SCHEDULE 2 – THE SERVICES

A. Anticoagulation in Primary Care Service Specification

Service Specification No.	
Service	**Anticoagulation in Primary Care (Warfarin Only)**
Commissioner Lead	NHS Mansfield and Ashfield CCG
Provider Lead	General Practice Providers
Period	December 2014 to March 2016
Date of Review	31st December 2017

1. Population Needs

1.1 National/local context and evidence base

This service specification replaces all previous specifications for the provision of anticoagulation of service provision in primary care. The specification should be read in conjunction with the Anticoagulation Standard Operating Procedure (2014). This service was previously provided under Local Enhanced Service arrangements. New primary care providers are invited to participate.

Anticoagulation has long been a recognised therapeutic intervention to reduce risk of harmful clotting in those patients deemed to be at higher risk, e.g. Atrial Fibrillation, diseases of the heart. Depending on presenting complaint patients can be on therapy for life.

In M&A CCG approximately 23,000 prescription items are dispensed per year, at a cost of over £235K. The most commonly used therapy is Warfarin, accounting for 93% of anticoagulant items dispensed.

Whilst Warfarin remains the main drug of choice for anticoagulation it should be noted that use of alternative 'Novel Oral Anticoagulants' (NOACs) is becoming more common, e.g. Dabigatran, Rivaroxaban. These drugs do not require INR monitoring, but pose other significant considerations in determining patients' suitability for prescribing. As their use continues to increase there may be impact on the requirement for anticoagulation monitoring services. **This specification relates only to patients who are on Warfarin**.

Although patient outcomes are positive, it is noted that Warfarin has a narrow therapeutic window, so requires close safety monitoring. Within primary care anticoagulants are amongst those most commonly associated with fatal medication errors.

The fourth report from the Patient Safety Observatory (2007) stated, "In 2004, the Department of Health estimated the costs of medication-related admissions to hospitals to be in the order of £200–400 million a year.[1] Figures from the largest UK-based study of hospital admissions data suggest that 4.7 per cent of all admissions were as a result of avoidable (definitely preventable and possibly preventable) harms from medicines".

[1] Department of Health. Standards for better health. (2006).

The most common causes of medication errors include wrong dose, strength and frequency

of medication. Anticoagulants are amongst the highest therapeutic group identified in medication errors, especially those causing severe harm or death.

Excerpt from Department of Health Report – Building a safer NHS for patients, Improving Medication Safety 2004

Warfarin dosing is critical

While abroad, a 78-year-old woman underwent emergency surgery to remove a clot from her leg. She was prescribed warfarin tablets 2.5 mg once a day. This strength is not available in England, and on her return her GP prescribed warfarin tablets 3 mg once a day, and arranged an appointment in an anticoagulant clinic. There was a delay in her being seen in the clinic, and she developed bleeding, with an INR greater than 10. In spite of treatment with Vitamin K, an antidote, she died. The 20% increase in dosage was enough to cause a fatal haemorrhage.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

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

2.2 Local defined outcomes

This proposal will contribute to the CCGs objectives in the Plan on a Page, as part of the NHS Operating Framework, “Everyone counts: Planning for Patients 2013/14”, for example:

- Building the System to manage the rising demand for healthcare
- Joining up services to improve care

3. Scope

3.1 Aims and objectives of service

The aim for the proposed service is to commission Anticoagulation Monitoring services, which provide high quality with improved convenience and accessibility to patients. Services will also demonstrate value for money to commissioners, enabling effective use of available resources.

In delivering the aims, the service will:

- Promote better ongoing monitoring of patients requiring Anticoagulation therapy
- Promote delivery of care closer to the patients home
- Improve patient choice and access to services
- Manage increasing demand
- Reduce inequity of care
- Improve long term management of conditions where anticoagulation therapy is indicated

The model uses a revised version of the Standard Operating Procedure (SOP) for provision

of Anticoagulation Monitoring Services, October 2014. This will be a fundamental driver for quality and service delivery.

