Prescribing Clinical Network

Application for change in colour classification

GREEN - Non-Specialist Drugs GPs (or non-medical prescribers in primary care) are able to take full responsibility for initiation and continuation of prescribing
BLUE - Specialist Input WITHOUT Formal Shared Care Agreement Prescribing initiated and stabilised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement
AMBER - Specialist Initiation WITH Shared Care Guidelines Prescribing initiated and stabilised by specialist but has potential to transfer to care under a formal shared care agreement
RED - Specialist ONLY drugs Treatment initiated and continued by specialist clinicians
BLACK – NOT recommended Not recommended for use in any health setting across Surrey and NW Sussex health economy

Medicine details

Name, brand name and manufacturer	**Bicalutamide**	
Licensed indication, formulation and usual dosage	Oral tablets 50mg, 150mg **Licensed indications and usual dosage** <u>Adults (including the elderly)</u> 50 mg - advanced prostate cancer in combination with LHRH analogue therapy or surgical castration 150 mg - alone or as adjuvant to radical prostatectomy or radiotherapy in locally advanced prostate cancer at high risk for disease progression - locally advanced, non-metastatic prostate cancer where surgical castration or other medical intervention is not considered appropriate or acceptable <u>Paediatric Population:</u> Not recommended.	
Traffic Light Status	**Current status**	**Proposed status**
	BLUE – WITH info leaflet **Minimum one month from specialist**	**BLUE – NO info leaflet OR UPDATED info leaflet** **Minimum one month from specialist**
Reason for requested change		

Please use PCN decision making criteria to inform reasons for change

20160526_colour classification guideline

The Midland Therapeutic Review & Advisory Committee (MTRAC) looked into the evidence of bicalutamide use in shared care. The original decision to recommend shared care agreement with bicalutamide was revised in 2012. The current advice is that bicalutamide should be initiated by a specialist but that no shared care agreement is required, provided that the initiating specialist specifies who has the responsibility for monitoring LFTs and PSA.

Local CCGs position

Bicalutamide is classified as 'blue' on Brighton and Hove Formulary. It is recommended for specialist initiation only without formal shared care agreement as there is no specific monitoring required or monitoring is on-going by specialist. There is no specific information sheet available.
Coastal West Sussex Formulary classifies bicalutamide as 'green'. Initiation, repeat prescribing and monitoring may occur in any care setting.
West Kent Formulary classifies bicalutamide as 'amber' without shared care guidance. It is to be initiated by specialist, monitoring of either medicine or disease does not necessarily require specialist skills or equipment.

CHMS Formulary classifies bicalutamide as blue with no information sheet.

The revision of the colour re-classification would help align with existing practice in other CCGs.

The current Information sheet for bicalutamide on the Surrey PAD does not provide important information such as monitoring intervals for LFTs, PSA as well as the dosage regimens and duration.

Monitoring

i. PSA

The frequency of monitoring is defined by NICE guidelines on prostate cancer.
Similarly, National Institute for Health Research published a systematic review of T1–T2 (low risk) localised prostate cancer clinical trials and summarised typical PSA monitoring frequencies and triggers for clinical review and management change criteria. They concluded there is little evidence or expert consensus over active surveillance or monitoring as the clinician's decision is multifactorial, often including factors other than cancer, such as co-morbidities, patient age, patient preference and psychological status.
It is desirable that frequencies of PSA monitoring and trigger criteria (changes in Gleason score, PSA kinetics, and number of positive cores) are specified clearly to GP as clinical practice differs between hospital trusts.

ii. Toxicities and LFT monitoring

For monitoring requirements, side effects, interactions and contraindications consult Casodex® SPC online via Electronic Medicines Compendium.
Liver function should be monitored periodically (frequency not stated) as rare cases of liver injury have been reported with bicalutamide. Livertox database from US National Library of Medicine states the latency to onset of liver injury was 2 to 3 months (shorter with re-exposure). The typical pattern of serum enzyme elevations is hepatocellular and severe.

Key Considerations

Cost implications to the local health economy

Annual cost per patient:
Bicalutamide 50 mg tablets:
£ 1.89 pm, £ 22.68 pa (336 days)

Bicalutamide 150 mg tablets:
£ 4.36 pm, £ 52.32 pa (336 days)

Availability of patient access scheme and details (if appropriate): not applicable

Availability of homecare service (if appropriate): not applicable

Impact to current prescriber or medication initiator

The current impact is documented on the information sheet and this is detailed below:

Secondary care prescriber will be responsible for :

1. Diagnosis of condition and ensuring other treatment options have been fully explored
2. Initiate treatment with bicalutamide (initial 1 month supply from Acute Trust Pharmacy).
3. Monitoring for response and adverse drug reactions (ADRs) during initiation period
4. Liaison with the general practitioner (GP) to continue the patient's care when a proven benefit has been established
5. Advising GP on related issues such as drug interactions etc.
6. Outlining to GP when therapy may be reduced and stopped assuming no relapse in patient's condition. **The initiating prescriber should communicate to GP the exact monitoring details, course duration and frequency of review periods.**
7. Outline to GP when to re-refer patient to secondary care, using clear trigger criteria.
8. Responding to issues raised by GP after care of patient has been transferred
9. Explain to the patient / carer their roles

Impact to proposed prescriber or medication initiator

Prescribing will continue to be initiated by a specialist in a secondary care setting with a 1 month supply provided as per BLUE classification. The roles and responsibilities of primary care prescribers will differ depending on each proposal:

Two proposals

1. **As the PSA and LFT monitoring is personalised according to the patient and indication for use, then the specialist will communicate the information as part of the transfer of care letter to the GP**

OR

2. **The information sheet remains but is updated to include dose regimen information, monitoring and re-referral criteria**

If the first proposal is the accepted choice, the primary care prescribers will be responsible for:

1. Subsequent prescribing of bicalutamide at the dose recommended
2. Monitor patient's overall health and well being
3. Report adverse effects to the hospital consultant.
4. Be responsible for all monitoring **as per specialist advice and communications**
5. GP to re-refer patient to specialist when clinically needed

If the second proposal is the accepted choice, the primary care prescribers will be responsible for:

1. Subsequent prescribing of bicalutamide at the dose recommended
2. Monitor patient's overall health and well being
3. Report adverse effects to the hospital consultant.
4. Be responsible for all monitoring **as per the updated information sheet or specialist advice and communications**
5. GP to re-refer patient to specialist when clinically needed

Impact to patients

No changes from status quo

Additional comments

Identified lead for development of necessary documents e.g. shared care agreement

Name: n/a
Designation:
Organisation:
Estimated date of preparation:

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Date: 21st October 2016

References

Bicalutamide Information Sheet, The Surrey Prescribing Advisory Database, last update June 2011.
Midland Therapeutic Review & Advisory Committee: 'Bicalutamide Verdict Sheet 03/17', last updated 27/07/2012.
National Institute for Health and Care Excellence (NICE). 'Prostate Cancer: diagnosis and treatment'. Jan 2014.
Casodex SPC available online from Electronic Medicines Compendium, last updated 3/12/2015.
Simpkin AJ, Rooshenas L, Wade J, Donovan JL, Lane JA, Martin RM, et al. Development, validation and evaluation of an instrument for active monitoring of men with clinically localised prostate cancer: systematic review, cohort studies and qualitative study. Health Serv Deliv Res 2015;3(30).
Bicalutamide monograph, Livertox, US National Library of Medicine, last updated 6/9/2016