PHARMAC
Pharmaceutical Management Agency

New Zealand Government

February 2011

Special Foods - Notification of Funding and Access Changes from 1 April

NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

Changes to the Access and Funding of Special Foods from 1 April 2011

The PHARMAC Board has made a number of decisions regarding the access and funding of Special Food products subsidised through the Pharmaceutical Schedule.

These changes will increase the number of prescribers able to initiate funding, introduce funding pathways consistent with international guidelines, reduce administration, and address concerns over current funding sustainability, given that growth is significantly higher than general Pharmaceutical Budget growth.

We appreciate the efforts of all those who responded to the consultation document (www.pharmac.govt.nz/2010/01/19), and who met with us during this process. As a result modifications were made to a number of the proposals.

A summary of the changes is provided below.

Summary of the changes

The changes (effective from 1 April 2011 unless otherwise stated) are:

Special Authority Authorisation

- All vocationally registered medical practitioners and dietitians will be able to make initial applications for Special Food Special Authorities.

- Due to a number of system changes required by the Ministry of Health, the date that dietitians will be able to make Special Authority applications is currently unknown. We will notify you once the date is known.

Infant Formula

- Lactose free, soy and goats' milk (Delact, S26 Soy, Karicare Soy All Ages and Karicare Goats Milk) infant formula will no longer be funded, and the products will be delisted from the Pharmaceutical Schedule.

- A new funding pathway for elemental formula will be adopted. This will require:

    - extensively hydrolysed formula (and soy formula if considered appropriate) to be trialled before amino acid formula except in patients with anaphylaxis reactions to cows' milk and eosinophilic oesophagitis.

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- a reassessment of the patient (and reapplication) every 6 months to determine if a less specialised formula can be used.

Patients who currently have a valid Special Authority would not be affected by this change until their Special Authority approvals expire.

- Those infant formula that remain listed will be fully funded (currently some attract a surcharge).

Standard and Specialised Oral Feeds

- The current funding distinction between patients who use oral feeds as a supplement to their diet (500 ml daily volume limit) and those who use them as a complete diet will be removed.

Access to Standard Adult Oral Feeds (liquids and powders)

- The access criteria for standard adult oral feeds will be changed so that patients are either required to be malnourished and have tried other dietary measures prior to being funded, or meet other specified criteria (i.e. they are children, tube-fed or have a specified medical condition).

- Funding for powder and ready-mixed liquid oral feeds will be able to be accessed via the same Special Authority (separate forms are currently required).

Funding of Standard Adult Oral Feeds (liquids and powders)

- Reference pricing will be applied between the ready-mixed liquids and the powdered standard adult oral feeds. This will result in powdered products being fully funded and the subsidy for ready-mixed products being reduced to the level of the powdered products. - Whether the ready-mixed liquids remain fully subsidised depends upon whether the suppliers reduce their prices. If not, extra costs (a surcharge) would apply for patients wishing to use these products.

- The powder and ready-mixed liquid standard adult oral feeds will be added to the Discretionary Community Supply (DCS) list. This would enable DHB hospitals to provide these products to patients living in the community for up to 10 days prior to hospitalisation and 30 days following discharge without a Special Authority (funding would be from the DHB hospital's budget).

Gluten Free Food

- There will be no change to the current products and subsidies. However, PHARMAC will cease active management of gluten-free foods in the Pharmaceutical Schedule – no changes to the listings including the restrictions, subsidies and product range will occur. Over time we would expect that availability of subsidies would decrease.

Foods and Supplements for Inborn Errors of Metabolism

- All patients with inborn errors of metabolism will be eligible for lifetime Special Authority approval for specific supplements and low protein baking mix and pasta. Subsidies will be increased to fully-fund those products that presently attract a surcharge.

Other issues

We received a number of consultation responses in relation to possible sole-supply funding of some special foods, and also in relation to funding of food thickeners.

While we are not presently implementing any changes in these areas, we will be considering such options as we monitor the impact of the large number of changes that are being made.