3.2 Service description/care pathway

Patient Pathway for each level

- Refer to the following sections in the Standard Operating Procedure for the provision of a level 2 formerly 3 and level 3 formerly level 4 Anticoagulation Services Section:

6 – Responsibilities of Anticoagulation Provider

7 – Responsibilities of patient's General Practitioner

8 – Target Population

9 – Secondary Care Referrals

10- Actions for patients excluded from Primary Care management

11 – Actions for patients not wishing to transfer to Primary Care management

13 – Primary Care – At Home/Care Home

14 – Primary Care – Self Monitoring

15 – Call & Recall Procedures

16 – Clinical Appointments

17 – Clinical Management

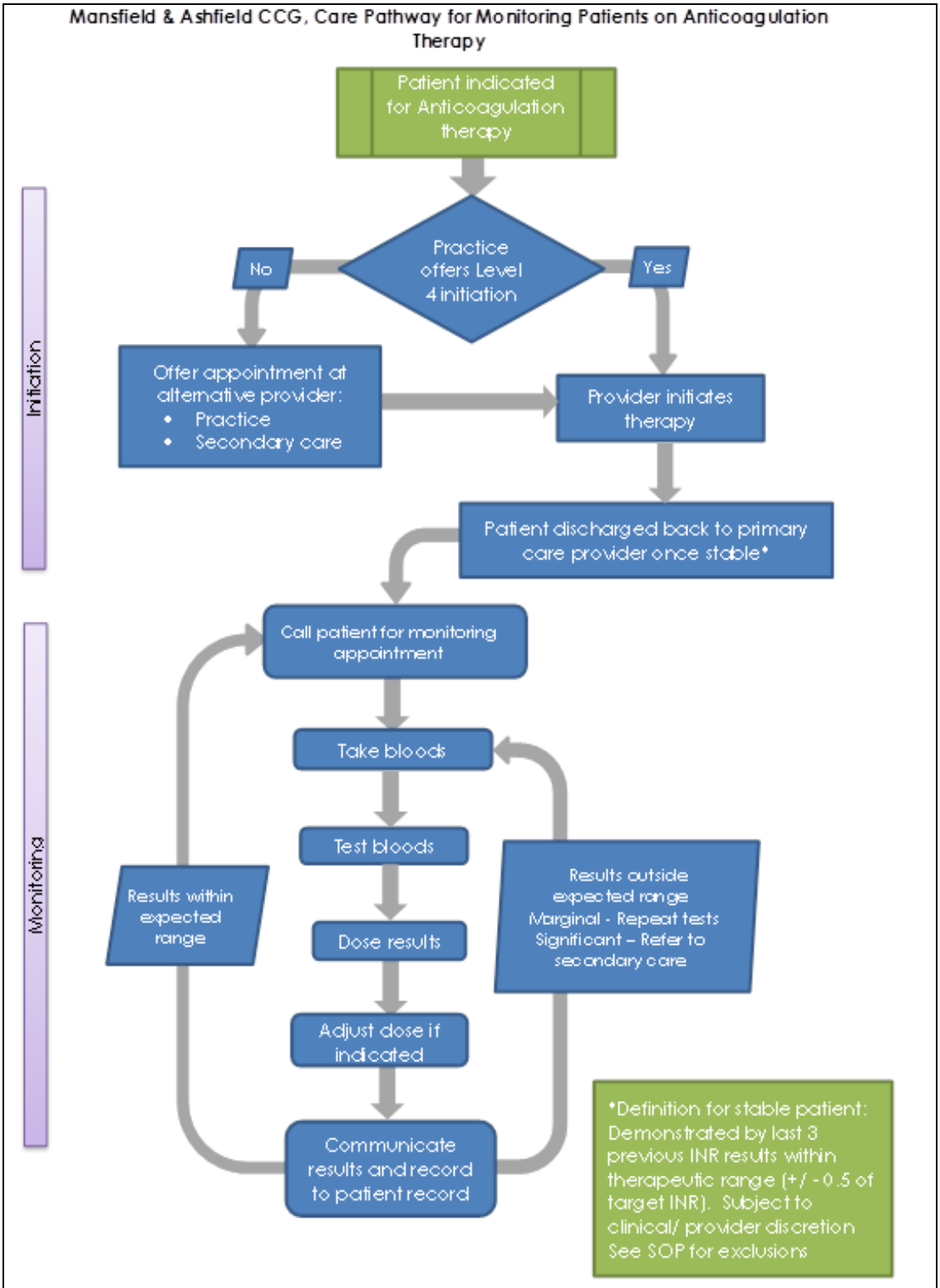
18 – Documentation

19 – Anticoagulation therapy supply, testing and dosing

20 – Initiating therapy – Level 3 formerly Level 4

21 – Discontinuation

- Also includes those patients that wish to self-monitor



3.3 Population covered

Mansfield and Ashfield has a population of 184,000. The national benchmark rate for people requiring anti-coagulation therapy is 1.40% per 100,000. Applying this rate and accepting that the local area has a higher prevalence due to the age profile and deprivation, indicates that there are an estimated 2,500 people requiring anti-coagulation therapy.

