

January 2010

# Special Foods Consultation Document

Proposals regarding the funding and  
access arrangements for a number of  
Special Foods



## Funding and access for a number of Special Foods

### Summary

Foods are subsidised in the Pharmaceutical Schedule for a wide range of medical conditions including gluten intolerance, phenylketonuria, and as general nutritional supplements.

Special Foods expenditure in the 2008/09 financial year was \$18 million, up 18% (\$2.8 million) over the previous year. The growth in expenditure was primarily due to increases of 38% in elemental infant formula, where our costs are 80% higher than Australia's on a per capita basis, and 13% in Adult Product Standard oral feeds. In addition to the already high growth rate, we are considering whether it would be appropriate to increase the types of prescribers who are eligible to authorise Special Authorities; if this occurs growth would be expected to increase further.

To ensure that funding is focused on clinical need and value for money we are proposing a number of changes to the access and funding of a number of Special Foods. These proposals would not affect patients with clinical conditions where Special Foods are plainly necessary (for example phenylketonuria or maple syrup disease).

In summary we are proposing to, with effect from 1 July 2010:

### Access

- Widen the range of medical practitioners who can apply for Special Authorities.

### Infant formula

- Introduce a treatment algorithm requiring a trial of soy formula (for infants over 6 months) and an extensively hydrolysed formula before an amino acid formula will be subsidised (except in anaphylaxis) – as per the Australian guidelines.
- Create a soy based formula Special Authority and replace the current elemental formula Special Authority with Special Authorities for extensively hydrolysed and amino acid formula – this would also include delisting of Karicare goats milk infant formula.
- Reduce the initial approval period for extensively hydrolysed and amino acid formula from 12 months to 4 months.
- Run sole supply processes for soy based infant formula, extensively hydrolysed infant formula, and amino acid based infant formula. This would mean that only one brand of each of these products would be funded.

### Oral Feeds

- Remove the current funding distinction between patients who use oral feeds as a supplement to their diet and those who use them as a complete diet. This would mean that there would no longer be a daily volume limit for subsidised oral feeds.

### Adult Product Standard Oral Feeds (Liquids and Powders)

- Merge the Oral Supplement and Adult Product Standard groups. This would result in the standard powders and liquids being able to be accessed under the same Special Authority and therefore the powders and liquids would be interchangeable.

- Change the Special Authority for these products so that it includes a malnutrition assessment and dietary measures such as food fortification for 4 weeks before standard adult powders and liquid sip feeds are subsidised. The initial approval period would also be reduced from 12 months to 3 months.
- Add standard adult powders and liquid sip feeds to the Discretionary Community Supply (DCS) list. This would enable DHB hospitals to provide these products to patients living at home for 10 days prior to hospitalisation and 30 days following discharge without a Special Authority (we note that when DCS is used the funding comes from the hospital's budget).
- Reference price the standard adult liquid sip feeds to the powder alternatives. This may result in sip feeds being partially funded and patients incurring a charge.
- Run sole supply processes for enteral feeds, milk-based and juice-based feeds. This may result in the listing of juice-based feeds.

### **Gluten Free Food**

- Cease active management of gluten-free foods (we would make no changes to the current listings – including restrictions, subsidies and product range). This would mean that the biopsy requirement would remain and that over time patient costs would increase (subsidies would not be increased to match price increases) and product availability would decrease (discontinuations would not be replaced by new products).

### **Foods and Supplements for Inborn Errors of Metabolism - PKU**

- Remove the Special Authority requirement for PKU foods (phenyl free baking mix and phenyl free pasta) – it would still be required for PKU supplements.
- Exempt pregnant women and patients under 16 from having to demonstrate compliance to a PKU diet for 12 months in order to access subsidies for PKU supplements.

### **Food Thickeners**

- Remove the renewal requirement for food thickeners. We are also seeking advice regarding how access to food thickeners could be extended to additional patient groups.

### **Feedback Sought**

We welcome your views on these proposals/issues as well as any other aspect of the funding and listings of Special Foods in the Pharmaceutical Schedule. We request that all feedback to this consultation document is submitted in writing by **Friday, 19 March 2010**. Due to the number of items and the potential impact of any changes, we would also welcome the opportunity to meet with interested groups.

If you would like to meet with us, or provide written feedback, please contact:

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If you would like to discuss these issues further or if you have a question regarding this review, please contact Stephen Woodruffe directly on 04 916 7555, or at the email address above.

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## Background

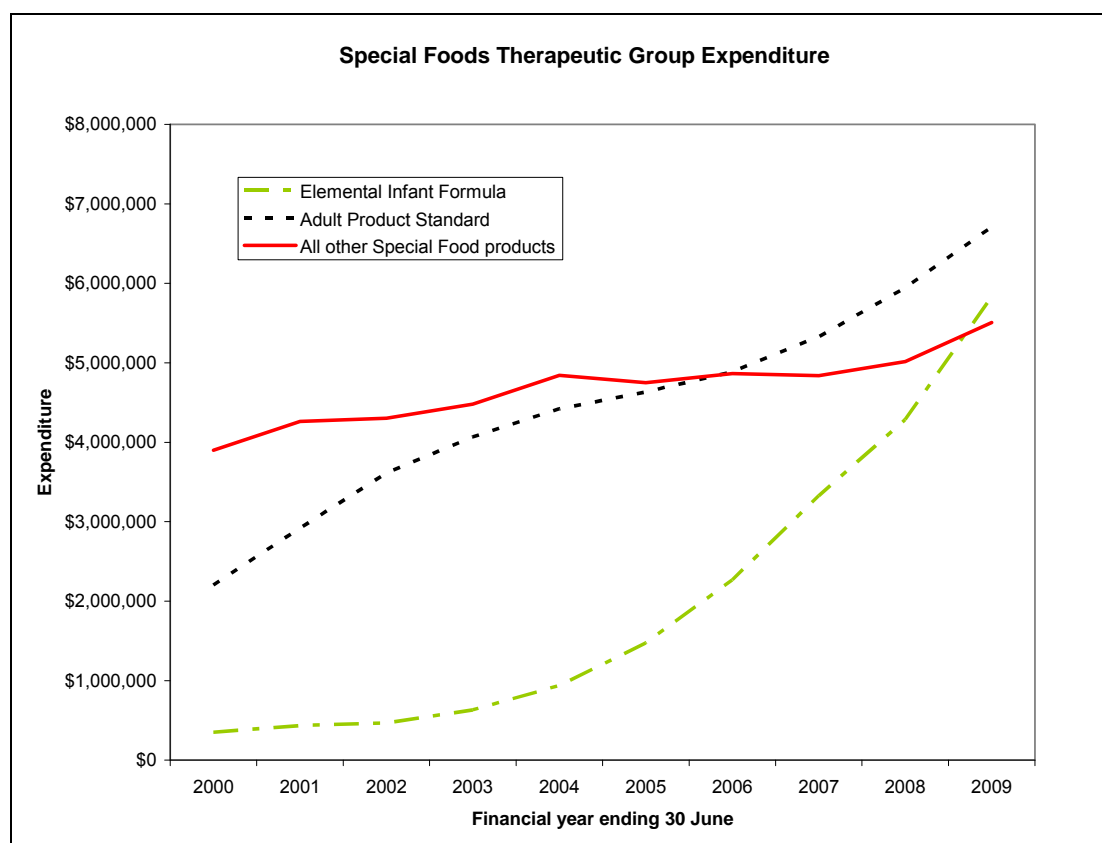
A large number of foods are subsidised in the Pharmaceutical Schedule for a wide range of medical conditions, such as coeliac disease, phenylketonuria, and malabsorption. For some patients these products replace their complete diet (e.g. patients using enteral feeds) while for others they are a partial replacement of their normal diet (e.g. gluten free products) or a supplement to their normal diet (e.g. phenylketonuria tablets). The cost for these “foods” for each patient can range from a few dollars a day through to tens of thousands per year for some of the highly specialised products.

For the financial year ending 30 June 2009, expenditure on Special Foods was \$18 million, up \$2.8 million over 2008. This represents an 18% growth rate and comes on top of growth rates of 12% and 13% for the 2006/07 and 2007/08 financial years respectively.

While there are a number of Special Food products showing significant growth, the two areas that account for the majority of the growth (and total expenditure) are:

- Elemental Formula (Neocate, Neocate LCP, Neocate Advance, Pepti Junior and Vivonex Pediatric); and
- Adult Product Standard (enteral feed 1 kcal/ml, enteral feed with fibre 1 kcal/ml, enteral feed with fibre 1.5 kcal/ml, oral feed 1.5 kcal/ml and oral feed with fibre 1.5 kcal/ml).

In 2008/09, expenditure on elemental formula was \$5.8 million (38% annual growth) and expenditure on adult product standard oral feed was \$6.7 million (13% annual growth), as shown below:



New Zealand's subsidised expenditure on elemental formula is about 1.8 times that of Australia per capita. This is due to:

- higher usage – New Zealand uses about 60% more elemental formula than Australia on a per capita basis; and
- higher pricing – our pricing is 12% to 40% higher than the equivalent pricing in Australia.

Of the \$6.7 million expenditure on adult product standard oral feeds in 2009, \$5.7 million (84%) was for oral feed 1.5 kcal/ml (with, and without fibre).

As a result of the high expenditure and growth in these products, we have been considering how we can ensure that prescribing, and therefore expenditure, is focused on clinical need and value for money. This has resulted in a number of the proposals contained in this document, upon which we would like your views.

We propose to implement these changes from **1 July 2010**. Please note that where we are proposing to run supply process for certain products, the implementation of sole supply may be after this date.

## Who can authorise subsidies for Special Foods

### Summary

- We propose to enable initial Special Authority applications to be made by Vocationally Registered General Practitioners who are acting within their scope of practice as well as Specialists.

### Background

Recently PHARMAC has been reviewing the use of the “prescriber type” restrictions in the Pharmaceutical Schedule. Some of these have been replaced with Special Authority restrictions, more restrictive Special Authority criteria, or endorsements when it is necessary to restrict access to particular patient groups.

Currently those able to prescribe Special Foods are limited to specialists and General Practitioners, with only specialists being able to apply for initial Special Authorities (General Practitioners can apply for renewals on the recommendation of a specialist).

### Proposal

We propose to increase the number of prescribers eligible to authorise Special Food Special Authorities by including the term “Vocationally Registered General Practitioners”.

Increasing the number of prescribers eligible to submit Special Food Special Authority applications is likely to result in more equitable usage throughout New Zealand in addition to an increase in overall usage.

We are not proposing to extend subsidy rights to include Dietitians at this time – however we note that there is a separate piece of activity currently in progress (the Pharmaceutical Subsidy Eligibility and Delivery Review) in relation to this issue.

## Elemental infant formula

### Summary

- We propose to adopt the Australian guidelines for the use of infant formula in patients with intolerance/allergy to cows' milk protein; this would require the following treatment pathway to be adhered to in order to obtain funding.

Breast milk

- cows' milk based formula (unfunded)
  - soy based formula (for infants older than 6 months)
    - extensively hydrolysed formula
      - amino acid formula

- We propose to create a soy based formula Special Authority and replace the current elemental formula Special Authority with Special Authorities for extensively hydrolysed and amino acid formula – this would also include delisting of Karicare goats milk infant formula.
- We propose to reduce the period of the initial approval for extensively hydrolysed and amino acid formula from 12 months to 4 months.
- We propose to run a sole supply process for a single supplier of soy based formula, a single supplier of extensively hydrolysed formula, and a single supplier of amino acid based formula.

### Background

In 2008, an Australian Position Statement/Guideline was published for the use of infant formula in treating cows' milk protein allergy (Kemp et al)<sup>1</sup>. The Guidelines recommend the following treatment pathway (following cessation of breast feeding):

Cows' milk based formula → soy based formula (for infants older than 6 months) → extensively hydrolysed formula → amino acid based formula.

This treatment pathway is consistent with the Australian funding requirements for extensively hydrolysed and amino acid based formula, although is more restrictive than the current New Zealand's funding requirements. In New Zealand, both extensively hydrolysed formula (Pepti Junior Gold) and amino acid based formulae (Neocate and Vivonex Pediatric) are funded for infants "suffering from malabsorption and other gastrointestinal problems" without a requirement to trial soy based formula (in those over 6 months), or trial an extensively hydrolysed formula prior to an amino acid based formula.

The Special Foods Subcommittee of PTAC (October 2009) has recommended that PHARMAC adopt the treatment pathway for the use of infant formula recommended by the Australian Panel. When considering this, the Subcommittee noted that currently some patients are being prescribed more expensive amino acid formula when a soy or a protein hydrolysate formula would be appropriate. The Subcommittee also

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<sup>1</sup> "Guidelines for the use of infant formulas to treat cows milk protein allergy: an Australian consensus panel opinion" (Kemp et al, 2008 MJA 2008; 188 (2) p 109-112). This article is available on The Medical Journal of Australia website at: [http://www.mja.com.au/public/issues/188\\_02\\_210108/kem10722\\_fm.html#forward-cites](http://www.mja.com.au/public/issues/188_02_210108/kem10722_fm.html#forward-cites)

considered reducing the period of the initial approval from 12 months to 4 months would also be appropriate.

The relevant minutes of the Special Foods Subcommittee are attached in Appendix 1.

### Proposals

We propose to adopt the Australian Guidelines treatment algorithm by replacing the current elemental infant formula Special Authority restriction with two separate Special Authority restrictions (one for extensively hydrolysed formula and one for amino acid based formula). We also propose to create a soy based formula Special Authority and delist goats' milk infant formula - the Special Foods Subcommittee of PTAC, Nov 2008, "considered that the delisting of Karicare Goats Milk Formula was appropriate"). The proposed Special Authorities are shown below.

In addition to the adoption of the proposed Special Authorities, we also propose to run sole supply processes (Request for Proposals) for a single supplier of:

- Soy based formula;
- Extensively hydrolysed formula; and,
- Amino acid based formula.

To enable the pricing of the products to be considered in any changes we anticipate running a Request for Proposals for the above products within the consultation period.

We note that the Special Foods Subcommittee of PTAC considered that only one brand for each type of the above formula is required and that infants should be able to switch relatively easily between formulas if brand changes occur as a result of a sole supply process.

#### **Soy based formula**

<p><b>INITIAL APPLICATION</b> Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid for 12 months.</p> <p>Prerequisites (tick boxes where appropriate)</p> <p><input type="checkbox"/> Congenital lactose deficiency or <input type="checkbox"/> Disaccharide intolerance or <input type="checkbox"/> Galactosemia or <input type="checkbox"/> Severe food allergy or severe multiple food allergy (not infant colic, constipation or gastro-oesophageal reflux) where the child has failed to respond to a cow's milk formula or <input type="checkbox"/> Severe malabsorption (not infant colic, constipation or gastro-oesophageal reflux) where the child has failed to respond to cow's milk formula</p>
<p><b>RENEWAL</b> Current approval Number (if known):.....</p> <p>Applications only from a relevant specialist, vocationally registered general practitioner, or general practitioner on the recommendation of a relevant specialist or vocationally registered general practitioner. Approvals valid for 12 months.</p> <p>Prerequisites (tick box where appropriate)</p> <p><input type="checkbox"/> The treatment remains appropriate and the patient is benefiting from treatment</p>

## Extensively hydrolysed formula

### INITIAL APPLICATION

Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid for 4 months.

Prerequisites (tick boxes where appropriate)

- Severe food allergy or severe multiple food allergy (not infant colic, constipation or gastro-oesophageal reflux) where the child has failed to respond to both a cow's milk formula and a soy milk formula (a trial of soy milk formula is only required in infants over 6 months of age)
- or
- Severe malabsorption (not infant colic, constipation or gastro-oesophageal reflux) where the child has failed to respond to both a cow's milk formula and soy milk formula (a trial of soy milk formula is only required in infants over 6 months of age)
- or
- Short bowel syndrome
- or
- Intractable diarrhea
- or
- Biliary atresia
- or
- Cholestatic liver diseases causing malabsorption
- or
- Chylous ascites
- or
- Chylothorax
- or
- Cystic fibrosis
- or
- Proven fat malabsorption
- or
- Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months
- or
- Severe intestinal motility disorders causing significant malabsorption

### RENEWAL

Current approval Number (if known):.....

Applications only from a relevant specialist, vocationally registered general practitioner, or general practitioner on the recommendation of a relevant specialist or vocationally registered general practitioner. Approvals valid for 12 months.

Prerequisites (tick box where appropriate)

- The treatment remains appropriate and the patient is benefiting from treatment

## Amino acid based formula

### INITIAL APPLICATION

Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid for 4 months.

Prerequisites (tick boxes where appropriate)

- Severe food allergy or severe multiple food allergy (not infant colic, constipation or gastro-oesophageal reflux) where the child has failed to respond to a cow's milk formula and a soy milk formula and an extensively hydrolysed formula (a trial of soy milk formula is only required in infants over 6 months of age)
- or
- Severe food allergy where the child has responded to cow's milk formula with anaphylaxis
- or
- Eosinophilic oesopagitis or eosinophilic gastroenteritis
- or
- Severe malabsorption (not infant colic, constipation or gastro-oesophageal reflux) where the child has failed to respond to a cow's milk formula and a soy milk formula and an extensively hydrolysed formula (a trial of soy milk formula is only required in infants over 6 months of age)
- or
- Short bowel syndrome
- or
- Intractable diarrhea
- or
- Severe intestinal motility disorders causing significant malabsorption

### RENEWAL

Current approval Number (if known):.....

Applications only from a relevant specialist, vocationally registered general practitioner, or general practitioner on the recommendation of a relevant specialist or vocationally registered general practitioner. Approvals valid for 12 months.

Prerequisites (tick box where appropriate)

- The treatment remains appropriate and the patient is benefiting from treatment

## **Removal of the funding distinction for patients using oral feeds as a supplement and as a total diet**

### Summary

- We propose to remove the current funding distinction between patients who use oral feeds as a supplement to their diet and those who use them as a complete diet. This would mean that a patient's funding would not be affected by the daily volume that the patient receives.

### Background

A number of standard and specialised sip and tube feeds are subsidised in the Pharmaceutical Schedule. The funding provided for these products are differentiated according to whether the product is being used as a supplement in addition to the patient's diet (subsidised up to a maximum of 500 ml per day), or whether it is being used as a complete diet (there is no limit to the volume subsidised per day).

### Proposal

We propose to remove the current funding distinction between patients who use sip and enteral feeds as supplements (subsidy provided to a maximum of 500 ml per day) and as complete diets (no limit to the volume subsidised per day). This would mean that patients using oral feeds as supplements could have more than 500 ml subsidised per day.

# Merging of the Oral Supplement and Adult Product Standard sections

## Summary

- We propose to merge the Oral Supplement (1 kcal/ml powder feeds) section with the Adult Product Standard (1.5 kcal/ml liquid feeds - enteral and sip feeds, with and without fibre) section.
- This would result in Sustagen Hospital Formula, Ensure powder, Fortisip, Ensure Plus, Resource Plus, and Fortisip Multi Fibre being in the same section and therefore able to be accessed under the same Special Authority (currently two Special Authority approvals are required).

## Background

Currently there are a number of standard and specialised sip and tube feeds subsidised in the Pharmaceutical Schedule. Patients are eligible for funding for these products under various Special Authority criteria. The current criteria for the Oral Supplements (1 kcal/ml powders) and the Adult Product Standard (1 kcal/ml and 1.5 kcal/ml tube and sip feeds - with and without fibre) are shown below:

<b>Oral Supplements (1 kcal/ml powders) Special Authority criteria</b>
<ul style="list-style-type: none"><li>• Cystic fibrosis</li><li>• Cancer in children</li><li>• Inflammatory bowel disease</li><li>• Cancers affecting the alimentary tract where there are malabsorption problems in patients over the age of 20 years</li><li>• Malnutrition requiring nutritional support</li></ul>
<b>Adult Product Standard (1 kcal/ml and 1.5 kcal/ml tube and sip feeds, with and without fibre) Special Authority criteria</b>
<ul style="list-style-type: none"><li>• Cystic fibrosis</li><li>• Any condition causing malabsorption</li><li>• Failure to thrive</li><li>• Increased nutritional requirements</li></ul>

The oral supplement powders have the same or a similar clinical effect (they make up a 1 kcal/ml liquid when mixed with water and a 1.5 kcal/ml liquid when mixed with milk) to the adult product standard oral liquid feeds. However, patients cannot easily switch between these products as they require different Special Authority approvals.

## Proposal

We propose to merge the Oral Supplement (1 kcal/ml powder feeds) section with the Adult Product Standard (1.5 kcal/ml liquid feeds - enteral and sip feeds, with and without fibre) section.

This would result in both the powder (Sustagen Hospital Formula, Ensure powder) and the liquid oral feeds (Fortisip, Ensure Plus, Resource Plus, and Fortisip Multi Fibre) being able to be accessed via the Adult Product Standard Special Authority (we note that criteria would alter under the next proposal to introduce a malnutrition assessment tool and other dietary guidelines to the criteria).

## Use of a malnutrition assessment tool and other dietary measures prior to access to subsidised sip feeds

### Summary

- We propose to amend the Special Authority restriction for standard 1 kcal/ml powder feeds and standard 1.5 kcal/ml liquid feeds (with and without fibre) so that it includes a requirement for the use of a malnutrition assessment tool and other dietary measures, such as food fortification for 4 weeks, prior to patients being eligible for funding. This would not apply to:
  - patients being fed via a tube (tube fed patients would also not require an additional approval when using or transitioning to sip feeds);
  - children aged between 8 and 18 years old; and,
  - the specialised sip feeds (this would be reviewed after 1 year).

In addition, the initial approval period would also be reduced from 12 months to 3 months.

- We propose that the standard 1 kcal/ml powder feeds and the standard 1.5 kcal/ml liquid feeds (with and without fibre) are placed on the Discretionary Community Supply (DCS) list for use in the Community/non-hospitalised patients for 10 days prior to hospitalisation and 30 days following discharge (note that when DCS is used the funding comes from the hospital's budget rather than the Community Pharmaceutical Budget).
- We note that this proposal includes listing the 1 kcal/ml powder oral supplements (Sustagen Hospital Formula and Ensure) in the same section and under the same Special Authority criteria as the 1.5 kcal/ml liquid oral feed (with and without fibre) (Fortisip, Ensure Plus, Resource Plus, Fortisip Multi Fibre).
- We propose to amend the Diabetic Products Special Authority criteria (which apply to oral feed 1 kcal/ml liquid - Diasip, Resource Diabetic and Glucerna Select) so that it includes a requirement that the patient is experiencing "weight loss and malnutrition that requires nutritional support".

### Background

Currently there are a number of standard and specialised sip and tube feeds subsidised in the Pharmaceutical Schedule. Patients are eligible for funding for these products under various Special Authority criteria.

Internationally there are a number of guidelines that have been developed to assist in the prescribing of funded sip feeds. A number of the guidelines were developed to assist general practitioners prescribing practices and they are based upon the NICE Nutrition Support in Adults Clinical Guidelines (February 2006)<sup>2</sup>.

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<sup>2</sup> Nutrition support in adults Oral nutrition support, enteral tube feeding and parenteral nutrition (National Collaborating Centre for Acute Care, February 2006). Available on the National Institute for Health and Clinical Excellence (NHS) website at: <http://www.nice.org.uk/Guidance/CG32/Guidance/pdf/English>

The NICE Guidelines note that assessments for malnutrition, and the risk of malnutrition, in both the hospital and community settings, should consider:

- the patient's BMI;
- the patient's percentage unintentional weight loss;
- the time over which the nutrient intake has been unintentionally reduced; and
- the likelihood of future impaired nutrient intake.

There are a number of assessment tools available internationally. These include both validated and non-validated tools. A commonly used tool is the Malnutrition Universal Screening Tool (MUST)<sup>3</sup>. This tool uses a BMI score, a Weight Loss score (unplanned weight loss in the past 3-6 months) and an Acute Disease Effect score to determine the patient's risk of malnutrition and their resulting Care Plan.

Clinical guidelines, such as the West Essex NHS<sup>4</sup>, Greater Glasgow and Clyde NHS<sup>5</sup>, and South Staffordshire NHS<sup>6</sup> guidelines include an assessment tool to identify patients who are at risk of malnutrition and require nutritional support/advice, as well as providing guidelines for the treatment of these patients. Generally, the use of funded oral (sip) feeds is only recommended in patients who:

- met the requirements for additional oral nutrition support through the use of an assessment tool;
- have tried and failed on first-line dietary measures such as food fortification using the principle of "Food First";
- have tried and failed on over the counter dietary supplements such as Complan or Vitaplan; and,
- have an appropriate medical condition.

In addition the need for (sip) feeds is recommended to be reviewed monthly with the usual period being 2 to 3 months.

The Special Foods Subcommittee of PTAC (December 2009) consider it appropriate that PHARMAC incorporate an assessment tool and other relevant guidelines into the Standard Adult Sip Feed Special Authority criteria. The intention of this is not to screen all patients for malnutrition, but to use the assessment tool and associated guidelines to provide clinicians with an appropriate framework when considering nutritional support, and to ensure that the funding of sip feeds is targeted to clinically relevant patients.

The relevant minutes of the Special Foods Subcommittee are attached in Appendix 2.

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<sup>3</sup> Available at [http://www.bapen.org.uk/must\\_tool.html](http://www.bapen.org.uk/must_tool.html)

<sup>4</sup> Guidelines for the Implementation of Oral Nutrition Support in Adults Across West Essex PCT (West Essex Primary Care Trust, 2007). Available at <http://www.westsexpct.nhs.uk/pubs/pdfs/guideons.pdf>

<sup>5</sup> Prescribing Guidelines for Oral Nutritional Supplements (sip feeds) in the Community (Greater Glasgow and Clyde NHS, 2009). Available at <http://www.glasgowformulary.scot.nhs.uk/oral%20nutritional%20supplements.pdf>

<sup>6</sup> Guidance for the use of Oral Nutritional Supplements for Adults in General Practice (South Staffordshire Primary Care Trust, 2009). Available at <http://www.southstaffordshirepct.nhs.uk/YourHealth/docs/meds/PPS/SipFeedsForAdults.pdf>.

## Proposals

We propose to alter the initial approval period (from the current 12 months to 3 months), and include a requirement for the use of an assessment tool and other relevant guidelines (dietary measures) prior to patients being eligible for a subsidy for the standard 1 kcal/ml powder feeds and the standard 1.5 kcal/ml liquid feeds (with and without fibre) (i.e. Sustagen Hospital Formula, Ensure powder, Fortisip, Ensure Plus, Resource Plus, and Fortisip Multi Fibre). We note that these requirements would not apply to patients being fed via a tube (tube fed patients would also not require an additional approval when using or transitioning to sip feeds), those under 18 years old, and the specialised sip and tube feeds (this would be reviewed in 1 year).

As the Special Authority requirements are unlikely to be able to be met in some patients prior to surgery or following discharge from hospital (i.e. the requirement for four weeks of food fortification), we also propose that the standard 1 kcal/ml powder feeds and the standard 1.5 kcal/ml liquid feeds (with and without fibre) are placed on the Discretionary Community Supply (DCS) list for up to 10 days prior to hospitalisation and up to 30 days following discharge. This would enable hospital staff to provide these products to patients, for use in their homes, for up to 10 days prior to hospitalisation or up to 30 days following discharge. When DCS is used, a Special Authority approval is not required as the funding for the product comes from the relevant hospital's budget instead of the Community Pharmaceutical Budget. It is therefore the responsibility of each hospital to determine whether or not DCS can be used.

The proposed Special Authority for standard 1 kcal/ml powder feed and the standard 1.5 kcal/ml liquid feeds is shown below:

### Oral Supplements

<p><b>INITIAL APPLICATION - Tube feeding</b> Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid for 1 year.</p> <p>Prerequisites (tick boxes where appropriate)</p> <p><input type="checkbox"/> Patient is being feed via a tube or <input type="checkbox"/> A tube is to be inserted into the patient for the purpose of feeding</p>		
<p><b>RENEWAL - Tube feeding</b> Current approval Number (if known):.....</p> <p>Applications only from a relevant specialist, vocationally registered general practitioner, or general practitioner on the recommendation of a relevant specialist or vocationally registered general practitioner. Approvals valid for 2 years.</p> <p>Prerequisites (tick box where appropriate)</p> <p><input type="checkbox"/> Patient is being feed via a tube</p>		
<p><b>INITIAL APPLICATION - Children</b> Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid for 3 months.</p> <p>Prerequisites (tick boxes where appropriate)</p> <p><input type="checkbox"/> Patient is under 18 years of age and</p> <table border="1"><tr><td><p><input type="checkbox"/> Any condition causing malabsorption or <input type="checkbox"/> Failure to thrive or <input type="checkbox"/> Increased nutritional requirements</p></td></tr></table> <p>and</p> <table border="1"><tr><td><p><input type="checkbox"/> A weight gain goal has been set (i.e. maintain current weight, gain a specific weight, reach a specific BMI) or <input type="checkbox"/> The goal of treatment is that the patients eating returns to normal</p></td></tr></table>	<p><input type="checkbox"/> Any condition causing malabsorption or <input type="checkbox"/> Failure to thrive or <input type="checkbox"/> Increased nutritional requirements</p>	<p><input type="checkbox"/> A weight gain goal has been set (i.e. maintain current weight, gain a specific weight, reach a specific BMI) or <input type="checkbox"/> The goal of treatment is that the patients eating returns to normal</p>
<p><input type="checkbox"/> Any condition causing malabsorption or <input type="checkbox"/> Failure to thrive or <input type="checkbox"/> Increased nutritional requirements</p>		
<p><input type="checkbox"/> A weight gain goal has been set (i.e. maintain current weight, gain a specific weight, reach a specific BMI) or <input type="checkbox"/> The goal of treatment is that the patients eating returns to normal</p>		

**RENEWAL - Children**  
 Current approval Number (if known):.....

Applications only from a relevant specialist, vocationally registered general practitioner, or general practitioner on the recommendation of a relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months.

Prerequisites (tick boxes where appropriate)

The patient has not obtained the weight gain goal that was set (i.e. maintain current weight, gain a specific weight, reach a specific BMI)  
 or  
 The patients eating has not returned to normal

**INITIAL APPLICATION - Adults**  
 Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid for 3 months.

Prerequisites (tick boxes where appropriate)

**Malnourished Patient**

Patient has a body mass index (BMI) of less than 18.5 kg/m<sup>2</sup>  
 or  
 Patient has unintentional weight loss greater than 10% within the last 3 - 6 months  
 or  
 Patient has a BMI of less than 20 kg/m<sup>2</sup> and unintentional weight loss greater than 5% with the last 3-6 months

and

Patient has not responded to first-line dietary measures including increased frequency, food fortification and "over the counter supplements" over a 4 week period by:

increasing their intake frequency (i.e. snacks between meals)  
 and  
 using high-energy foods (i.e. milkshakes, full fat milk, butter, cream, cheese, sugar etc)  
 and  
 using over the counter supplements (i.e. complain)

and

Patient has one of the following medical conditions

Short bowel syndrome  
 or  
 Intractable malabsorption  
 or  
 Proven inflammatory bowel disease  
 or  
 Bowel fistulae  
 or  
 Disease related malnutrition

and

A weight gain goal has been set (i.e. maintain current weight, gain a specific weight, reach a specific BMI)  
 or  
 The goal of treatment is that the patients eating returns to normal

**RENEWAL - Adults**  
 Current approval Number (if known):.....

Applications only from a relevant specialist, vocationally registered general practitioner, or general practitioner on the recommendation of a relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months.

Prerequisites (tick boxes where appropriate)

The patient has not obtained the weight gain goal that was set (i.e. maintain current weight, gain a specific weight, reach a specific BMI)  
 or  
 The patients eating has not returned to normal

While we are proposing that the MUST tool is used to determine malnutrition status, we welcome suggestions regarding any other assessment tools and/or guidelines that could be used as an alternative to those proposed.

When considering the above proposal, the Special Foods Subcommittee also considered that the Diabetic Products Special Authority criteria should be amended so that it included a requirement that the patient is experiencing "weight loss and malnutrition that requires nutritional support". We therefore also propose to amend the Diabetic Products Special Authority criteria (which applies to oral feed 1 kcal/ml liquid - Diasip, Resource Diabetic and Glucerna Select) to include this criteria as follows:

## Diabetic products

### INITIAL APPLICATION

Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid for 1 year.

Prerequisites (tick boxes where appropriate)

Patient has Type I or Type II diabetes who require nutritional supplementation

and

Patient has experienced weight loss

and

The patient has malnutrition requiring nutritional support

### RENEWAL

Current approval Number (if known):.....

Applications only from a relevant specialist, vocationally registered general practitioner, or general practitioner on the recommendation of a relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

Prerequisites (tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

## **Reference pricing of liquid oral feed 1.5 kcal/ml and 2.0 kcal/ml to the standard powder 1 kcal/ml oral feed and sole supply processes**

### Summary

- We propose to reduce the subsidy for standard adult liquid sip feeds (1.5 kcal/ml and 2 kcal/ml) to the equivalent subsidy for the oral supplement powders (1 kcal/ml) through the application of reference pricing. This would mean that the standard adult 1.5 kcal/ml and 2 kcal/ml liquid sip feeds would not be fully funded and the patients would be required to pay between approximately \$0.76 and \$2.10 per pack, unless the suppliers of these products reduce their prices to match the new subsidies. Oral supplement powders would be fully funded.
- We would appreciate advice on which patient groups are being prescribed the standard adult liquid sip feed (2 kcal/ml).
- We also anticipate running sole supply processes for the following adult standard products:
  - enteral feeds;
  - milk-based sip feeds; and
  - juice-based sip feeds.

### Background

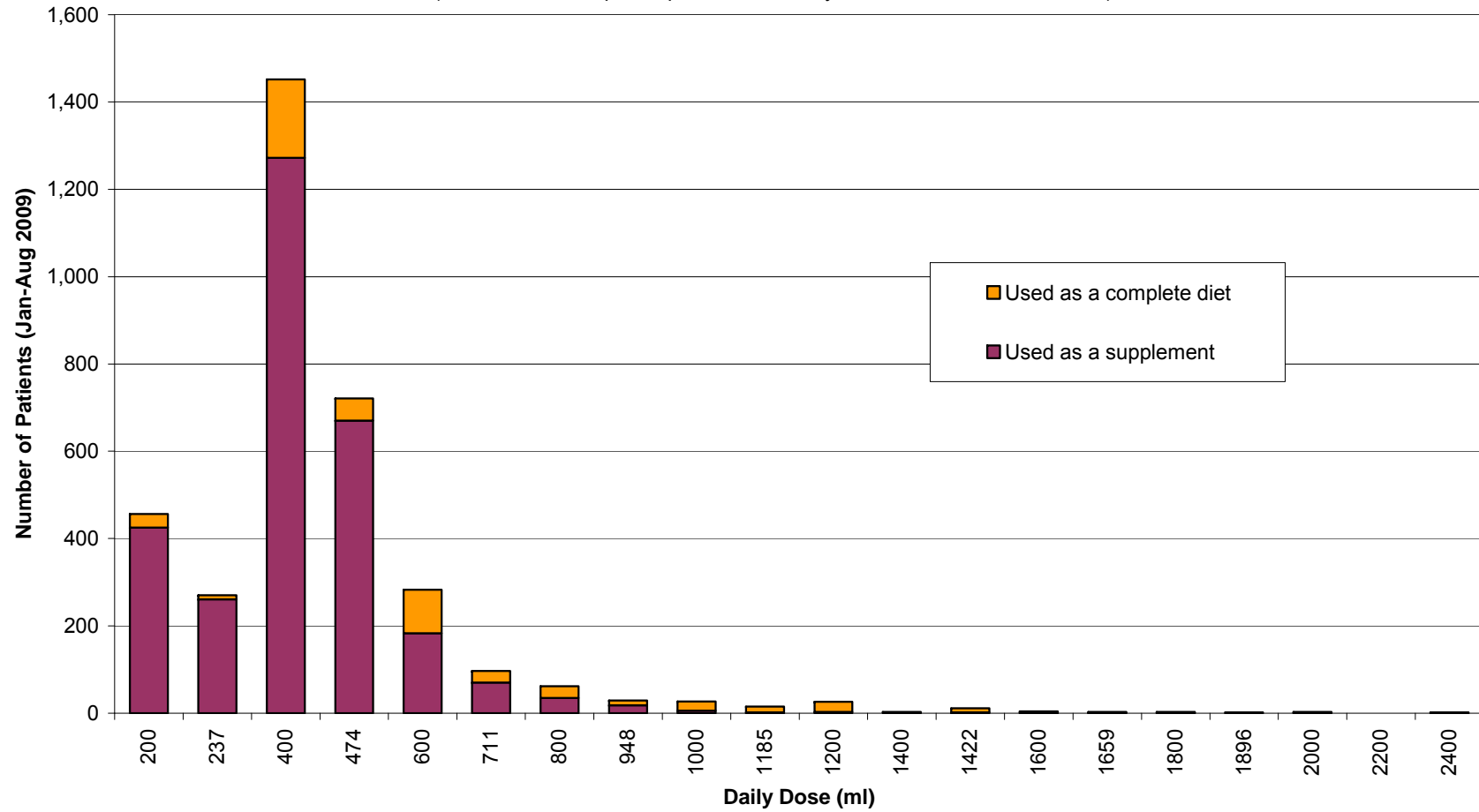
Standard liquid 1.5 kcal/ml oral feeds (with and without fibre) and standard liquid 2 kcal/ml oral feeds are currently listed in the Pharmaceutical Schedule. Some patients use these products as a replacement for their complete diet whilst others use them as a partial replacement of their normal diet or as a supplement to their normal diet. Given the different uses of the liquid oral feeds the daily consumption can vary considerably (as shown in the following graphs illustrating the daily doses that patients are prescribed when they are used as a supplement, and as a complete diet), however in all of these cases the patients do not contribute to what is essentially a “food cost” and therefore incur a lower “food cost” than those in the general population.

An alternative product to the liquid oral feeds are the powder oral feeds. The powder oral feeds can be made up with either water or milk to make a 1 kcal/ml or a 1.5 kcal/ml liquid product. The Special Foods Subcommittee of PTAC considered the powder and liquid oral feeds to have the same, or a similar, therapeutic effect; although it did note that the liquid oral feeds are preferred over the powders for a variety of reasons including convenience, portability, and that they do not require mixing.

The relevant minutes of the Special Foods Subcommittee are attached in Appendix 3.

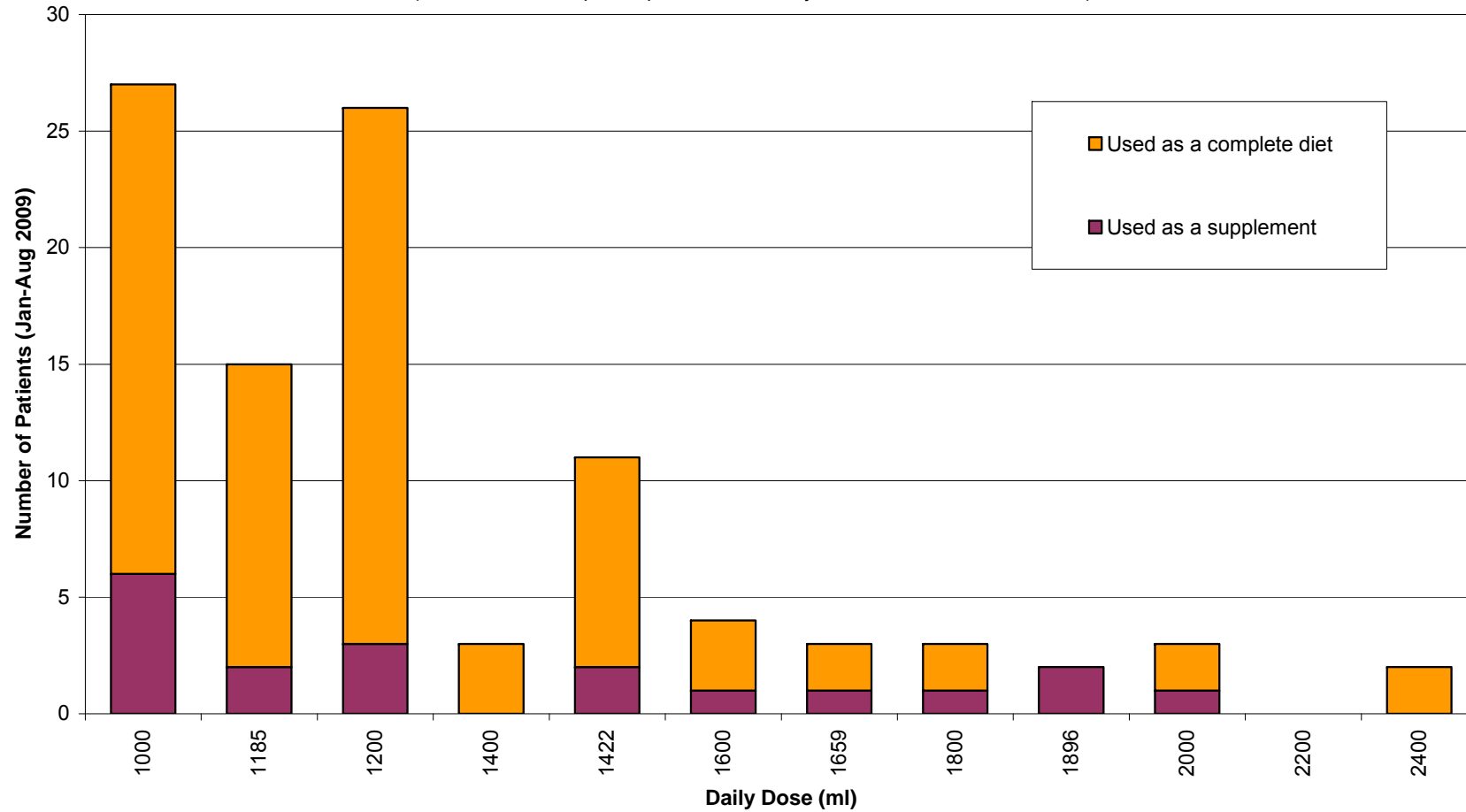
### Daily dose for patients using oral feed 1.5 kcal/ml (200 ml to 2,400 ml)

(based on 27% of prescriptions where daily dose information is available)



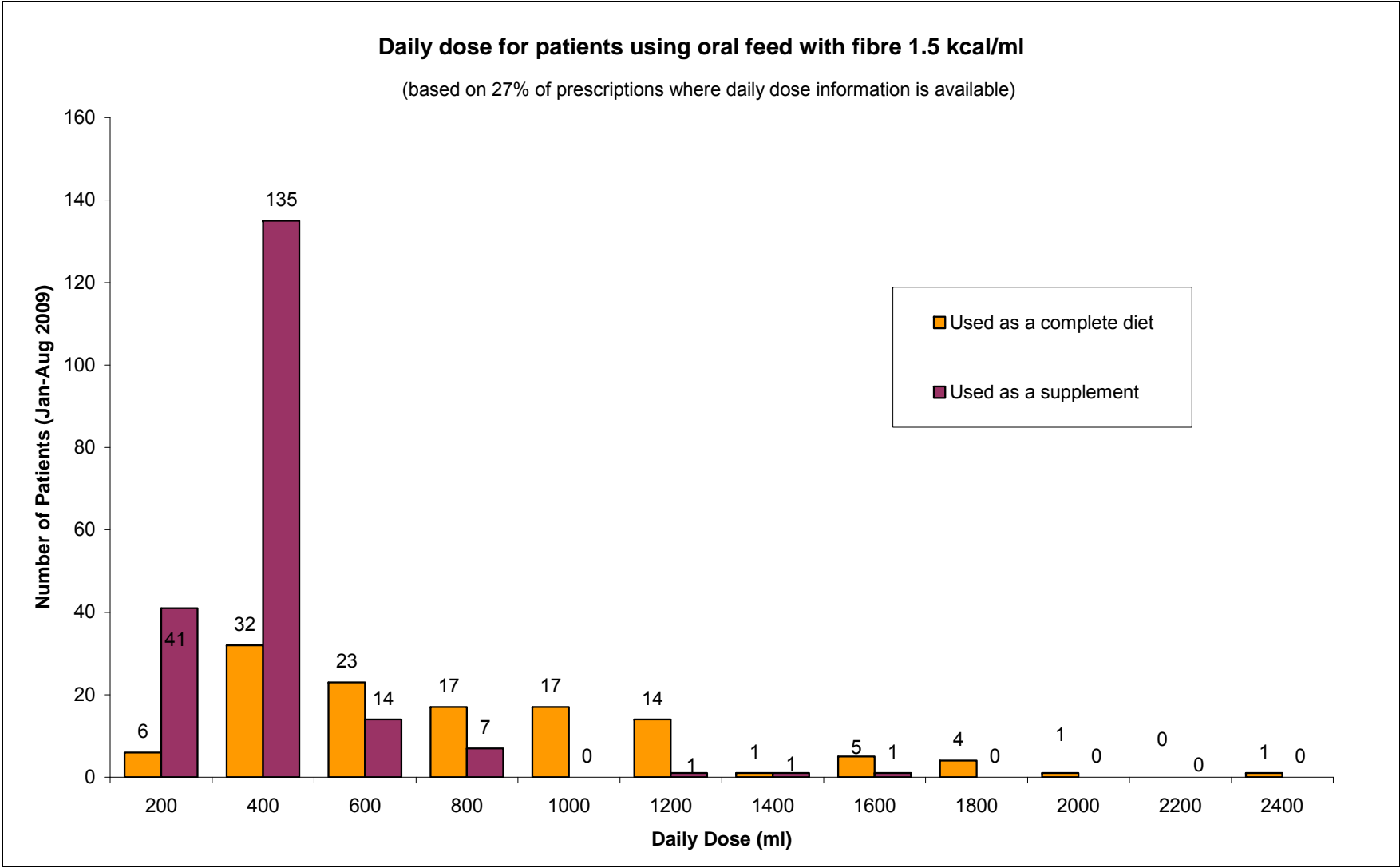
### Daily dose for patients using oral feed 1.5 kcal/ml (1,000 ml to 2,400 ml)

(based on 27% of prescriptions where daily dose information is available)

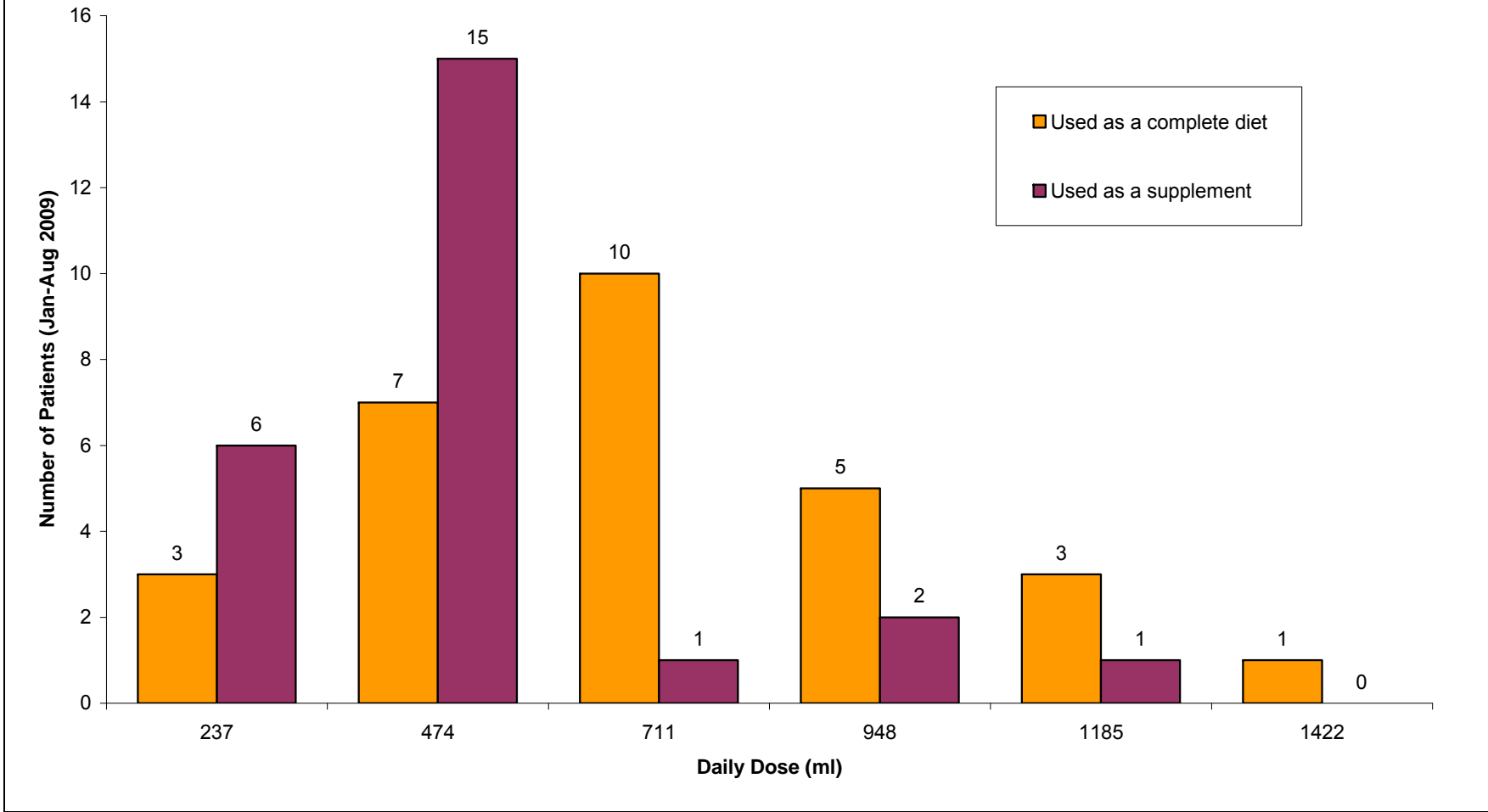


**Daily dose for patients using oral feed with fibre 1.5 kcal/ml**

(based on 27% of prescriptions where daily dose information is available)



**Daily dose for patients using oral feed 2.0 kcal/ml**  
(based on 25% of prescriptions where daily dose information is available)



## Proposals

As powder and liquid oral feeds have the same, or a similar, therapeutic effect, we propose to reduce the subsidy for standard adult liquid feeds (1.5 kcal/ml) to the equivalent subsidy for the oral supplement powders (1 kcal/ml) through the application of reference pricing on a per kcal basis.

This would result in the liquid feeds being partially subsidised instead of being fully subsidised (unless the pharmaceutical suppliers of these products reduce their prices to match the proposed subsidies). The following table illustrates the subsidies and patient charges that would result from the proposal (the patient charge includes an estimated 85% pharmacy mark-up and includes GST):

Brand	Flavours	Pack size	Price	Current Subsidy	Proposed Subsidy	Patient charge*
<b>Oral Supplement 1 kcal/ml (Powder)</b>						
Sustagen Hospital Formula	Chocolate, vanilla	900 g OP	\$9.22	\$9.22	\$9.22	-
Ensure	Chocolate, strawberry, vanilla	400 g OP	\$7.22	\$4.75	\$4.75	\$4.59
<b>Oral Feed 1.5 kcal/ml (Liquid)</b>						
Fortisip	Banana, chocolate, strawberry, toffee, tropical fruit, vanilla	200 ml OP	\$1.12	\$1.12	\$0.71	\$0.76
Ensure Plus	Banana, chocolate, fruit of the forest, strawberry, vanilla	200 ml OP	\$1.45	\$1.12	\$0.71	\$1.38
Ensure Plus	Chocolate, coffee, strawberry, vanilla	237 ml OP	\$1.33	\$1.33	\$0.84	\$0.91
Resource Plus	Chocolate, strawberry, vanilla	237 ml OP	\$1.33	\$1.33	\$0.84	\$0.91
<b>Oral Feed with Fibre 1.5 kcal/ml (Liquid)</b>						
Fortisip	Chocolate, strawberry, vanilla	200 ml OP	\$1.12	\$1.12	\$0.71	\$0.76
<b>Oral Feed 2.0 kcal/ml (Liquid)</b>						
2 Cal HN	Vanilla	237 ml OP	\$2.25	\$2.25	\$1.12	\$2.10

\* Potential part charge (based on 86% pharmacy mark-up and including the effect of GST) if prices are not reduced in line with the subsidy.

These patient charges equate to the following daily and weekly patient costs if the partially funded liquid feeds are used instead of the fully funded powder alternatives:

**1.5 kcal/ml (Fortisip and Ensure Plus 200 ml pack)**

Volume per day	Kcal/day	Fortisip 200 ml		Ensure Plus 200 ml	
		Patient charge per day	Patient charge per week	Patient charge per day	Patient charge per week
200 ml	300 kcal	\$0.76	\$5.32	\$1.38	\$9.66
400 ml	600 kcal	\$1.52	\$10.64	\$2.76	\$19.32
600 ml	900 kcal	\$2.28	\$15.96	\$4.14	\$28.98
800 ml	1,200 kcal	\$3.04	\$21.28	\$5.52	\$38.64
1,000 ml	1,500 kcal	\$3.80	\$26.60	\$6.90	\$48.30
1,200 ml	1,800 kcal	\$4.56	\$31.92	\$8.28	\$57.96
1,400 ml	2,100 kcal	\$5.32	\$37.24	\$9.66	\$67.62
1,600 ml	2,400 kcal	\$6.08	\$42.56	\$11.04	\$77.28
1,800 ml	2,700 kcal	\$6.84	\$47.88	\$12.42	\$86.94
2,000 ml	3,000 kcal	\$7.60	\$53.20	\$13.80	\$96.60

**1.5 kcal/ml (Resource Plus and Ensure Plus 237 ml pack)**

Volume per day	Kcal/day	Resource Plus/Ensure Plus 237 ml	
		Patient charge per day	Patient charge per week
237 ml	356 kcal	\$0.91	\$6.37
474 ml	711 kcal	\$1.82	\$12.74
711 ml	1,067 kcal	\$2.73	\$19.11
948 ml	1,422 kcal	\$3.64	\$25.48
1,185 ml	1,778 kcal	\$4.55	\$31.85
1,422 ml	2,133 kcal	\$5.46	\$38.22
1,659 ml	2,489 kcal	\$6.37	\$44.59
1,896 ml	2,844 kcal	\$7.28	\$50.96
2,133 ml	3,200 kcal	\$8.19	\$57.33

## 2.0 kcal/ml (Two Cal HN)

Two Cal HN 237 ml			
Volume per day	Kcal/day	Patient charge per day	Patient charge per week
237 ml	474	\$2.10	\$14.70
474 ml	948	\$4.20	\$29.40
711 ml	1,422	\$6.30	\$44.10
948 ml	1,896	\$8.40	\$58.80
1,185 ml	2,370	\$10.50	\$73.50
1,422 ml	2,844	\$12.60	\$88.20

In comparison, the 2009 University of Otago Estimated Food Costs Survey reported that a moderate weekly food cost for an adult was between \$73 and \$80, and for an adolescent was between \$73 and \$101, depending upon the location in New Zealand.

Given the above patient charges we anticipate that a number of patients may switch from the liquid feeds to the powder feeds, if the suppliers do not reduce the prices of liquid feeds. Alternatively patients may use a combination of the two products to maintain some variety and ease of use while having a lower patient cost. We note that the Special Foods Subcommittee considered that if patients developed taste fatigue when using the powders then their taste could be varied by adding flavouring.

### Sole Supply Processes

To minimise the patient part-charge on the liquid sip feeds we anticipate running a sole supply process for milk-based and for juice-based sip feeds. This could result in the listing of juice-based sip feeds on the Pharmaceutical Schedule.

While we are not proposing to reference price the 1 kcal/ml and 1.5 kcal/ml enteral feeds (with and without fibre), we propose to run a sole supply process for these items.

We note that the Special Foods Subcommittee of PTAC considered that sole supply of enteral feeds was appropriate and that sole supply of milk-based sip feeds was appropriate if a juice-based alternative was available.

The relevant minutes of the Special Foods Subcommittee are attached in Appendix 4.

# Gluten Free Food

## Summary

- We propose to cease active management of gluten-free foods (we would make no changes to the current listings – including restrictions, subsidies and product range). This would mean that the biopsy requirement would remain and that over time patient costs would increase (subsidies would not be increased to match price increases) and product availability would decrease (discontinuations would not be replaced by new products).

## Background

Currently a number of gluten free foods are subsidised, although none are fully funded, under the Gluten Free Foods Special Authority for patients with coeliac disease. Due to the partial subsidises and pharmacy mark-ups, we have had a number of comments that patients can obtain gluten free foods at lower prices in supermarkets than from pharmacies via prescription. We are not sure that this is the case over all of New Zealand and we would like your feedback regarding this.

Some clinicians have also requested that the biopsy requirement in the Special Authority is replaced with blood tests for various markers. This has arisen due to the publication of several articles indicating a high correlation between these markers and biopsy results, potentially lengthy delays in obtaining biopsies at some hospitals, the cost of biopsies and their invasive nature.

We sought the advice from the Pharmacology and Therapeutic Advisory Committee (PTAC) regarding whether it would be appropriate to replace the biopsy requirement with blood tests. PTAC's recommendation was that the biopsy requirement should be maintained as while the quality of the testing is improving they are not yet of a standard sufficient to remove the requirement for a biopsy (the relevant minutes are attached in Appendix 5). This view was reinforced in discussions at the 2009 New Zealand Society of Gastroenterology Conference.

If the biopsy requirement is removed then it is likely that some patients would receive funding for gluten-free foods without having coeliac disease, resulting in an inappropriate use of funding. Alternatively, if the biopsy requirement is maintained then patients would need to either:

1. be maintained on a diet which includes gluten until a biopsy can be performed, which can take some time in some hospitals, in order to maintain the accuracy of the biopsy; or,
2. not have a biopsy and purchase gluten free foods without a subsidy, and perhaps at a cheaper price than they would obtain it with a subsidy.

While gluten free foods may be obtained at a cheaper cost to the patients through supermarkets than through a prescription (via pharmacy) in many areas, we are aware that one supplier is running a gluten free foods direct-to-patients distribution scheme for prescriptions which provides products to patients cheaper than what they would have to pay at supermarkets or pharmacy. However, this distribution scheme is not nationwide and therefore creates equity issues.

## Proposal

Given the above issues we propose to cease active management of gluten-free foods (we would not increase subsidies or increase the number of additional products). This would mean that with successive price increases the cost of gluten-free foods would be cheaper in supermarkets (if they are not already), and over time we would expect that the part-charge would be such that they are delisted. This would also result in the removal of the funding incentive for patients to have a biopsy and therefore not disadvantage patients if clinician's choose to use blood tests to diagnosis coeliac disease instead of a biopsy.

# Foods and Supplements for Inborn Errors of Metabolism - PKU

## Summary

- We propose to remove the Special Authority requirement for PKU foods (phenyl free baking mix and phenyl free pasta) – it would still be required for PKU supplements.
- We propose to exempt pregnant women and patients under 16 from having to demonstrate compliance to a PKU diet for 12 months in order to access subsidies for PKU supplements.

## Background

Currently patients are required to demonstrate compliance to a PKU diet (by having average blood phenylalanine levels < 900 micromol/litre over the last 12 months) in order to access subsidy for PKU foods (phenyl free baking mix and phenyl free pasta) and PKU supplements (aminoacid formula without phenylalanine). This is with the intention of targeting funding to those patients who are likely to be compliant and therefore gain the most benefit.

However, it is difficult for patients to have blood phenylalanine levels < 900 micromol/litre if they are coming back onto a PKU diet as they could not achieve these levels without being on the diet in the first place. In addition, it is important that women do not have high phenylalanine levels during pregnancy as this can cause foetal brain damage.

## Proposals

We propose to remove the Special Authority requirement for PKU foods – it would remain for PKU supplements. This would mean that patients would not have to demonstrate compliance to a PKU diet in order to obtain subsidised PKU foods, thus there would be no impediments to patients resuming a PKU diet. In addition, we propose that pregnant women and patients under 16 (as per the current criteria) would not have to demonstrate compliance to a PKU diet for 12 months in order to access subsidies for PKU supplements.

The proposed Special Authority for PKU supplements (not PKU food – this would not have any restrictions) is shown below (changes are marked in bold and strikethrough):

### PKU

<b>INITIAL APPLICATION</b> Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid for 1 year.  Prerequisites (tick boxes where appropriate)  <input type="checkbox"/> Patient is pregnant or <input type="checkbox"/> Patient is aged under 16 or <input type="checkbox"/> Patient is compliant with a phenylalanine diet (their blood phenylalanine level is an average of <900 mmol/litre over the last 12 months)
---

<b>RENEWAL</b> Current approval Number (if known):..... Applications only from a relevant specialist, vocationally registered general practitioner, or general practitioner on the recommendation of a relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.  Prerequisites (tick boxes where appropriate)  <input type="checkbox"/> Patient is pregnant or <input type="checkbox"/> Patient is aged under 16 or <input type="checkbox"/> Patient is compliant with a phenylalanine diet (their blood phenylalanine level is an average of <900 mmol/litre over the last 12 months)
--

## Food Thickeners

### Summary

- We propose to remove the renewal requirement for food thickeners.
- We are seeking advice regarding how access to food thickeners could be extended to additional patient groups.

### Background and Proposal

We propose to remove the current annual requirement to renew the Special Authority approval for food thickeners. The proposed Special Authority is shown below:

#### Food thickeners

<b>INITIAL APPLICATION</b> Applications only from a relevant specialist, or vocationally registered general practitioner. Approvals valid without further renewal unless notified. Prerequisites (tick box where appropriate) <input type="checkbox"/> patient has motor neurone disease with swallowing disorder
--

In addition, we are also considering how access to food thickeners could be widened for additional patient groups as currently access is limited to those with motor neurone disease. The Special Foods Subcommittee has recommended that access is widened to include patients with dysphagia as determined via a swallowing assessment conducted by a speech-language therapist. However, the Subcommittee also considered that there is a risk of overuse if access is widened and that there are other options that patients can use such as the addition of cornstarch or the use of smoothies and milkshakes.

The Subcommittee recommended that PHARMAC staff consult with speech language therapists, neurologists, dietitians, paediatricians and geriatricians regarding altering the wording of the Special Authority and creating usage guidelines so that food thickeners could be targeted to patient groups which are at the most risk.

We would also welcome suggestions regarding appropriate criteria that could be applied so that access to food thickeners could be widened to include additional patient groups with dysphagia.

The relevant minutes of the Special Foods Subcommittee are attached in Appendix 6.

PHARMAC  
Pharmaceutical Management Agency

New Zealand Government

# Appendices



## **Appendix 1 – Infant formula for gastrointestinal and other malabsorption problems Special Authority and Sole Supply**

### **Special Foods Subcommittee Minutes (October 2009)**

#### **Application**

The Subcommittee reviewed the infant formula for gastrointestinal and other malabsorption problems Special Authority and considered the potential for sole supply.

#### **Recommendation**

The Subcommittee recommended that the following Special Authorities are adopted for infant formula for gastrointestinal and other malabsorption problems:

##### ***Extensively hydrolysed formula***

Initial application – from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1. Severe food allergy or severe multiple food allergy (not infant colic, constipation or gastro-oesophageal reflux) where the child has failed to respond to both a cow's milk formula and a soy milk formula (a trial of soy milk formula is only required in infants over 6 months of age); or
2. Severe malabsorption (not infant colic or constipation) where the child has failed to respond to both a cow's milk formula and soy milk formula (a trial of soy milk formula is only required in infants over 6 months of age); or
3. One of the following conditions:
  - Short bowel syndrome
  - Intractable diarrhoea
  - Biliary atresia
  - Cholestatic liver diseases causing malabsorption
  - Chylous ascites
  - Chylothorax
  - Cystic fibrosis
  - Proven fat malabsorption
  - Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months
  - Severe intestinal motility disorders causing significant malabsorption

Renewal – [for 1 year] only from any relevant practitioner where treatment remains appropriate and the patient is benefiting from treatment.

##### ***Amino acid formula***

Initial application – from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1. Severe food allergy or severe multiple food allergy (not infant colic, constipation or gastro-oesophageal reflux) where the child has failed to respond to a cow's milk formula and a soy milk formula and an extensively hydrolysed formula (a trial of soy milk formula is only required in infants over 6 months of age); or
2. Severe food allergy where the child has responded to cow's milk formula with anaphylaxis; or
3. Eosinophilic oesophagitis or eosinophilic gastroenteritis; or
4. Severe malabsorption (not infant colic or constipation) where the child has failed to respond to both a cow's milk formula and a soy milk formula and an extensively hydrolysed formula (a trial of soy milk formula is only required in infants over 6 months of age); or
5. Short bowel syndrome; or

6. Intractable diarrhoea; or
7. Severe intestinal malabsorption from severe intestinal motility disorders.

Renewal – [for 1 year] only from any relevant practitioner where treatment remains appropriate and the patient is benefiting from treatment.

## **Discussion**

The Subcommittee noted the current Special Authority in New Zealand and the protein hydrolysate and amino acid Special Authorities used in Australia.

The Subcommittee noted the Australian Position Statement (Kemp et al, 2008 “Guidelines for the use of infant formulas to treat cows milk protein allergy: an Australian consensus panel opinion” MJA 2008; 188 (2) p 109-112) and considered it to be of high quality.

The Subcommittee considered that the treatment algorithm proposed in the Australian Position Statement was appropriate and that currently some patients were being prescribed expensive amino acid formula when a soy or a protein hydrolysate formula would be appropriate.

The Subcommittee considered that the protein hydrolysate and amino acid based formulas should not be available for infants with colic or constipation.

The Subcommittee considered that a 3 month period for an initial Special Authority, as per the Australian criteria, was slightly short and that a 4 month period for the initial Special Authority could be used.

The Subcommittee considered that the use of soy based formula prior to a hydrolysate formula was appropriate in infants aged 6 months and older.

The Subcommittee noted the additional restrictions applied in Australia for patients over 2 years of age and considered whether they should be applied in New Zealand. The Subcommittee considered that this would be a small patient population with a requirement for yearly renewal and therefore any additional restrictions for patients over 2 years of age would not have a significant fiscal impact and were therefore not required.

The Subcommittee considered that Sole Supply for one protein hydrolysate formula and for one amino acid formula was appropriate. The Subcommittee considered that both a protein hydrolysate formula and an amino acid formula were required even if the amino acid formula was cheaper because a protein hydrolysate formula is required for infants with short gut syndrome, chronic liver conditions and some cardiac conditions.

The Subcommittee considered that infants should be able to switch relatively easily between formula brands or from amino acid formula to protein hydrolysate or soy formula. The Subcommittee considered that to assist infants to switch products a transition over two days using an initial 1:3 formula mix and progressing to a 2:2 then a 3:1 and finally a 4:0 formula mix could be used.

The Subcommittee noted that protein hydrolysate formula tastes better than the amino acid formula and that sweeteners such as golden syrup or vanilla could be added to a formula to resolve taste issues and aid in any transition.

The Subcommittee considered that there is a lack of knowledge regarding the appropriate treatment algorithm for infant formula in infants with milk protein intolerance/allergy and that circulation of the Australian Position Statement (Kemp et al, 2008) with a flowchart summary would be useful for practitioners.

## **Appendix 2 – Adult Standard Sip Feeds Special Authority**

### **Inclusion of a screening (diagnosis) tool and other dietary measures**

#### **Special Foods Subcommittee Minutes (December 2009)**

The Subcommittee considered a proposal from PHARMAC staff to include a screening (diagnosis) tool and other dietary measures into the Special Authority for Standard Adult Sip Feeds.

The Subcommittee noted the Malnutrition Universal Screening Tool (MUST) is used to identify adults who are malnourished, or at risk of malnutrition, through the use of a BMI score, a Weight Loss score (unplanned weight loss in the past 3-6 months) and an Acute Disease Effect score. The Subcommittee also noted the Screening Tool for the Assessment of Malnutrition in Paediatrics (STAMP) and the NICE, West Essex NHS, South Staffordshire NHS, Greater Glasgow and Clyde NHS, and Waitemata DHB guidelines for the use of oral nutritional supplements (sip feeds).

The Subcommittee noted that MUST was designed and validated for use in adults in both the community and hospital setting while STAMP was designed for use in hospitalised children.

The Subcommittee noted that the intention of the proposal was to use a screening tool and associated guidelines to target the sip feeds to appropriate patients; not to screen all patients for malnutrition.

The Subcommittee noted that some screening tools are already in use in some hospitals and dietitian practices, although this is not universal, and that appropriate information on the use of oral nutritional supplements is lacking in general practice.

The Subcommittee recommend that the use of a screening tool and relevant guidelines are incorporated in the Standard Adult Sip Feed Special Authority criteria. The Subcommittee considered that this would provide clinicians with a clinically appropriate framework for prescribing subsidised sip feeds.

The Subcommittee considered that the incorporation of a screening tool into the Special Authority may highlight the issue of malnutrition and as a result it could increase the usage of sip feeds. The Subcommittee considered that if this occurred then it would be appropriate as it would be meeting an unmet health need. However, the Subcommittee noted that increased use could result in increased expenditure and some workforce issues in some areas if dietitians' workloads increased significantly.

