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| NHS Board Service Outline and Governance Checklist Zytiga® (Abiraterone) | |
| General Information | |
| Brand name | **zytiga®** |
| approved name | **abiraterone acetate** |
| manufacturer | **janssen-cilag ltd** |
| indication this proposal relates to | The treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.  The treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.  Both are licensed indications |
| costs of treatment | 56x500mg £2735, 60x250mg £2930  Note: There will be a 6 month cross over period where 250mg/500mg are both available before discontinuation of 250mg in September 2017 |
| acquistion parity | Janssen will supply direct to Community Pharmacy |
| Barriers to community acquistion | Pharmacies must register and set up an account with Janssen and order each supply using the approved ordering form and mechanism.  Supply will be direct from the manufacturers rather than through local wholesaler |
| Medicine formulation and route of administration | 250mg tablet – oral or 500mg film-coated tablet - oral |
| equipment and ancillaries | N/A |
| Dosing information | The recommended dose is 1,000 mg as a single daily dose that must not be taken with food.  Abiraterone is to be taken with low dose prednisone or prednisolone. The recommended dose of prednisone or prednisolone is 10 mg daily. |
| Specific storage requirements | This medicinal product does not require any special storage conditions.  (SPC [**http://www.medicines.org.uk/emc/medicine/24976**](http://www.medicines.org.uk/emc/medicine/24976) ) |
| smc status | Both indications are accepted for use in NHS Scotland  SMC no: 873/13; abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men 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:  12/10/2015. - [**link**](http://www.scottishmedicines.org.uk/SMC_Advice/Advice/873_13_abiraterone_Zytiga/abiraterone_Zytiga_IRP)  SMC no: 764/12; with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.  SMC restriction: abiraterone is restricted to use in patients who have received only one prior chemotherapy regimen ; Status: Restricted; Date Advice Published:  13/08/2012 - [**link**](http://www.scottishmedicines.org.uk/SMC_Advice/Advice/764_12_abiraterone_Zytiga/abiraterone_Zytiga_Resubmission) |
| date of patent expiry | SPS notes that UK patent expiry – 2018 however horizon scanning intelligence suggests that there may be further patent protection until 2027.  [**https://www.sps.nhs.uk/medicines/abiraterone/**](https://www.sps.nhs.uk/medicines/abiraterone/) |
| patient access scheme status | A PAS is in place.  Rebates are collected by NHS retrospectively on usage figures. |
| 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 abiraterone. This community pharmacy will be the only supplier of abiraterone 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 prescribing team with information about the patient, their current medication assessed for interactions and the abiraterone 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 abiraterone 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 abiraterone 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 abiraterone 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 abiraterone. This will be reviewed on an individual patient basis. |
| Anticipated number of patients using the service | In 2016:  At the Beatson there were 79 patients receiving 537 prescriptions for abiraterone.  Across the West of Scotland there were 165 patients receiving 1212 prescriptions for abiraterone. |
| Scope of the service (medicines) | Abiraterone must be given concurrently with prednisolone 10mg daily. This may be given as 10mg once daily or 5mg twice daily. |
| 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 abiraterone  Notify the secondary care team of any concerns regarding the patient or any adverse events relating to abiraterone.  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 abiraterone 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 abiraterone. |
| 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 prescribing team about any patients that will be collecting abiraterone from them.  The first supply of abiraterone 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 | Tier 1 – 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. |
| Dispoasl of waste | Abiraterone 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 abiraterone, 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 abiraterone 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 Oncology clinic, 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 abiraterone 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 | Please include any other relevant information pertinent to the contracting of a service to deliver this medicine |