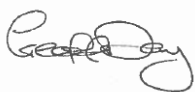


<b>Date:</b>	23 <sup>rd</sup> August 2018
<b>Meeting:</b>	Joint Primary Care Commissioning Committee
<b>Item Number:</b>	13.0
<b>Public/Private:</b>	Public <input checked="" type="checkbox"/> Private <input type="checkbox"/>

<b>Author:</b> (Name, Title)	Helen Phillips Programme Lead, NHS England
<b>GB Lead:</b> (Name, Title)	Geoff Day Interim Director of Primary Care
<b>Director approval</b> (Name)	Geoff Day
<b>Director Signature</b> <b>(MUST BE SIGNED)</b>	

<b>Report Title:</b>
Local Services Specifications:- <ul style="list-style-type: none"> <li>• Shared Care Monitoring</li> <li>• Post-Operative Dressings and Suture Removal</li> <li>• Minor Surgery</li> <li>• Minor Injury</li> <li>• Anticoagulation</li> <li>• Care for Patients with Diabetes</li> </ul>
<b>Decisions to be made:</b>
Approve Specifications

<b>Link to a Strategic Objective?</b>	<input type="checkbox"/>	
<b>Link to a Strategic Risk</b>	<input type="checkbox"/>	

<b>Continue to improve the quality of services</b>	<input checked="" type="checkbox"/>	<b>Improve patient experience</b>	<input checked="" type="checkbox"/>		
<b>Reduced unwarranted variations in services</b>	<input checked="" type="checkbox"/>	<b>Reduce the inequalities gap in North Lincolnshire</b>	<input checked="" type="checkbox"/>		
<b>Deliver the best outcomes for every patient</b>	<input checked="" type="checkbox"/>	<b>Statutory/Regulatory</b>	<input type="checkbox"/>		
<b>Purpose (tick one only)</b>	Approval <input checked="" type="checkbox"/>	Information <input type="checkbox"/>	To note <input type="checkbox"/>	Decision <input type="checkbox"/>	Assurance <input type="checkbox"/>

<b>Executive Summary (Question, Options, Recommendations):</b>
<b>Background</b>  NL CCG currently has in place a contract with each of the 19 GP practices across the CCG to provide a number of local services covering:- <ul style="list-style-type: none"> <li>• Shared Care Monitoring</li> <li>• Post Operative Dressings and Suture Removal</li> <li>• Minor Surgery</li> </ul>

- Minor Injury
- Anticoagulation
- Care for Patients with Diabetes

The current contracts will end 31<sup>st</sup> March 2019.

A review of all the specifications has taken place and has been overseen by a working group. The Clinical Lead for the review is Dr Toby Blumenthal. Dr Salim Modan has also reviewed and supported the specifications as Primary Care Lead.

During the review of the specifications the following were highlighted that require further consideration/action:-

1. **Shared Care Monitoring** – There are currently no guidelines to support Primary Care in taking over the monitoring of patients in the community, the CCG will need to work with colleagues in NLG to ensure the governance around discharging patients to primary care is in place for 1<sup>st</sup> April 2019
2. **Post-Operative Dressings** – During the review it became apparent that there is no definition of what simple wound dressings and complex wound dressings are, the CCG should consider whether this needs to be defined to support primary care

<b>Recommendations</b>	The PCCC is asked to:- <ul style="list-style-type: none"> <li>• Note the contents of the report</li> <li>• Note the actions that need to be undertaken in readiness for service commencement 1<sup>st</sup> April 2019 in relation to Shared Care Monitoring and Post-Operative Dressings</li> <li>• Approve the specifications to enable the procurement process to commence.</li> </ul>		
<b>Report history</b>	N/A		
<b>Equality Impact</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
<b>Sustainability</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
<b>Risk</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
<b>Legal</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
<b>Finance</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

<b>Patient, Public, Clinical and Stakeholder Engagement to date</b>									
	<b>N/A</b>	<b>Y</b>	<b>N</b>	<b>Date</b>		<b>N/A</b>	<b>Y</b>	<b>N</b>	<b>Date</b>
<b>Patient:</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<b>Clinical:</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
<b>Public:</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<b>Other:</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

Mandatory headings 1 – 4. Mandatory but detail for local determination and agreement

Optional headings 5-7. Optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

Service Specification No.		
Service	Shared Care Monitoring	
Commissioner Lead	Interim Director of Primary Care	
Provider Lead		
Period	1 April 2019 to 31 March 2022	
Date of Review	Review process for Shared Care as required - in line with drug updates and significant changes.	
Version Control: V3	Reviewer:	Local Services working group
	Date:	
	Changes made:	

#### 1. Population Needs

##### 1.1 National / Local context and evidence base

National/local context and evidence base

The treatment of several diseases within the fields of medicine, particularly in rheumatology, is increasingly reliant on drugs that, while clinically effective, need regular blood monitoring. This is due to the potentially serious side-effects that these drugs can occasionally cause. It has been shown that the incidence of side-effects can be reduced significantly if this monitoring is carried out in a well-organised way, close to the patient's home. The mechanism for shared care, agreed locally, includes a traffic light system for the classification of drugs. Amber drugs are those classified as appropriate for shared care, with the General Practitioner taking over the responsibility for ongoing care after an agreed period of time.

Since this service is heavily reliant on the shared care arrangements between primary and secondary care in North Lincolnshire, the commissioner has determined that this is a service that should be provided within a GP practice environment by the patient's registered practice. As such this specification is concerned with those aspects of care that extend

beyond the scope of essential services as defined in core GMS/PMS/APMS contracts.

## 1.2 GP Providers of Service

All GP practices are expected to provide 'essential' and those additional services they are contracted to provide under GMS/PMS/APMS to all their patients. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

The NHS Outcomes Framework sets five "domains" through which the effectiveness of health care will be measured (Department of Health, 2011):

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

#### Applicable Local Standards:

- Workforce - Providers must demonstrate that all staff have the necessary skills to undertake the requirements of this specification. Staff must be able to demonstrate that clinical competencies are maintained and safe staffing levels must be maintained in accordance with national policy/standards.
- Patient, public and staff safety – Providers will be required to demonstrate that evidence based clinical protocols are being used. Providers must have in place appropriate health and safety and risk management systems and premises that are safe and patient friendly. They should also ensure that any risk assessments and significant events are both documented and audited regularly, learning outcomes identified and any changes implemented. Services should comply with national requirements for recording, reporting, investigation and implementation of learning from incidents.
- Clinical audit and review – Providers must identify and undertake a programme of clinical audit to support the delivery of the service.
- Patient and public involvement – Providers are required to demonstrate active engagement with patients in evaluating services. Providers must demonstrate how systematic patient feedback is being used to shape and improve services.
- Managing complaints – Responsive protocols and procedures must be in place for managing patient complaints (in line with national requirements). Complaints must be reviewed at regular intervals and learning from these shared and applied as appropriate to ensure that services are continually improved.
- Infection Control – Providers will ensure that they comply with national and local guidance on infection prevention and control. This includes having robust systems and processes in place including audits, as appropriate.

### 2.2 Performance Monitoring/Reporting

Providers will be asked to submit data via the Portal <https://secure.yhcs.org.uk/nyhat->

<invoice/LogOn.aspx?ReturnUrl=%2fnyhat-invoice%2f>

Full records should be maintained in such a way that aggregated data and details of individual patients (including histology reports) are readily accessible. Practices should regularly audit and peer review work.

### **2.3 Outcomes / Measures / Reporting Requirements will include:**

Providers of the service should maintain adequate clinical records, incorporating all known information relating to any significant events arising from services provided under this specification (e.g. hospital admissions, wound infections, drug reactions), including patient treatment and outcomes, that can be the subject of clinical audit and review.

## **3. Scope**

### **3.1 Aims and objectives of service**

North Lincolnshire CCG wishes to commission a service for registered patients who require monitoring in primary care under established shared care guideline arrangements with secondary care providers. This may involve the taking of bloods and other tests or examinations at pre-determined intervals.

The shared care monitoring specification is designed to be one in which therapy should only be started for recognised indications for specified lengths of time.

This service aims to:

- i. provide patients with ongoing support in a safe primary care environment following initial treatment and stabilisation of their condition in secondary care;
- ii. provide a convenient service for patients;
- iii. ensure the service is clinically safe by continually assessing the need to continue treatment, liaising with specialists in secondary care as necessary;
- iv. ensure therapy is discontinued when appropriate;
- v. ensure the most cost effective use of NHS resources.

### **3.2 Service description/care pathway**

This service will only apply where the drug monitoring arrangements are covered by a shared care guideline agreed by Northern Lincolnshire Area Prescribing Committee (NLAPC).

This list will be reviewed quarterly to take account of changes to existing shared care guidelines and the introduction of new shared care guidelines following agreement at NLAPC. In such circumstances the Commissioner will advise the Provider how these changes affect the drugs covered by this agreement. The details of the shared care arrangements are to be found on the following website:

<http://www.northernlincolnshireapc.nhs.uk/>

Patient monitoring carried out under this arrangement must be done under a shared care agreement between the GP and the patient's Consultant. This agreement must have been approved by the NLAPC and the agreement should specify the respective roles and responsibilities of the GP and the hospital specialist with regards to monitoring and clinical management of the patient.

The monitoring should be done at appropriate intervals in accordance with a Prescribing/ Shared Care Framework.

The level of input required from the Provider will be dependent on the specific shared care guideline reflecting the following bandings:

**Level 2** – Patient under active shared care arrangement. The Provider organises laboratory test and takes responsibility for dosing in accordance with shared care guidelines. Sampling undertaken by District Nurse or another externally funded Provider.

**Level 3** – Patient under active shared care arrangement. The Provider organises laboratory test and takes responsibility for dosing in accordance with shared care guidelines. Practice also undertakes sampling.

The banding will determine the level of remuneration available in respect of each drug. In some cases the contribution required from the Provider is fixed; in other cases the level of input is optional.

This scheme only applies to the drugs listed in the table (Appendix A).

Clinicians must exercise proper clinical judgment about their competence to manage and enter into shared care arrangements in individual cases. They will not be obliged to agree to every request to take on shared care arrangements but must be prepared to engage in appropriate education and training opportunities where this is available.

### **3.3 Specific requirements**

The Provider will provide/ensure the following requirements are met:

**Patient register.** The Provider should be able to produce and maintain an up-to-date register of all shared care drug monitoring service patients, this register should be updated annually.

**Call and recall.** To ensure that there is a failsafe arrangement in place that ensures patients are recalled for appointments at the required intervals as necessary either in a hospital or general practice setting and to have systems in place to identify and follow up patients in default.

**Continuing information for patients.** To ensure that all patients (and/or their carers and support staff when appropriate) are informed of how to access appropriate and relevant information.

**Patient record.** To ensure that relevant shared care protocol is in the patient record.

**Professional links.** To work together with other professionals, especially consultants and/or nurse specialists as identified in the Prescribing Framework when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained.

**Referral policies.** Where appropriate, to refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist.

**Record keeping.** To maintain adequate records of the service provided, incorporating all known information relating to any significant events e.g. adverse reactions, hospital admissions, relevant deaths of which the practice has been notified. This information should

be recorded in the patient's record and READ coded accordingly. Any serious untoward incidents associated with the provision of this service should be reported via the Commissioner's reporting system.

**Training.** The Provider must ensure that all staff involved in providing any aspect of care under this scheme has the necessary training and skills to do so. All nurses involved in providing this service should be registered with the NMC.

### **3.4 Population Covered**

Patients registered with a GP practice that is a member of North Lincolnshire CCG.

### **3.5 Any acceptance and exclusion criteria and thresholds**

The service is restricted to patients who are receiving treatment under a Shared Care arrangement agreed by NLAPC and includes one of the drugs listed above.

Drugs should only be used for the indications specified.

### **3.6 Interdependence with other services/providers**

Northern Lincolnshire Area Prescribing Committee  
Northern Lincolnshire and Goole NHS Foundation Trust  
Hull and East Yorkshire Hospitals NHS Trust  
North of England Commissioning Support (NECS)  
Voluntary organisations and support groups

## **4. Applicable Service Standards**

### **4.1 Applicable national standards (e.g. NICE)**

As stated in paragraphs SC2 (Regulatory Requirements) and SC3 (Service Standards) the Provider is required to adhere to all national standards as issued from time to time by any relevant Regulatory and Statutory bodies including guidance issued by appropriate competent bodies (e.g. Royal Colleges).

### **4.2 Applicable local standards**

The service provided must conform to the standards set out in the shared care guidelines issued from time to time by the Northern Lincolnshire Area Prescribing Committee.

<http://www.northernlincolnshireapc.nhs.uk/>

## **5. Applicable quality requirements and CQUIN goals**

### **5.1 Applicable quality requirements (See Schedule 4 Parts A-D)**

The Provider will develop and follow a standard operating policy for provision of this service.

### **5.2 Sepsis**

The provider is required to ensure all relevant staff are trained in sepsis awareness, including recognition, diagnosis and early management in line with NICE guidance (NG51 section 1.12). <https://www.nice.org.uk/guidance/ng51/resources/sepsis-recognition-diagnosis-and-early-management-pdf-1837508256709>.

The provider will ensure all relevant staff undergo training, utilising Health Education

England's Think Sepsis resources; <https://www.e-lfh.org.uk/programmes/sepsis/>

The service should ensure NEWS assessments scores are used to identify deteriorating patients and should ensure there is an audit programme in place to monitor use of NEWS Scores.

### 5.3 Safeguarding

The Provider will have in place arrangements which ensure compliance with the following legislation/ statutory guidance, or successor documents:

- Children Act 2004, sections 10 and 11
- Care Act 2014, sections 42-26
- Working Together to Safeguarding Children (2015)
- Care and support statutory guidance: Chapter 14
- CQC Fundamental Standards (2014); Regulation 13
- North Lincolnshire Safeguarding Children Board Policies and Procedures - <http://www.northlincsiscb.co.uk/professionals/policies/>
- North Lincolnshire Safeguarding Adult Board Policy and Procedures - <http://www.northlincssab.co.uk/wp-content/uploads/2017/09/MA-Policy-Procedures-Updated-2017.pdf>

The Provider will also ensure compliance in accordance with new legislation/ statutory guidance on implementation.

In order to demonstrate compliance, the Provider will ensure they have arrangements as outlined within the Safeguarding adult and children standards for providers section in NLCCG Safeguarding Policy, and provide evidence to the Commissioner as requested and as outlined in Performance and monitoring of providers section of the same policy.

### 5.4 Applicable CQUIN goals (See Schedule 4 Part E)

## 6. Location of Provider Premises

### 6.1 Premises

The service will be provided from the Provider's premises registered with the CQC.

## 7. Individual Service User Placement

Not applicable.

## 8. Pricing



## Shared Care Monitoring

Drugs covered under the shared care monitoring specification include:-

Drug	BNF Classification and Indication
Azathioprine	Rheumatic disease
Azathioprine and 6- mercaptopurine	Inflammatory Bowel Disease
Ciclosporin	Psoriasis
Leflunomide	Disease modifying anti-rheumatic drug
Methotrexate (Oral)	Disease modifying anti-rheumatic drug
Methotrexate (Oral)	Psoriasis
Midazolam (Buccal)	For the management of Status Epilepticus in adults and children
Mycophenolate mofetil	Disease-modifying anti-rheumatic drug – rheumatoid arthritis
Penicillamine	Disease-modifying anti-rheumatoid arthritis
Riluzole	Treatment of amyotrophic lateral sclerosis
Sodium Aurothiomalate (IM Gold)	Disease-modifying anti-rheumatic drug - rheumatoid arthritis
Suphasalazine	DMARD and Immunosuppression
Somatropin (Children)	Treatment of growth hormone deficiency (including short stature in Turner's syndrome)

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

Mandatory headings 1 – 4. Mandatory but detail for local determination and agreement

Optional headings 5 - 7. Optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

Post Hospital Dressings and Suture Removal		
Service Specification No.		
Service	Post Hospital Dressings and Suture Removal	
Commissioner Lead	Interim Director of Primary Care	
Provider Lead		
Period	1 April 2019 to 31 March 2022	
Date of Review	Annual	
Version Control: V3	Reviewer:	Local Services working group
	Date:	
	Changes made:	

#### 1. Population Needs

##### 1.1 National / Local context and evidence base

In North Lincolnshire there were 65,264 A&E attendances between 1 April 2017 and 31 March 2018; and 47,321 patients admitted to hospital during the same period. A significant proportion of these patients require support in the community following discharge from hospital. This may take the form of the removal of sutures or changing of post-operative and post A&E dressings. Historically these activities have been undertaken by a combination of GP practices and staff in district nursing teams.

Wound care management and suture removal is an area of care that can best be delivered in a primary care setting, supporting the aim for patients to be discharged from hospital as quickly as is appropriate and for care to be followed up in the community.

The management of wounds that are non-complex and not chronic (i.e. are not chronic leg ulcers or other chronic complex wounds that require compression bandaging or alternative treatments) and suture removal in mobile patients will be commissioned from general practice via this Local Service.

##### 1.2 GP Providers of Service

All GP practices are expected to provide 'essential' and those additional services they are

contracted to provide under GMS/PMS/APMS to all their patients. This local service specification for the Post Hospital Dressings and Suture Removal in primary care outlines the more specialised service to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

The NHS Outcomes Framework sets five "domains" through which the effectiveness of health care will be measured (Department of Health, 2011):

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

#### Applicable Local Standards:

- Workforce - Providers must demonstrate that all staff have the necessary skills to undertake the requirements of this specification. Staff must be able to demonstrate that clinical competencies are maintained and safe staffing levels must be maintained in accordance with national policy/standards.
- Patient, public and staff safety – Providers will be required to demonstrate that evidence based clinical protocols are being used. Providers must have in place appropriate health and safety and risk management systems and premises that are safe and patient friendly. They should also ensure that any risk assessments and significant events are both documented and audited regularly, learning outcomes identified and any changes implemented. Services should comply with national requirements for recording, reporting, investigation and implementation of learning from incidents.
- Clinical audit and review – Providers must identify and undertake a programme of clinical audit to support the delivery of the service.
- Patient and public involvement – Providers are required to demonstrate active engagement with patients in evaluating services. Providers must demonstrate how systematic patient feedback is being used to shape and improve services.
- Managing complaints – Responsive protocols and procedures must be in place for managing patient complaints (in line with national requirements). Complaints must be reviewed at regular intervals and learning from these shared and applied as appropriate to ensure that services are continually improved.
- Infection Control – Providers will ensure that they comply with national and local guidance on infection prevention and control. This includes having robust systems and processes in place including audits, as appropriate.

## **2.2 Performance Monitoring/Reporting**

Providers will be asked to submit data via the Portal <https://secure.yhcs.org.uk/nyhat-invoice/LogOn.aspx?ReturnUrl=%2fnyhat-invoice%2f>

Full records should be maintained in such a way that aggregated data and details of individual patients (including histology reports) are readily accessible. Practices should regularly audit and peer review work.

## **2.3 Outcomes / Measures / Reporting Requirements will include:**

Providers of the service should maintain adequate clinical records, incorporating all known information relating to any significant events arising from services provided under this Contract (e.g. hospital admissions, wound infections, drug reactions), including patient treatment and outcomes, that can be the subject of clinical audit and review.

## **3. Scope**

### **3.1 Aims and objectives of service**

The aim of this service is to provide wound care including suture removal to mobile patients arising as a result from attendance at secondary care. The aim is for patients to be discharged from hospital as quickly as is appropriate and for care to be followed up in the community, rather than by re-attendance at outpatient or other clinics wherever clinically possible.

The intention of this local service is to ensure that mobile patients do not need to travel to secondary care for follow-up care to a secondary care procedure involving wound care / dressings or suture/staple removal.

### **3.2 Service description / care pathway**

The service aims to provide practice-based post-operative care for patients as appropriate and will cover:

- The removal of sutures/staples following treatment for injury.
- Simple wound management involving the changing of simple dressings.

This scheme does not cover those tests and investigations that are carried out in primary care in relation to the delivery of essential or other services that are subject to a separate funding arrangement. Tests carried out on patients on referral to hospital are also excluded. The Provider will use appropriate READ codes for information recording purposes.

### **3.3 Population Covered**

Patients registered with a GP practice that is a member of North Lincolnshire CCG.

### **3.4 Any acceptance and exclusion criteria and thresholds**

The commissioned service does not include care for wounds that are complex and/or chronic (i.e. service scope does not include chronic leg ulcers or other chronic complex wounds that require compression bandaging or alternative treatments).

### 3.5 Interdependence with other services/providers

District nursing provides wound care for patients as part of their core service, for the period they are clinically house-bound, whether the wounds arise from a long-term condition or following discharge from hospital.

District nursing, in some cases, may also be commissioned to provide specialist clinics for highly complex wounds, particularly severe leg ulcers, as an alternative to outpatient referral (such as to Dermatology) or hospital admission. In some cases where appropriate, the services of a Tissue Viability Nurse (TVN) for chronic or wounds that are not healing should be utilised.

Northern Lincolnshire and Goole Hospitals NHS Trust  
RDaSH

## 4. Applicable Service Standards

### 4.1 Applicable national standards (e.g. NICE)

**National Institute of Clinical Excellence, CG74 Surgical site infections: prevention and treatment, NICE October 2008 (updated February 2017)**  
<https://www.nice.org.uk/guidance/cg74>

[National Institute of Clinical Excellence. Prevention and control of healthcare associated infections overview, NICE  
https://pathways.nice.org.uk/pathways/prevention-and-control-of-healthcare-associated-infections#path=view%3A/pathways/prevention-and-control-of-healthcare-associated-infections/prevention-and-control-of-healthcare-associated-infections-overview.xml&content=view-index](https://pathways.nice.org.uk/pathways/prevention-and-control-of-healthcare-associated-infections#path=view%3A/pathways/prevention-and-control-of-healthcare-associated-infections/prevention-and-control-of-healthcare-associated-infections-overview.xml&content=view-index)

[National Institute of Clinical Excellence, CG 139, Healthcare Associated Infections: prevention and control in Primary Care and Community Care, NICE update February 2017  
https://www.nice.org.uk/guidance/cg139/resources/healthcareassociated-infections-prevention-and-control-in-primary-and-community-care-pdf-35109518767045](https://www.nice.org.uk/guidance/cg139/resources/healthcareassociated-infections-prevention-and-control-in-primary-and-community-care-pdf-35109518767045)

[National Institute of Clinical Excellence, QS 161 Sepsis NICE 13 September 2017  
https://www.nice.org.uk/guidance/qs161](https://www.nice.org.uk/guidance/qs161)

As stated in paragraphs SC2 (Regulatory Requirements) and SC3 (Service Standards) the Provider is required to adhere to all national standards as issued from time to time by any relevant Regulatory and Statutory bodies including guidance issued by appropriate competent bodies (e.g. Royal Colleges).

### 4.2 Applicable local standards

There are no local quality standards in addition to the requirements pertaining to facilities and staff competencies and as set in the General Conditions.

## 5. Applicable quality requirements and CQUIN goals

### 5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

The Provider will develop and follow a standard operating policy for provision of this service.

### 5.2 Applicable CQUIN goals (See Schedule 4 Part E)

### 5.3 Sepsis

The provider is required to ensure all relevant staff are trained in sepsis awareness, including recognition, diagnosis and early management in line with NICE guidance (NG51 section 1.12). <https://www.nice.org.uk/guidance/ng51/resources/sepsis-recognition-diagnosis-and-early-management-pdf-1837508256709>.

The provider will ensure all relevant staff undergo training, utilising Health Education England's Think Sepsis resources; <https://www.e-lfh.org.uk/programmes/sepsis/>

The service should ensure NEWS assessments scores are used to identify deteriorating patients and should ensure there is an audit programme in place to monitor use of NEWS Scores.

### 5.4 Safeguarding

The Provider will have in place arrangements which ensure compliance with the following legislation/ statutory guidance, or successor documents:

- Children Act 2004, sections 10 and 11
- Care Act 2014, sections 42-26
- Working Together to Safeguarding Children (2015)
- Care and support statutory guidance: Chapter 14
- CQC Fundamental Standards (2014); Regulation 13
- North Lincolnshire Safeguarding Children Board Policies and Procedures - <http://www.northlincsiscb.co.uk/professionals/policies/>
- North Lincolnshire Safeguarding Adult Board Policy and Procedures - <http://www.northlincssab.co.uk/wp-content/uploads/2017/09/MA-Policy-Procedures-Updated-2017.pdf>

The Provider will also ensure compliance in accordance with new legislation/ statutory guidance on implementation.

In order to demonstrate compliance, the Provider will ensure they have arrangements as outlined within the Safeguarding adult and children standards for providers section in NLCCG Safeguarding Policy, and provide evidence to the Commissioner as requested and as outlined in Performance and monitoring of providers section of the same policy.

## 6. Location of Provider Premises

### 6.1 Premises

The service will be provided from the Providers premises registered with the CQC.

## 7. Individual Service User Placement

Not applicable.

## 8. Prices

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

Mandatory headings 1 – 4. Mandatory but detail for local determination and agreement

Optional headings 5-7. Optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

Service Specification No.		
Service	Minor Surgery	
Commissioner Lead	Head of Primary Care	
Provider Lead		
Period	1 April 2019 to 31 March 2022	
Date of Review	Annual	
Version Control: V2	Reviewer:	Local Services working group
	Date:	
	Changes made:	

### 1. Population Needs

#### 1.1 National / Local context and evidence base

This locally service seeks to ensure that there is the opportunity to provide the maximum range of minor surgery in the primary care sector. Its purpose is to divert minor surgery from being undertaken in secondary care to a primary care setting where appropriate facilities and skills exist.

#### 1.2 Evidence Base

There is evidence from within the UK and abroad that minor surgical procedures carried out by general practitioners in general practice premises have high levels of patient satisfaction and are highly cost effective.

1. Lowy A, Brazier J, Fall M, Thomas KJ, Williams BT. Quality of minor surgery by general practitioners in 1990 and 1991. British Journal of General Practice 1995; 44; 364-365

2. Tarraga Lopez PJ, Marin Nieto E, Garcia Olmo D, Celada Rodriguez A, Solera Albero J. [Economic impact of the introduction of a minor surgery program in primary care]. [Spanish] Atencion Primaria 2001;27(5):335-8.

3. Lopez Santiago A, Lara Penaranda R, de Miguel Gomez A, Perez Lopez P, Ribes

Martinez E. [Minor surgery in primary care: consumer satisfaction]. [Spanish] Atencion Primaria 2000;26(2):91-5.)

### 1.3 GP Providers of Service

All GP practices are expected to provide 'essential' and those additional services they are contracted to provide under GMS/PMS/APMS to all their patients. This local service specification for the Minor Injury in primary care outlines the more specialised service to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

The NHS Outcomes Framework sets five "domains" through which the effectiveness of health care will be measured (Department of Health, 2011):

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

### 2.2 Local Defined Outcomes

Service Outcomes will include:

- Effectiveness
- Patient Safety
- Patient Experience
- Performance Monitoring/Reporting

Audit: Full records of all procedures should be maintained in such a way that aggregated data and details of individual patients (including histology reports) are readily accessible. Practices should regularly audit and peer review minor surgery work.

**Patient monitoring.** Practices must ensure that details of the patient's monitoring are included in his or her lifelong record. If the patient is not registered with the practice, then the practice must send this information to the patient's registered practice for inclusion in the patient's notes.

#### Applicable Local Standards:

- Workforce - Providers must demonstrate that all staff have the necessary skills to undertake the requirements of this specification. Staff must be able to demonstrate that clinical competencies are maintained and safe staffing levels must be maintained in accordance with national policy/standards.
- Patient, public and staff safety – Providers will be required to demonstrate that



evidence based clinical protocols are being used. Providers must have in place appropriate health and safety and risk management systems and premises that are safe and patient friendly. They should also ensure that any risk assessments and significant events are both documented and audited regularly, learning outcomes identified and any changes implemented. Services should comply with national requirements for recording, reporting, investigation and implementation of learning from incidents.

- Clinical audit and review – Providers must identify and undertake a programme of clinical audit to support the delivery of the service.
- Patient and public involvement – Providers are required to demonstrate active engagement with patients in evaluating services. Providers must demonstrate how systematic patient feedback is being used to shape and improve services.
- Managing complaints – Responsive protocols and procedures must be in place for managing patient complaints (in line with national requirements). Complaints must be reviewed at regular intervals and learning from these shared and applied as appropriate to ensure that services are continually improved.
- Infection Control – Providers will ensure that they comply with national and local guidance on infection prevention and control. This includes having robust systems and processes in place including audits, as appropriate.

### **3. Scope**

#### **3.1 Aims and objectives of service**

The aims of this service are:

- To provide a local, convenient service to patients.
- Reduce the need for patients to travel in a predominantly rural area
- Maintain valuable technical skills within a general practice setting
- Ensure a good patient experience, based on a prompt response
- Ensure there is high awareness of the service amongst the practice population, supported by effective information and advertising

#### **3.2 Service description/care pathway**

##### **Delivery of Service**

The scope of this service is to provide minor surgery beyond those items included in additional services and the Nationally Directed Enhanced Service for minor surgery. It covers the following procedures:

- Rigid Sigmoidoscopy
- Vasectomy
- ....and procedures requiring prior approval:
- Chalazion

#### **3.3 Population Covered**

Patients registered with a GP practice that is a member of North Lincolnshire CCG.

Where a practice is unable to/does not wish to undertake a procedure following a referral from another practice, they should inform the referring practice promptly of this decision.

### **3.4 Any acceptance and exclusion criteria and thresholds**

#### **Inclusion**

See 'Service Scope' described above.

#### **Exclusion**

The service must be provided in accordance with NICE Cancer Service Guidance: Improving Outcomes Guidance for People with Skin Melanoma (May 2010) and jointly agreed local cancer network/ strategic cancer network guidance.

Procedures undertaken must be in keeping with North Lincolnshire Clinical Commissioning Group Prior Approval Policy and current commissioning policies.

### **3.5 Interdependence with other services/providers**

Appropriate links with secondary and tertiary care providers, supporting the delivery of a robust and timely pathway of treatment and care. Appropriate support also to be offered to the patient and their carer(s).

## **4. Applicable Service Standards**

### **4.1 Applicable national standards (e.g. NICE)**

**See exclusion criteria above.**

National Institute of Clinical Excellence, CG74 Surgical site infections: prevention and treatment, NICE October 2008 (updated February 2017) <https://www.nice.org.uk/guidance/cg74>

National Institute of Clinical Excellence, CG 139, Healthcare Associated Infections: prevention and control in Primary Care and Community Care, NICE update February 2017  
<https://www.nice.org.uk/guidance/cg139/resources/healthcareassociated-infections-prevention-and-control-in-primary-and-community-care-pdf-35109518767045>

National Institute of Clinical Excellence, QS 161 Sepsis NICE 13 September 2017 (accessed 26/2/18)  
<https://www.nice.org.uk/guidance/qs161/resources/sepsis-pdf-75545595402181>

National Institute of Clinical Excellence, Prevention and control of healthcare associated infections overview, NICE (accessed 28/9/17) <https://pathways.nice.org.uk/pathways/prevention-and-control-of-healthcare-associated-infections#path=view%3A/pathways/prevention-and-control-of-healthcare-associated-infections/prevention-and-control-of-healthcare-associated-infections-overview.xml&content=view-index>

### **4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)**

Applicable standards not previously included in specification. Details of requirements and standards will be included in the Service Development and Improvement Plan (SDIP).

### **4.3 Applicable local standards**

Procedures undertaken must be in keeping with North Lincolnshire Clinical Commissioning Group Prior Approval Policy and must comply with the NHS requirement for patients to be treated with 18 weeks from date of referral.

## **5. Applicable quality requirements and CQUIN goals**

### **5.1 Applicable quality requirements (See Schedule 4 Parts A-D)**

#### **5.2 Eligibility to Provide the Service:**

A practice may be accepted for the provision of this locally enhanced service if it has a partner, employee or sub-contractor, who has the necessary skills and experience to carry out the contracted procedures in line with the principles of generic GPs with Special Interests guidance or the specific examples as they are developed. Clinicians taking part in minor surgery should be competent in resuscitation and, as for other areas of clinical practice, have a responsibility for ensuring that their skills are regularly updated. Doctors carrying out minor surgery should demonstrate a continuing sustained level of activity, conduct regular audits, be appraised on what they do and take part in necessary supportive educational activities.

Where North Lincolnshire Clinical Commissioning Group believes a doctor carrying out minor surgery is not complying with the terms of the contract, it will invoke a remedial notice according to the procedure laid out in Regulation. There is considerable guidance available on techniques and facilities for conducting minor surgery in general practice.

#### **5.3 Staff Competence:**

The GP(s)/ Subcontractor can provide evidence that they have the experience and qualifications to undertake the procedure(s) and all personnel providing the service is competent to provide those aspects of the service for which they are responsible and will keep their skills up to date.

Registered nurses can provide care and support to patients undergoing minor surgery. Nurses assisting in minor surgery procedures should be appropriately trained and competent, taking into consideration their professional accountability and the Nursing and Midwifery Council guidelines on the scope of professional practice.

GPs will be accredited on an individual basis in accordance with HSG 1996 (031). Practitioners presently accredited under the minor surgery referral scheme will continue.

#### **5.4 Satisfactory facilities**

The CCG will need to be satisfied that practices carrying out minor surgery have a facility for performing minor surgical procedures which comply with "Infection Control Guidance for General Practice" published jointly by the Community Infection Control Nurses Network and the Royal College of General Practitioners and the "Health Act 2006." The CCG expects the practice to be able to demonstrate that they meet the standards and will permit an appropriate inspection of their premises by a suitably qualified CCG representative.

All personnel providing the service through the contract have appropriate indemnity cover to meet in full claims made against them as individuals.

Adequate and appropriate equipment should be available for the doctor to undertake the procedures chosen, and should also include appropriate equipment for resuscitation. Practitioners should be trained in the use of equipment.

### **5.5 Sterilisation and infection control.**

Although general practitioner minor surgery has a low incidence of complications, it is important that practices providing the procedures listed in this specification operate to the highest possible standards. Practices must use one of the following arrangements for sterilisation:

- (a) disposable sterile instruments
- (b) sterile packs from an accredited CSSD

Practices must have infection control policies that are compliant with national guidelines including the handling of used instruments, excised specimens, aseptic technique and the disposal of clinical waste.

### **5.6 Consent**

In each case the patient should be fully informed of the treatment options and the treatment proposed. The patient should give written consent for the procedure to be carried out and the completed NHS consent form should be filed in the patient's lifelong medical record.

### **5.7 Pathology**

All tissue removed by minor surgery should be sent routinely for histological examination unless there are exceptional or acceptable reasons for not doing so.

### **5.8 Sepsis**

The provider is required to ensure all relevant staff are trained in sepsis awareness, including recognition, diagnosis and early management in line with NICE guidance (NG51 section 1.12). <https://www.nice.org.uk/guidance/ng51/resources/sepsis-recognition-diagnosis-and-early-management-pdf-1837508256709>.

The provider will ensure all relevant staff undergo training, utilising Health Education England's Think Sepsis resources; <https://www.e-lfh.org.uk/programmes/sepsis/>

The service should ensure National Early Warning scores (NEWs) scores are used to identify deteriorating patients and should ensure there is an audit programme in place to monitor use of NEWs Scores.

### **5.9 Safeguarding**

The Provider will have in place arrangements which ensure compliance with the following legislation/ statutory guidance, or successor documents:

- Children Act 2004, sections 10 and 11
- Care Act 2014, sections 42-26
- Working Together to Safeguarding Children (2015)
- Care and support statutory guidance: Chapter 14

- CQC Fundamental Standards (2014); Regulation 13
- North Lincolnshire Safeguarding Children Board Policies and Procedures - <http://www.northlincsiscb.co.uk/professionals/policies/>
- North Lincolnshire Safeguarding Adult Board Policy and Procedures - <http://www.northlincsab.co.uk/wp-content/uploads/2017/09/MA-Policy-Procedures-Updated-2017.pdf>

The Provider will also ensure compliance in accordance with new legislation/ statutory guidance on implementation.

In order to demonstrate compliance, the Provider will ensure they have arrangements as outlined within the Safeguarding adult and children standards for providers section in NLCCG Safeguarding Policy, and provide evidence to the Commissioner as requested and as outlined in Performance and monitoring of providers section of the same policy.

#### **5.10 Applicable CQUIN goals (See Schedule 4 Part E)**

### **6. Location of Provider Premises**

The service will be provided from the Providers premises registered with the CQC.

### **7. Individual Service User Placement**

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

Mandatory headings 1 – 4. Mandatory but detail for local determination and agreement

Optional headings 5-7. Optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

Service Specification No.		
Service	Minor Injury Services	
Commissioner Lead	Interim Director of Primary Care	
Provider Lead		
Period	1 April 2019 to 31 March 2022	
Date of Review	Annual	
Version Control: V3	Reviewer:	Local Services working group
	Date:	
	Changes made:	

### 1. Population Needs

#### 1.1 National / Local context and evidence base

The Department of Health estimates suggest that approximately half of all patients visiting A&E have relatively minor injuries or illnesses. It is often these patients who experience the longest waiting times for treatment. In recent years many A&E departments have restructured their access arrangements so as to target patients with less serious conditions. Although such schemes can lead to significant improvements in the time in which patients are adequately treated there remains considerable scope to manage those with less serious injuries in alternative settings.

It is also acknowledged that the continued reliance on major A&E facilities for the management of minor injuries is neither appropriate nor convenient for many patients and that access to unscheduled care needs to be simplified so that patients can be quickly directed to the most appropriate site for treatment.

Across North Lincolnshire, minor injury services are delivered through a combination of providers, including A&E Units and GP Practices. The overall aim is to ensure that patients are seen as close-to- home as possible, in the most appropriate clinical setting.

It is recognised that General Practices across North Lincolnshire provide a level of minor injury service to their patients. The extent to which services are provided varies between practices. Typically, those practices located within very rural settings provide a wider range and greater volume of minor injury procedures that those in more urban areas.

## 1.2 GP Providers of Service

All GP practices are expected to provide 'essential' and those additional services they are contracted to provide under GMS/PMS/APMS to all their patients. This local service specification for the Minor Injury in primary care outlines the more specialised service to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

The NHS Outcomes Framework sets five "domains" through which the effectiveness of health care will be measured (Department of Health, 2011):

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

#### Applicable Local Standards:

- Workforce - Providers must demonstrate that all staff have the necessary skills to undertake the requirements of this specification. Staff must be able to demonstrate that clinical competencies are maintained and safe staffing levels must be maintained in accordance with national policy/standards.
- Patient, public and staff safety – Providers will be required to demonstrate that evidence based clinical protocols are being used. Providers must have in place appropriate health and safety and risk management systems and premises that are safe and patient friendly. They should also ensure that any risk assessments and significant events are both documented and audited regularly, learning outcomes identified and any changes implemented. Services should comply with national

requirements for recording, reporting, investigation and implementation of learning from incidents.

- Clinical audit and review – Providers must identify and undertake a programme of clinical audit to support the delivery of the service.
- Patient and public involvement – Providers are required to demonstrate active engagement with patients in evaluating services. Providers must demonstrate how systematic patient feedback is being used to shape and improve services.
- Managing complaints – Responsive protocols and procedures must be in place for managing patient complaints (in line with national requirements). Complaints must be reviewed at regular intervals and learning from these shared and applied as appropriate to ensure that services are continually improved.
- Infection Control – Providers will ensure that they comply with national and local guidance on infection prevention and control. This includes having robust systems and processes in place including audits, as appropriate.

## **2.2 Local Defined Outcomes**

### **Service Outcomes - Provision of:**

- an accessible minor injury service, enabling easy and timely access to urgent health services, ensuring patient safety
- a single point of access for care, performing all urgent tests as a one-stop service enabling the majority of patients to be discharged back to their normal place of residence, or the most appropriate community-based services, rather than into secondary care services

Service Outcomes will include:

- Effectiveness
- Patient Safety
- Patient Experience
- Performance Monitoring/Reporting

### **Clinical Outcomes**

Improved health and wellbeing through better clinical outcomes and patient experience, whilst promoting confidence in self-care and maximising independence.

### **Performance Monitoring/Reporting**

Providers will be asked to submit data via the Portal <https://secure.yhcs.org.uk/nyhat-invoice/LogOn.aspx?ReturnUrl=%2fnyhat-invoice%2f>

Full records should be maintained in such a way that aggregated data and details of individual patients (including histology reports) are readily accessible. Practices should regularly audit and peer review work. If appropriate - North Lincolnshire Clinical Commissioning Group will provide details of the audit protocol and the timescales for submission of an audit report when necessary.

### **Outcomes / Measures / Reporting Requirements will include:**

Providers of the service should maintain adequate clinical records, incorporating all known information relating to any significant events arising from services provided under this Contract (e.g. hospital admissions, wound infections, drug reactions), including patient treatment and outcomes, that can be the subject of clinical audit and review.



### **3. Scope**

#### **3.1 Aims and objectives of service**

The aim of the service is to ensure that patients are seen as close-to-home as possible, in the most appropriate setting, through provision of an accessible minor injury service, enabling easy and timely access to urgent health services, ensuring patient safety.

#### **3.2 Service description/care pathway**

##### **Delivery of Service**

This service is aimed to be a primarily nurse led scheme, with advice available from a GP as required.

The service will provide:

- Initial triage including immediately necessary clinical action to staunch haemorrhage and prevent further exacerbation of the injury.
- History taking, relevant clinical examination, documentation
- Wound assessment to ascertain suitability for locally based treatment and immediate wound dressing where indicated
- Assessment, advice, treatment and onward referral as appropriate for a broad range of minor injuries that would not be considered to be covered by requirements of GMS, PMS or APMS contracts. Illustrations of minor injuries covered under this specification are given in Section 3.4
- Appropriate and timely referral and/or follow up arrangements
- Adequate facilities including premises and equipment, as necessary to enable to proper provision of minor injury services including facilities for cardiopulmonary resuscitation.
- Registered nurses to provide care and support to patients undergoing minor injury services
- Maintenance of infection control standards
- Information to patients on the treatment options and the treatment proposed
- Maintenance of records of all procedures including appropriate clinical coding
- Advertisement of practice arrangements for minor injury, including operating hours and staffing arrangements.
- Audit of minor injury service provision will take place when required.

The service is to be provided between the hours of 8.00 am – 6.30 pm, Monday to Friday. Practices that normally close over the lunchtime period should provide appropriate access to the minor injury service for this period. (e.g. emergency contact telephone number on the practice answer phone and displayed).

### 3.3 Population Covered

Patients registered with a GP practice that is a member of North Lincolnshire CCG.

### 3.4 Any acceptance and exclusion criteria and thresholds

Professional consensus indicates that injuries and wounds over 48 hours old should usually be dealt with through normal primary care services, as should any lesion of a non-traumatic origin.

The following list gives examples on the types of injuries and circumstances that lead to the use of Minor Injury Services. This list is not exhaustive and clinicians are expected to use clinical judgment in deciding whether to accept a patient into the service:

- lacerations capable of closure by simple techniques (stripping, gluing, suturing)
- bruises
- foreign bodies
- non-penetrating superficial ocular foreign bodies
- following advice to attend specifically given by a general practitioner
- following recent injury of a severity not amenable to simple domestic first aid
- following recent injury where it is suspected stitches may be required
- following blows to the head where there has been no loss of consciousness
- recent eye injury
- partial thickness thermal burns or scalds involving broken skin
  - a) not over 1 inch diameter
  - b) not involving the hands, feet, face, neck, genital areas
- foreign bodies superficially embedded in tissues
- minor trauma to hands, limbs or feet.

Patients in the following categories or with the following conditions are **not** appropriate for treatment by the Minor Injury Service, but this contract covers the appropriate referral of these patients elsewhere:

- 999 call (unless attending crew speak directly to the doctor)
- any patient who cannot be discharged home after treatment
- any patient with airway, breathing, circulatory or neurological compromise
- actual or suspected overdose
- accidental ingestion, poisoning, fume or smoke inhalation
- blows to the head with loss of consciousness or extremes of age
- sudden collapse or fall in a public place
- penetrating eye injury
- chemical, biological, or radioactive contamination injured patients
- full thickness burns
- burns caused by electric shock
- partial thickness burns over 1 inch diameter or involving:
  - a) injuries to organs of special sense
  - b) injuries to the face, neck, hands, feet or genitalia
- new or unexpected bleeding from any body orifice if profuse
- foreign bodies impacted in bodily orifices, especially in children
- foreign bodies deeply embedded in tissues
- trauma to hands, limbs or feet substantially affecting function
- penetrating injuries to the head, torso, abdomen
- lacerating/penetrating injuries involving nerve, artery or tendon damage.

These arrangements are for in hours periods only. Out of Hours arrangements are subject to separate arrangements.

The provider will be expected to maintain a system to record the intervention undertaken for each patient attending the service together with details of any complications and advice given. This requirement must be met for patients who are registered with the provider.

### **3.5 Interdependence with other services/providers**

Excluded patients should be appropriately referred elsewhere, for example to local A&E services, Minor Injury Services, Walk in Centre etc.

## **4. Applicable Service Standards**

### **4.1 Applicable national standards (eg NICE)**

None specific to the service

### **4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)**

None specific to the service

### **4.3 Applicable local standards**

Staff providing minor injury services would be expected to:

- Have either current experience of provision of minor injury work, or
- Have current minor surgery experience, or
- Have recent accident and emergency experience, or
- Have training which satisfies relevant appraisal and revalidation procedures

Staff carrying out minor injury services must be trained in resuscitation and, as for other areas of clinical practice, have a responsibility for ensuring that their skills are regularly updated. Staff carrying out minor injury activity should demonstrate a continuing sustained level of activity, conduct audit data and take part in appropriate educational activities.

## **5. Applicable quality requirements and CQUIN goals**

### **5.1 Applicable quality requirements (See Schedule 4 Parts A-D)**

### **5.2 Sepsis**

The provider is required to ensure all relevant staff are trained in sepsis awareness, including recognition, diagnosis and early management in line with NICE guidance (NG51 section 1.12). <https://www.nice.org.uk/guidance/ng51/resources/sepsis-recognition-diagnosis-and-early-management-pdf-1837508256709>.

The provider will ensure all relevant staff undergo training, utilising Health Education England's Think Sepsis resources; <https://www.e-lfh.org.uk/programmes/sepsis/>

The service should ensure National Early Warning scores (NEWs) scores are used to identify deteriorating patients and should ensure there is an audit programme in place to monitor use of NEWs Scores.

### 5.3 Safeguarding

The Provider will have in place arrangements which ensure compliance with the following legislation/ statutory guidance, or successor documents:

- Children Act 2004, sections 10 and 11
- Care Act 2014, sections 42-26
- Working Together to Safeguarding Children (2015)
- Care and support statutory guidance: Chapter 14
- CQC Fundamental Standards (2014); Regulation 13
- North Lincolnshire Safeguarding Children Board Policies and Procedures - <http://www.northlincsiscb.co.uk/professionals/policies/>
- North Lincolnshire Safeguarding Adult Board Policy and Procedures - <http://www.northlincssab.co.uk/wp-content/uploads/2017/09/MA-Policy-Procedures-Updated-2017.pdf>

The Provider will also ensure compliance in accordance with new legislation/ statutory guidance on implementation.

In order to demonstrate compliance, the Provider will ensure they have arrangements as outlined within the Safeguarding adult and children standards for providers section in NLCCG Safeguarding Policy, and provide evidence to the Commissioner as requested and as outlined in Performance and monitoring of providers section of the same policy.

### 5.4 Applicable CQUIN goals (See Schedule 4 Part E)

Not applicable.

## 6. Premises

The service will be provided from the Providers premises registered with the CQC.

## 7. Individual Service User Placement

## 8. Prices

## SCHEDULE 2 – THE SERVICES

### A. Service Specification

<b>Service Specification No.</b>		
<b>Service</b>	Anticoagulation Level 3 & 4 Service	
<b>Commissioner Lead</b>	Interim Director of Primary Care	
<b>Provider Lead</b>		
<b>Period</b>	1 April 2019 – 31 March 2022	
<b>Date of Review</b>	Annual	
<b>Version Control: V3</b>	Reviewer:	Local Services working group
	Date:	
	Changes made:	

#### 1. Population Needs

##### 1.1 National and local context; evidence base

Anticoagulation therapy is most commonly required for patients at high risk of thromboembolism, either following an episode of venous thromboembolism (VTE), or in those with Atrial Fibrillation (AF) or prosthetic heart valves.

AF is the most common sustained cardiac arrhythmia and if left untreated is a significant risk factor for stroke and other morbidities. It is often only detected after patients present with serious complications of AF, such as stroke, thromboembolism or heart failure. Patients with AF who develop a stroke have greater mortality, more disability, more severe strokes, longer duration of in-hospital stay and a lower rate of discharge to their own homes. Appropriate anticoagulation therapy (adjusted-dose warfarin) in people with AF can reduce mortality and morbidity.

VTE is a condition in which a blood clot (a thrombus) forms in a vein, most commonly in the deep veins of the legs or pelvis. This is known as deep vein thrombosis, or DVT. The thrombus can dislodge and travel in the blood, particularly to the pulmonary arteries. This is known as pulmonary embolism, or PE. When DVT and PE occur together, it is called VTE

People with newly diagnosed VTE, including pulmonary embolism (PE) and deep vein thrombosis (DVT), are likely to be prescribed anticoagulation therapy for short periods of time (3–6 months). There is an additional group of people with VTE who will be on anticoagulation therapy long term.

The National Institute for Health and Clinical Excellence (NICE) identifies a number of potential benefits to commissioning an effective anticoagulation therapy service. These include:

- Ensuring that appropriate patients receive anticoagulation therapy and prompt

monitoring

- Reducing inequalities in access to anticoagulation therapy
- Improving anticoagulation control in patients and reducing drug-associated complications
- Reducing the risk of stroke in patients with AF, which may impact positively on stroke service requirement and capacity
- Better value for money, through helping commissioner to manage their commissioning budgets
- Implementing more cost effective treatments – this may include opportunities for clinicians to undertake local service redesign to meet local requirements in novel ways.

Warfarin is mainly used in the management of increasing numbers of patients and conditions including those conditions outlined above: eg atrial fibrillation, DVTs and other disorders. While it is a very effective drug in these conditions, it can also have serious side effects, e.g. severe haemorrhage. These side effects are related to the International Normalised Ratio (INR) level, which measures the delay in the clotting of the blood caused by the warfarin. While the 'normal' INR is 1, the specific range of INR values depends on the disease and the clinical conditions. Warfarin monitoring aims to stabilise the INR within set limits to help prevent serious side-effects while maximising effective treatment.

As an alternative there is increasing use of Direct Oral Anticoagulants (DOACs) eg Dabigatran, Rivaroxaban. These drugs do not require INR monitoring, but post other significant considerations in determining a patients' suitability for prescribing.

## 1.2 Local context

Historically, there has been limited access to a community based anticoagulation in North Lincolnshire. Provision has mainly been accessed within secondary care.

There are many significant benefits to the patient for delivering this service in the primary care setting, primarily eliminating the delay in waiting for the result to be processed by the hospital laboratory, and the subsequent delay in informing the patient of their dosing advice. However the service must be undertaken within the confines of safe practice involving quality control procedures.

## 1.3 GP Providers of Service

All GP practices are expected to provide 'essential' and those additional services they are contracted to provide under GMS/PMS/APMS to all their patients. This local service specification for the Initiation of Insulin in primary care outlines the more specialised service to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term	✓

	<b>conditions</b>	
<b>Domain 3</b>	<b>Helping people to recover from episodes of ill-health or following injury</b>	✓
<b>Domain 4</b>	<b>Ensuring people have a positive experience of care</b>	✓
<b>Domain 5</b>	<b>Treating and caring for people in safe environment and protecting them from avoidable harm</b>	✓

## 2.2 Applicable Local Standards:

- Workforce - Providers must demonstrate that all staff have the necessary skills to undertake the requirements of this specification. Staff must be able to demonstrate that clinical competencies are maintained and safe staffing levels must be maintained in accordance with national policy/standards.
- Patient, public and staff safety – Providers will be required to demonstrate that evidence based clinical protocols are being used. Providers must have in place appropriate health and safety and risk management systems and premises that are safe and patient friendly. They should also ensure that any risk assessments and significant events are both documented and audited regularly, learning outcomes identified and any changes implemented. Services should comply with national requirements for recording, reporting, investigation and implementation of learning from incidents.
- Clinical audit and review – Providers must identify and undertake a programme of clinical audit to support the delivery of the service.
- Patient and public involvement – Providers are required to demonstrate active engagement with patients in evaluating services. Providers must demonstrate how systematic patient feedback is being used to shape and improve services.
- Managing complaints – Responsive protocols and procedures must be in place for managing patient complaints (in line with national requirements). Complaints must be reviewed at regular intervals and learning from these shared and applied as appropriate to ensure that services are continually improved.
- Infection Control – Providers will ensure that they comply with national and local guidance on infection prevention and control. This includes having robust systems and processes in place including audits, as appropriate.

## 2.3 Performance Monitoring/Reporting

Providers will be asked to submit data via the Portal <https://secure.yhcs.org.uk/nyhat-invoice/LogOn.aspx?ReturnUrl=%2fnyhat-invoice%2f>

Full records should be maintained in such a way that aggregated data and details of individual patients (including histology reports) are readily accessible. Practices should regularly audit and peer review work.

## 2.4 Outcomes / Measures / Reporting Requirements will include:

Providers of the service should maintain adequate clinical records, incorporating all known information relating to any significant events arising from services provided under this Contract (e.g. hospital admissions, wound infections, drug reactions), including patient treatment and outcomes, that can be the subject of clinical audit and review.

## 3. Scope

This service will provide broader access to community based anticoagulation monitoring

service.

### **3.1 Service aims**

The overall aim of this service is to ensure that North Lincolnshire patients have equal access to a high quality, safe and effective initiation, stabilisation, monitoring and dosing and prescribing anticoagulation monitoring service. Including:

- Appropriate patients receive anticoagulation therapy and monitoring promptly, in line with the relevant national service standards and guidelines;
- Reducing the risk of thromboembolic stroke in AF, which may impact positively on stroke service requirement and capacity;
- Reducing inequalities in access to anticoagulation therapy;
- Improving anticoagulation control in patients, and reducing drug-associated complications by establishing regular monitoring of patients to stabilise their INR levels whilst continuing to maximise the benefit of such treatment;
- Providing value for money.

### **3.2 Objectives of the service include:**

- Monitoring and dosing anticoagulant therapy in a community setting that reduces bleeding risk.
- Produce standardised and clinically effective anticoagulation management to patients receiving warfarin therapy whilst minimising risks associated with anticoagulation.
- Initiate warfarin for suitable patients
- Produce optimal management of INR control
- Provide education to patients to understand their treatment
- Provide a service to the patient that is convenient
- The need for continuation of therapy is reviewed regularly
- High quality service in line with applicable local, national and professional standards
- Share learning and best practice to improve quality.

### **3.3 Service description/care pathway**

The community based anticoagulation service provides an anticoagulation monitoring service that optimises INR levels in patients. This monitoring service encompasses 2 levels as outlined below.

Providers are expected to cover the costs of the equipment, consumables and licences required to deliver the service, including the point-of-care testing device, testing strips, quality controls and software.

#### **Level 3 Service**

The Provider will undertake the necessary venous blood tests. These bloods will be tested externally. On receipt of the results, the Provider will take responsibility for adjusting warfarin dosing as clinically determined by an appropriately qualified health professional. The Provider will also be responsible for the issuing of prescriptions. Individual patient treatment plans should be updated as part of this process.

#### **Level 4 Service**

The Provider will undertake point of care (near patient) testing adjusting warfarin dosages as necessary and providing dosing advice to patients. The Provider will also be



responsible for the issuing of prescriptions. Individual patient treatment plans should be updated as part of this process.

Standard requirements applicable to all service providers

The Provider will:

Develop and maintain a register of patients receiving warfarin and have a personalised treatment plan for each patient that is reviewed at regular intervals. For each patient this register should include:-

- Patients name
- Date of birth
- The indication for and duration of treatment
- Dose of anticoagulation
- Target INR
- Relevant clinical history, examination findings and test results
- Date of next appointment / Follow up arrangements
- Information from the prescriber (where appropriate)
- Details of the Computerised Decision Support Software (CDSS) used (Level 4 only)
- Be in line with NSPA actions and take account of NICE guidance for Commissioning Anticoagulation Therapy (2013)
- Ensure an effective and systematic call and recall of patients takes place. Informing patients of the advised dose and date of follow-up blood test (recorded in the patient's notes). The INR frequency determined by following guidelines or CDSS.
- Systems for identifying patients who have not attended for INR blood test within the recommended timescales should be in place.
- Determine the frequency for monitoring based on the needs of the individual patient which will depend on whether the patient has recently started therapy, has a stable INR within target or has poor INR control.
- An adequate system is in place for people failing to attend their follow up appointments (DNAs) to ensure warfarin is not prescribed unmonitored.
- Providers should retain patients in treatment up to the end of the indicated treatment duration (including life-long treatment) and have a robust process of documentation including reasons for discontinuing Warfarin.
- To work together with other professionals when appropriate. Any health professional involved in the care of patients should be appropriately trained.
- Where appropriate, refer patients promptly to other necessary services and relevant support agencies using locally agreed guidelines and referral policies where they exist.
- Ensure that all newly diagnosed patients (and/or their carers and support staff where appropriate) receive appropriate management of, and prevention of, secondary complications of their condition including the provision of patient-held booklets (yellow book).
- All patients on warfarin will be provided with an individual management plan which will include the diagnosis, planned duration and therapeutic range to be obtained (e.g. the yellow book). At each attendance this plan must be updated to include clear daily dosing information and date of next follow up appointment.
- At initial diagnosis, and at least annually, complete an appropriate review of the patient's health including checks for potential complications and, as necessary, a review of the patient's own monitoring records. Also a review of the patients understanding of the information given to them on initiation.

- Have written procedures and clinical protocols for the safe use of oral and injectable anti-coagulant therapy. The protocol should adhere to the recommendations made in “Patient Safety Alert 18 – Actions that make anticoagulant therapy safer” (NPSA March 2007)
- Review the need for continuity of therapy at each visit and review every patient taking anticoagulation therapy at least annually taking account of:
  - reassessment of stroke or venous thromboembolism (VTE) risk
  - reassessment of bleeding risk
  - assessment of renal function
  - incidence of adverse events relating to anticoagulation therapy since last review
  - assessment of compliance
  - choice of alternative anticoagulant.
- Have systems that ensure it can respond appropriately and in a timely way to changes in co-prescribed medication.
- Ensure that all clinical information is recorded in the patient’s medical record. This includes ensuring that all clinicians are aware of the current prescribing of warfarin including the clinical indication for it and this information is flagged in the patients active major/significant problem list.
- To maintain adequate records of the performance and result of the service provided, incorporating appropriate known information. This may include the number of bleeding episodes requiring hospital admission and deaths caused by anti-coagulants.
- Carry out clinical audit of the care of patients against the above criteria, including untoward incidents. This should also review the success of the provider in maintaining its patients within the designated INR range as part of quality assurance.

