NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Interim Commissioning Statement

Point-of-Care Coagulometers

for Self-Monitoring Coagulation Status

April 2015

This commissioning policy has been endorsed by and applies to patients within:
NHS South Worcestershire Clinical Commissioning Group (CCG)
NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
NHS Wyre Forest Clinical Commissioning Group (CCG)

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Review date:	April 2018
Lead Executive/Director:	Chris Emerson – Head of Commissioning &Service Redesign
Name of originator/author:	Fiona Bates – Medicines Commissioner & Public Health Support
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Distribution:	GPs, Secondary Care Providers (NHS and Private), CCG Websites
Equality & Diversity Impact Assessment	Developed - December 2014 Endorsed - January 2015

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Contribution list

Key individuals involved in developing the document

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Circulated to the following individuals/groups for comments

Name	Date
Area Prescribing Committee	November 2014
County-wide Anticoagulation Group	November 2014
Worcestershire Clinical Policy Collaborative	October 2014

Review and Amendment Log

Version No	Type of Change	Date	Description of change

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COMMISSIONING SUMMARY

Worcestershire Clinical Commissioning Policy Collaborative (CCPC) in collaboration with Worcestershire Anticoagulant Committee and the Worcestershire Area Prescribing Committee has reviewed the evidence and necessary requirements associated with use of point-of-care coagulometers for self-monitoring coagulation status.

Point-of-care coagulation tests are intended for use in suitable people on long-term vitamin K antagonist therapy, such as those with atrial fibrillation or artificial heart valves who are at risk of thrombosis and require regular INR (international normalised ratio) monitoring.

Self-testing is when patients perform the point-of-care coagulation test themselves and the results of the test are managed by healthcare professionals. **Self-management** is when patients perform the point-of-care coagulation test and alter the dose of anticoagulation therapy themselves according to a personalised protocol. Self-testing and self-management are together called **self-monitoring**.

It has been concluded that:

1. Point-of-care coagulometers for self-monitoring coagulation status are not currently funded for patients in Worcestershire. This is in consideration of the essential requirements for safe systems to govern widespread use of self-monitoring coagulometers which are not currently available or established.
2. Testing strips for use in point-of-care coagulometers may not be prescribed by General Practitioners in Worcestershire on FP10 prescription forms.

The Worcestershire Anticoagulant Committee is leading a review of the arrangements for anticoagulant services; this review will further consider use of point-of-care coagulometers.

1. Definitions

1.1 **Coagulometers** are devices used to measure the ability of the blood to clot (coagulate) and the time taken to do so, through measurement of the International Normalised Ratio.

1.2 **International Normalised Ratio (INR)** is a standard unit for measuring the time it takes for blood to clot, this is the blood coaguability.

1.3 **Point-of-care coagulometers** are personal INR testing machines that can be used at home. It is believed that the use of point-of care tests, for self-monitoring may avoid unnecessary visits to hospitals while allowing regular INR monitoring and timely adjustment of warfarin dosing to avoid adverse events such as stroke and major bleeding. This may also result in improved patient outcome such as quality of life.

1.4 **Self-testing** is when patients perform the point-of-care coagulation tests themselves and the results of the test are managed by healthcare professionals.

1.5 **Self-management** is when patients perform the point-of-care coagulation tests and alter the dose of anticoagulation therapy themselves according to a personalised protocol.

1.6 **Self-monitoring** comprises both self-testing and self-management. Self-monitoring is considered as one of the options for INR monitoring.

1.7 **Thromboembolic events** occur from a **thromboembolism** which arises from a blood clot that forms due to blood changes in which cellular material, such as red and white blood cells and platelets become bound together by fibrin strands creating a thrombus. This thrombus may form directly within the vascular system to impede blood flow or cause an obstruction, or may be carried as emboli in the blood stream to lodge in a vessel and cause an embolism. The manifestations of the thrombus and emboli are thromboembolic events and include clots in the lower limbs (deep vein thrombosis) and clots in the blood vessels of the lungs (pulmonary embolism), heart (myocardial infarction) and brain (stroke).

1.8 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.

1.9 *A* **Similar Patient** refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. When the treatment meets the regional criteria for supra-CCG policy making, then the similar patient may be in another CCG with which the local CCG collaborates. The existence of one or more similar patients indicates that a policy position is required of the CCG.

1.10 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.

1.11 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the CCG agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

2. Scope of policy:

2.1 This policy should be considered in line with all other Worcestershire Commissioning Policies. Copies of these Commissioning Policies are available on the following website address:
http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/

2.2 This policy applies to all patients that the Worcestershire CCGs have responsibility for including:

- People provided with primary medical services by GP practices who are members of one of the CCGs or

- People usually resident in the area covered by the CCG's and not provided with primary medical services by any CCG.

2.3 This policy applies to all patients receiving vitamin K antagonist medicine to reduce clot formation and prevent the occurrence of strokes and thromboembolism in at risk patients who require regular monitoring of their blood coaguability; this most commonly includes but is not limited to patients with atrial fibrillation and those with artificial heart valves.

2.4 For patients who do not meet the policy and where there is demonstrable evidence that the patient has clinically exceptional circumstances, an Individual Funding Request may be considered. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "clinically exceptional circumstances", please refer to the Definitions section of this document.

3. Background:

3.1. NHS principles have been applied in the agreement of this policy.

3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (termed "the Commissioners") consider all lives of all patients whom it serves to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3. Where an NHS commissioned service is provided by the Independent Sector (a privately funded provider), any patient referred for NHS funded treatment MUST also comply with the Provider's exclusion criteria for treatment; for example, at time of referral (and treatment) they must:

- Be aged 18 or over
- Have a BMI of 40 or less
- Not have an incapacitating disease which is a constant threat to life
- Have had no previous adverse events or complications as a result of anaesthesia
- Not have an unstable mental condition, receiving psychiatric treatment

	*NOTE 1: The Independent Sector Provider Exclusion Criteria have been supplied by BMI Droitwich (via their Directory of Services) but are used by all Independent Sector Providers.*
	NOTE 2: Patients excluded from accessing treatment within the Independent Sector may access treatment at NHS provider services where their care can be managed in accordance with their circumstances.

3.4. The blood coaguability of patients taking warfarin is measured in terms of international normalised ratio (INR) which is a standard unit for measuring the time it takes for blood to clot. INR monitoring can be delivered using various options in the NHS, most commonly through clinics based in hospitals or primary care.

3.5. The use of personal INR testing machines at home (point-of-care) allows patients to perform self-testing or self-management. Self-testing is when patients perform the test

themselves and the results of the test are managed by healthcare professionals. Self-management is when patients perform the test and alter the dose of anticoagulation therapy themselves according to a personalised protocol. Self-testing and self-managing are together called self-monitoring. Self-monitoring is considered as one of the options for INR monitoring.

4. Relevant National Guidance and Facts

4. 1 NICE Diagnostic Guidance 14; September 2014

This guidance recommends:

1. The CoaguChek XS system is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if:
   - The person prefers this form of testing and
   - The person or their carer is both physically and cognitively able to self-monitor effectively.

2. The InRatio2 PT/INR monitor is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if:
   - The person prefers this form of testing and
   - The person or their carer is both physically and cognitively able to self-monitor effectively.

Although there is greater uncertainty of clinical benefit for the InRatio2 PT/INR monitor than for the CoaguChek XS system, the evidence indicates that the precision and accuracy of both monitors are comparable to laboratory-based INR testing.

Patients and carers should be trained in the effective use of the CoaguChek XS system or the INRatio2 PT/INR monitor and clinicians involved in their care should regularly review their ability to self-monitor.

Equipment for self-monitoring should be regularly checked using reliable quality control procedures and by testing patients' equipment against a healthcare professional's coagulometer which is checked in line with an external quality assurance scheme. Ensure accurate patient records are kept and shared appropriately.

For people who may have difficulty with or who are unable to self-monitor, such as children or people with disabilities, their carers should be considered to help with self-monitoring.

5. Evidence of Safety and Efficacy

5.1 Evidence of Safety

After an extensive review of the available evidence NICE have determined that Point of care INR monitors (Coaguckeck XS system and INRatio2 PT/INR monitor) are safe to use. Evidence indicates that the precision and accuracy of both monitors are comparable to laboratory-based INR testing. Patients and carers should be trained in the effective use of the CoaguChek XS system or the INRatio2 PT/INR monitor and clinicians involved in their care should regularly review their ability to self-monitor.

5.2 Evidence of Efficacy

5.2.1 Intermediate Outcomes

Time and values in therapeutic range

- Overall INR time in therapeutic range (TTR) was the same or better for self-monitoring patients compared with standard care (reported by 18 trials).
- Twelve trials reported INR values in therapeutic range, ten of the trials reported higher proportion of INR measurements or larger proportions of participants in therapeutic range for self-monitoring than for standard care.
- Among participants with artificial heart valves, self-monitoring resulted in a significantly higher INR time in therapeutic range or INR values in therapeutic range compared with standard care.

Time to test result

The time spent for each INR monitoring by self-managed participants was significantly lower compared with the time spent by participants receiving standard care

Patient adherence/compliance with testing

Only two trials reported on patient adherence/compliance with testing. One trial reported more than 98% compliance with self-testing. In another trial 75% (30/40) of participants did not report any problems with the use of the device and expressed willingness to continue with self-monitoring.

5.2.2 Clinical Outcomes

Bleeding

Twenty-one trials involving 8394 participants, reported a total of 1472 major and minor bleeding events. No statistically significant differences were observed between self-monitoring participants (self-testing and self-management) and those in standard care for any bleeding events, major bleeding events and minor bleeding events. In subgroup analysis, when only minor bleeding events were assessed, there was a statistically significant increased risk in self-testing participants compared with those in standard care. No significant differences in the risk of major bleeding were observed between self-management and self-testing compared with standard care. No statistically significant subgroup differences were found for bleeding events according to the type of clinical indication or the type of control standard care (2- with atrial fibrillation, 6-with artificial heart valves and 13 with mixed indication).

Thromboembolic events

Twenty-one trials involving 8394 participants, reported 351 major and minor thromboembolic events. Self-monitoring (self-testing and self-management) showed a statistically significant reduction in the risk of thromboembolic events by 42% compared with standard care. The risk reduction further increased to 48% when only major thromboembolic events were considered. Self-management halved the risk of thromboembolic events compared with standard care. The subgroup difference between self-management and self-testing was statistically significant Self-monitoring participants with artificial heart valves showed a statistically significant reduction in the number of thromboembolic events compared with those in standard care.

Mortality

Thirteen trials involving 6537 participants, reported 422 deaths due to all-cause mortality. The risk reduction for all-cause mortality was not statistically significant between self-monitoring (self-testing and self-management) and standard care. There was risk reduction of death by 32% through self-management but not through self-testing. The test for subgroup differences was not statistically significant. Self-monitoring halved the risk of mortality in participants with artificial heart valves. The subgroup difference between

participants with artificial heart valves and those with mixed indication with regard to the number of deaths was statistically significant.
Statistically significantly fewer deaths were recorded among participants who self-monitored their therapy compared with those who were routinely managed by their GP/ physician in primary care.

5.2.3 Patient Reported Outcomes

Anxiety associated with waiting time for results and unknown coagulation status and risk
One trial (n=28) compared self-management with self-testing in children and reported that one parent did not favour self-management because of the increased anxiety related to INR measurements.

Acceptability of the tests
Four trials conducted a questionnaire survey to assess acceptability to participants of self-testing and self-management using point-of-care devices. These trials reported high rates of acceptance for both self-management and self-testing (77% to 98%). When asked about the overall relative satisfaction with the device, 43% of participants favoured INRatio, 36% CoaguChek S, and 21% both devices in equal way. One trial conducted in children, reported that the majority of participants (13 out of 14 participating families, 92%) opted for the use of CoaguChek XS device.

An unpublished review from the National Thrombosis Service in the Netherlands reported the INR values from over 5000 patients on vitamin K antagonist therapy using either the CoaguChek XS system or the INRatio2 PT/INR monitor for self-monitoring. This review reported that the choice of monitor appeared to have no clinically relevant effect on the time in therapeutic range or adverse outcomes in people on long-term vitamin K antagonist therapy.

Health-related quality of life
Health-related quality of life outcomes were reported in 9 trials using a variety of different measures:

- Four trials used Sawicki's questionnaire to measure quality of life and significantly greater improvements in treatment satisfaction and self-efficacy were reported in the self-management arm compared with the standard care arm of the trials. All 4 trials reported a reduced level of distress and daily hassles.
- Two UK-based trials reported no significant differences in quality of life outcomes between self-monitoring participants and those having standard care. Five common themes emerged from the interviews conducted on participants in self-management: knowledge and management of condition and self-empowerment, increased anxiety and obsession with health, self-efficacy, relationship with health professionals, and societal and economic cost.
- One trial compared self-management with self-testing in children and provided quality of life data using the KIDCLOT PAC QL© parent- proxy (parents QOL and their assessment of child's' QOL) and the child teen KIDCLOT PAC QL©. The five common themes identified were: awareness, communication, relationship between parent and child, flexibility, and anxiety.

6. Patient Eligibility and Pathway of Care

6.1 In consideration of the essential requirements for safe systems to govern the widespread use of point-of-care coagulometers (including arrangements for training of patients, quality control of devices and servicing of equipment) which are not currently available or

established in Worcestershire, point-of-care coagulometers are not currently funded for patients in Worcestershire.