While the Subcommittee considered that the MUST tool was appropriate for adults, it also noted that other options that could be considered included the Mini Nutritional Assessment (MNA), the Subjective Global Assessment (SGA) and the modified SGA. The Subcommittee considered that it may be appropriate to include multiple tools as options to be used in the Special Authority if they provide consistent outcomes and are already in use.

The Subcommittee considered whether the use of a screening tool and relevant guidelines should be incorporated into the Special Authorities for the more specialised sip feeds as well as the Standard Adult Sip Feeds. The Subcommittee considered that any changes should be limited to Standard Adult Sip Feeds and oral supplements initially, although this could be reviewed in 12 months. The Subcommittee noted that the Special Authority requirement for Diabetic Products only requires that the patient has type 1 or type 2 diabetes and requires nutritional supplementation. The Subcommittee recommended that the Special Authority should be amended to include weight loss and malnutrition requiring nutritional support.

The Subcommittee noted that some children, aged between 8 and 18 years old, also used Standard Adult Sip Feeds. The Subcommittee considered that they should be able to continue to access these feeds while not being subjected to the MUST screening tool and associated guidelines as the MUST tool was not designed for this patient population.

The Subcommittee considered that any changes to the Special Authority that included the use of a screening tool and other guidelines should be reviewed after 12 months.

The Subcommittee noted that the inclusion of a screening tool and relevant guidelines may result in delays to the access of sip feeds for patients leaving hospital. The Subcommittee therefore recommended that Adult Sip Feeds should be included on the Discretionary Community Supply (DCS) list for 1 month and that this would be especially useful for patient's following surgery. Members noted that there may be some practical issues associated with having Special Foods dispensed by hospital pharmacies.

### **Appendix 3 – Reference pricing of Adult Standard Sip Feeds 1.5 kcal/ml, 1.5 kcal/ml with fibre, and 2 kcal/ml to the 1 kcal/ml powder**

#### **Special Foods Subcommittee Minutes (December 2009)**

The Subcommittee considered a proposal from PHARMAC staff to reference price the Adult Standard Sip Feeds 1.5 kcal/ml, 1.5 kcal/ml with fibre, and 2 kcal/ml, to the 1 kcal/ml powder.

The Subcommittee noted that the proposal would result in at least one fully funded sip feed powder, fully funded enteral feeds, and partially funded liquid sip feeds.

The Subcommittee considered liquid sip feeds were preferred over mixing the powder as: sip feeds are more convenient than the powders; the sip feeds are more portable for school children; and some patients may find mixing the powder difficult or do this incorrectly.

The Subcommittee noted that liquid sip feeds can be used in some tube fed patients and that sip feeds would not be fully funded for these patients. The Subcommittee noted that fully funded options for these patients would be enteral feeds or the powder. The Subcommittee considered that the sip feeds are preferred to the enteral feed products as the enteral feeds in soft-pack RTH containers could be difficult to open, there may be storage issues for half used packs, and wastage may increase. The Subcommittee considered that the sip feeds are preferred to the powder feed as the powder may block feeding tubes, making the powders up may be difficult for some elderly patients, and there may be consistency issues with the powders. However, the Subcommittee also noted that pre-made liquid sip feeds can also block feeding tubes if care is not taken with maintaining the tube.

The Subcommittee noted that the usual sip feed doses for children and adults would be 400 to 600 ml per day when they are used as a supplement and that doses higher than this would generally indicate that the patient is using the sip feed as an enteral feed. However, the Subcommittee also considered that children with inflammatory bowel disease would use about 1600 to 1800 mls of sip feeds per day for a 2 month period as during this time they would be used as a complete diet.

The Subcommittee considered that the majority of use of the 2 kcal/ml sip feeds would be by cystic fibrosis patients, although noted there are other patient groups, and that it would be appropriate for PHARMAC to consult on restricting access to these patients.

The Subcommittee considered it appropriate to establish a therapeutic subgroup comprising of 1 kcal/ml powder and the Adult Standard Sip Feeds 1.5 kcal/ml, 1.5 kcal/ml with fibre, and 2 kcal/ml. The Subcommittee also considered that it was appropriate to apply reference pricing between these products on a kcal/ml basis as the products have the same or similar clinical effect.

The Subcommittee noted that adding milk to powder would not be appropriate for patients intolerant to lactose or who required a low residue diet; and that if Sustagen powder was used with milk as a complete diet (>1100 ml) then the diet would exceed the upper limit for vitamin A and calcium and be deficient in zinc and iron for some under 18 year old age groups.

The Subcommittee considered that there may be transition issues from hospitals to the community if patients are started on sip feeds in the hospitals and then are discharged into the community on the powders.

The Subcommittee considered that if patients were using the powders and had taste fatigue then they could vary the flavour of the made up powder by adding other product flavours such as milo.

The Subcommittee considered that to improve the implementation of any reference pricing it would be useful to list additional 1 kcal/ml powders, including with fibre, and smaller enteral feed packs for use in tube feeds.

## **Appendix 4 – Oral Feeds listings and Sole Supply Special Foods Subcommittee Minutes (October 2009)**

### **Application**

The Subcommittee considered whether a sole supply process for milk-based and juice-based 1.5 Kcal/ml adult oral feed is appropriate.

### **Discussion**

The Subcommittee noted that in 2008 responses to a proposed sole supply tender for milk-based adult oral feed included concerns regarding the availability of an appropriate alternative should the funded product not be suitable for a patient for a number of reasons including packaging and taste fatigue.

The Subcommittee noted that currently juice-based products were not funded through the Pharmaceutical Schedule and that if they were listed it would result in increased usage of oral feed products overall because it would be used as an additional product in some patients as it has a desirable taste. The Subcommittee noted that the juice-based products were not a complete diet and therefore should only be used as a supplement.

The Subcommittee also considered that an increase in the overall usage of oral feeds would occur if other oral feed based products such as yoghurt or crème were listed in the Pharmaceutical Schedule and that there currently was not a clinical need to fund additional bases.

The Subcommittee considered that it would be appropriate to have two categories of adult product standard in the Pharmaceutical Schedule. The first category would be products used as a complete diet and would include enteral feeds which could be subject to a sole supply arrangement. The second category would be products used as a supplement and would include milk-based and juice-based oral feeds with each of these able to be subject to a sole supply arrangement.

While the Subcommittee considered that sole supply of enteral feeds would be appropriate, it noted that the supply and interchangeability of enteral feed pumps would need to be considered. The Subcommittee also noted that while enteral feeds have historically been initiated in hospitals they are now also initiated in the community.

The Subcommittee noted that sole supply of different presentations of oral feed could impact on the suppliers as it may result in losing suppliers having only a small share of the market and therefore exiting the market entirely, however it could alternatively distribute the Special Foods market more evenly across suppliers therefore encouraging the suppliers to stay in the Special Foods market.

## **Appendix 5 – Requirement for a biopsy in the Gluten Free Foods Special Authority**

### **PTAC Minutes (February 2009)**

The Committee reviewed the biopsy requirement in the Gluten Free Special Foods Special Authority for the diagnosis of coeliac disease.

The Committee noted letters from two clinicians requesting that the biopsy requirement for patients to be eligible for the Gluten Free Special Authority is removed based upon the lack of biopsy facilities, significant delays in the patient having a biopsy, risk associated with a biopsy and the accuracy of tissue transglutaminase blood tests. One clinician recommended that gluten-free foods should be available to patients with a strongly positive tissue transglutaminase blood test and the other clinician recommended that they should be available to all patients with a positive tissue transglutaminase blood test.

The Committee noted that the difficulty with relying on tissue transglutaminase blood tests to diagnose coeliac disease was the issue of false positives.

The Committee noted studies by Barker et al (Pediatrics 2005;115:1341-1346) and Hill and Holmes (Aliment Pharmacol & Ther 2008;27:572-7) which examined whether there were levels of tissue transglutaminase antibodies at which false-positive results are minimised or do not occur at all.

The Committee noted that Barker et al (2005) found that only one patient with a test result over 100 U had a negative biopsy outcome. The Committee noted that Hill and Holmes (2008) found that a cut off level of 30U/ml resulted in no negative biopsy outcomes. The Committee noted that these studies used different tissue transglutaminase tests.

The Committee noted the North American Society for Paediatric Gastroenterology, Hepatology and Nutrition 2004 Guideline for the Diagnosis and Treatment of Coeliac Disease in Children, and the AGA Institute Medical Position Statement on the Diagnosis and Management of Coeliac Disease (2006), which still considers that a biopsy remains the Gold Standard and should be used in the diagnosis of coeliac disease.

The Committee considered that an accurate diagnosis is important and that while the screening tests are useful, the tests used, and the prevalence of coeliac disease are not consistent throughout the country making the generalisability of the studies reviewed an issue.

The Committee considered that while the quality of the testing is improving it is not yet of a standard sufficient to remove the requirement for a biopsy.

The Committee recommended that the biopsy requirement remain in the Gluten Free Special Foods Special Authority.

## **Appendix 6 – Food Thickeners**

### **Special Foods Subcommittee Minutes (Oct 2006)**

The Subcommittee considered an application from Novartis for the widening of Special Authority criteria for Resource Thicken Up, a powder maize starch food thickener.

The Subcommittee noted that it was proposed that the Special Authority criteria for Resource Thicken Up be widened to include patients with dysphagia caused by stroke.

The Subcommittee noted that currently subsidy for food thickeners was restricted under Special Authority to patients with motor neurone disease and associated swallowing disorder.

The Subcommittee noted that it had reviewed the access criteria for food thickeners in July 2001 and October 2003.

The Subcommittee considered that there was an outstanding need for food thickeners in a number of conditions that cause dysphagia. The Subcommittee considered that it was important to target subsidies for food thickeners appropriately, as there was potential for significant overspend in this area.

The Subcommittee considered that a Speech and Language Therapist would be the most appropriate professional to assess a patient's need for a food thickener.

The Subcommittee recommended that the application to widen the Special Authority criteria to include dysphagic patients caused by stroke be declined.

The Subcommittee recommended that the Special Authority criteria for food thickeners be amended to include all dysphagic patients on recommendation from a registered Speech and Language Therapist following consultation. The Subcommittee noted that it would need to approve the final wording of any proposed amendments to the Special Authority criteria applying to Special Foods.