PHARMAC
Pharmaceutical Management Agency

16 April 2015

Decisions to list, delist and amend restrictions on various pharmaceuticals

PHARMAC is pleased to announce decisions to list, delist and amend the restrictions for various pharmaceuticals in Section B or Part II of Section H of the Pharmaceutical Schedule (the Hospital Medicines List; HML), from 1 May 2015. All of these were the subject of a consultation letter dated 9 March 2015, available on PHARMAC's website at http://www.pharmac.health.nz/news/consultation-2015-03-09-various-pharmaceuticals/

The proposals were approved essentially as consulted on, with the exception of the following:

- No decision has yet been made on the proposed changes to the Special Authority criteria for dornase alfa. We expect to make a decision on these changes within the next two months.
- Minor amendments were made to the proposed restriction changes for infliximab for severe ulcerative colitis.
- Minor amendments were made to the proposed criteria changes for Fat Modified Products and Food Modules/Nutrient Modules.
- Minor amendments to the product description for multivitamin and mineral supplement.

A summary of the decisions is provided below; for further details please refer to the consultation letter.

The following new listing will occur on 1 May 2015:

- Glycopyrronium bromide inj 200 mcg per ml, 1 ml ampoule, will be listed fully subsidised in Section B of the Pharmaceutical Schedule. Up to ten injections will also be subsidised on a Practitioners Supply Order.

The following products will be listed in Part II of Section H of the Pharmaceutical Schedule (the Hospital Medicines List; HML) from 1 May 2015:

- Mannitol powder for inhalation.
- Alteplase inj 2 mg vial.
- Cardioplegia solution (e.g. Custodiol-HTK).
- Multivitamin and mineral supplement for patients with burns subject to restrictions.

The restrictions relating to the following products will be amended in Section B and/or Part II of Section H of the Pharmaceutical Schedule (as applicable) as follows from 1 May 2015:

- Menthol: the restrictions will be amended to allow compounding with a dermatological base or a proprietary Topical Corticosteroid-Plain preparation.
- Erlotinib and gefitinib: access will be widened to allow patients experiencing intolerance within the first six weeks of starting either treatment to switch between these treatments.

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

- Trastuzumab (early breast cancer): access will be widened to include neoadjuvant treatment.
- Zoledronic acid (Aclasta): HML access will be widened to include inherited bone fragility disorders.
- Infliximab: the HML restrictions for Ulcerative Colitis will be amended to include paediatric measures of severity as follows (additions in bold):

Restriction
Initiation - severe ulcerative colitis
Gastroenterologist
All of the following:

1. Patient has histologically confirmed ulcerative colitis; and
2. **Either;**
   - **2.1 Patient is 18 years or older and** the Simple Clinical Colitis Activity Index (SCCAI) is ≥ 4**; or**
   - **2.2 Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (PUCAI) score is ≥ 65; and**
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate; and
5. Patient must be reassessed for continuation after 3 months of therapy.

Continuation - severe ulcerative colitis
Gastroenterologist
All of the following:

1. Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and
2. **Either:**
   - **2.1 Patient is 18 years or older and the** SCCAI score has reduced by ≥ 2 points from the SCCAI score when the patient was initiated on infliximab**; or**
   - **2.2 Patient is under 18 years and the PUCAI score has reduced by ≥ 30 points from the PUCAI score when the patient was initiated on infliximab;** and
3. Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

The restrictions relating to the following products will be amended in Section D and Part II of Section H of the Pharmaceutical Schedule (as applicable) as follows from 1 May 2015:

- Amino acid formula and extensively hydrolysed formula: the criteria will be amended to include definition of a reasonable trial.
- Paediatric Products: access to the products listed under the Paediatric Products subheading in the Special Foods therapeutic group will be widened to include patients who have or are expected to eat little or nothing for 3 days.
- Fat Modified Products: the modular feed criterion will be amended as follows (additions in bold):

Special Authority for Subsidy
Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

1 Patient has metabolic disorders of fat metabolism; or
2 Patient has a chyle leak; or
3 Modified as a modular feed**, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule,** for adults.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

- Food Modules/Nutrient Modules: Carbohydrate, fat and protein products listed under these subgroups with the criterion "modular formula" will be amended as follows:

  For use as a component in a modular formula **made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.**
  Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

The following product will be delisted from Part II of Section H of the Pharmaceutical Schedule from 1 May 2015:

- Diclofenac sodium eye drops 0.1%, single dose

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 25 March 2015 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposals, and the following issues were raised in relation to specific aspects of the proposals:

Theme	Comment
Concern regarding the frequency of dispensing of glycopyrronium bromide for terminally-ill patients in the community on a one-off or very short term basis and so the potential for part-packs to remain in community pharmacy. Request that the wastage rule be applied to glycopyrronium bromide in the community.	PHARMAC staff consider that due to the dosing nature of the product, i.e. as required and continuous subcutaneous infusion, wastage is not likely to be a significant issue for community pharmacy. Therefore, the wastage rule will not be applied to this product. We would be pleased to reconsider this decision in the future should information be provided to demonstrate that significant wastage is occurring. We have permitted up to 10 injections (one whole pack) to be ordered on a PSO by practitioners. This should reduce the likelihood to part packs in pharmacy.

Theme	Comment
Requests for clarification regarding whether the proposals for multivitamins and nutrient modules related to adults only or whether the proposals also relate to children. Concern that the details of folic acid and molybdenum were at a level above that recommended and the correct doses should be 37.5 mcg and 12.5 mcg respectively.	The HML listing for multivitamins relates to both adults and children with burns who meet the restrictions. The amendments to the criteria for nutrient modules apply to both adults and children. The product description note has been amended.
Request for review of erlotinib, gefitinb and for original pack status and if implemented that either the wastage rule or original pack status be applied.	PHARMAC staff consider that due to the dosing and pack sizes of erlotinib and gefitinib, wastage is not likely to be a significant issue for community pharmacy. Therefore, the wastage rule will not be applied to this product. We would be pleased to reconsider this decision in the future should information be provided to demonstrate that significant wastage is occurring
Concern that there appears to be no option for single-agent trastuzumab use in the adjuvant setting following neoadjuvant administration.	The changes made are consistent with advice from the Cancer Treatments Subcommittee of PTAC. It is acknowledged that chemotherapy is not administered for the entire duration of trastuzumab treatment.
Concern that the proposed continuation criteria for infliximab for Severe Ulcerative Colitis for children specifies that remission is required, where the adult criteria require only reduction in SCCAI rather than induction of remission. Request that the continuation criteria for children be amended to require moderate improvement (e.g. a 30 point reduction in PUCAI) rather than requiring remission (<10).	The continuation criteria for infliximab for UC in children have been amended to require at least a 30 point reduction in PUCAI score to indicate a clinically significant response to treatment. PHARMAC staff consider this amendment is consistent with evidence and with the existing HML requirements for adult patients where a reduction in SCCAI score is required rather than complete remission to continue treatment.

More information

If you have any questions about these decisions, 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.