3.4 Any acceptance and exclusion criteria and thresholds

Patients with the following conditions must not be managed in Primary Care;

- Children under 16 years of age
- Pregnant Women
- People undergoing chemotherapy

http://www.nice.org.uk/usingguidance/commissioningguides/AnticoagulationTherapy.jsp

3.5 Interdependence with other services/providers

Patients may start their anticoagulation in secondary care, with ongoing monitoring and dosing being carried out by Primary Care. All excluded patients should be cared for by secondary care. There are three levels of service described in the Standard Operating Procedure, only levels 2 and 3 have been approved by the Clinical Executive and are being commissioned under this specification see below;

Description of Service Levels

As per the revised Standard Operating Procedures **Level 2** Formerly known as level 3	Primary care provider takes the blood samples, undertakes the tests, indicates the dose and communicates the results to the patient. This level will include those patients who have been initiated on anticoagulation during an inpatient stay or discharged from ambulatory clinic and the INR will continue by the primary care provider
Level 3 Formerly known as level 4	Primary care provider **initiates** and continues treatment, takes the blood samples, undertakes the tests, indicates the dose and communicates the results to the patient.

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

http://www.nice.org.uk/usingguidance/commissioningguides/AnticoagulationTherapy.jsp

4.2 Applicable professional standards

British Committee for Standards in Haematology. Guidelines on oral anticoagulation (Anticoagulation Therapy):fourth edition - 2011

http://www.bcshguidelines.com/documents/warfarin_4th_ed.pdf

National Patient Safety Agency – Patient Safety Alert – Actions that can make anticoagulant therapy safer, March 2007

http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814

4.3 Applicable local standards

See Appendix A – Standard Operating Procedure October 2014

5. Applicable quality Requirements and Outcomes

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

5.2 Expected Outcomes

Anticoagulation Service that will;

- Provide standardised and clinically effective anticoagulation management to patients receiving Anticoagulation Therapy whilst minimising the risks associated with anticoagulation
- Identify patients receiving Anticoagulation Therapy and offer transfer of care from hospital to primary care clinics for appropriate patients
- Initiate Anticoagulation Therapy for suitable patients
- Produce optimum management of INR control
- Educate patients in understanding their treatment, in terms of their condition requiring Anticoagulation Therapy, target range for INR, the effects of over and under anticoagulation, diet, lifestyle and drug interactions
- Maintain a register of all patients receiving Anticoagulation Therapy
- Provide each patient with a treatment plan and to review the need for continuation of therapy at each visit annually
- Identify and manage appropriately patients with specific needs i.e. poor compliance, unstable INR control or frequent non-attendees
- Optimise care to patients receiving anticoagulant therapy in terms of accessibility, continuity and waiting times
- Ensure complete and accurate documentation of the clinic process
- Use point of care testing
- If a patient leaves the Practice there should be a safe transfer of care to the patient's new GP Practice, including details of most recent INR blood test, the current prescription, and the due date of the next blood test. It should be made clear to the patient's new GP that the patient has been in receipt of anticoagulation care through a primary care service and will require an immediate appointment or referral to the appropriate service in their new location

5.3 Potential Risks of the Service

Non compliance with the Standard Operating Procedure for the provision of a Level 2 and 3 Anticoagulation Services

5.4 Governance

- Providers will demonstrate that they have achieved or are working towards level 2 Information Governance standards
- Providers will monitor the uptake of this service on different target groups, to include gender, gender identity (transgender), race, religion/belief, age, disability, sexual orientation, social exclusion and economic deprivation
- The provider will comply with the Local Safeguarding Children and Adult Board procedures as outlined on the following websites: -

Adults

http://www.nottinghamshire.gov.uk/caring/adultsocialcare/backgroundsupport/safeguardingadults/policy-and-procedure/

Children

http://www.nottinghamshire.gov.uk/caring/protecting-and-

safeguarding/nscb/informationprofessionals/procedures-practice-guidance/

- The provider will have internal policies for safeguarding and promoting the welfare of children and vulnerable adults which are in line with "Working Together to Safeguard Children 2013" and "No Secrets" Guidance 2009 including: -
    - Safeguarding Policy
    - Dealing with allegations against staff
    - Whistleblowing Policies
- On the request of the Co-ordinating commissioner will provide evidence to give assurance of compliance with safeguarding standards.
- **All Practices delivering the service should be willing to see patients from other Practices, where their registered GP does not provide the service**

5.5 Competency, Eligibility and Accreditation

Each service provider must ensure that they comply with section *22 – Training* in the Standard Operating Procedure for the provision of level 2 and 3 Anticoagulation Services.

