Anti-Coagulation Monitoring (warfarin, acenocoumarol, phenindione)  
Primary Care Service (PCS:01)


This pack contains:

1. **Service Specification:** (to be inserted Schedule 2 Part A: Contract Particulars)  
2. **Schedule of Payment:** (to be inserted Schedule 3 Part H: Contract Particulars)  
3. **Monitoring Form:** (to be inserted Schedule 3 Part A: Contract Particulars)  
4. **Audit Template:** (to be inserted Schedule 3 Part A: Contract Particulars)

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### 1. Service Specification:

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

<table>
<thead>
<tr>
<th>Service Specification No.</th>
<th>PCS:01</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Service</strong></td>
<td>Primary Care Anti-Coagulation Monitoring Service (warfarin, acenocoumarol, phenindione)</td>
</tr>
<tr>
<td><strong>Commissioner Lead</strong></td>
<td>Jon Hayhurst, Head of Medicines Management, NHS Bristol Clinical Commissioning Group</td>
</tr>
<tr>
<td><strong>Provider Lead</strong></td>
<td>As per provider signatory</td>
</tr>
<tr>
<td><strong>Period</strong></td>
<td>1st April 2015 – 31st March 2016</td>
</tr>
<tr>
<td><strong>Date of Review</strong></td>
<td>October 2015</td>
</tr>
</tbody>
</table>

### 1. Population Needs

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

This service specification for the provision of anti-coagulant monitoring outlines one of the more specialised services that may 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. Prior to the creation of CCGs this was a national enhanced service, and the CCG wishes to continue to endorse these national recommendations to promote safe practices.
Warfarin is used in the management of a large number of patients and conditions. While it is a very effective drug, it can also have serious side effects, e.g. severe haemorrhage if it is not prescribed safely. Side effects are related to the International Normalised Ratio (INR) of the patient’s blood, which measures the delay in the clotting of the blood caused by the warfarin. While the “normal” INR in an unwarfarinised patient is 1, the specific range of INR targets used in warfarin treatment 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.

2. Outcomes

2.1 NHS Outcomes Framework Domains and Indicators

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
<th>Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain 1</td>
<td>Preventing people from dying prematurely</td>
<td>✔</td>
</tr>
<tr>
<td>Domain 2</td>
<td>Enhancing quality of life for people with long-term conditions</td>
<td>✔</td>
</tr>
<tr>
<td>Domain 3</td>
<td>Helping people to recover from episodes of ill-health or following injury</td>
<td>✔</td>
</tr>
<tr>
<td>Domain 4</td>
<td>Ensuring people have a positive experience of care</td>
<td>✔</td>
</tr>
<tr>
<td>Domain 5</td>
<td>Treating and caring for people in safe environment and protecting them from avoidable harm</td>
<td>✔</td>
</tr>
</tbody>
</table>

2.2 Local defined outcomes

It is expected that by delivering the service, Providers will be able to deliver the following outcomes:

**Domain 1 Preventing people from dying prematurely**

- ✔ To ensure patients are monitored appropriately preventing under or over anticoagulation

**Domain 2 Enhancing quality of life for people with long-term conditions**

- ✔ The need for continuation of therapy is regularly reviewed and discontinued when appropriate

**Domain 3 Helping people to recover from episodes of ill-health or following injury**

- ✔ To encourage good communications between primary and secondary care in relation to anticoagulation support

**Domain 4 Ensuring people have a positive experience of care**

- ✔ To ensure patients have a high quality, safe anticoagulation monitoring service across Bristol

**Domain 5 Treating and caring for people in safe environment and protecting them from avoidable harm**

- ✔ To ensure information about INR control is accurately documented and acted upon when appropriate

3. Scope

3.1 Aims and objectives of service

The Provider will work with the Commissioner to ensure that the Service meets the following aims and objectives:

3.1.1 Aims of the service include:
To offer therapeutic anticoagulation management to patients within NHS Bristol CCG who are receiving anticoagulant therapy, either via venous blood sampling or near patient testing within the local community. This service aims to be convenient, normally initiated in secondary care, for recognised indications for specified lengths of time.

3.1.2 Objective of the service include:

- To provide standardised and clinically effective anticoagulation management to patients receiving warfarin therapy whilst minimising the risks associated with anticoagulation
- To produce optimum management of INR control
- To educate patients in understanding their treatment, in terms of their condition requiring warfarin, target range for INR, the effects of over and under anticoagulation, diet, lifestyle and drug interactions
- To appropriately manage patients who are over anti-coagulated
- To ensure the need for continuation of therapy is reviewed regularly and the therapy is discontinued when appropriate
- To identify and manage appropriately patients with specific needs i.e. poor compliance, unstable INR control or frequent non-attendees
- To ensure complete and accurate documentation of the clinic process

3.2 Service description/care pathway

This Service commissioned by NHS Bristol Clinical Commissioning Group will fund:

- **The development and maintenance of a register.** Practices should be able to produce an up to date register of all anti-coagulation monitoring service patients, indicating patient name, date of birth, the indication for, and length of, treatment, including the target INR.

- **Call and recall.** To ensure that systematic call and recall of patients on this register is taking place either in a hospital or general practice setting. Providers should have systems in place to identify and act quickly when a person has failed to attend an appointment to have their INR measured.

- **Professional links.** To work together with other professionals when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained.

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

- **Education and newly diagnosed patients.** To ensure that all newly diagnosed patients (and/or their carers and support staff when appropriate) receive appropriate information on the management of, and prevention of, secondary complications of their condition including the provision of a patient-held NPSA warfarin booklet.

- **Individual management plan.** To prepare with the patient an individual management plan, which details the diagnosis, the planned duration of therapy and the therapeutic range of INR that is targeted.

- **Clinical procedures.** To ensure that at initial diagnosis and at least annually an appropriate review of the patient’s health is carried out including checks for potential...
complications and, as necessary, a review of the patient’s own monitoring records. To ensure that all clinical information related to the Service is recorded in the patient’s own GP held lifelong record, including the completion of the “significant event” record that the patient is on warfarin.

- **Safe Prescribing of concomitant drugs.** To ensure that patients only receive concomitant medications that will affect the efficacy of warfarin therapy (i.e. due to drug interactions) when they are prescribed safely and appropriately. Communication with relevant providers of care should be involved.

- **Record-keeping.** To maintain adequate records of the performance and result of the service provided, incorporating appropriate known information, as appropriate. This may include the number of bleeding episodes requiring hospital admission and deaths caused by anti-coagulants. These patients should be clearly read-coded.

- **Audit.** To carry out clinical audit of the care of patients against the above criteria, including untoward incidents. This should also review the success of the practice in maintaining its patients within the designated INR range as part of quality assurance. NHS Bristol CCG will provide a template for this purpose.

- **Training.** Each practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so.

- **Review.** All practices involved in the scheme should perform an annual review details of which are provided in the audit template.

### 3.3 Risk management and untoward events

It is a condition of participation in this Service that practitioners will give notification to NHS Bristol CCG of all emergency admissions or deaths of any patient covered under this service, where such admission or death is, or may be due to usage of the drug(s) in question or attributable to the relevant underlying medical condition. This must be reported verbally within 24 hours and written information within 48 hours of the practitioner being aware of the incident. This is in addition to a practitioner’s statutory obligations. The practice should undertake a significant event audit (SEA) where appropriate and share the findings with the commissioner.

### 3.4 Training and accreditation

Each practice must ensure that all staff involved in providing any aspect of care under this scheme has the necessary training and skills to do so and that such training and competency is recorded and retained to allow production on request.

Those doctors who have previously provided the National Enhanced Service or services similar to this local service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the local service shall be deemed professionally qualified to do so.

There are two e-learning modules available from the BMJ learning portfolio which looks at starting patients on anticoagulants and maintaining patients on anticoagulant therapy and can be found at:

http://www.nrls.npsa.nhs.uk/resources/?entryid45=61790&q=0~anticoagulant:

### 3.5 Population covered

The Provider must hold a list of patients therefore only practices in Bristol will be eligible as the service needs to be delivered at a local level and based in primary care, led by General
3.6 Any acceptance and exclusion criteria and thresholds

The following criteria must be met:

- All patients currently being treated with warfarin, acenocoumarol or phenindione may be included in service
- Need to refer to specialist for treatment review if patient non-compliant with testing regime, and/or if INR levels are often out of specified therapeutic range e.g. <50%TTR over the last year (after the initial stabilisation period)

3.7 Interdependence with other services/providers

Providers will need to:

- work closely with the anticoagulation service to ensure timely INRs
- contact the anticoagulation service if patient started on a medicine likely to affect INR, in order to ensure timely additional INR testing where needed

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

NHS Employers - Anticoagulation monitoring, National enhanced service specification:  

NPSA: anticoagulant actions that can make anticoagulant therapy safer:  
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814

NICE guidance: Support for commissioning: Anticoagulation Therapy:  
http://publications.nice.org.uk/support-for-commissioning-anticoagulation-therapy-cmg49:

5. Contract Monitoring, Reporting and Financial Information

5.1 Outcomes, contract monitoring and evaluation

The service will be measured against the service outcomes as defined in Section 2, using the key performance indicators which will be captured via monitoring forms and an annual audit as set out in the table below:

<table>
<thead>
<tr>
<th>Technical Guidance Reference</th>
<th>Quality Requirement / Outcome</th>
<th>Method of Measurement</th>
<th>Frequency</th>
<th>Used by Commissioner to evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain 1: Preventing people from dying prematurely</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients prescribed warfarin have a documented stop date/ duration of treatment</td>
<td>Audit</td>
<td>Annual</td>
<td>To ensure patients are monitored appropriately preventing under or over anticoagulation</td>
<td></td>
</tr>
<tr>
<td>Number of audited patients on Level 1a and Level 3 service with INRs &gt; 5 but ≤8 on one or more occasion</td>
<td>Audit</td>
<td>Annual</td>
<td>To ensure patients are monitored appropriately preventing under or over anticoagulation</td>
<td></td>
</tr>
<tr>
<td>Number of audited patients on Level 1a and Level 3 service with INRs &gt; 8 on one</td>
<td>Audit</td>
<td>Annual</td>
<td>To ensure patients are monitored appropriately preventing under or over anticoagulation</td>
<td></td>
</tr>
<tr>
<td>Domain 1</td>
<td>2015-16 NHS Outcome Domain 1</td>
<td>Practice has a mechanism in place to deal with DNA's</td>
<td>Audit declaration</td>
<td>Annual</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>Domain 2: Enhancing quality of life for people with long-term conditions</td>
<td>2015-16 NHS Outcome Domain 2</td>
<td>Patients prescribed warfarin have a documented stop date/ duration of treatment so that treatment is not continued inappropriately</td>
<td>Audit</td>
<td>Annual</td>
</tr>
<tr>
<td>Domain 3: Helping people to recover from episodes of ill-health or following injury</td>
<td>2015-16 NHS Outcome Domain 3</td>
<td>Patients prescribed warfarin have a documented INR target or INR range</td>
<td>Audit</td>
<td>Annual</td>
</tr>
<tr>
<td></td>
<td>2015-16 NHS Outcome Domain 3</td>
<td>Practice feedback with regards to liaison with secondary care</td>
<td>Audit</td>
<td>Annual</td>
</tr>
<tr>
<td>Domain 4 Ensuring people have a positive experience of care</td>
<td>2015-16 NHS Outcome Domain 4</td>
<td>Number of INR tests reflects number of patients receiving anticoagulation monitoring</td>
<td>Claim form</td>
<td>6 monthly</td>
</tr>
</tbody>
</table>
2015-16 NHS Outcome Domain 4  
Staff prescribing warfarin have read the NPSA patient safety alert 18 ‘Actions that can make anticoagulant therapy safer’ and NPSA/BMJ work competencies on anticoagulants  
Audit declaration  
Annual  
Confirming staff aware of safety recommendations about anticoagulants

**Domain 5 Treating and caring for people in safe environment and protecting them from avoidable harm**

<table>
<thead>
<tr>
<th>2015-16 NHS Outcome Domain 5</th>
<th>Patients prescribed warfarin have a documented indication</th>
<th>Audit</th>
<th>Annual</th>
<th>Information about INR control is accurately documented and acted upon when appropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-16 NHS Outcome Domain 5</td>
<td>Patients prescribed warfarin have a documented INR target or INR range</td>
<td>Audit</td>
<td>Annual</td>
<td>Information about INR control is accurately documented and acted upon when appropriate</td>
</tr>
</tbody>
</table>

All Providers will be required to produce an audit of the Service. A template for this purpose will be provided by NHS Bristol CCG. Receipt of the audit will be required for the previous year prior to the first payment of the subsequent year.

GP practice-based pharmacists may be able to offer support towards the audit activity.

### 5.2 Financial information

There are two bands of service available through this local service:

#### 5.2.1 Level 1a definition

The Practice takes the blood sample, testing is undertaken by the hospital trust, and dosing is undertaken by the hospital trust. These patients should be clearly read-coded.

#### 5.2.2 Level 3 definition

The Practice takes the blood sample, testing is undertaken by the hospital trust, but dosing is undertaken by the practice. These patients should be clearly read-coded.

The Commissioner will make a payment for each patient receiving this service during the year:

- Level 1a £57 per patient per year  
  (66QC = Anticoagulation monitoring - secondary care)
- Level 3 £85.24 per patient per year  
  (66QD = Anticoagulation monitoring - primary care)

Payment will be made in quarterly instalments. Providers will be required to submit a claim form giving details of the number of patients receiving Level 1a service and the number of patients receiving Level 3 service. Providers should note patients receiving Level 3 cannot also be counted towards Level 1a. Payments will not be made until:

- the audit report related to the previous year has been received
- a completed claim form for the related two quarters activity is received
5.3 EMIS Codes
You may choose to have your quarterly monitoring information captured via EMIS Search and Report. If you chose to have your payment data collected by EMIS Search and Report you must use the following codes:

- Level 1a  66QC = Anticoagulation monitoring - secondary care
- Level 3  66QD = Anticoagulation monitoring - primary care

6. Location of Provider Premises
The Provider’s Premises are located at: