6 November 2015

Proposal for various pharmaceuticals - Special Foods

PHARMAC is seeking feedback on a proposal for various pharmaceuticals, including amendments to funding restrictions, to take effect from 1 January 2016. The proposed changes are summarised below. Details of the proposed changes and background information can be found on the following pages.

In summary

The restrictions applying to the following products would be amended in Section D and/or Part II of Section H of the Pharmaceutical Schedule (as applicable). These changes would be implemented from 1 January 2016:

- Standard Supplements used as exclusive enteral nutrition: The Special Authority criteria would be amended to include the use of Standard Supplements for the treatment of Crohn's disease in children. In addition, for liquid oral feed 1.5kcal/ml Standard Supplement when used as exclusive enteral nutrition for inducing remission in children with Crohn's disease, an additional subsidy would be available via endorsement which would make the product fully subsidised for those patients.

- Standard Supplements Special Authority for adults transitioning from hospital Discretionary Community Supply: The Special Authority initiation criteria for Discretionary Community Supply would be removed as it is no longer required.

- Extensively hydrolysed formula: The Special Authority initiation criteria and hospital restrictions for extensively hydrolysed formula would be widened to include people transitioning from amino acid formula. The definition of reasonable trial would be expanded.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 27 November 2015** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under

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the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Details of the proposal

Details of the proposed changes are provided below. Existing Special Authority criteria and Hospital Medicines List (HML) restrictions for these pharmaceuticals can be found on PHARMAC's website at the links below – for practical reasons these have not been reproduced in their entirety for all pharmaceuticals in this consultation document.

www.pharmac.govt.nz/PharmaceuticalSchedule/Schedule?osq

www.pharmac.health.nz/tools-resources/pharmaceutical-schedule/section-h/

Standard Supplements used as exclusive enteral nutrition

From 1 January 2016 we propose to make the following changes to Special Authority criteria applying to Standard Supplements in Section D of the Pharmaceutical Schedule (additions in bold):

> Initial application — (Children **– indications other than exclusive enteral nutrition for Crohn's disease)** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
> All of the following:
> 1 The patient is under 18 years of age; and
> 2 Any of the following:
> 2.1 The patient has a condition causing malabsorption; or
> 2.2 The patient has failure to thrive; or
> 2.3 The patient has increased nutritional requirements; and
> 3 Nutrition goal has been set (eg reach a specific weight or BMI).
>
> Renewal — (Children — **indications other than exclusive enteral nutrition for Crohn's disease)** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
> All of the following:
> 1 The patient is under 18 years of age; and
> 2 The treatment remains appropriate and the patient is benefiting from treatment; and
> 3 A nutrition goal has been set (eg reach a specific weight or BMI).
>
> **Initial application – (Children — exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist, or a dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:**
> **Both:**
> 1. **The patient is under 18 years of age; and**
> 2. **It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease.**

Renewal – (Children — exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist, or dietitian or vocationally registered general practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. **The patient is under 18 years of age; and**
2. **It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and**
3. **General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date contacted.**

The Higher Subsidy by Endorsement criteria would be amended for oral feed 1.5kcal/ml Standard Supplements in Section D of the Pharmaceutical Schedule from 1 January 2016 as follows, (additions in bold, deletions in strikethrough):

ORAL FEED 1.5 KCAL / ML – Special Authority see SA1228 – Hospital pharmacy [HP3]
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube**,** ~~or~~ who have severe epidermolysis bullosa~~.~~ **or as exclusive enteral nutrition in children under the age of 18 years for the treatment of Crohn's disease.**

Standard Supplements Special Authority for Adults transitioning from hospital Discretionary Community Supply

The Special Authority applying to Standard Supplements would be removed as follows in Section D of the Pharmaceutical Schedule from 1 January 2016 (deletions in strikethrough):

~~Initial application — (Adults transitioning from hospital Discretionary Community Supply) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:~~
~~All of the following:~~
~~1 The patient has had up to a 30 day supply of a 1.0 or a 1.5 kcal/ml Standard Oral Supplement; and~~
~~2 A nutrition goal has been set (eg reach a specific weight or BMI); and~~
~~3 Any of the following:~~
~~Patient is Malnourished~~
~~3.1 Patient has a body mass index (BMI) of less than 18.5 kg/m2; or~~
~~3.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or~~
~~3.3 Patient has a BMI of less than 20 kg/m2 and unintentional weight loss greater than 5% within the last 3-6 months.~~

