NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

8 April 2015

Decision to fund abiraterone, list additional presentations of epoetin alfa and reduce expenditure on methylphenidate hydrochloride extended release and topiramate.

PHARMAC is pleased to announce the approval of a proposal for abiraterone (Zytiga), methylphenidate hydrochloride extended release (Concerta), topiramate (Topamax) and epoetin alfa (Eprex). The proposal was the subject of a consultation letter dated 26 February 2015, available on PHARMAC's website.

In summary, the effect of the decision is that:

- From 1 May 2015 abiraterone acetate (Zytiga) 250 mg tablets will be funded, subject to Special Authority criteria, for patients with metastatic castration resistant prostate cancer that is resistant to androgen deprivation therapy (ADT);
- From 1 May 2015 two new presentations of epoetin alfa (Eprex) – Inj 8000 iu in 0.8 ml syringe and Inj 40,000 iu in 1 ml syringe will be funded; and
- From 1 July 2015 the net costs of methylphenidate hydrochloride extended-release tablets (Concerta) and topiramate tablets and sprinkle capsules (Topamax) will be reduced.

The decision is as consulted on, with the exception of the following changes:

- minor changes to the Special Authority/restriction applying to abiraterone; and
- the application of the Wastage rule to abiraterone.

This decision is expected to result in up to 1000 men with advanced prostate cancer receiving funded abiraterone per year. Further details of the decision and feedback can be found below and on the following pages.

Details of the decision

Zytiga

- Abiraterone acetate (Zytiga) 250 mg tablets will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 May 2015. The following price and subsidy will apply (all prices are ex-manufacturer and exclude GST):

Chemical	Presentation	Brand	Pack size	Price/Subsidy
Abiraterone acetate	Tab 250 mg	Zytiga	120	$4,276.19

- Confidential rebates will apply to Zytiga, reducing its net price to the Funder and/or DHB Hospitals.

- Abiraterone acetate (Zytiga) will be listed in Section B of the Pharmaceutical Schedule subject to Special Authority criteria as follows:

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Abiraterone acetate – Retail Pharmacy - Specialist
Special Authority for Subsidy
Initial Application only from a medical oncologist, radiation oncologist or urologist or any other medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 5 months for applications meeting the following criteria:
All of the following:

1. Patient has prostate cancer; and
2. Patient has metastases; and
3. Patient's disease is castration resistant; and
4. Either:
   - 4.1. All of the following:
     - 4.1.1. Patient is symptomatic; and
     - 4.1.2. Patient has disease progression (rising serum PSA) after second line anti-androgen therapy; and
     - 4.1.3. Patient has ECOG performance score of 0-1; and
     - 4.1.4. Patient has not had prior treatment with taxane chemotherapy; or
   - 4.2. All of the following:
     - 4.2.1. Patient's disease has progressed following prior chemotherapy containing a taxane; and
     - 4.2.2. Patient has ECOG performance score of 0-2; and
     - 4.2.3. Patient has not had prior treatment with abiraterone.

Renewal only from a medical oncologist, radiation oncologist or urologist or any other medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 5 months for applications meeting the following criteria:
All of the following:

1. Significant decrease in serum PSA from baseline; and
2. No evidence of clinical disease progression; and
3. No initiation of taxane chemotherapy with abiraterone; and
4. The treatment remains appropriate and the patient is benefiting from treatment.

- Abiraterone acetate (Zytiga) will be listed in Part II of Section H of the Pharmaceutical Schedule, subject to restrictions similar to the proposed Special Authority criteria above for Section B.

- Zytiga will have protection from subsidy reduction and delisting until 30 June 2018.

- The Wastage rule will be applied to dispensings of abiraterone acetate (Zytiga) in Section B of the Pharmaceutical Schedule from 1 May 2015.

Eprex

- Two additional presentations of epoetin alfa (Eprex) will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 May 2015 as follows (all prices are ex-manufacturer and exclude GST):

Chemical	Presentation	Brand	Pack size	Price/Subsidy
Epoetin alfa [erythropoietin alfa]	Inj 8,000 iu in 0.8 ml, syringe	Eprex	6	$352.69
Epoetin alfa [erythropoietin alfa]	Inj 40,000 iu in 1 ml syringe	Eprex	1	$263.45

- The subsidy rules that currently apply to the other strengths of Eprex will also apply to these new listings, including Special Authority, wastage claimable and Sole Subsidised Supply and Hospital Supply Status until 28 February 2018.

- Confidential rebates will also apply to these presentations of Eprex, reducing their net price to the Funder and/or DHB Hospitals.

Concerta

- There will be no change to the listings of methylphenidate hydrochloride extended-release tablets (Concerta) in Section B and in Part II of Section H of the Pharmaceutical Schedule.
- From 1 July 2015 new confidential rebates will apply to all strengths of Concerta, reducing its net price to the Funder and/or DHB Hospitals.
- Concerta will have protection from subsidy reduction and delisting until 30 June 2018.

Topamax

- There will be no change to the listings of topiramate (Topamax) tablets and sprinkle capsules in Section B and in Part II of Section H of the Pharmaceutical Schedule.

- From 1 July 2015 new confidential rebates will apply to all strengths of Topamax, reducing its net price to the Funder and/or DHB Hospitals.
- Topamax will have protection from subsidy reduction and delisting until 30 June 2018.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 12 March 2015 were considered in their entirety in making a decision on the proposed changes. While the majority of responses were supportive of the proposal, the following issues, outlined in the table below and continued on the following pages, were raised in relation to specific aspects of the proposal:

Theme	Comment
Request that funding for abiraterone be extended to include patients with poorer performance state (ECOG 2) noting that Janssen's compassionate access programme for abiraterone included patients with ECOG 0-2	We have amended the proposal to include ECOG 2 patients in the post chemotherapy group. This is consistent with Janssen's prior access programme and abiraterone clinical trial data.

Theme	Comment
Requests for changes to the Special Authority criteria for abiraterone to ensure it is being used in the appropriate patient group and that treatment is discontinued promptly when the disease is no longer responding to treatment.	Minor changes have been made the Special Authority criteria. The changes provide clarity on the intended patient population and are to ensure that patients do not receive funded abiraterone where other funded oral hormone treatments remain clinically appropriate and more cost effective. We have amended the approval period from six to five months. We consider this approval period balances the need for timely discontinuation of abiraterone where it is no longer working with sufficient time for patients to have their clinic visits and any testing to be reported to enable ongoing treatments decisions to be made.
Concern that patients will have to be in pain to meet the "symptomatic" criteria for funding. Considers that earlier treatment with abiraterone would result in a better outcome.	There are no distinct symptoms of metastatic prostate cancer. When symptoms occur, the type and frequency of the symptoms will depend on the size and location of the metastases. The proposed Special Authority criteria do not specify the type, frequency or severity of symptoms needed, whether or not the patient is 'symptomatic' will be determined by prescriber using their clinical judgment. We acknowledge that some clinical trials enrolled patients with prostate-specific antigen (PSA) progression and no symptoms or mild symptoms. However, the proposed criteria require patients be symptomatic and failing to respond to other treatments. We consider that this maximizes the cost effectiveness of abiraterone and avoids early use of abiraterone where other funded oral hormone treatments remain clinically appropriate and more cost effective.
Concerns that the list price of abiraterone is very high, therefore could result in pharmacies being left with unused part packs if prescribers deviate from standard dosing which would be a significant cost to pharmacies. Requests that they be funded as "Original Pack" or that the Wastage rule be applied to avoid adverse financial impacts on pharmacies.	PHARMAC notes that abiraterone comes in packs of 120 tablets, which is consistent with its standard dosing regimens. The Medsafe approved recommended dosage of abiraterone is 1000 mg (four 250 mg tablets) as a single daily dose. Dose adjustment is not recommended in the Medsafe approved Datasheet. However, if dose adjustments or alternative regimens are prescribed there is the potential for significant cost impacts to pharmacy. The 'Wastage rule' has been applied to abiraterone to allow community pharmacies to claim for unused part-packs.

Theme	Comment
Concerns about the high cost of funding abiraterone.	Abiraterone is an expensive medicine, however the actual cost of the medication to the Funder and DHB Hospitals will be lower because of confidential rebates PHARMAC has negotiated with the supplier, Janssen. This means the actual price is lower than the list price in the Pharmaceutical Schedule. There will be a relatively high distribution cost to DHBs through community pharmacy because of the high list price of abiraterone, however the spend on distribution costs will be offset by reduced distribution costs resulting from price decreases on other medicines now and in the future resulting from our continued focus on reducing costs on funded medicines, for example via our annual tender process.
Comments about who theappropriate prescribers of abiraterone are (with some considering prescribing should be limited to oncologists and others considering urologists should also be able to prescribe).	Abiraterone is approved by Medsafe as a prescription medicine meaning it can be prescribed by any authorised prescriber, there are no specific restrictions on the prescribing or dispensing of abiraterone.
Concerns about the impact of a large number of prostate cancer patients needing DHB services.	We note that whilst currently it is appropriate that all mCRPC patients are referred to medical oncology (to discuss chemotherapy options) it will not be necessary to continue to refer patients to this service to receive abiraterone. We consider that patients on abiraterone can be managed by urologists and radiation oncologists as well as medical oncologists or other medical practitioners on the recommendations of any of these specialists. DHBs and departments may need to change their clinical pathways to enable mCRPC patients to remain under the care of urologists and/or radiation oncologists rather than being transferred to medical oncology. Chief Medical Officers have been consulted on this.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.