6.2 Coagulometers may be self-funded or donated by charities; the Worcestershire NHS service provider will be responsible for determining whether the patient is suitably trained and competent to continue with a self-testing arrangement. The provider should consider a documented agreement covering the following:

- Initial training in use (this may be provided by the manufacturer of the machine).
- Ability to calibrate the device regularly in accordance with the manufacturer's instructions
- Ability of patient or carer to use the meter and finger pricking device; consider vision and dexterity
- Responsibility for ensuring correct use and correlation of results with those from the laboratory/near patient testing devices in practices (consider annual parallel venous tests to ensure that the meter correlates with the laboratory/practice analyser).
- Agreement in advance what happens if test results don't correlate eg. revert to practice testing.
- Reporting of results and responsibility for dosing.
- Recording of results and sharing as appropriate.
- Clinical responsibility remains with the clinician prescribing the vitamin K antagonist treatment eg. warfarin, even though the patient is self-testing.

6.3 Where a self-testing arrangement has been agreed with a Worcestershire NHS service provider (hospital or primary care based), testing strips for use with the coagulometer will be provided at NHS expense by the service provider in sufficient quantity for appropriate clinical monitoring. Funding for test strips is included within the provider contracts for carrying out INR monitoring; patients using more than a box a year should be reviewed as they may not be suitable for self-testing.

6.4 Testing strips for point-of-care coagulometers may not be prescribed by General Practitioners in Worcestershire on FP10 prescription forms.

6.5 Quality control equipment required for quality assurance of point-of-care coagulometers will not be supplied at NHS expense by Worcestershire NHS service providers; patients pursuing a self-testing arrangement will be required to source their own quality control equipment either through direct purchase, manufacturer supply or charity donation.

6.6 Self-management is currently not supported, but there are external non-NHS courses which a patient may wish to enrol on at their own expense, the decision to whether the patient can self-manage would require discussion and mutual agreement between the patient and the prescriber to ensure that all the measures in 6.3 are met and that the patient was deemed competent in dosing.

7. Supporting Documents

- www.nice.org.uk/Guidance/DG14

- Worcestershire Clinical Commissioning Policy Collaborative: Assessment of Implications arising from NICE Diagnostic Guidance 14 "Point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor) for self-monitoring coagulation status in people on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease". October 2014

- Worcestershire CCGs: Operational Policy for Individual Funding Requests
- Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
- West Midlands Strategic Group Commissioning Policy 1: Guiding principles and considerations to underpin priority setting and resource allocation within collaborative commissioning arrangements
- West Midlands Strategic Group Commissioning Policy 4: Use of cost-effectiveness, value for money and cost effectiveness thresholds
- West Midlands Strategic Group Commissioning Policy 16: Prior Approval
- West Midlands Strategic Group Commissioning Policy 9: Individual funding requests

NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Equality Impact Assessment

Department	Public health/Commissioning	Name of person completing EIA	Prasad Godbole, Jennifer Weigham
Date of EIA	10/12/2014	Accountable CCG Lead	Chris Emerson
		CCG Sign off and date	January 2015

Piece of work being assessed	Self-Monitoring Coagulometers
Aims of this piece of work	To assess the impact of the policy on all of the protected groups.
Other partners/stakeholders involved	Public Health
Who will be affected by this piece of work?	Patients using anti-coagulation medication necessitating INR monitoring within Wyre Forest CCG, Redditch and Bromsgrove CCG and South Worcestershire CCG.

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? Eg population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	Artificial Heart Valve - Aortic valve problems in adults are more common in men than women. Atrial Fibrillation – Women have higher risk of stroke related death. Men are at a 25% higher risk of having a stroke, and at a younger age, compared to women. Although, because they live longer than men, there are more incidences of stroke in women. Pregnancy increases the risk of clots.	Yes
Race	Atrial Fibrillation - South Asian, black African and black Caribbean people in the UK are more at risk of stroke than the rest of the population	Yes
Disability	Cancer increases the risk of clots, sickle cell is a risk factor for increasing clots	Yes
Religion/ belief	Artificial Heart Valve – Some people who are Muslim may not be able to have a pig skin valve	No

Sexual orientation	-	-
Age	Artificial Heart Valve Atrial Fibrillation – Most people who have strokes are aged over 55, and the risk increases as you get older.	Yes
Social deprivation	Atrial Fibrillation – Drug and alcohol abuse is associated with AF.	Yes
Carers	Artificial Heart Valve – N/A Atrial Fibrillation – N/A The proposal specifies that carers would be involved and could be nominated to perform the self-testing/management for the patient. Children are also included in the proposal and therefore this would include their parents/guardians performing the self-testing/management.	Yes
Human rights	Will this piece of work affect anyone's human rights?	No

Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead

The decision has been made that at the current time self-testing/management is not feasible for Worcestershire. Therefore there will be no suggestion actions in relation to the assessment.