments which are not normally commissioned by the CCGs in Leeds, and is designed to ensure consistency in this decision making process.

The policy is underpinned by the following key principles:

- The decisions of the IFR panels outlined in the policy are fair, reasonable and lawful, and are open to external scrutiny.

- Funding decisions are based on clinical evidence and not solely on the budgetary constraints.
- Compliance with standing financial instructions / and statutory instruments in the commissioning of healthcare in relation to contractual arrangements with providers.

Whilst the majority of service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the National Health Service (NHS). This may be due to advances in medicine or the introduction of new treatments and therapies or a new cross-Leeds Clinical Commissioning Group statement. The IFR process therefore provides a mechanism to allow drugs/treatments that are not routinely commissioned by the Leeds CCGs to be considered for individuals in exceptional circumstances.

3 Scope

Leeds CCGs *do not routinely commission* aesthetic (cosmetic) surgery and other related procedures that are medically unnecessary.

Policy development and review: consultation and engagement

The policy was developed to:

- Ensure a clear and transparent approach is in place for exceptional/individual funding request decision making; and
- Provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner.

It was originally developed in line with NICE or equivalent guidance where this was available or based on a review of scientific literature. This included engagement with hospital clinicians, general practice, CCG patient advisory groups, and the general public cascaded through a range, mechanisms.

The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy

Providing certain criteria are met, Leeds CCGs will commission aesthetic (cosmetic) surgery and other procedures to improve the functioning of a body part or where medically necessary even if the surgery or procedure also improves or changes the appearance of a portion of the body.

Please note that, whilst this policy addresses many common procedures, it does not address all procedures that might be considered to be cosmetic. Leeds CCGs reserve the right not to commission other procedures considered

Cosmetic and not medically necessary. This policy is to be used in conjunction with the Individual Funding Requests (IFR) Policy for Leeds CCGs and other related policies.

The CCGs in Leeds have established the processes outlined in this policy to consider and manage IFRs in relation to the following types of requests:

This policy relates specifically to insulin pumps and glucose monitors in adults and children.

Leeds CCGs routinely commission interventional procedures where National Institute for Health and Care Excellence (NICE) guidance arrangements indicate "normal" or "offered routinely" or "recommended as option(s)" and the evidence of safety and effectiveness is sufficiently robust.

Leeds CCGs *do not* routinely commission interventional procedures where NICE guidance arrangement indicates "special", "other", "research only" and "do not use".

The commissioning statements for individual procedures are the same as those issued by NICE. (www.nice.org.uk).

An individual funding request (IFR) may be submitted for a patient who is felt to be an exception to the commissioning statements as per the Individual Funding Request Policy.

The CCGs accept there are clinical situations that are unique (five or fewer patients) where an IFR is appropriate and exceptionality may be difficult to demonstrate.

Whilst the Leeds CCGs are always interested in innovation that makes more effective use of resources, in year introduction of a procedure does not mean the CCGs will routinely commission the use of the procedure.
An individual funding request is not an appropriate mechanism to introduce a new treatment for a group or cohort of patients. Where treatment is for a cohort larger than five patients, that is a proposal to develop the service, the introduction of a new procedure should go through the usual business planning process. CCGs will not fund interventional procedures for cohorts over 5 patients introduced outside a business planning process.

Endpoints

Following completion of the agreed treatment, a proportionate follow up process will lead to a final review appointment with the clinician where both patient and clinician agree that a satisfactory end point has been reached. This should be at the discretion of the individual clinician and based on agreeing reasonable and acceptable clinical and/ or cosmetic outcomes.

Once the satisfactory end point has been agreed and achieved, the patient will be discharged from the service.

Requests for treatment for unacceptable outcomes post treatment will only be considered through the Individual Funding Request route. Such requests will only be considered where a) the patient was satisfied with the outcome at the time of discharge and b) becomes dissatisfied at a later date. In these circumstances the patient is not automatically entitled to further treatment. Any further treatment will therefore be at the relevant Leeds Clinical Commissioning Group's discretion, and will be considered on an exceptional basis in accordance with the IFR policy.

Leeds CCGs are committed to supporting patients to stop smoking in line with NICE guidance in order to improve short and long term patient outcomes and reduce health inequalities. Referring GPs and secondary care clinicians are reminded to ensure the patient is supported to stop smoking at every step along the elective pathway and especially for flap based procedures (in line with plastic surgery literature: abdominoplasty, panniculectomy, breast reduction, other breast procedures).

4 Definitions

The CCGs in Leeds are not prescriptive in their definitions. Each IFR will be considered on its merits, applying this Policy.

Routinely commissioned – this means that this intervention is routinely commissioned as outlined in the relevant policy, or when a particular threshold is met. Prior approval may or may not be required, refer to the policy for more information.

Exceptionality request – this means that for a service which is not routinely commissioned, or a threshold is not met, the clinician may request funding on the 'grounds of exceptionality' through the individual funding request process. Decisions on exceptionality will be made using the framework defined in the overarching policy 'Individual Funding Requests (IFR) Policy for the Clinical Commissioning Groups in Leeds'.

5 Duties

Whilst this policy and associated decision making policies will be applied on a cross- Leeds basis for patients from all three CCGs in Leeds, each individual CCG will retain responsibility for the decision making for its own patients. To this end, each CCG will delegate its decision-making in relation to IFRs to a CCG specific decision maker for patients from that specific CCG, in accordance with its own Constitution.

This decision maker will attend the relevant IFR panel and will also have responsibility for approving the triage process for patients from their own CCG population. The triage process is the process of screening requests to see whether the request meets the policy criteria and which referrals need to be considered by an IFR panel; see sections on IFR panels for more information. The decision maker for each CCG is responsible for decision making solely for patients within their own CCG registered population. This

will normally be the Medical Director or their designate. This will be detailed in the CCG Constitution as an Appendix.

In exceptional circumstances, when a CCG is unable to send a delegated decision maker to the IFR panel, the panel may discuss the case in their absence and may make a recommendation. However, the decision maker for the specific CCG must make the final decision whether or not to approve the IFR.

6 Main Body of Policy

Exceptionality funding can be applied for in line with the overarching policy through the IFR process if you believe your patient is an exception to the commissioning position. Please refer to the overarching policy for more information.

Insulin pumps and or monitors in adults, children and young people are routinely commissioned in the following circumstances. In other circumstances may be approved by exceptionality approval process.

6.1 Insulin pump therapy (without Continuous Glucose Monitoring System (CGMS))

6.1.1 Type 1 diabetes when complying with NICE TA151 for adults and Children over the age of 12 years

6.1.2 Type 1 diabetes patients with gastroparesis (as per NICE NG17: 1.15.26):

6.1.3 Insulin-treated diabetes (of whatever type) in pregnancy when complying with NICE NG3:
Then Review post-delivery:
(i) if type 1 diabetes and complies with other NICE guidance then continue
(ii) if not type 1 diabetes and not gestational diabetes, but planning further pregnancy then consider continuing for duration of already purchased pump contract.
(iii) If not type 1 diabetes, and no plans for further pregnancy, then stops pump therapy. Ensure pump and remaining period of contract can be used by a different patient.

6.1.4 Patients with non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production (e.g. cystic fibrosis-related diabetes, post-pancreatic destruction, post-pancreatectomy diabetes): Where these patients fulfill NICE TA151 in every regard other than having type 1 diabetes.

6.1.5 For Children less than 12 years with Type 1 diabetes, insulin pump therapy is indicated as possible treatment when multiple daily injections are not practical or not considered appropriate.

6.2 Insulin pump therapy with CGMS

In type 1 diabetes in used in line with NG17, NG18, QS 125 and DG21: Offer CGMS (i.e. sensor-augmented pump therapy) to patients on insulin pump who continue to have severe hypoglycemia despite good self-care and use of insulin pump therapy.

6.2.1 In type 1 diabetes use in line with NG17 This intervention will only be continued if it addresses the specific NICE indication. The circumstances/indications are:

- More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycaemia.
- Frequent (more than 2 episodes a week) significant hypoglycaemia that is causing problems with daily activities.
- Hypoglycaemia associated with extreme fear of further and severe hypoglycaemia.

- Hyperglycemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. In this case, continue real-time continuous glucose monitoring only 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.

Where the indication for CGMS in a pump-treated patient is hypoglycaemia-related then the CGMS options will be limited to those that are compatible with pumps. Where the indication for CGMS in a pump-treated patient is persistent hyperglycaemia, then the CGMS can be delivered by a monitor that is not directly linked to a pump, if this is a cheaper option.

The default CGMS for patients not requiring an insulin pump should be the most cost-effective option available at the time. This includes consideration of using flash glucose monitoring where this fulfils the clinical need.

6.2.2 In Children and Young People In type 1 diabetes use in line with NG18 Section 1.2.62 and 1.2.63 This intervention will only be continued if it addresses the specific NICE indication. The circumstances/indications are:

Offer on-going real-time CGM with **alarms** to children and young people who have:

- Frequent severe hypoglycaemia
- Impaired awareness of hypoglycaemia associated with adverse consequences
- Inability to recognise or communicate about symptoms of hypoglycaemia.

Consider on-going real-time CGM **with alarms** for:

- Neonates, infants and pre-school children; children and young people who undertake high levels of physical activity; children and young people who have comorbidities (e.g. anorexia nervosa) or who are receiving treatments

that can make blood glucose control difficult (e.g. corticosteroids)

Consider intermittent (real-time or retrospective) CGM to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.

6.3 Ongoing CGMS in adult patients not on an insulin pump

6.3.1 In type 1 diabetes use in line with NG17 This intervention will only continued if it addresses the specific NICE indication. The circumstances/indications are:

- More than 1 episode a year of severe hypoglycemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycemia.
- Frequent (more than 2 episodes a week) significant hypoglycaemia that is causing problems with daily activities.
- Hypoglycaemia associated with extreme fear of further and severe hypoglycaemia.
- Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day . In this case, continue real-time continuous glucose monitoring only 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.

6.3.2 In Children and Young People with type 1 diabetes use in line with NG18 This intervention will only continued if it addresses the specific NICE indication. The circumstances/indications are:

Offer on-going real-time CGM with alarms to children and young people who have:

- Frequent severe hypoglycaemia
- Impaired awareness of hypoglycaemia associated with adverse consequences
- Inability to recognise or communicate about symptoms of hypoglycaemia.

Consider on-going real-time CGM for:

- Neonates, infants and pre-school children; children and young people who undertake high levels of physical activity; and children and young people who have comorbidities (e.g anorexia nervosa) or who are receiving treatments that can make blood glucose control difficult (e.g. corticosteroids).

Consider intermittent (real-time or retrospective) CGM to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.

The default CGMS for patients not requiring an insulin pump should be the most cost-effective option available at the time. This includes consideration of using flash glucose monitoring where this fulfils the clinical need. However, consideration should be given as to whether the clinical situation requires use of a CGMS device that has a hypoglycaemia warning alarm function.

6.4 CGMS in pregnancy

6.4.1 Insulin-treated diabetes (any type) in pregnancy in line with NG3 when any of the following fulfilled:

- Who have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia)
- Who have unstable blood glucose levels (to minimise variability) to gain information about variability in blood glucose levels.

Where the indication for CGMS in a pump-treated patient is hypoglycaemia-related then the CGMS options will be limited to those that are compatible with pumps. Where the indication for CGMS in a pump-treated patient is persistent hyperglycemia, then the CGMS can be delivered by a monitor that is not directly linked to a pump, if this is a cheaper option. The default CGMS for patients not requiring an insulin pump should be the most cost-effective option available at the time. This includes consideration of using flash glucose monitoring where this fulfils the clinical need and whether the clinical situation requires use of a CGMS device which has a hypoglycaemia warning alarm function.

6.5 Inability to undertake standard self-monitoring of glucose

Devices should be considered for patients for whom standard glucose monitoring by finger stick isn't possible e.g. severe needle phobia despite psychological assessment and therapy, loss of hand(s) or severely injured hands. CGMS or flash glucose monitoring may need to be used during assessment or while waiting for assessment and treatment.

The default CGMS for patients not requiring an insulin pump should be the most cost-effective option available at the time. This includes consideration of using flash glucose monitoring where this fulfils the clinical need.

6.6 Transition of young adults to the adult services

Continuation of access to Insulin Pumps and or Continuous Glucose Monitoring for young people transferring to adult services should be maintained based on their individual criteria for initiation of pump and CGM therapy rather than the criteria applied to new adults to be initiated on pump and/or CGM therapy.

7 Equality Impact Assessment (EIA)

This document has been assessed, using the EIA toolkit, to ensure consideration has been given to the actual or potential impacts on staff, certain communities or population groups, appropriate action has been taken to mitigate or eliminate the negative impacts and maximise the positive impacts and that the and that the implementation plans are appropriate and proportionate.

Include summary of key findings/actions identified as a result of carrying out the EIA. The full EIA is attached as Appendix A.

8 Implications and Associated Risks

This policy and supporting frameworks set evidence based boundaries to interventions available on the NHS. It may conflict with expectations of individual patients and clinicians.

9 Education and Training Requirements

Members of the panels will undergo training at least every three years, particularly in relation to the legal precedents around IFRs. Effective policy dissemination is required for local clinicians.

10 Monitoring Compliance and Effectiveness

Each IFR panel will maintain an accurate database of cases approved and rejected, to enable consideration of amendments to future commissioning intentions and to ensure consistency in the application of the CCGs in Leeds Commissioning Policies.

The financial impact of approvals outside of existing Service Level Agreements will be monitored to ensure the Leeds CCGs identify expenditure and ensure appropriate value for money. Member Practice clinicians need to be aware that all referrals will ultimately be a call on their own CCG budgets.

11 Associated Documentation

This policy must be read in conjunction with the underpinning Leeds CCGs decision-making frameworks.

12 References

NICE (2016) NG17 Type 1 diabetes in adults: diagnosis and management

NICE (2016) NG18 Diabetes (type 1 and type 2) in children and young people: diagnosis and management

NICE (2016) QS125 Diabetes in children and young people

NICE (2008) TA 151 Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus

NICE (2016) DG21 Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system)

NICE (2015) NG3 Diabetes in pregnancy: management from preconception to the postnatal period

Appendices

A Equality Impact Assessment

Title of policy	Insulin Pumps and Glucose Monitors Policy	
Names and roles of people completing the assessment	Fiona Day Consultant in Public Health Medicine, Helen Lewis, Head of Acute Provider Commissioning	
Date assessment started/completed	27.3.17	30.3.17

1. Outline	
Give a brief summary of the policy	The purpose of the commissioning policy is to enable officers of the Leeds CCGs to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCGs. This policy relates to requests for insulin pumps and glucose monitors.
What outcomes do you want to achieve	We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness.

2. Evidence, data or research	
Give details of evidence, data or research used to inform the analysis of impact	See list of references

3. Consultation, engagement	
Give details of all consultation and engagement	Discussion with clinicians and patient representatives on the principles of decision-making. Discussion with patient leaders relating to changes in the content of the policy and

activities used to inform the analysis of impact	advice on proportionate engagement. The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy. Local clinical commissioning and clinical providers have had the opportunity to comment on the draft policies.

4. Analysis of impact

This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to;

Eliminate unlawful discrimination; advance equality of opportunity; foster good relations

	Are there any likely impacts? **Are any groups going to be affected differently?** **Please describe.**	**Are these negative or positive?**	**What action will be taken to address any negative impacts or enhance positive ones?**
Age	yes	positive	Ensures evidence based commissioning policy based on patient need
Carers	no		
Disability	yes	positive	Ensures evidence based commissioning policy based on patient need
Sex	no		
Race	no		
Religion or belief	no		
Sexual orientation	no		
Gender Reassignment	no		

Pregnancy and maternity	yes	positive	Ensures evidence based commissioning policy based on patient need
Marriage and civil partnership	no		
Other relevant group			

If any negative/positive impacts were identified are they valid, legal and/or justifiable? **Please detail.**	Ensures evidence based commissioning policy based on patient need

5. Monitoring, Review and Publication			
How will you review/monitor the impact and effectiveness of your actions	Annual report of IFR activity reported through relevant committees to Governing Bodies of the 3 CCGs. A limited equity audit is undertaken as part of this. Complaints and appeals monitoring.		
Lead Officer	Helen Lewis	**Review date:**	July 2017

6.Sign off			
Lead Officer	Helen Lewis		
Director on behalf of the 3 Leeds CCG Medical Directors	Dr Simon Stockill, Medical Director, Leeds West CCG	**Date approved:**	12 July 2017

B Policy Consultation Process:

Title of document	Insulin Pumps and Glucose Monitors in Adults, Children and Young People
Author	F Day
New / Revised document	New
Lists of persons involved in developing the policy	F Day Consultant in Public Health Medicine, Leeds City Council M Mansfield, LTHT; S Kassim, LWCCG; F Campbell LTHT
List of persons involved in the consultation process:	See appendix A

C Version Control Sheet

Version	Date	Author	Status	Comment
V1	15.7.17	M Mansfield, F Day, S Kassim	Draft interim	Updated interim policy pending full review based on New NICE guidance.
V2	11.3.17	FM Campbell for CYP Diabetes	Draft awaiting adoption	Updated following transfer of commissioning responsibility for childrens insulin pumps and monitors to CCGs April 2017