14 December 2015

Decisions to amend restrictions on various pharmaceuticals - Special Foods

PHARMAC is pleased to announce decisions to amend the restrictions for various pharmaceuticals in Section D and/or Part II of Section H of the Pharmaceutical Schedule (the Hospital Medicines List; HML), from 1 January 2016. All of these were the subject of a consultation letter dated 6 November 2015, available on PHARMAC's website: http://www.pharmac.health.nz/news/consultation-2015-11-06-special-food/

The proposals were approved as consulted on. A summary of the decisions is provided below; for further details please refer to the consultation letter. All changes will occur on 1 January 2016.

In summary, the effect of the decision is that:

- Standard Supplements used as exclusive enteral nutrition (EEN): The Special Authority criteria will 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 will be available via endorsement which will 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 will be removed as it is no longer required.

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

Details of the decision are as follows:

Standard Supplements used as exclusive enteral nutrition

The Special Authority criteria applying to Standard Supplements in Section D of the Pharmaceutical Schedule will be amended from 1 January 2016 as follows (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).

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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 for oral feed 1.5kcal/ml, Standard Supplements, in Section D of the Pharmaceutical Schedule will be amended 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.** The prescription must be endorsed accordingly.

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

The Special Authority criteria applying to Standard Supplements in Section D of the Pharmaceutical Schedule will be amended from 1 January 2016 as follows (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/m^2; 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 in Section D of the Pharmaceutical Schedule will be amended from 1 January 2016 as follows (additions in bold, deletions in strikethrough):

Special Authority for Subsidy
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 restriction criteria applying to extensively hydrolysed formula – Gastrointestinal and Other Malabsorptive Problems in Part II of Section H of the Pharmaceutical Schedule will be amended from 1 January 2016 as follows (additions in bold, deletions in strikethrough):

Restricted
Initiation - new patients
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 For step down from Amino Acid Formula.

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

~~Initiation - step down from amino acid formula~~
~~Both:~~
~~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.~~

Continuation
Both:
1 An assessment as to whether the infant can be transitioned to a cows' 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.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by Friday, 27 November 2015 were considered in their entirety in making a decision on the proposed changes. The majority of responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Exclusive enteral nutrition (EEN) funding will alleviate difficulties arising from using powdered supplements for this patient group and their families. Liquid supplements improve the success of this important treatment of Crohn's disease.	Noted.
Sort clarification regarding whether repeat courses of EEN following a relapse would be funded and the funding situation following the end of the transition period. Requested extension of the criteria to include adults >18 years who require EEN.	PHARMAC expect a maximum of two courses per patient per year. Following completion of the transition period, powdered standard supplements would be the funded option. Clinical advice received supported the efficacy of EEN in children only, where the disease can be more severe. We would be happy to consider a funding application, along with evidence to support the use of this treatment for a wider patient group.

Theme	Comment
Highlighted community pharmacies carry the financial burden when dispensing liquid Special Foods. Reimbursement does not cover the entire wholesalers charge and freight fees. Requested acknowledgement that special foods are not fully reimbursed into pharmacy with a formal mechanism to pass on funding shortfalls to patients.	PHARMAC notes that the issues of wholesale margin funding and additional patient charges are matters for the Community Pharmacy Services Agreement, not the Pharmaceutical Schedule.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz.