NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

11 December 2013

Decision to award sole supply to Imatinib-AFT for indications other than Gastro Intestinal Stromal Tumours

PHARMAC has decided to approve the proposal to award Imatinib-AFT capsules Sole Subsidised Supply status in the community and DHB hospitals for all indications other than Gastro Intestinal Stromal Tumours (GIST). This was the subject of a consultation letter dated 22 October 2013.

Three changes were made to the proposal as a result of consultation feedback:

- Patient co-payments will be waived for Imatinib-AFT for at least the whole of 2014;
- A brand switch fee for pharmacists will be applied to Imatinib-AFT; and
- The Note applying to the listing of Imatinib-AFT was amended, it will be as follows:

  > Note: Imatinib-AFT is not registered for the treatment of Gastro Intestinal Stromal Tumours (GIST). The Glivec brand of imatinib mesilate (supplied by Novartis) remains fully subsidised under Special Authority for patients with unresectable and/or metastatic malignant GIST, see SAXXX.

The effect of the decision is that:

- From 1 April 2014 Imatinib-AFT (imatinib mesilate 100 mg capsule), will be listed in Section B (Community), and Part II of Section H (Hospital), of the Pharmaceutical Schedule without restriction, subject to the 'three months dispensed all at once' instruction and a brand switch fee will be applied; and
- Imatinib-AFT will be the Sole Subsidised Supply brand of imatinib mesilate in the community and DHB hospitals for all indications, other than GIST, from 1 July 2014 to 30 June 2017; and
- The currently listed brand, Glivec (imatinib mesilate 100 mg tablet), will remain fully funded via Special Authority, for patients with unresectable and/or metastatic malignant GIST. The funding of Glivec for GIST will be widened from 1 July 2014 to include patients with c-kit negative disease; and
- CML patients will receive a two month delivery of Glivec in late March 2014; this will be their last direct delivery. After this delivery, these patients will need to obtain ongoing supplies of imatinib (Imatinib-AFT) through their community pharmacy. Imatinib-AFT will not be subject to a co-payment, at least in the short term. There would be no change to Glivec direct distribution for GIST patients.

PHARMAC will be communicating directly with patients affected by this decision, their Specialists, GPs and pharmacists over the next few months in order to ensure that they understand the changes and what actions they need to take in order to continue to receive their fully funded imatinib in a timely manner.

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 November 2013 were considered in their entirety in making a decision on the proposal.

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A summary of the key issues/questions raised and PHARMAC comments on these issues are discussed in the table on the next two pages:

Theme	PHARMAC Comment
Concern about the supplier, quality and source of Imatinib-AFT.	AFT Pharmaceuticals is a New Zealand Company. Imatinib-AFT is manufactured in Europe and has been approved by Medsafe, the NZ regulator. The same product, under a different brand name, has also been approved by the European medicines regulator. This means that the manufacturing site, processes and the product itself meets all necessary European and NZ quality standards.
Will Imatinib-AFT work the same as Glivec?	Imatinib-AFT has been approved by Medsafe and the European regulator on the basis of human clinical trial data showing it is bioequivalent to Glivec. Both contain the same amount of the active drug imatinib mesilate. The rate and the extent of absorption, and the concentration of imatinib in the plasma, are equivalent for both brands so Imatinib-AFT will work the same as Glivec.
Will Imatinib-AFT have different side effects to Glivec?	There are some differences between the two formulations; however, we do not expect any of the Imatinib-AFT excipients to cause increased side effects compared with Glivec.
I have difficulty swallowing capsules	Imatinib-AFT capsules are small therefore we consider it unlikely that patients will find them more difficult to swallow compared with Glivec tablets.
If Imatinib-AFT does not work for me can I go back to Glivec?	Whilst we do not consider there would be any reason that Imatinib-AFT would not work as well as Glivec, we would consider requests for Glivec funding on an exceptions basis.
Can I get a prescription from my GP or haematologist?	Patients would have the option of obtaining a prescription from either their GP or public haematologist. PHARMAC will contact each patient's nominated GP and current prescribing haematologist to inform them of the changes.
Obtaining a prescription every 3 months will be difficult and expensive	The co-payment for Imatinib-AFT will be waived, at least initially. If patients are on other medications we recommend they request repeat prescriptions for imatinib at the same time as for their other medicines to reduce visit costs. Patients with a High Use Health Card or Community Services Card may be also entitled to reduced fees and other assistance.
Will my pharmacy have sufficient stock of Imatinib-AFT for me?	PHARMAC will contact each patient's nominated community pharmacy directly to inform them of the need to stock Imatinib-AFT for their patient.
I take many imatinib tablets. Is it possible to fund a higher strength. A 400 mg Glivec tablet is available overseas.	A 400 mg presentation of Imatinib-AFT capsule has been approved by Medsafe and we will work with AFT to see if it could be funded.

Theme	PHARMAC Comment
The government spends much more than would be saved from this proposal on funding yachting, rugby and other sporting. We pay our taxes why should we be made to change?	PHARMAC's principal objective is to secure for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided. One way we do this is to change the funded brands of older medicines so that other patients can benefit from new medicines with the money that is saved.
A Brand Switch Fee should be applied to reflect the work undertaken by pharmacy.	A brand switch fee has been applied.
Imatinib-AFT should be funded as an original pack, or have the wastage rule applied, to ensure that community pharmacies are protected from any potential financial loss due to part packs.	Most patients on Imatinib-AFT would be long term users and it is likely that Imatinib-AFT would be prescribed in 3-monthly amounts rather than days or weeks' worth of treatment. Therefore, we consider it unlikely that pharmacies would be left with unsold part packs. In addition, we will ask existing patients to nominate a local pharmacy where they would pick up their Imatinib-AFT stock, so aside from these pharmacies there would be no need for others to routinely stock Imatinib-AFT.
Requests a Special Authority be applied to Imatinib-AFT. Concern about non-haematologists prescribing imatinib for disorders where it is either ineffective, or where off-label use is unproven.	Special Authorities, or indeed any other PHARMAC restrictions, aim to ensure subsidies are targeted towards patients who are likely to get the best health gains; they are not to direct appropriate prescribing of medicines which is the responsibility of prescribers. In our view targeting of funding for Imatinib-AFT is unnecessary given the cost.
Support for the proposal. The savings made will enable other medicines to be funded.	Noted
Being able to get medicine every 3 months from a pharmacy will be better.	Noted

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.