11 June 2014

Decision to fund diazoxide 50 mg per ml, 30 ml oral liquid (Proglycem)

PHARMAC is pleased to announce the approval of an agreement with Link Pharmaceuticals Limited, to fund diazoxide oral liquid 50 mg per ml, 30 ml (Proglycem Liquid) from 1 July 2014, subject to Special Authority and hospital access restrictions. This was the subject of a consultation letter dated 11 April 2014, available on PHARMAC's website at: http://www.pharmac.health.nz/news/consultation-2014-04-11-diazoxide/

Details of the decision

- Proglycem Liquid will be listed in Section B, and in the Hospital Medicines List (HML, Part II of Section H), of the Pharmaceutical Schedule from 1 July 2014 at a price and subsidy of \$620.00 per 30 ml bottle (ex-manufacturer, excluding GST).
- Proglycem Liquid will be listed in Section B of the Pharmaceutical Schedule subject to the same Special Authority criteria as diazoxide capsules:

Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months where used for the treatment of confirmed hypoglycaemia caused by hyperinsulinism

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment

 Proglycem Liquid will be listed in the HML subject to the same restrictions as diazoxide capsules:

Restricted

For patients with confirmed hypoglycaemia caused by hyperinsulinism

Care with dispensing and prescribing

PHARMAC staff would like to highlight the difference in strengths between diazoxide proprietary oral liquid (50 mg per ml) and the previous extemporaneous compounded oral liquid (10 mg per ml).

As this product is prescribed as having a weight-based dose, the change of strengths between the extemporaneous (10 mg per ml) and proprietary products (50 mg per ml) has a potential risk of a fivefold overdose. Therefore, extra care will be needed with prescriptions and dispensing, to ensure that the strength of the medicine and the milligram dosing is clearly prescribed and dispensed.

It will be important to make sure patients and/or parents (caregivers) have appropriate education when this product is dispensed so that any risks are mitigated.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 30 April 2014 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
One responder acknowledged that it was not up to PHARMAC to develop a service fee for dispensing unregistered medicines however believes that a specific fee should be applied	PHARMAC is acutely aware of the issues regarding funding unregistered medicines, however it considers that in this particular case, the listing of this unregistered proprietary liquid should not cause any additional costs for pharmacists above those experienced already; this is because the currently extemporaneously compounded liquid is compounded from unregistered capsules.
One responder noted that it would be beneficial if PHARMAC provided information to clinicians on the issues of providing advance notice to pharmacies when they require an unregistered medicine due to the delays in ordering the product.	PHARMAC will include an article in the Pharmaceutical Schedule Update new stories to highlight this point, however we note it is not always practicable for clinicians to anticipate which pharmacy a patient would choose to use.

More information

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