#### When providing Level 4

- Where used, ensure appropriate Computerised Decision Support Software (CDSS) is utilised and the appropriate licences are in place
- When providing INR testing at level 4, the meters used should meet the agreed standard for medical devices and arrangements are in place for internal and external quality assurance (eg. NEQAS)
- Each contractor must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills
- Have a named clinical lead that has overall responsibility for ensuring the service is delivered in accordance with the service specification and relevant clinical guidelines.

### **3.4 Population covered**

Patients registered with a GP Practice that is a member of North Lincolnshire CCG.

### **3.5 Acceptance and Exclusion Criteria**

The service is available to those patients who require prescribed anticoagulation therapy in accordance with all applicable NICE guidelines and clinical practice.

The specification applies to:

- patients on the anticoagulation register who are subject to active monitoring (ie patients who have been monitored in the last three months).
- existing patients who are currently on warfarin therapy in Primary Care
- new patients that require warfarin initiation

The service does not include:

- Initiation of anticoagulation postoperatively.
- Prophylaxis of VTE following hip-or knee surgery.
- Continual monitoring of patients initiated on DOACs and subsequently discharged to the care of their GP
- Below-knee graduated compression stockings for proximal DVT
- Self-testing and self-management of patients on warfarin (other than by further agreement for patient pathways as developed)
- Children under the age of 16

### **3.6 Interdependence with other services/providers:**

- North Lincolnshire Area Prescribing Committee
- North Lincolnshire and Goole NHS Foundation Trust
- Hull and East Yorkshire Hospitals NHS Trust
- North of England Commissioning Support (NECS)

## **4. Applicable Service Standards**

### **4.1 Applicable national standards eg NICE**

As stated in paragraphs SC2 (Regulatory Requirements) and SC3 (Service Standards) the Provider is required to adhere to all national standards as issued from time to time by any relevant Regulatory and Statutory bodies including guidance issued by appropriate competent bodies (eg Royal Colleges).

The Provider should be aware of, and adhere to as applicable, the following key documents and sources of reference:

- Guidelines on oral anticoagulation with warfarin (BCSH)  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2011.08753.x/full>
- Actions that can make anticoagulant therapy safer: Alert and other information (NPSA)  
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814>

### **4.2 Applicable local standards**

- Providers must ensure that all staff involved in providing any aspect of care under this specification has the necessary training and skills to do so.
- Any staff involved in the provision of this service will satisfy at appraisal (and revalidation if necessary) that they have such continuing clinical experience, training and competence as is necessary to enable them to provide the service as outlined in this specification.
- Any new providers will be required to undertake an assessment visit prior to commencing the service.
- Providers will be subject to an annual review via a self assessment template and the CCG may visit GP Practices to perform any checks.

- All Providers to follow the local prescribing guidance and joint formulary

## **5. Applicable quality requirements and CQUIN goals**

### **5.1 Applicable quality requirements (See Schedule 4 Parts A-D)**

The Provider will develop and follow a standard operating policy for provision of this service.

### **5.2 Internal Quality Assurance**

As directed by the manufacturers, calibration of the equipment. In addition, the manufacturer will double check the accuracy of results by repeating the assessment on an agreed number of samples.

### **5.3 External Quality Assurance**

The Provider is expected to be registered with UK NEQAS, which is the UK National External Quality Assessment Service for Blood Coagulation and is part of Sheffield Teaching Hospitals NHS Foundation Trust.

The CCG will benchmark Practice data with the CCG average based on population size and demographics. In the event of benchmarks being significantly above or below averages, the CCG will enter into discussions with the Practice to understand the variance.

### **5.4 Applicable CQUIN goals (See Schedule 4 Part E)**

### **5.5 Sepsis**

The provider is required to ensure all relevant staff are trained in sepsis awareness, including recognition, diagnosis and early management in line with NICE guidance (NG51 section 1.12). <https://www.nice.org.uk/guidance/ng51/resources/sepsis-recognition-diagnosis-and-early-management-pdf-1837508256709>

The provider will ensure all relevant staff undergo training, utilising Health Education England's Think Sepsis resources; <https://www.e-lfh.org.uk/programmes/sepsis/>  
The service should ensure NEWs assessments scores are used to identify deteriorating patients and should ensure there is an audit programme in place to monitor use of NEWs Scores.

### **5.6 Safeguarding**

The Provider will have in place arrangements which ensure compliance with the following legislation/ statutory guidance, or successor documents:

- Children Act 2004, sections 10 and 11
- Care Act 2014, sections 42-26
- Working Together to Safeguarding Children (2015)
- Care and support statutory guidance: Chapter 14
- CQC Fundamental Standards (2014); Regulation 13
- North Lincolnshire Safeguarding Children Board Policies and Procedures - <http://www.northlincsiscb.co.uk/professionals/policies/>

- North Lincolnshire Safeguarding Adult Board Policy and Procedures -

<http://www.northlincsab.co.uk/wp-content/uploads/2017/09/MA-Policy-Procedures-Updated-2017.pdf>

The Provider will also ensure compliance in accordance with new legislation/ statutory guidance on implementation.

In order to demonstrate compliance, the Provider will ensure they have arrangements as outlined within the Safeguarding adult and children standards for providers section in NLCCG Safeguarding Policy, and provide evidence to the Commissioner as requested and as outlined in Performance and monitoring of providers section of the same policy.

#### **6. Location of Provider Premises**

The service will be provided from the Provider's premises registered with the CQC

#### **7. Individual Service User Placement**

Not applicable.

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

Mandatory headings 1 – 4. Mandatory but detail for local determination and agreement

Optional headings 5-7. Optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

<b>Service Specification No.</b>		
<b>Service</b>	Providing Care for Patients with Diabetes – including Insulin Initiation, GLP-1 Initiation, MDT and glucose tolerance testing.	
<b>Commissioner Lead</b>	Interim Director of Primary Care	
<b>Provider Lead</b>		
<b>Period</b>	1 April 2019 to 31 March 2022	
<b>Date of Review</b>	Annual	
<b>Version Control: V2</b>	Reviewer:	Local Services working group
	Date:	
	Changes made:	

### 1. Population Needs

#### 1.1 National / Local context and evidence base

##### National context

Everyone Counts 2014/15<sup>1</sup> directs Clinical Commissioning Groups (CCGs) to focus on reducing health inequalities and advance equality in a drive to improve outcomes for patients. In particular, Domain 1 is relevant for commissioning of diabetes care as it outlines the need to:

- Wider primary care, provided at scale
- A modern model of integrated care.

Diabetes UK Best Practice for Commissioning Diabetes Services. An Integrated Care Framework<sup>2</sup>, states that providing better integrated diabetes care has been shown to improve patient experience, quality of clinical care and reduce hospital admissions for vulnerable patients.

##### Local context

According to estimates produced by the Yorkshire and Humber Public Health Observatory,

North Lincolnshire CCG has a coded diabetic registered population of 12,603; this is a prevalence of 9.0% of their population.<sup>3</sup>

North Lincolnshire Clinical Commissioning Group (NL CCG) are committed to commission services where all or part of the care can be provided within a Care Network locality and aims to improve patient experience by providing services closer to home, in accessible community venues and supporting residents to live and work well. Diabetes is one of the services noted as suitable for this type of approach.

The approach previously taken to provide diabetes care for the population of North Lincolnshire has been through an enhanced Integrated Diabetes Service for Primary Care and an enhanced specification for Insulin Initiation.

Following local discussion – it has been agreed that a model for a diabetes local service should incorporate provision of:

- Insulin Initiation and/or intensification of insulin regimen(s)
- GLP-1 Initiation
- Primary Care MDT;
- Glucose Tolerance Testing (when clinically appropriate)
- Type 1 and Type 2 diabetes requiring complex treatment regimens
- Drug induced diabetes management
- Diabetes and palliative care

This Service Specification has been developed based on the above model of service.

## **1.2 GP Providers of Service**

All GP practices are expected to provide 'essential' and those additional services they are contracted to provide under GMS/PMS/APMS to all their patients. This local service specification for the Initiation of Insulin, GLP1 and management of treatment regimens, as stated above, in primary care outlines the more specialised service to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

1 <http://www.england.nhs.uk/wp-content/uploads/2013/12/5yr-strat-plann-guid-wa.pdf>

2 <http://www.diabetes.org.uk/Documents/Position%20statements/best-practice-commissioning-diabetes-services- integrated-framework-0313.pdf>

3 <http://www.yhpho.org.uk/DEFAULT.ASPX?RID=154049>

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

The NHS Outcomes Framework sets five "domains" through which the effectiveness of health care will be measured (Department of Health, 2011):

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

### 2.2 Local Defined Outcomes

#### Applicable Local Standards:

- Workforce - Providers must demonstrate that all staff have the necessary skills to undertake the requirements of this specification. Staff must be able to demonstrate that clinical competencies are maintained and safe staffing levels must be maintained in accordance with national policy/standards.
- Patient, public and staff safety – Providers will be required to demonstrate that evidence based clinical protocols are being used. Providers must have in place appropriate health and safety and risk management systems and premises that are safe and patient friendly. They should also ensure that any risk assessments and significant events are both documented and audited regularly, learning outcomes identified and any changes implemented. Services should comply with national requirements for recording, reporting, investigation and implementation of learning from incidents.
- Clinical audit and review – Providers must identify and undertake a programme of clinical audit to support the delivery of the service.
- Patient and public involvement – Providers are required to demonstrate active engagement with patients in evaluating services. Providers must demonstrate how systematic patient feedback is being used to shape and improve services.
- Managing complaints – Responsive protocols and procedures must be in place for managing patient complaints (in line with national requirements). Complaints must be reviewed at regular intervals and learning from these shared and applied as appropriate to ensure that services are continually improved.
- Infection Control – Providers will ensure that they comply with national and local guidance on infection prevention and control. This includes having robust systems and processes in place including audits, as appropriate.

#### Performance Monitoring/Reporting

Providers will be asked to submit data via the Portal <https://secure.yhcs.org.uk/nyhat-invoice/LogOn.aspx?ReturnUrl=%2fnyhat-invoice%2f>

#### Clinical Outcomes

Increased numbers of patients with improved blood glucose control (within NICE



recommended targets) via the provision of a community based diabetes care service and pharmacotherapy use and monitoring.

A reduction in first and follow up outpatient attendances within acute services through primary care management of appropriate patients.

Increase in the proportion of patients who achieve good blood glucose control and target HbA1c levels in line with NICE guidance (NG17 for Type 1 and NG28 for Type 2)

Reduction in the risk of long-term diabetic complications (including foot problems, renal problems, cardiovascular problems, visual impairment and neuropathy)

Reduction in amputations.

Contribution to reduction in diabetic related A&E attendances and unplanned admissions.

### **3. Scope**

This service will convert those people who are not achieving adequate diabetic control through lifestyle modification and oral hypoglycemic agents (OHAs) to insulin or GLP-1 therapy and provide a high quality community based diabetic care service.

#### **3.1 Aims and objectives of service**

- To enhance continuity of care.
- Deliver an accessible service to the patient that is convenient and timely.
- To facilitate keeping the person with diabetes in primary care.
- Early identification of patients that are at risk of developing Type2 Diabetes.
- Provide Insulin and GLP-1 initiation and Glucose Tolerance Tests (GTT) (only where appropriate and in line with guidance) within Primary Care.
- Modify/change treatment pathways and maintain individualised care for each patient who accesses the intermediate primary care diabetes service
- Provide lifestyle education at an any stage.
- Increase diabetes skill levels within Primary Care (GP/Practice Nurse workforce).

#### **3.2 Service description/care pathway**

This service will be provided to patients identified as possibly having diabetes or who have been diagnosed with Type 1 or Type 2 diabetes, as outlined below.

Insulin and GLP1 Initiation when clinically appropriate in type 2 diabetes – OGTT when clinically appropriate for suspected type 2 diabetes.

<https://cks.nice.org.uk/insulin-therapy-in-type-2-diabetes>

<https://cks.nice.org.uk/insulin-therapy-in-type-1-diabetes>

<https://pathways.nice.org.uk/pathways/type-2-diabetes-in-adults/managing-blood-glucose-in-adults-with-type-2-diabetes#content=view-node:nodes-drug-treatment>

<https://www.nice.org.uk/guidance/NG28/resources>

<https://www.nice.org.uk/guidance/ng28/resources/algorithm-for-blood-glucose-lowering-therapy-in-adults-with-type-2-diabetes-pdf-2185604173>

A Primary Care Multi Disciplinary Team (MDT) (utilising input from integrated specialist services (including Consultant Diabetologist and diabetes nurse specialists / community MDT should meet twice per year, where the findings from reviews will be shared and discussed. This practice MDT information should also be used to inform Community MDT and specialist teams.

<https://www.nice.org.uk/guidance/cg138/chapter/quality-statements>  
<http://www.nice.org.uk/guidance/qs6/chapter/quality-statement-3-care-planning>  
<https://www.nice.org.uk/guidance/cg138/chapter/quality-statements>  
<http://www.nice.org.uk/guidance/qs6/chapter/quality-statement-2-nutrition-and-physical-activity-advice>

In addition the Provider of this service should be:

- Maintaining an up to date register of all patients converted to insulin in the practice.
- Ensuring the systematic recall of all patients who have undergone insulin/GLP-1 conversion and that there are systems in place for ensuring regular contact during initial stages for dose adjustment.
- Ensuring that all people converted to insulin (and/or their carers) receive appropriate education and advice on the management of insulin treated diabetes. This should include written information.
- Ensuring that staff providing care under this scheme are trained and accredited to do so, and work in accordance with the guidance provided by the local Specialist Diabetes Service. Keeping up-to-date with current evidence and guidance
- Accepting clinically agreed transfers of care; where patients under the care of the hospital service are deemed stable and where general practice is the right place for care, the practice will accept the transfer of care at the point they agree with the integrated specialist service an appropriate treatment plan with ongoing support provided by the specialist when needed.
- Participating in the annual National Diabetes Audit (NDA), by either opting in for automatic extraction of data through their clinical system, or by uploading data through the appropriate portal. The National Diabetes Audit is a major national clinical audit, which measures the effectiveness of diabetes healthcare against NICE Clinical Guidelines and NICE Quality Standards, in England and Wales. The NDA collects and analyses data for use by a range of stakeholders to drive changes and improvements in the quality of services and health outcomes for people with diabetes.

#### **HbA1c and Oral Glucose Tolerance Testing (OGTT):**

**In 2011 WHO recommended that quality assured HbA1c could be used for the diagnosis (HbA1c  $\geq 48$ mmol/mol) of diabetes in certain circumstances.**

[http://www.who.int/diabetes/publications/report-hba1c\\_2011.pdf](http://www.who.int/diabetes/publications/report-hba1c_2011.pdf)

**An expert group published guidance for the UK in 2012:** Expert Position Statement Use of HbA1c in the diagnosis of diabetes mellitus in the UK. The implementation of World Health Organization guidance 2011

<http://onlinelibrary.wiley.com/doi/10.1111/j.1464-5491.2012.03762.x/epdf>

**It is important to note that HbA1c should not and cannot be used in all clinical presentations and patient groups.**

**Clinicians should make an assessment based on the patient and the clinical situation as to which diagnostic test should be carried out. (If in doubt please consult with Consultant Biochemist or Consultant Diabetologist)**

### **3.3 Primary care clinician/nurse education**

Practices should complete diabetes education programmes as required including:

- Insulin Initiation
- GLP1
- Foot screening (provided by the podiatry service)
- General diabetes management and patient education.

### **Delivery of Service**

**In order to provide this service, the provider team must:**

- Have the knowledge of the potential barriers to insulin/GLP-1 initiation.
- Be aware of the strategies to overcome potential barriers to insulin/GLP-1 initiation in primary care.
- Understand the role that primary care team members play in developing and supporting insulin/GLP-1 initiation.
- Be able to identify the need for early intervention of insulin therapy and support this with the individual practice.
- Work with the Specialist Diabetes Services, where appropriate.
- Apply local and national guidelines to the care and management of people with diabetes.
- Provide the indications for early initiation of insulin or GLP-1 treatment in diabetes patients.
- Initiate and adjust insulin/GLP-1 therapy safely and effectively.
- Be able to identify causes and signs and symptoms of hypoglycaemia and advice on appropriate treatment, including management of patients with hypoglycaemic unawareness
- Discuss the various insulin delivery devices available and demonstrate effective injection techniques suitable for the individual.
- Where a practice is delivering the service to a patient not registered with their practice, the provider will be responsible for implementing a system of reporting information to other practices (see 3.3).
- Telephone advice and support for HCP's and patients.
- Management and optimisation of complex treatment regimens, whether Type 1 or Type 2 diabetes and associated issues including carbohydrate counting, blood ketone testing, etc.
- Dealing with problems of clinical inertia across the care network.

Where initiation is undertaken by a practice that is not the patient's registered practice, the practice providing the service will be responsible titration of insulin doses and optimisation of insulin type and injection regime for 12 months post initiation. The providing practice will also review HbA1C and insulin regime at 6 and 12 months and report information to the practice at which the patient is registered (see 3.3).

### **3.4 Population Covered**

Patients registered with a GP practice that is a member of North Lincolnshire CCG.

### **3.5 Any acceptance and exclusion criteria and thresholds**

The service is available for (non-complex) adults with diabetes.

The decision to start the patient on insulin/GLP-1 therapy is usually precipitated by one or more of the following situations:-

- worsening symptoms of hyperglycaemia
- a persistently elevated HbA1c level despite maximal or near maximal doses of oral hypoglycaemic agents
- intercurrent illness or patient commenced on steroid therapy.

It is essential to review patient's lifestyle including diet and exercise and compliance with medication prior to making the decision to commence insulin.

### Exclusions

- Children & Adolescents (non paediatric)
- Diabetic Foot care patients. (within predefined criteria for North Lincolnshire; high risk patients as identified in the existing foot care pathway)
- Patients clinically assessed as unsuitable for insulin initiation.
- Very low eGFR or patients on renal dialysis
- Antenatal patients and diabetic patients planning pregnancy
- Children, young people and pregnant women

Patients excluded from general practice diabetic care and who should be referred into the hospital service as per the exclusion criteria:

- Children & Adolescents
- Diabetic Foot care patients. (within predefined criteria for North Lincolnshire; high risk patients as identified in the existing foot care pathway)
- Poorly controlled, newly diagnosed or complex Type 1 diabetes patients
- Low eGFR or patients on renal dialysis
- Antenatal patients and diabetic patients planning pregnancy

Where there are clinical concerns over general practice management of a patient outside of the exclusion criteria the practice should contact the integrated diabetes specialist service to discuss the patient and either agree a management plan in primary care with the support of the specialist service, or agree a referral into the hospital service to stabilise the patient to enable a transfer back to general practice for on-going management.

### **3.6 Interdependence with other services/providers**

The service must link appropriately with secondary/tertiary care providers to ensure and support a streamlined and robust care and treatment pathway for the patient. This will include provision of appropriate support to the patient and their carer(s). Other services include:

- Secondary/tertiary care – including the specialist element of the Integrated Diabetes model
- Community services
- Other GP practices and providers of the insulin initiation enhanced service
- Voluntary services
- Out of hours service

## 4. Applicable Service Standards

### 4.1 Applicable national standards (e.g. NICE)

As stated in paragraphs SC2 (Regulatory Requirements) and SC3 (Service Standards) the Provider is required to adhere to all national standards as issued from time to time by any relevant Regulatory and Statutory bodies including guidance issued by appropriate competent bodies (e.g. Royal Colleges).

For Insulin see:

#### **NICE Guideline NG28 Type 2 diabetes in adults: management (replaced NICE CG87).**

*(In May 2017 NICE added text on sodium–glucose cotransporter 2 (SGLT-2) inhibitors to the section on initial drug treatment. NICE also updated the algorithm for blood glucose lowering therapy in adults with type 2 diabetes to revise footnote b with links to relevant NICE guidance on SGLT-2 inhibitors, and added new information on SGLT-2 inhibitors to the box on action to take if metformin is contraindicated or not tolerated.)*

<https://www.nice.org.uk/guidance/ng28>

#### **NICE Guideline NG17 Type 1 Diabetes in adults: diagnosis and management**

<https://www.nice.org.uk/guidance/ng17>

NICE guideline CG66, NICE technology appraisal guidance 248 and NICE technology appraisal guidance 203.

NICE guideline 17. Type 1 Diabetes in adults: diagnosis and management. August 2015 Last updated: July 2016 This guideline updates and replaces the sections for adults in NICE guideline CG15.

<https://www.nice.org.uk/guidance/ng17>

NICE Guideline 18. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. August 2015 <https://www.nice.org.uk/guidance/ng18> This guideline updates and replaces the sections for children and young people in NICE guideline CG15

NICE Guideline 19. Diabetic foot problems: prevention and management. August 2015. <https://www.nice.org.uk/guidance/ng19> This guideline updates and replaces NICE guidelines CG10 and CG119, and the recommendations on foot care in NICE guideline CG15.

### 4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

Royal College of General Practitioners. Clinical resources diabetes.

<http://www.rcgp.org.uk/clinical-and-research/clinical-resources/diabetes.aspx>

All staff involved in providing any aspect of care under this scheme will have necessary training and skills to do this. The GP or Nurse Practitioner Prescriber and their team should have evidence of training in the modern management of diabetes together with evidence of

continuing professional development as follows:-

Via accredited training eg MERIT Insulin Initiation available locally, whereby nurse assessment includes how many insulin starts are appropriate to the individual nurse and competence assessed and signed off by MERIT.

Or:

Warwick Certificate in Diabetes Care Diploma and Warwick Intensive Management Type 2 Diabetes which includes the evidence of a minimum of 10 initiations under the supervision of the Diabetes Specialist Nurse “or an equivalent qualification in insulin management or significant longstanding experience in insulin initiation and management with agreement from the CCG’s Medical Director”

BSc (Hons) in diabetes care.

Appropriate (CSII) qualification/training and continued updates.

At least one member of the practice team should hold these qualifications, one of whom should be a prescriber and at least two should have the above Warwick diabetes qualifications.

CCG will check qualification / skills level before commencement of services provision.

## **5. Applicable quality requirements and CQUIN goals**

### **5.1 Applicable quality requirements (See Schedule 4 Parts A-D)**

The provider will report annually to confirm that at least one MDT meeting per year has been agreed to with the specialist service, and that the meeting was recorded within the affected patients’ notes.

### **5.2 Applicable CQUIN goals (See Schedule 4 Part E)?**

### **5.3 Sepsis**

The provider is required to ensure all relevant staff are trained in sepsis awareness, including recognition, diagnosis and early management in line with NICE guidance (NG51 section 1.12). <https://www.nice.org.uk/guidance/ng51/resources/sepsis-recognition-diagnosis-and-early-management-pdf-1837508256709>.

The provider will ensure all relevant staff undergo training, utilising Health Education England’s Think Sepsis resources; <https://www.e-lfh.org.uk/programmes/sepsis>

The service should ensure National Early Warning scores (NEWs) scores are used to identify deteriorating patients and should ensure there is an audit programme in place to monitor use of NEWs Scores.

### **5.4 Safeguarding**

The Provider will have in place arrangements which ensure compliance with the following legislation/ statutory guidance, or successor documents:

- Children Act 2004, sections 10 and 11
- Care Act 2014, sections 42-26

- Working Together to Safeguarding Children (2015)
- Care and support statutory guidance: Chapter 14
- CQC Fundamental Standards (2014); Regulation 13
- North Lincolnshire Safeguarding Children Board Policies and Procedures - <http://www.northlincsiscb.co.uk/professionals/policies/>
- North Lincolnshire Safeguarding Adult Board Policy and Procedures - <http://www.northlincssab.co.uk/wp-content/uploads/2017/09/MA-Policy-Procedures-Updated-2017.pdf>

The Provider will also ensure compliance in accordance with new legislation/ statutory guidance on implementation.

In order to demonstrate compliance, the Provider will ensure they have arrangements as outlined within the Safeguarding adult and children standards for providers section in North Lincolnshire CCG Safeguarding Policy, and provide evidence to the Commissioner as requested and as outlined in Performance and monitoring of providers section of the same policy.

## **6. Location of Provider Premises**

### **6.1 Premises**

The service will be provided from the Provider's Premises registered with the CQC.

## **7. Individual Service User Placement**

Not applicable.

## HbA1c and Oral Glucose Tolerance Testing (OGTT):

**In 2011 WHO recommended that quality assured HbA1c could be used for the diagnosis (HbA1c  $\geq 48$  mmol/mol) of diabetes in certain circumstances.**

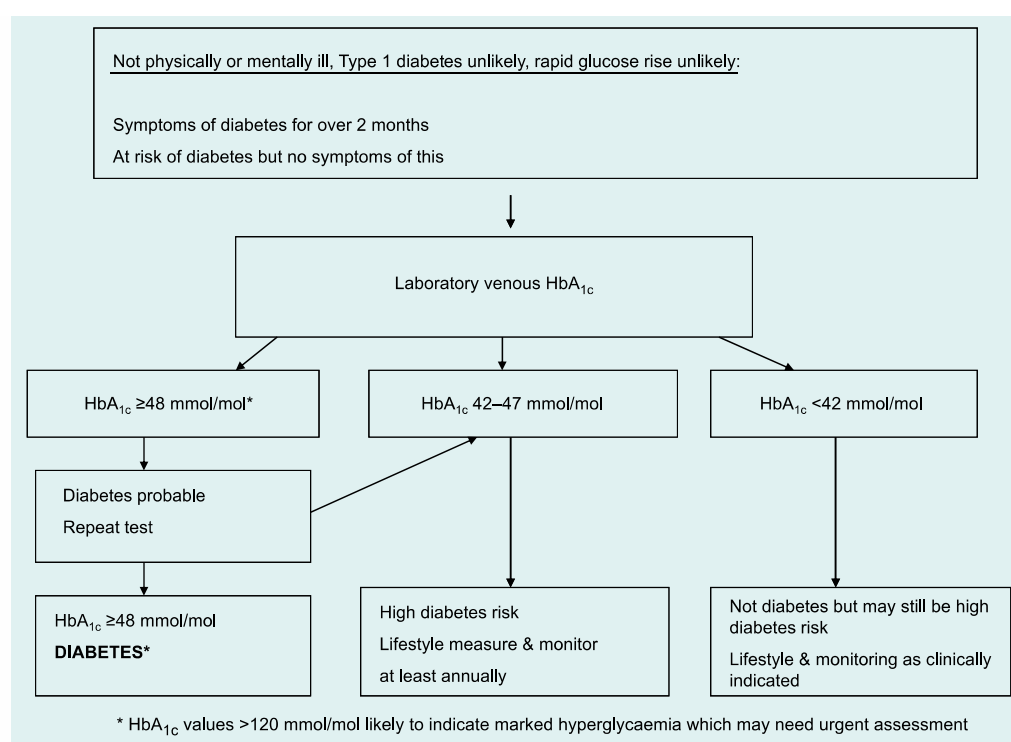
[http://www.who.int/diabetes/publications/report-hba1c\\_2011.pdf](http://www.who.int/diabetes/publications/report-hba1c_2011.pdf)

**An expert group published guidance for the UK in 2012:** Expert Position Statement Use of HbA1c in the diagnosis of diabetes mellitus in the UK. The implementation of World Health Organization guidance 2011  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1464-5491.2012.03762.x/epdf>

**It is important to note that HbA1c should not and cannot be used in all clinical presentations and patient groups.**

**The previous diagnostic criteria still apply and clinicians should make an assessment based on the patient and the clinical situation as to which diagnostic test should be carried out. (If in doubt please consult with Consultant Biochemist or Consultant Diabetologist)**

### **Using HbA1c to diagnose diabetes and impaired glucose regulation states**



**In asymptomatic patients HbA1c should be repeated in 2 weeks to confirm result.**

**DO NOT USE HbA1c in the following patient groups (If in doubt please consult with Consultant Biochemist or Consultant Diabetologist):**

- All children and young people.
- Pregnancy—current or recent (< 2 months).



- Suspected Type 1 diabetes, no matter what age
- Short duration of diabetes symptoms.
- Patients at high risk of diabetes who are acutely ill (HbA1c  $\geq$  48 mmol/mol confirms pre-existing diabetes, but a value  $<$  48 mmol/mol does not exclude it and such patients must be retested once the acute episode has resolved).
- Patients taking medication that may cause rapid glucose rise; for example, corticosteroids, antipsychotic drugs (2 months or less). HbA1c can be used in patients taking such medication long term (i.e. over 2 months) who are not clinically unwell.
- Acute pancreatic damage or pancreatic surgery.
- Renal failure.
- Human immunodeficiency virus (HIV) infection.
- Anaemia
- Haemoglobinopathy

In the above groups HbA1c should still be taken to aid clinical assessment but should not be used for diagnosis or contradict clinical judgment, fasting or random glucose results.

### **Impaired glucose tolerance/impaired fasting glycaemia**

Suitable patients previously diagnosed with either of these impaired glucose regulation states can be monitored with at least annual HbA1c (provided they are not listed in the group above).

Oral glucose tolerance testing should be carried in patients not suitable for HbA1c estimation.

### **HbA1c – impaired glucose regulation/pre-diabetes –definition and management**

HbA1c 42–47 mmol/mol (6.0–6.4%)

- High risk of diabetes.
- Provide intensive lifestyle advice.
- Warn patients to report symptoms of diabetes.
- Monitor HbA1c annually.
- Manage other cardiovascular risk factors e.g. lipids

HbA1c under 42 mmol/mol (6.0%)

- These patients may still have a high diabetes risk
- Review the patient's personal risk and treat as 'high diabetes risk', as clinically indicated.

**If patient is acutely unwell and diabetes suspected, the following steps should be taken:**

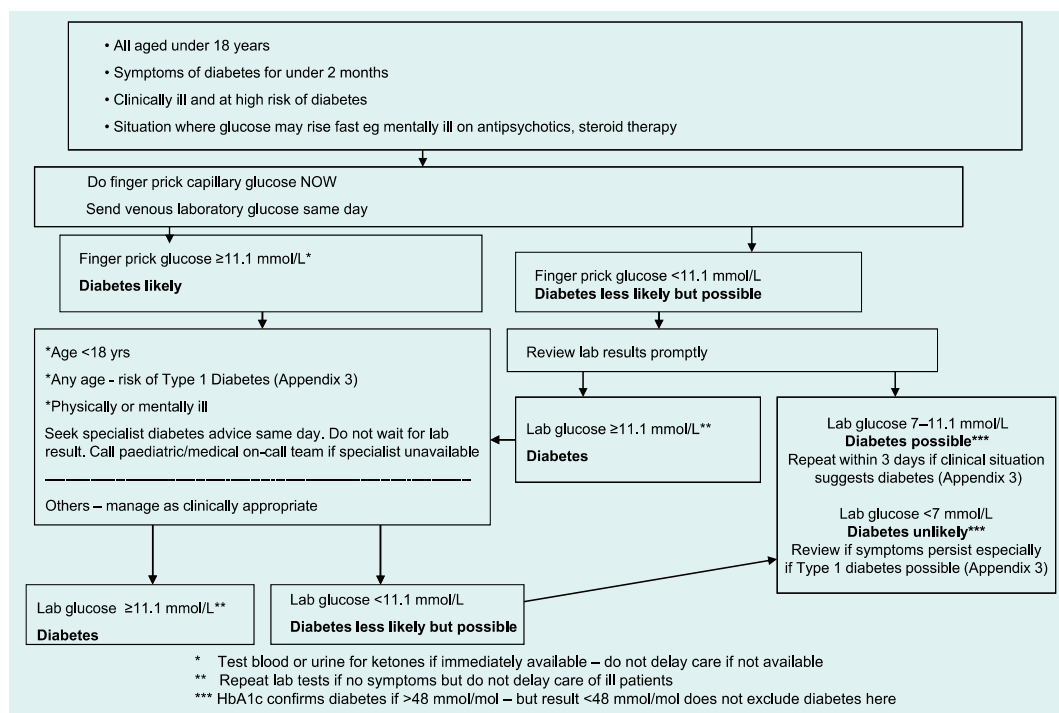


FIGURE 4.10 Diabetes diagnosis

### Oral GTT tests for patients unsuitable for HbA1c measurement

- The patient should be asymptomatic of diabetes. A fasting glucose blood test should be carried out, and patients will have fasted for ten hours prior to the test.
- The patient should be on a normal mixed diet with no decreased carbohydrate intake for 2 weeks prior to the test. Patients should read supporting information (or be given it verbally if more appropriate).
- The test should be carried out in the early morning.
- Blood sample will be taken including capillary blood using the glucose meter. If the result of the capillary sample is greater than 9mmol/L the GP must decide if the test is still appropriate and safe to continue due to small risk of DKA (Diabetic Ketoacidosis Crisis)
- The result of the test should be between 6.1-6.9mmol/L. This indicates the need for OGTT.
- Following the first test 75g of glucose should be given to the patient and this must be done within 5 minutes of the test
- Two hours post glucose load collect the second blood sample.
- This test does not apply to pregnant women, whose tests will continue in a hospital setting.

Interpretation (WHO criteria, June 1999) guidance is shown below:

### Venous Plasma Glucose – mmol/L

	FASTING	TWO HOURS
Diabetes Unlikely	6.0 or less	<7.8
Impaired Fasting Glycaemia	6.1 – 6.9	<7.8
Impaired Glucose Tolerance	<7.0	7.8 – 11.0
Diabetic	7.0 or above	≥11.1

**If OGTT results are negative but the patient is considered to be high risk it is suggested that a fasting glucose test is carried out annually.**

Clinicians should make an assessment based on the patient and the clinical situation as to which diagnostic test should be carried out. If in doubt, please consult with Consultant Diabetologist.

HbA1c should be used to diagnose asymptomatic appropriate patients with Type 2 diabetes or to diagnose and monitor pre-diabetes/impaired glucose regulation states but with specified exceptions.

OGTT should only be carried out for patients not suitable for diagnosis of diabetes or monitoring of impaired glucose regulation by HbA1c as set out in locally agreed guidelines.

If an OGTT is required (patient is unsuitable for HbA1c estimation) than following guidelines apply:

Oral Glucose Tolerance Testing (OGTT) is used to identify and monitor pre-diabetes states, including impaired fasting glycaemia, impaired glucose tolerance and also to diagnose diabetes. WHO guidelines suggest that borderline HbA1c levels i.e. from 42-47mmol/L indicate pre-diabetes.

Impaired Fasting Glycaemia (IFG) has been introduced to classify individuals who have fasting glucose values above the normal range but below those diagnostic of diabetes. (Fasting Plasma Glucose 6.1-6.9mmol/L). Impaired Glucose Tolerance (IGT) is a stage of impaired glucose regulation (Fasting Plasma Glucose <7.0mmol/L and OGTT 2 hour value >7.8mmol/L but <11.1mmol/L). IGT and IFG are not clinical entities in their own right but rather risk categories for cardiovascular disease and/or future diabetes. Diabetes UK recommends that all those with IFG should have an OGTT to exclude the diagnosis of diabetes.