Extensively hydrolysed formula

The Special Authority criteria applying to extensively hydrolysed formula – Gastrointestinal and Other Malabsorptive Problems, would be amended as follows in Section D of the Pharmaceutical Schedule from 1 January 2016 (additions in bold, deletions in strikethrough):

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner.
Approvals valid for 6 months for applications meeting the following criteria:
Any of the following:
1 Both:
1.1 Cows milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
1.2 Either:
1.2.1 Soy milk formula has been reasonably trialled without resolution of symptoms; or
1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
2 Severe malabsorption; or
3 Short bowel syndrome; or
4 Intractable diarrhoea; or
5 Biliary atresia; or
6 Cholestatic liver diseases causing malsorption; or
7 Cystic fibrosis; or
8 Proven fat malabsorption; or

9 Severe intestinal motility disorders causing significant malabsorption; or
10 Intestinal failure**; or**
11 All of the following:
11.1 For step down from Amino Acid Formula; and
11.2 The infant is currently receiving funded amino acid formula; and
11.3 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula; and
11.4 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

Note: A reasonable trial is defined as a 2-4 week trial~~.~~**, or signs of an immediate IgE mediated allergic reaction.**

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 An assessment as to whether the infant can be transitioned to a cow**'**s milk protein or soy infant formula has been undertaken; and
2 The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula; and
3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

~~Renewal - (Step Down from Amino Acid Formula) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:~~
~~All of the following:~~
~~1 The infant is currently receiving funded amino acid formula; and~~
~~2 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula; and~~
~~3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.~~

The restrictions for extensively hydrolysed formula in Part II of Section H would be amended in the same way.

Background

In relation to Standard Supplements used as exclusive enteral nutrition

- Powdered oral feed Standard Supplements are fully funded under Special Authority. Liquid feeds are subject to a manufacturer's surcharge (therefore are part-funded) under the same Special Authority. An additional subsidy which results in liquid feeds being fully funded, is available for patients being bolus-fed through a feeding tube, or who have severe epidermolysis bullosa; if the prescription is endorsed accordingly.

- The Pharmacology and Therapeutics Advisory Committee (PTAC) and the Special Foods Subcommittee of PTAC recommended that fully subsidised access to Standard Supplement liquid oral feeds should be extended to patients aged up to 18 years for use in the remission of Crohn's disease for a 6-8 week period as a sole diet and then for an additional 4 week transition period. The Subcommittee and PTAC gave this recommendation a high priority. The proposed criteria are in line with the advice received, which can be found on PHARMAC's website at:

  http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=1251

- This proposal would result in access to fully funded liquid oral nutrition 1.5kcal/ml Standard Supplements for children up to the age of 18 for a treatment period of six to eight weeks, when used as exclusive enteral nutrition to induce remission of Crohn's disease.

- A further four weeks transition period to allow a move from exclusive enteral nutrition back to a regular diet would also be funded.

- We anticipate that approximately 50 people per year would have access to fully funded liquid exclusive enteral nutrition as a result of this proposal. Feedback on this estimate would be appreciated.

Standard Supplements Special Authority for adults transitioning from hospital Discretionary Community Supply

- The establishment of Section H of the Pharmaceutical Schedule, also known as the Hospital Medicines List (HML), in July 2013 removed the need for the Discretionary Community Supply (DCS) criteria in the Pharmaceutical Schedule. These criteria are still being accessed by small numbers of prescribers.

- Pharmaceutical Schedule Section H rules allow, in defined circumstances, a DHB hospital to dispense pharmaceuticals for use in the community. Therefore, the Standard Supplements Special Authority initial application criteria for adults transitioning from hospital DCS is no longer required in the Pharmaceutical Schedule.

In relation to infant formula

- The Special Food Subcommittee of PTAC recommended amending the Special Authority criteria for extensively hydrolysed formula to include an additional criterion of 'Step down from funded amino acid formula', to ensure a pathway was in place to allow patients receiving amino acid formula to be transferred to extensively hydrolysed formula when appropriate.

- Correspondence with prescribers has indicated that the current renewal criteria for extensively hydrolysed formula as a step down from amino acid formula does not work in practice, as the two products are funded under different Special Authorities. The proposal is therefore that the step down criteria are moved to the initiation criteria for extensively hydrolysed formula.

- The Special Foods Subcommittee also advised that the definition of reasonable trial should be expanded to include from 'a 2-4 week trial' to 'a 2-4 week trial or signs of an immediate IgE mediated allergic reaction'.