6. Individual Service User Placement

Practices may treat patients from other surgeries provided that surgery has not registered to provide this service.

All quality standards including keeping accurate records of patient treatment will apply to patients who are not registered with the Practice.

The Provider must comply with *Section 6 Responsibilities of the Provider* within the Standard Operating Procedure. In particular the provider must ensure that the patient's GP is aware of changes to medication and if there are any changes to the patient's condition.

The patient's GP will remain responsible for issuing prescriptions for anticoagulation therapy, as described in *Section 7 Responsibilities of the Patient's General Practitioner* within the Standard Operating Procedure.

7. Performance Management, Service Review and Development

The Clinical Commissioning Group Contracting Team will monitor Quality Performance Indicators/activity returns by the provider as outlined in the 'Quality Performance Indicators and Data requirements' section below;

In the event of any of the following occurring;

- Incorrect prescribing/dosage
- Inadequate monitoring of patients and equipment
- Non Treatment of side effects
- Inattention of interacting medicines

The provider will be expected to have submitted the incidence form provided in the Standard Operating Procedure Appendix 11 *Near Miss, incident and serious untoward incident reporting form*, and to undertake an investigation in line with the principles of significant event audit.

Following investigation by the Quality and Safety Team and if proven that a Service Provider cannot meet the required competencies of the Standard Operating Procedure than NHS Mansfield and Ashfield CCG will take measures to decommission the service from that provider.

8. Location of Provider Premises

To be delivered from the Primary Care Contractor's premises. Clinics must be provided in rooms which are;

- Compliant with the Health Act 2006
- Disability Discrimination Act compliant
- Meet infection control requirements
- Provide confidentiality

Patients that are to undertake self-monitoring have to comply with the following conditions to;

- Receive training in the use of their chosen monitors
- Demonstrate that they have the necessary skills to self-monitor safely
- Agree how they will communicate with their provider with regard to dosing post testing
- Attend for a periodic review with their provider

9. Quality Performance Indicators and Data Requirements

- To undertake audit requirements as outlined in *section 25 – Audit of the Standard Operating Procedure*
- To provide NHS Mansfield and Ashfield CCG, when requested, with details of patients treated, or referred to secondary care
- To report untoward incidences supported by the relevant documentation outlined in the Standard Operating Procedure Appendix 11 *Near Miss, serious incident and serious untoward incident reporting form*
- To work with the CCG to resolve patients complaints and learn lessons
- To undertake an annual patients survey, to reflect on the findings and to implement the associated action plan
- To implement Infection Control action plans following audits carried out the by NHS Mansfield and Ashfield CCG Infection Control Team

10. Standard Operating Procedure

- Attached as Appendix A

11. Prices and Contractual Arrangements

11.1 Price

On agreeing to this service specification with the CCG commencing on the 1st April 2014, providers will receive the payments listed below.

2014/15 Payment Rates		
Level 2	**Monitoring** **£38.30** per patient per quarter	**Ongoing payment for monitoring patients**
Level 3	**Initiation** **£49.92** per patient per quarter	**Paid for the 1st year only then subsequent years monitoring**

Under this agreement no additional payments will be made

- **all costs have been included**
- **includes home visits**

PAYMENT WILL ONLY BE MADE IF THE PRACTICE HAS SIGNED AN NHS STANDARD CONTRACT AND THE QUALITY STANDARDS OUTLINED WITHIN THE SERVICE LEVEL AGREEMENT ARE MET

Providers will receive quarterly payments in arrears on production of the following quarterly minimum data set

- Number of patients registered with the Practice for Anticoagulation Management
- Dates of attendance
- Number of patients initiated on to anticoagulation therapy and start date
- Number of follow ups with the provider
- Reporting of any adverse events
- Number of patients referred back to secondary care
- Number of DNA's
- Number of patients discharged from the service
- Number of complaints

11.2 Procurement Method

This service will be contracted via a direct award under a Standard NHS Contract held between the CCG and the Practice

The contract will be reviewed at 12 month intervals as part of contract monitoring arrangements.

The NHS Standard Contract requires a minimum of 6 month's notice by either party.

Changes to the contract may be introduced via a contact variation in negotiation with the provider.