Chemotherapy Protocol

PROSTATE

ABIRATERONE-PREDNISOLONE

Funding may be required for specific indications

Regimen

- Prostate-Abiraterone-Prednisolone

Indication

- Second line treatment of hormone resistant prostate cancer following chemotherapy (NICE)
- First line treatment of hormone resistant prostate cancer where chemotherapy is contra-indicated (CDF)
- Performance status 0, 1, 2

Toxicity

Drug	Adverse Effect
Abiraterone	Peripheral oedema, hypokalaemia, hypertension, urinary tract infection, raised LFTs, cholesterol and triglycerides
Prednisolone	Weight gain, GI disturbances, hyperglycaemia, CNS disturbances, cushingoid changes, osteoporosis

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

Monitoring

- U&Es
- Liver function including serum transaminases and bilirubin should be measured prior to starting treatment, every two weeks for the first three months of treatment and monthly thereafter.
- Blood pressure, serum potassium and fluid retention should be monitored before treatment and at least monthly thereafter.
- Cholesterol and triglycerides every four months

Dose Modifications

The dose modifications listed are for haematological, liver and renal function and drug specific toxicities only. Dose adjustments may be necessary for other toxicities as well.

Haematological

Abiraterone is not myelosuppressive therefore dose modifications due to haematological parameters are not applicable.

Consider blood transfusion if patient symptomatic of anaemia or has a haemoglobin of less than 8g/dL.

Hepatic Impairment

Drug	Bilirubin µmol/L		AST/ALT units/L	Dose (% of original dose)
Abiraterone	N/A		5xULN or greater	1st Occurrence Withhold treatment. Treatment may be re-started at 500mg daily once LFTs return to baseline 2nd Occurrence Stop treatment
	N/A		20xULN or greater	Stop treatment

Abiraterone should be avoided in patients with pre-existing moderate or severe hepatic impairment (Child-Pugh Class B or C) as there is no safety data to support its use.

Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Abiraterone	N/A	Caution in severe renal impairment

Other

Abiraterone should be used with caution in patients with a history of cardiovascular disease. Safety in patients with left ventricular ejection fraction less than 50% or NYHA Class III or IV heart failure has not been established. Before treatment hypertension must be controlled and hypokalaemia must be corrected.

Regimen

28 day cycle until disease progression (6 cycles will be set in Aria)

Drug	Dose	Days	Administration
Abiraterone	1000mg	1-28 inclusive	Oral
Prednisolone	5mg twice a day	1-28 inclusive	Oral

Dose Information

- Abiraterone is available as 250mg tablets.
- Prednisolone is available as 5mg (uncoated) and 2.5mg and 5mg (enteric coated) tablets.

Administration Information

- The prednisolone should be taken with or after food
- Abiraterone should be taken on an empty stomach at least two hours after food or at least one hour before food. Tablets should be swallowed whole with water.

Additional Therapy

- Gastric protection with a proton pump inhibitor or a H_2 antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

Additional Information

- Patients should continue to receive an LHRH agonist during abiraterone treatment.
- Abiraterone treatment should be supervised by a consultant oncologist.
- Patients who stop abiraterone may require a gradual withdrawal of the prednisolone.

Coding (OPCS 4.6)

- Procurement – X74.1
- Delivery – X73.1

References

1.Zytiga SPC, Janssen-Cilag International, 5th September 2011
2.de Bono JS., Logothetis CJ, Molina A, et al. Abiraterone and Increased Survival in Metastatic Prostate Cancer. N Engl J Med 2011; 364: 1995-2005.

REGIMEN SUMMARY

Abiraterone-Prednisolone

Day 1

Take Home Medicines

1. Abiraterone 1000mg once a day oral

2. Prednisolone 5mg twice a day oral
   Administration Instructions
   Take with or after food. The dose of this medicine may need to be reduced gradually before stopping treatment.

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.1	May 2015	Header changed OPCS code updated Prednisolone admin instructions added. Disclaimer added	Donna Kimber Pharmacy Technician	Rebecca Wills Pharmacist
1	Jan 2013	None	Rebecca Wills Pharmacist Dr Deborah Wright Pharmacist	Dr Joanna Gale Consultant Medical Oncologist Dr Matthew Wheater Consultant Medical Oncologist

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust
NHS Isle of Wight
Portsmouth Hospitals NHS Trust
Salisbury Hospitals NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors which occur as a result of following these guidelines.