NHS Board Service Outline and Governance Checklist - Xtandi® (Enzalutamide)

General Information	
BRAND NAME	*XTANDI®*
APPROVED NAME	*ENZALUTAMIDE*
MANUFACTURER NAME	*ASTELLAS PHARMA LTD*
INDICATION THIS PROPOSAL RELATES TO	The treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated The treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy Both are licensed indications
COSTS OF TREATMENT	£2734.67 for 112 tablets (4 week course)
ACQUISITION PARITY	Astellas will supply to community pharmacy using Alliance Healthcare. Phone Astellas on 0203 3798721 to register the pharmacy and order directly. Enzalutamide held on PSD database. Confirmed by Don Page (PSD) Enzalutamide flagged as zero discount (ZD) on eVadis to ensure correct payment. Confirmed by Don Page (PSD).
BARRIERS TO COMMUNITY ACQUISITION	Astellas use Alliance as their sole provider for procurement for enzalutamide. Terms will be as for any other drug procured through this route. Pharmacies must register with Astellas and order each supply using the approved ordering form and mechanism.
MEDICINE FORMULATION AND ROUTE OF ADMINISTRATION	Soft capsule - oral
EQUIPMENT AND ANCILLARIES	N/A

DOSING INFORMATION	The recommended dose is 160 mg enzalutamide (four 40 mg capsules) as a single oral daily dose. The capsules should be swallowed whole with water, and can be taken with or without food. Treatment is continued until progression or unacceptable toxicity.
SPECIFIC STORAGE REQUIREMENTS	This medicinal product does not require any special storage conditions. (SPC http://www.medicines.org.uk/emc/medicine/27912)
SMC STATUS	Both indications are accepted for use in NHS Scotland SMC no: 1066/15; Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. Status: Accepted; Date Advice Published: 07/03/2016. - link SMC no: 911/13; Treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy.; Status: Accepted; Date Advice Published: 11/11/2013 - link
DATE OF PATENT EXPIRY	2028 (https://www.sps.nhs.uk/medicines/enzalutamide/
PATIENT ACCESS SCHEME STATUS	A PAS is in place. Rebates are done retrospectively based on usage. NHS Boards have their own mechanisms in place.
PRESCRIBING ARRANGEMENTS	Prescribing will take place in secondary care at the patient's urology oncology clinic. Prescriptions may be written by a consultant oncologist, a medical registrar or staff grade or a non-medical prescribing nurse or pharmacist. Patients will nominate a single community pharmacy at which they will receive their enzalutamide. This community pharmacy will be the only supplier of enzalutamide for this patient. Full details of each patient's nominated community pharmacy will be kept in a register in the hospital pharmacy department. The nominated community pharmacy will be contacted by the Community Pharmacy Development Team (CPDT) with information

	about the patient, their current medication assessed for interactions and the enzalutamide service. Prescriptions will be written on an HBP and given to the patient to deliver to the community pharmacy. Patients will be seen at clinic at 4, 8 or 12 week intervals. The first supply of enzalutamide will be from the hospital pharmacy and will be for 5 weeks supply. This builds in an extra week's supply to allow the community pharmacy time to order enzalutamide upon receipt of the HPB without disrupting supply to the patient. Each prescription will be for 4 weeks supply. If patients are seen at 8 or 12 week intervals, they will receive two or three separate prescriptions for 4 weeks supply respectively. Patients will only collect 4 weeks supply at a time. Prescriptions will be forward dated to prevent the supply of more than 4 weeks at a time. Treatment will continue until disease progression or unacceptable toxicity. Decision to stop treatment will be made at the urology oncology clinic.
SCOPE OF THE SERVICE (PATIENTS)	This service would be offered to all patients receiving enzalutamide from the urology oncology clinic. There may be individual patients who due to personal circumstances it will not be possible to proceed with community dispensing of enzalutamide. This will be reviewed on an individual patient basis.
ANTICIPATED NUMBER OF PATIENTS USING THE SERVICE	In 2016: At the Beatson there were 130 patients receiving 779 prescriptions for enzalutamide. In A&A there were 79 patients receiving 540 prescriptions for enzalutamide. Across the West of Scotland there were 314 patients receiving 1883 prescriptions for enzalutamide.
SCOPE OF THE SERVICE (MEDICINES)	Enzalutamide – no additional medicines are routinely required
PRESCRIPTION MANAGEMENT REQUIREMENTS	Patients will only receive an HBP from urology oncology clinic if suitable to proceed with treatment. Patients will only receive 4 weeks supply at a time. Patients may hand in more than one 4 week prescription to the community pharmacy. These are for subsequent supplies and should be

	forward dated as appropriate. They should not be dispensed to the patient before the date on the prescription. No confirmation from the urology oncology clinic is required to dispense a subsequent supply. If for any reason a patient is not to receive subsequent supplies, the community pharmacy will be contacted by a member of the secondary care team. Dose modifications are uncommon. In the event that a patient requires a dose modification, the secondary care team will contact the community pharmacy and arrange for a new prescription.
PROPOSED TIER OF SERVICE TO BE PROVIDED	Tier 1 – No additional Pharmaceutical Care required out with the normal dispensing and supply of a new drug to the patient
OUTLINE OF ANY PHARMACEUTICAL CARE BUNDLE TO BE DELIVERED	It is expected that community pharmacists will: Provide pharmaceutical care including support with adherence Under CMS, create a PCR for each patient if they do not have one already, and document relevant issues as they arise. Liaise with GP/secondary care team if any new acute/routine medicines are prescribed that may significantly interact with enzalutamide Notify the secondary care team of any concerns regarding the patient or any adverse events relating to enzalutamide. Advise the patient to contact their GP/Cancer Treatment Helpline if signs of infection/felling unwell Notify the secondary care team if the patient does not collect their enzalutamide when expected.
OUTLINE OF TRAINING REQUIREMENTS TO BE PART OF AN SLA	Each pharmacy will designate a named pharmacist to be responsible for the on-going delivery of the scheme. The named pharmacist providing the service should read the service protocol and accompanying information and operate within the service specifications. Other staff should have general awareness that the service is in place to ensure continuity of service where possible. Pharmacy contractors are free to develop their own standard operating procedures to deliver the scheme in their own pharmacy.

REQUIREMENT FOR A CLINICAL INFORMATION SHEET	Community pharmacy will receive an information sheet which will include information on the clinical condition and the need for the service. It will also include contact details, frequently asked questions, specific dispensing and labeling requirements and information on when to contact the secondary care team. Community pharmacists are expected to consult the SPC for information specific to enzalutamide.
RESPONSIBILITIES OF INITIATING CONSULTANT	Patients will be reviewed and consented for treatment by an oncologist responsible for their care. Community pharmacies will receive notification from the CPDT about any patients that will be collecting enzalutamide from them. The first supply of enzalutamide will be from the hospital pharmacy and the patient will receive the appropriate education and counseling, with a baseline assessment of drug interactions with current medication. Patients will be reviewed regularly at the oncology clinic, initially every 4 weeks and where appropriate, review intervals may be widened to 8 weekly or 12 weekly visits. Patients will have the opportunity to return to clinic earlier than planned at the discretion of the secondary care team. Patients will receive regular scans, which will be used in conjunction with patient review to determine the appropriateness of continuing treatment. It is not anticipated that there will be a requirement for regular communication with the community pharmacy, however the community pharmacy details for each patient will be held in a register in the hospital pharmacy and therefore any ad hoc communications will take place by telephone.
RESPONSIBILITIES OF COMMUNITY PHARMACIST	T1 – Ensure that the supply of the drug to the patient is made in a timely manner using the correct route of supply from the identified supplier. Respond accordingly to the instruction and direction of the prescriber.
DISPOSAL OF WASTE	Enzalutamide is hormonal treatment. It is not cytotoxic and therefore disposal arrangements are the same as for any other medicine.
RESPONSIBILITIES OF THE PATIENT	Whilst there are no specific storage requirements for enzalutamide, it should be kept in a safe place, out of the reach of children and where it cannot be confused with other medication.

	Report any adverse drug reactions at clinic visits or, if urgent contact the CNS or Cancer Treatment Helpline as appropriate Keep clinic appointments for monitoring and follow up Check any new OTC medicines are safe to take, with the community pharmacist Agree to take enzalutamide as prescribed and collect supplies as arranged Notify the team of any missed doses
PATIENT EDUCATION AND COMMUNICATION	Patients will receive counseling on how to take the medication, potential side effects. Patients will sign consent prior to commencing treatment. Patients will receive contact details and information on what to do in the event of emergency/experience of side effects
CLINICAL GOVERNANCE	Any incidents or dispensing errors should be recorded as per standard procedures in the community pharmacy. Details of incidents or dispensing errors must be communicated with the secondary care team as soon as is possible. Where appropriate the patient must also be contacted as soon as possible. In the event of any ADRs the secondary care team must be notified and if appropriate the patient's GP. If a patient is unwell they must be advised to seek help immediately by contacting their GP, the Cancer Treatment Helpline or the emergency services as appropriate.
CONTINGENCY ARRANGEMENTS	In the event that a particular community pharmacy can no longer provide the service, the secondary care team must be contacted and will arrange either for a supply from the hospital pharmacy or a transfer of care to another community pharmacy that is convenient for the patient.
SPECIALIST SERVICE RESOURCES REQUIRED TO SUPPORT THE SERVICE	Completion of HBP prescriptions. Liaison with community pharmacies and any visit required to support the service
FUNDING	All prescribing will take place via HBP. As enzalutamide is over £1000 it can be subject to an advanced payment via PSD using the recognized method through the Primary Care Pharmacy Team.

PAYMENT	Tier 1 as defined in framework. £75 per annum or part thereof will be paid for every patient. Claims will be made to NHS Boards on the forms as outlined by the individual Board.
OTHER	The Community Pharmacy Development Team (CPDT) will generate a claim form on the anniversary of the initial referral (on the date that notification was initially sent to the community pharmacy). Submission of the claim form will generate the next annual payment; Where a claim is not submitted, one reminder will be generated after four weeks. This will be the only reminder sent. Contractors are advised to put a message on their PMR to advise of when the patients supply will annualise as a further reminder for future years payments. By signing the participation form you give CPDT explicit consent to process any and all claims relating to this service in line with GDPR principles.
DURATION OF SERVICE OUTLINE	This Service Outline will commence on 1st April 2022 and end on 31st March 2024.