Service Specification No.	EPCMS 13
Service	Prostate Cancer PSA Monitoring / Active Surveillance and follow-up in Primary Care
Commissioner Lead	Colin Webb, Commissioning Manager
Provider Lead	Hull Primary Care
Period	01 October 2021 – 31 March 2022
Date of Review	April - Annually

1. Population Needs

1.1 National/local context and evidence base

1.1.1 Prostate Cancer is the most commonly diagnosed cancer in men in the UK (Cancer Research UK. 2010). The majority of these men will remain well with the disease (the 10-year survival rate is currently 68%). This means that all men with prostate cancer could potentially be followed up for life, producing a burden for men and healthcare providers. The majority of patients with prostate cancer are managed (treatment and follow up) within secondary care. The Cancer Reform Strategy (2007) suggested considering alternatives to hospital-based follow-up (including nurse-led and proactive case management e.g., in a community setting or by telephone)

1.1.2 Prostate cancer incidence: The all-age age-standardised incidence (using the 2013 European standard Population) of prostate cancer in Hull in 2012-2014 (164.7 per 100,000 men) was lower than for England (181.8 per 100,000 men), the Yorkshire and Humber region (169.5 per 100,000 men) as well as the average of the ten comparator areas (174.2 per 100,000 men).

1.1.3 Also, at 117.4 per 100,000 men, the under 75 age-standardised incidences of Prostate cancer in Hull in 2012-2014 was similar to England (119.0 per 100,000 men), but higher than the Yorkshire and Humber region (110.7 per 100,000 men) as well as the average of the ten comparator areas (112.6 per 100,000 men).

1.1.4 Hull Inpatient hospital admissions due to prostate cancer: During 2008/09-2010/11 there was 450 admissions in men due to prostate cancer.

1.1.5 Prostate cancer mortality: Mortality rates in 2012-14 from prostate cancer among men in Hull were similar to, although slightly lower than, those for England, with the age standardised rate (using the 2013 European Standard Population) 44.8 per 100,000 men in Hull and 49.5 per 100,000 men in England. Rates were also a little lower than those for the Yorkshire and Humber region and most of the comparator areas.

1.1.6 NICE Guidance Prostate cancer diagnosis and management 2019 states: discharge the person to primary care if the level of suspicion is low; advise PSA follow-up at 6 months and then every year and set a PSA level for primary care at which to re-refer based on PSA density (0.15 ng/ml/ml) or velocity (0.75 ng/year).

References:

1. http://www.hullcc.gov.uk/pls/hullpublichealth/assets/JSNA/HullJSNAToolkit7ProstateCancer.pdf
2. https://www.nice.org.uk/guidance/ng131

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 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 Locally Defined Outcomes

By signing up to this contract, primary care will be required to implement a robust call/recall system and review patients as per secondary care discharge follow-up care plans.

This local service will improve outcomes for patients diagnosed with stable prostate cancer, as well at those without a diagnosis of cancer, who require regular PSA monitoring through:

- Establishment of a practice register of patients being followed up in primary care.
- Improved monitoring and management of patients on the register.
- Provision of care closer to home with reduced secondary care attendance.
- Reduced waiting times for treatment by reducing the follow-up burden on secondary care.
- Early detection, referral, and treatment of prostate cancer relapse.

This local service is expected to: -

- Reduce avoidable secondary care follow up appointments.
- Reduce need for hospital transport services by providing services closer to the patient's home.

3. Scope

3.1 Aims and objectives of service

The overall aim of the service is to improve the care of locally advanced prostate cancer patients who are stable on treatment by transferring some care from the acute hospital and into primary care by providing care closer to home in a safe and effective manner.

The service will provide proactive PSA monitoring for patients diagnosed by secondary care clinicians as suitable for primary care monitoring of prostate cancer.

These aims support NHS Hull Clinical Commissioning Group's strategic objectives to:-

- Deliver continuity of care closer to home in the most appropriate setting
- Provide a locally accessible service for patients
- Improve life expectancy and reduce health inequalities
- Provide more choice, improve access to, and reduce waits for all health services
- Deliver quality health care outcomes, focused on the need of the individual
- Reduce the variation in the quality of care.
- Lead sustainable change to transform health care provision in Hull
- Access to secondary care consultant if needed for advice and support

The following group of patients may be suitable for transfer from secondary care for primary care follow up:

- Patients who choose a watchful waiting approach as soon as they have a diagnosis of prostate cancer or presumed prostate cancer (NICE 2019)
- Patients who are stable following radical surgery and have a stable PSA of zero or <0.15ng/ml. (NICE 2019 recommends 2 years post-surgery)
- Patients who have had radical radiotherapy and have stable/not rising PSA (NICE 2019 recommends after 2 years)
- Patients who are two years post brachytherapy and have stable/not rising PSA (NICE 2019 recommends after 2 years)
- Patients on hormone manipulation therapy: fall of presenting PSA and improvement in any presenting symptoms such as lower urinary tract symptoms.

In exceptional circumstances and subject to agreement by both primary and secondary clinicians, patients who are over 2 years into active surveillance prior to radical treatment may also be included.

3.2 Service description/care pathway

3.2.1 Service Delivery / Pathways

The practice will maintain a register of patients for whom it holds monitoring responsibility. Patients will be added to the register when care is transferred from secondary to primary care.

Following investigation / treatment in secondary care, the consultant (either Oncology or Urology) responsible for the patient will send the initial discharge letter (IDL) to the patient's registered GP with supporting information (Appendices B&C) containing.

- Diagnosis
- Investigations to date (including summary findings)
- Current PSA & Care Plan
- Purpose of monitoring

The consultant will identify /thresholds requiring consultant review, such as:

- Increase of PSA to a specified level
- Increase of PSA by greater than 50% over baseline
- Development of obstructive symptoms
- Symptoms suggestive of metastatic disease etc.

The consultant will advise on the frequency of PSA monitoring.

Where a practice declines the transfer, the notification must be sent back to the Trust via eRS as per the Standard Operating Procedure. In these cases, The Trust will continue monitoring of the patient.

The Practice will monitor these patients within the agreed limits through PSA testing and clinical review.

The Practice will refer to the thresholds set out in IDL on receipt of PSA results in order to interpret them in the appropriate clinical context.

If any thresholds are met the GP will refer directly back to the original consultant via an urgent eRS new referral clearly stating PSA patient previously under the care of Urology as per the Standard Operating Procedure

The review of results and decisions made are the responsibility of the GPs providing this service. This must not to be delegated to other staff members unless they are suitably qualified and competent.

Providing Practices should ensure they have a system for ensuring that results have been received for all blood samples sent as part of the PSA recall system, and that these results have been reviewed by an appropriate clinician and patient informed of appropriate action to be taken (e.g. date of next test or referral back to secondary care).

Each practice accepts that:

- The practice providing this service will have and monitor a recall system to ensure it is safe and consistent.
- The patient's registered practice will arrange for the patient to attend for PSA blood tests at the practice.
- GPs/appropriately trained clinicians providing this service will perform a clinical assessment at a time when the test results will be available. The assessment may be telephone based unless clinical examination is part of the monitoring process or telephone consultation raises concern that warrants examination.

The clinical assessment of the patient will include:

- Review of PSA blood test results.
- Enquiry about bone pain and changes in urinary symptoms.

- Review of the care plan including the timing of the next review.
- Decision whether a specialist opinion is required based upon the triggers outlined by the secondary care consultant in the transfer of care arrangements.
- Referral to secondary care when needed using the 2 week wait system or an alternative means if more appropriate.
- Outcomes of the review will be recorded on the practice's clinical system.
- Rectal examination only if specified through the discharge process (not offered routinely following radical treatment whilst the PSA remains at baseline levels NICE 2019).

In the event of a patient DNA, the practice is responsible for contacting the patient again to re-book their appointment, ensuring that any 'informed dissent' is recorded in the register. Practices should attempt to contact the patient at least 3 times to re-book their appointment, two of which should be via a hard copy letter posted to the patient's home address.

The practice must ensure that all clinicians involved in the monitoring of these patients are familiar with the current NICE Guidelines appropriate to this service.

3.2.2 In addition, the Provider will:

- Maintain adequate records in the patient's lifelong record. This should include details of the patient's monitoring, any untoward incidents and evidence of patient consent to treatment.
- Ensure that primary care staff involved in providing any aspect of care under this scheme are adequately trained, have the necessary skills and are appropriately qualified.
- Ensure safe and suitable facilities for undertaking invasive procedures.

3.2.3 GP Responsibility:

By signing up to the agreement, practices are confirming that GPs involved in the surveillance of patients with stable prostate disease will:

- Provide PSA monitoring for patients being cared for on the Prostate Cancer Register, in accordance with secondary care discharge letter.
- Review patients at appropriate intervals and where indicated refer back for hospital assessment as stated in secondary care discharge letter.
- Undertake Digital Rectal Examination (DRE), where indicated in the management plan to determine on-going management of the patient (or following telephone/email advice from the consultant or urology specialist nurse).
- If uncertainty exists in the appropriate management of patients on the register, pro-active contact is to be made with acute urology provider colleagues for telephone/email advice and guidance.

3.3 Population covered

The service is available to all adults with prostate cancer who are registered with a Hull GP practice and have been discharged from secondary care with agreement to be further monitored in primary care.

3.4 Acceptance and exclusion criteria

3.4.1 Acceptance

Adult patients registered with a Hull GP practice who have been discharged from secondary care as deemed suitable for enhanced PSA monitoring and management in primary care.

3.4.2 Exclusion

- This service is for the monitoring of PSA levels in patients meeting the service criteria – any other enhanced monitoring of conditions is not covered within the scope of this service.
- The service is not provided to patients who are not registered with a Hull GP.
- Patients who are currently enrolled in clinical trials through secondary care.
- Patients being treated privately by secondary care consultants unless it is the patient's wish to transfer.
- Patients under care of a urologist for another cancer (e.g. bladder)
- Patients who are not clinically stable as identified by the Urologist at Hull University Teaching Hospitals Trust.

3.5 Funding Arrangements, Payment and Verification

3.5.1 Payments for this service will be made under the following arrangements.

- **£47.23 per follow up outpatient attendance to a maximum of 2 per year.**

3.5.2 Practices can only claim for procedures within the scope of this specification.

3.5.3 Claims are to be made by submitting activity onto the Enhanced Services Portal in line with all other NHS Hull CCG Extended Primary Care Medical Services.

3.5.4 The payment for the services includes development of a patient register, all consumables and aftercare associated with the procedure.

3.5.5 Renumeration for blood tests as part of this service are covered by the EPCMS2 Secondary Care Phlebotomy contract.

3.5.4 Primary Care Networks not wishing to provide this service but who require their patients receive PSA Monitoring and Active Surveillance within Primary Care will be expected to sign up to this specification and then sub-contract/refer this work to another Primary Care Network providing this service. Patients will be referred by way of the Electronic Referral System.

3.5.5 The Primary Care Networks will be subject to routine post payment verification (PPV) process in respect of delivery of this service. It is intended that practices continue to carry out those procedures currently undertaken within their existing work and keep a record of all enhanced procedures.

3.6 Interdependence with other services/providers/bodies

- Hull University Teaching Hospitals Trust (HUTHT)
- NHS Hull CCG GP practices and practice nurses
- District Nurses
- Macmillan nurses

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

4.1.1 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

- Operational Plan (NHS Hull) 2021/22
- NHS Outcomes Framework (DOH) (2021/22)
- NHS Hull CCG – Clinical Policies http://www.hullccg.nhs.uk/policies

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements

The Provider will develop and follow a standard operating policy for provision of this service. The provider will be expected to submit evidence such as an audit to the CCG to demonstrate compliance with the specification if requested to do so. Any significant failing in the monitoring process such as a delay in a patient's PSA monitoring of over 4 months must be reported to the Director of Primary Care or equivalent.

6. Location of Provider Premises

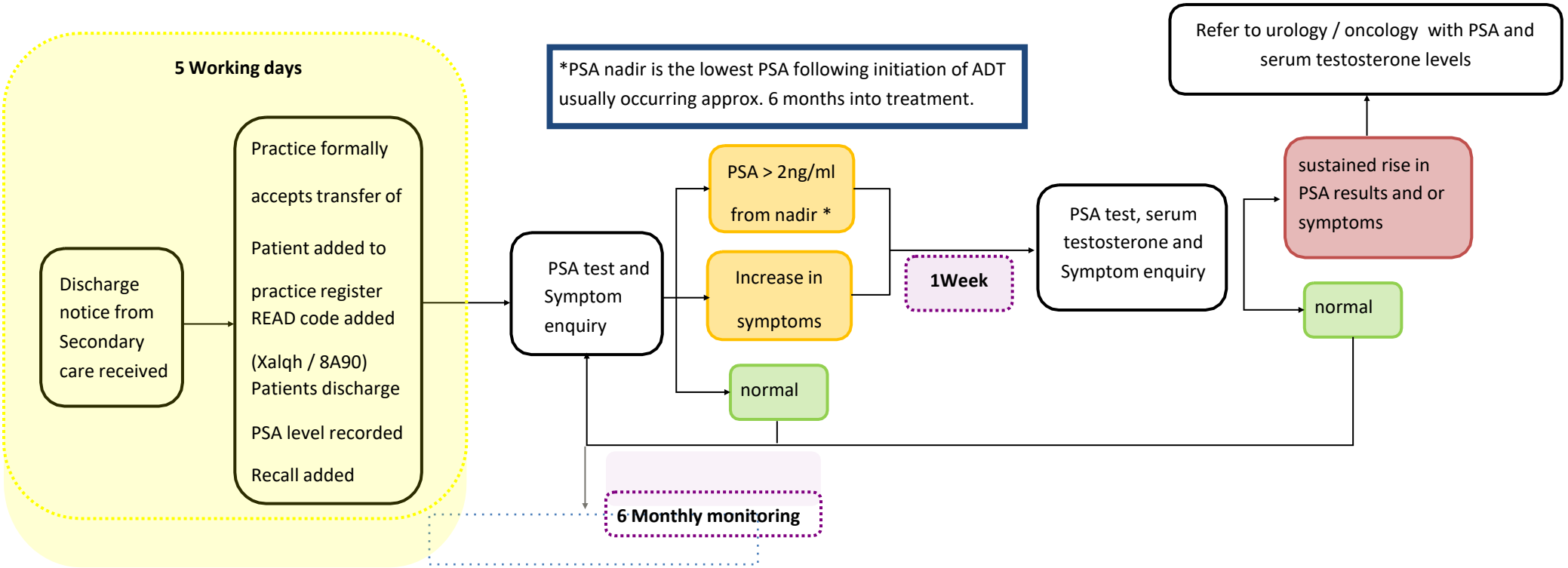
6.1 Premises

6.1.1 The service will be provided from the Provider's Premises located at: Hull GP Practices.

7. Individual Service User Placement

Not applicable

Appendix A - PSA Flow Chart



Symptom enquiry - Key symptoms to be mindful of; bone pain, back ache, fatigue, anorexia and deteriorating urinary symptoms or systemic symptoms

LFTs checked annually for patients prescribed Bicalutamide and Cyproterone as hepatic changes can occur

Appendix B

Stable Prostate Cancer Community Service Referral Form		
	GP Code	
	GP Practice	
	Discharge Date	

PATIENT DETAILS

Title		Surname	
First Name		Middle Name	
Date of Birth		NHS Number	
Address			
Post Code		Telephone no	
Urologist		Oncologist	

PROSTATE CANCER HISTORY

Date Diagnosed ____ Hospital ____

Gleason Score ☐ 6 ☐ 3+4 ☐ 4+3 ☐ 8 ☐ 9 ☐ 10 ☐ N/A

Diagnosis PSA ____ Nadir PSA ____

TNM Staging ____ / N ____ / M ____

Individual PSA ☐ Yes ☐ No

Individual PSA Trigger Value ____

If individual PSA, indicate the level of PSA which would trigger a referral back to hospital consultant

Management Pathway
☐ Hormonal Manipulation ☐ Radiotherapy
☐ Watchful Waiting ☐ Brachytherapy
☐ Radical Prostatectomy

Treatments ____ Date ____

Treatments ____ Date ____

PSA BLOOD TEST RESULTS

Lab Test Date ____ PSA Test Result ____

Lab Test Date ____ PSA Test Result ____

Referral Form Completed by ____ Date ____

Appendix C

PSA/Prostap Monitoring Transfer Form (Consultant to GP)

Date ……..

Surname	Date of birth
Forename	Sex M ☐ F ☐
Address	
NHS Number	

Patient Category: ***Please tick one of the following:***

Unconfirmed diagnosis – negative investigations ☐
Confirmed localised prostate adenocarcinoma – Active surveillance ☐
Confirmed localised prostate adenocarcinoma – treated with radical surgery ☐
Confirmed localised prostate adenocarcinoma – treated with radical radiotherapy ☐
Treated metastatic prostate adenocarcinoma – Stable on hormones ☐

Details of treatment so far e.g. radical prostatectomy, radiotherapy, brachytherapy, hormones, Active surveillance

CURRENT PSA LEVEL: ng/ml on DATE

Monitoring advised:

Please tick all the appropriate boxes below and complete the subsequent guidance:

☐ Please arrange a PSA test every ……. months for 1 year.
If stable, please continue to monitor the PSA every ……. months after 1 year.

☐ Please arrange Prostap injections every …….. months for 1 year
If stable, please continue to provide injections every ……..months after 1 year (NE Lincs only)

☐ Please refer back to clinic if PSA rises above …… ng/ml.

☐ Please refer back to clinic if there are 2 consecutive rises in PSA.

At each review, please enquire about any new bone pains or urinary symptoms.

In the event of any new patient concerns, queries regarding monitoring, or worries about treatment, please refer back into the Urology Service through the eRS process marking the referral URGENT if required and include the following information;