9 December 2013

PHARMAC decision relating to eltrombopag, zanamivir and various respiratory products

PHARMAC is pleased to announce the approval of an agreement with GlaxoSmithKline (GSK). This was the subject of a consultation letter dated 4 November 2013. In summary, the effect of the decision is that from 1 January 2014:

- Eltrombopag (Revolade) will be listed for use in the community and hospital for the treatment of idiopathic thrombocytopenic purpura (ITP) subject to restriction criteria;
- Zanamivir (Relenza Rotadisk) will be listed for use in hospital for treatment and prophylaxis of influenza in hospitalised patients subject to restriction criteria;
- The Special Authority and hospital restrictions will be removed from fluticasone with salmeterol combination inhalers (Seretide and Seretide Accuhaler).

Details of the decision

The proposal which was consulted upon was approved in its entirety except for:

1. The application of the 'Wastage Rule' to the listing of eltrombopag in Section B of the Pharmaceutical Schedule (see detail in 'Feedback received' section below); and

2. A change in the eltrombopag restriction criteria wording which does not alter the intent or access to treatment. The change is as follows (additions in bold, deletions in strike through):

   Community (Section B) restrictions:

   Initial application - (idiopathic thrombocytopenic purpura – post-splenectomy) only from a haematologist. Approvals valid for 6 weeks for applications meeting the following criteria:
   All of the following:
   1. Patient has had a splenectomy; and
   2. ~~Patient has failed 2~~**Two** immunosuppressive therapies **have been trialled and failed** after therapy of 3 months each (or 1 month for rituximab); and
   3. Either:
      3.1. Patient has a platelet count of ≤20,000 platelets per µL and has evidence of active bleeding; or
      3.2. Patient has a platelet count of ≤10,000 platelets per µL.

   Initial application - (idiopathic thrombocytopenic purpura – preparation for splenectomy) only from a haematologist. Approvals valid for 6 weeks where the patient requires eltrombopag treatment as preparation for splenectomy.

   Renewal– (idiopathic thrombocytopenic purpura – post-splenectomy) from a haematologist. Approvals valid for 12 months where the patient has obtained a response (see Note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.

   Note: Response to treatment is defined as a platelet count of >30,000 platelets per µL.

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

Hospital (Section H) restrictions:

Restricted
Haematologist
Initiation (idiopathic thrombocytopenic purpura – post-splenectomy)
Re-assessment required after 6 weeks.
All of the following:

1. Patient has had a splenectomy; and
2. ~~Patient has failed 2~~**Two** immunosuppressive therapies **have been trialled and failed** after therapy of 3 months each (or 1 month for rituximab); and
3. Either:
   3.1. Patient has a platelet count of ≤20,000 platelets per μL and has evidence of active bleeding; or
   3.2. Patient has a platelet count of ≤10,000 platelets per μL.

Initiation - (idiopathic thrombocytopenic purpura – preparation for splenectomy) Approvals valid for 6 weeks for patients requiring eltrombopag treatment as preparation for splenectomy.

Continuation – (idiopathic thrombocytopenic purpura – post-splenectomy)
Re-assessment required after 12 months where the patient has obtained a response (see note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.

Note: Response to treatment is defined as a platelet count of >30,000 platelets per μL.

The consultation letter is available on our website at: http://www.pharmac.health.nz/ckeditor_assets/attachments/573/consultation-2013-11-04-eltrombopag-zanamivir-and-others.pdf

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 15 November 2013 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Eltrombopag	
Three months is too long to wait to elicit if a patient is going to respond to a course of immunosuppressive treatment. Two months should be adequate. This requirement to trial other treatments for at least 3 months would encourage greater use of rituximab (1 month treatment), which is more expensive than other older immunosuppressives.	The Haematology Subcommittee was consulted on this feedback and it considered the proposed criteria were appropriate because the submitters proposed reduction from three to two months would be arbitrary. PHARMAC can ask the Subcommittee to review the criteria again if future experience reveals that the criteria are not appropriate.

Theme	Comment
Patients should also be allowed to be treated with eltrombopag whilst waiting for other immunosuppressive treatments to work. Currently, intravenous immunoglobulin is used to do this and it is expensive, at a cost of $11,000 per dose.	The Haematology Subcommittee was consulted on this feedback and it considered that it would be inappropriate to use eltrombopag in this way because it would complicate the treatment trial, making it difficult to distinguish which treatment was indeed effective for the patient. PHARMAC agrees and also considers that funding eltrombopag in such a patient group may present a fiscal risk by allowing patients who have not had a splenectomy to access eltrombopag.
It is unclear from the criteria if an unacceptably high steroid dose would be considered 'treatment failure'.	The Haematology Subcommittee was consulted on this feedback and it considered that an unacceptably high steroid dose is not necessarily treatment failure if the patient is responding to treatment. The Subcommittee considered that allowing eltrombopag to be used in patients who have experienced unacceptable toxicities as a result of those therapies would bring a fiscal risk given the subjective nature of the criteria. The Subcommittee considered that it would be appropriate to leave the proposed criteria as is and funding for this patient group to be considered through NPPA instead. PHARMAC can ask the Subcommittee to review the criteria again if future experience reveals that the criteria are not appropriate.
Eltrombopag is an expensive treatment and used by very few patients. A trial period of 6 weeks treatment could result in pharmacies being left with unused part packs because the medicine is packaged and dispensed in 4-week lots.	This has been noted and PHARMAC has implemented the 'Wastage rule' for eltrombopag which will allow community pharmacies to claim for unused part-packs.
Respiratory products	
The unequal access to funding for similar respiratory products creates a significant market advantage for Seretide which is inappropriate.	The proposal will provide significant commercial benefit which enables the removal of the Special Authority from the fluticasone with salmeterol combination inhalers. The choice of respiratory products will remain the same for previously eligible patients, as the budesonide with eformoterol combination inhalers will remain listed fully funded in the Pharmaceutical Schedule although access to these inhalers will remain by Special Authority. PHARMAC would be happy to consider commercial proposals from other suppliers seeking similar access to funding.

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.