More information

We will be providing a number of avenues to assist those practitioners wishing to obtain further information:

- Provision of education sessions/seminars about Special Foods to support health professionals with prescribing of these products.

- Development of written resources for health professionals about Special Foods.

- Provision of education about the changes to Special Foods through existing networks and links.

If you wish to find out more, or if you have any questions about any of these decisions, please call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.

Contents

Special Authority Authorisation

Decision

- The range of health practitioners who can initiate Special Authority applications will be increased to include all “Vocationally Registered Medical Practitioners” and “Dietitians”.
    - For dietitians this change will be implemented once the Special Authority system has been modified to recognise dietitians as a prescribing group.

Background

Funding for Special Foods is currently available via Special Authority application. The first (initial) application can only be made by a “Specialist” while renewal applications can be made by “Specialists” OR “General Practitioners upon the recommendation of a Specialist”.

Two issues can result. Firstly, it may be difficult for patients to access the appropriate authorisations potentially leading to treatment delays and contributing to the current inequity in the usage of Special Foods throughout New Zealand. Secondly, clinicians less involved in the dietary care of patients may be called upon to authorise the funding resulting in an administrative burden for these clinicians.

Details of the decision

The current *prescriber type* restrictions will be amended in all Special Foods such that initial and renewal applications will be able to be made by:

For **initial** applications:

Only from a vocationally registered medical practitioner [or dietitian].

For **renewal** applications:

Only from a vocationally registered medical practitioner [or dietitian] or other medical practitioner on the recommendation of a vocationally registered medical practitioner [or dietitian].

Other medical practitioners must include the name of the vocationally registered medical practitioner [or dietitian] and the date contacted.

Feedback received during consultation

The change that has been adopted is consistent with the proposal consulted upon - to widen access to those who could initiate Special Authorities to include “Vocationally Registered Medical Practitioners” and “Dietitians”.

Overall there was significant support for the proposal on the basis of easier and more equitable patient access and reduced clinician administration.

The feedback received raised a number of issues in relation to the proposal. We would like to provide the following responses to these issues as follows:

Theme	PHARMAC Response
Vocationally registered medical practitioners may not have sufficient expertise to manage Special Food patients appropriately including their ability to diagnose, prescribe and follow-up treatment. Particular emphasis was placed on metabolic disorders and paediatric disorders including cows' milk protein allergy.	The proposed Special Authority criteria would restrict eligibility for making applications for Special Food Special Authorities to health practitioners acting within their scope of practice. Competence in this regard is decided upon by the relevant Colleges/Boards.
Alternative suggestions to the proposal included: ▪ vocationally registered general practitioners being able to initiate Special Authorities for sip feeds only ▪ widening access to dietitians but not vocationally registered general practitioners	
Additional training and resources would be required for new Special Authority applicants. Particular areas include malnutrition assessment and treatment (including appropriate dietary options for high energy diets such as food fortification), the differences between the sip feed products, and when to refer a patient to a more specialised practitioner.	We acknowledge that some education would assist new prescribers. Additional educational activities that we will be undertaken are listed in the introduction to this paper. In addition, the new funding pathway for oral supplements and infant formula will provide some assistance.

Infant formula

Decisions

From 1 April 2011:

- Lactose free, soy and goats' milk infant formula will no longer be funded.

- Special Authority approvals for the presently defined 'elemental formula' will be split into two groups:

    - extensively hydrolysed formula; and
    - amino acid formula.

  Funding for the amino acid formula will only be available to patients who have trialled the extensively hydrolysed formula or who have had anaphylaxis on exposure to cows' milk, or who have eosinophilic oesophagitis.

- Reassessment for continued funding will be required every 6 months instead of every 12 months.

- Patients who currently have a valid Special Authority will not be affected by these changes, until their current Special Authority approval expires.

- Extensively hydrolysed formula and the amino acid formula will be fully funded.

- The PHARMAC Board also applied reference pricing to the amino acid formula. This means that the subsidy for the Neocate range will be reduced to the level of the Elecare products. The supplier of Neocate has indicated that it intends to reduce its pricing which would mean that Neocate would be fully subsidised for those meeting the new criteria. In the case that the price is not reduced, patients would have the option of receiving the fully subsidised Elecare product, or continuing to pay a surcharge to receive Neocate.

Background

There are a number of infant formulae products listed in the Pharmaceutical Schedule. These are used to treat specific medical conditions including Williams Syndrome, lactose intolerance, gastrointestinal and malabsorption syndromes, cows' milk protein intolerance and allergy. Some of these formulae are fully subsidised with others being partially subsidised. Presently funding is provided only for the costs over and above the cost of usual infant feeds available through retail outlets such as supermarkets. This results in a surcharge. Since pharmacies are free to mark-up the costs (unlike for fully-subsidised products), this approach does not necessarily achieve the objective of delivering the anticipated subsidy benefits to patients.

The less specialised formulae (lactose free, goats' and soy formula) are typically available as substitutes to cows' milk-based powders through retail outlets such as supermarkets, with the more specialised formulae (premature, low calcium, and elemental formula) typically available through pharmacies, and at a considerably higher cost.

Subsidised usage of these products is low, with the exception of elemental formula for which expenditure in 2008/09 was $5.8 million with around 38% annual growth. In

particular the more expensive amino-acid based formula products seem to be used as an early option in New Zealand. Our usage of these products is about 60% higher than Australia's on a per capita basis.

There is contention in the literature over the appropriate place of soy formula in the treatment hierarchy for gastrointestinal and malabsorption syndromes. In 2008, an Australian Position Statement/Guideline was published for the use of infant formula in treating cows' milk protein allergy (Kemp et al)[1]. A further perspective was published by the same authors in 2009[2] In general, the Australian Guideline/Perspective recommends the following treatment pathway (when breast milk and standard cows' milk formula is inappropriate):

> Soy based formula if infant is over 6 months (some exceptions) → extensively hydrolysed formula → amino acid based formula.

The Australian funding requirements for extensively hydrolysed and amino acid based formula require a trial of soy formula irrespective of age although this is not required for specialist applications.

New Zealand's current funding requirements are less restrictive, enabling the funding of amino acid formula first-line. This relatively unrestricted access is reflected in New Zealand dispensing data which indicates that 78% of infants are using the last-line amino acid formula without trial of an extensively hydrolysed formula. In contrast, the literature suggests that around 10% of infants would require an amino acid formula.

Advice was sought from the Special Foods Subcommittee of PTAC on how it could ensure that prescribing, and therefore expenditure, is focused on clinical need and value for money.

The Subcommittee recommended:

- The adoption of the treatment pathway proposed in the Australian Guidelines (with some exceptions).

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- A reduction in the period of Special Authority approval before a reassessment is required for ongoing funding.

- That the more costly Neocate range of amino acid based formula could be reference priced to the less expensive Elecare range of amino acid based formula as these brands have the same or similar therapeutic effect.

- The delisting of goats' milk infant formula on the basis of high cross-reactivity with cows' milk.

[1] "Guidelines for the use of infant formulas to treat cows milk protein allergy: an Australian consensus panel opinion" (Kemp et al, 2008; MJA; 188 (2) p 109-112). http://www.mja.com.au/public/issues/188_02_210108/kem10722_fm.html

[2] "Management of cow's milk protein allergy in infants and young children: An expert panel perspective" (Allen et al, 2009; Journal of Paediatrics and Child Health; 45 p 481-486).

Details of the decision

- Lactose free, soy and goats milk infant formula will no longer be funded through the Pharmaceutical Schedule and will be delisted.

  The new Special Authority criteria applying to extensively hydrolysed formula and amino acid formula will be as follows.

Extensively hydrolysed formula

Special Authority for Subsidy
Initial Application. Approvals valid for 6 months for applications meeting the following criteria:
Any of the following:

1 Cows milk formula is inappropriate due to severe intolerance or allergy to its protein content; and either:
  1.1 Soy milk formula has been trialled without resolution of symptoms; or
  1.2 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 Chylous ascites; or
8 Chylothorax; or
9 Cystic fibrosis; or
10 Proven fat malabsorption; or
11 Severe intestinal motility disorders causing significant malabsorption; or
12 Intestinal failure.

Renewal. Approvals valid for 6 months following assessment as to whether the infant can be transitioned to a cows milk protein formula.

Amino acid formula

Special Authority for Subsidy
Initial Application. Approvals valid for 6 months for applications meeting the following criteria:
Any of the following:

1 Extensively hydrolysed formula has been reasonably trialled and is inappropriate due to documented severe intolerance or allergy or malabsorption; or
2 History of anaphylaxis to cows milk protein formula or dairy products; or
3 Eosinophilic oesophagitis.

Renewal. Approvals valid for 6 months following assessment as to whether the infant can be transitioned to a cows milk protein formula or an extensively hydrolysed formula.

- Extensively hydrolysed formula and amino acid formula will be fully funded as follows:

Extensively hydrolysed formula			
Brand	**Pack size**	**Current Subsidy and Price (ex-man, excl. GST)**	**Subsidy from 1 April 2011 (ex-man, excl. GST)**
Pepti Junior	400 g OP	$15.52 ($19.01)	$19.01
Pepti Junior Gold	400 g OP	$11.72 ($15.21)	$15.21

Amino acid formula			
Brand	**Pack size**	**Current Subsidy and Price (ex-man, excl. GST)**	**Subsidy from 1 April 2011 (ex-man, excl. GST)**
Elecare Elecare LCP Elecare vanilla	400 g OP	$52.90 ($56.00)	$56.00
Neocate Neocate LCP	400 g OP	$63.97 ($67.08)	$56.00
Neocate Advance	400 g OP	$52.90 ($56.00)	$56.00
Vivonex Pediatric	48.5 g OP	$5.62 ($6.00)	$6.00

We note that the PHARMAC Board reference priced the Neocate range of amino acid based formula to the Elecare range. However the supplier of Neocate has indicated that it will reduce its pricing to the level of Elecare which would mean that it will be fully funded for eligible patients.

We have considered which of the milk-replacement options should be considered for funding versus which should be considered a private cost. Many products are available in supermarkets; other products are more medically specialised, and are priced substantially higher.

Given this, we have decided to fully subsidised the more specialised products (extensively hydrolysed formula and amino acid formula), and cease funding of the less specialised products available in supermarkets. In general these less specialised products should be trialled first before funding would be available for the more specialised products. As such the following products will be removed from the Pharmaceutical Schedule from 1 April 2011:

- Goats' milk infant formula (Karicare Goats Milk Infant Formula)
- Lactose free infant formula (Delact)
- Soya infant formula (S26 Soy)
- Infant soy formula (Karicare Soy All Ages)

Feedback received during consultation

The proposals consulted upon were to:

- create a funding pathway (similar to the Australian guidelines) for funded access to elemental formula;
- require a four monthly reassessment for infant formula; and
- reference price the Neocate range of amino acid formula to the less expensive Elecare range (this component was consulted upon separately on 30 July 2010).

Following consideration of the consultation responses, the proposals were amended so that:

- the requirement to trial soy formula prior to funding of extensively hydrolysed and amino acid based formula was removed – it remains included as an option for consideration;
- the reassessment period was extended to six months; and
- infant formula is only funded for medical conditions where less specialised formula are not suitable, and when doing at least one product in each subgroup is fully funded.

The feedback received raised a number of issues in relation to the proposal. We would like to note these issues and provide the following responses:

Themes
While there was strong support for adopting the Australian guidelines it was noted by some responders that the proposed Special Authority criteria did vary from the guidelines for a number of conditions including extreme irritability, food protein induced proctocolitis, colic, constipation and gastroesopageal reflux disease. It was also noted that the Australian guidelines state that in some cases it may be appropriate to start treatment with an extensively hydrolysed or amino-acid based formula and such cases should be managed by a paediatrician with expertise in these disorders.
There were a number of alterations suggested to the Special Authority criteria including the provision of subsidy for intestinal failure, for difficult to treat constipation and reflux, a definition of colic, and an allowance for the development of allergy through maternal transmission. It was also suggested that where allergy testing indicates possible soy allergy a trial should not be required and that infants with severe allergy should be able to proceed straight to an amino acid based formula.
Some responders indicated concern with the three step Special Authority process given that it could take some time for patients to move through all the steps. To reduce time-delays in processing applications it was suggested that the use of on-line Special Authority applications should be promoted with paediatricians.
Respondents noted that the proposed 4 month period for reassessment (to determine if they can switch to a less specialised therapy) would create an expectation of regular reviews which would increase demand on dietitians and consultants. There was a lack of consensus as to what this time period should be, with views ranging from 6 to 12 months.
A few respondents considered that the proposal should be withdrawn altogether and that both extensively hydrolysed and amino acid formula should be on the same Special Authority form on the basis of reducing application requirements.
PHARMAC Response
As noted above, we have removed the requirement to trial soy milk (although it remains an option), and have extended the reassessment period to every six months. We note that both of these products are currently funded through the same Special Authority approval, and that this has probably contributed to the 78% of infants using the last line amino acid formula without trial of an extensively hydrolysed formula.

Standard and Specialised Feeds – Removal of the Funding Distinction for Use as a Supplement or a Complete Diet

Decision

From 1 April 2011:

- The current funding distinction between patients who use oral or enteral feeds as a supplement to their diet and those who use them as a complete diet will be removed. This will remove the 500 ml daily subsidy limit for many patients..

Background

A number of standard and specialised sip and tube feeds are subsidised in the Pharmaceutical Schedule. The funding provided for these products is differentiated according to whether the product is being used as a supplement in addition to the patient's diet (subsidy is provided 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).

Details of the decision

From 1 April 2011, the distinction between using oral and enteral feeds as a complete diet or dietary supplement will be removed. If a standard/specialised feed is funded, it will be funded to the level specified in the Pharmaceutical Schedule, irrespective of the volume used by a patient.

Feedback received during consultation

The change that has been adopted is consistent with the proposal consulted upon.

Respondents welcomed the proposal as it would remove the administration requirement that have to be completed (clinicians have to complete a second Special Authority application and the initial one has to be cancelled) if a patient's requirements change. As a result no changes to the original proposal have been made.

One issue was raised in the responses to the proposal and we would like to provide the following response:

Issue	PHARMAC Response
Currently if patients require more than 500 ml per day, but not a complete diet, they have to purchase the additional product. So while removing this requirement appears result in savings for these patients, the actual savings will be small they will be offset by any part-charge that could result from the proposal to reference price the ready-made liquids to the powder products.	This change and the application of reference pricing to the standard oral feeds are not related, and each has been considered by the PHARMAC Board on its own merits. The intent of removing the 500 ml limit was to reduce clinician administration, while the intent of reference pricing the ready-made sip feeds to the powder alternatives was to reduce funding costs while still providing a fully funded supplement.

Access to Standard Supplements/Feeds (Adult Liquids and Powders)

Decisions

From 1 April 2011:

- The standard 1 kcal/ml powders (Ensure and Sustagen Hospital Formula) and the 1.5 kcal/ml ready-mixed liquid oral feeds (Ensure Plus, Fortisip, Fortisip Multi Fibre) will be accessed through a single "Standard Supplements" Special Authority form (currently these products require different Special Authority forms).
- The access criteria for Standard Supplements (powders, ready-mixed liquid and enteral liquids) will be changed. This will provide funding for:
    - children (under 18);
    - adults (malnourished and have tried first-line dietary measures);
    - adults transitioning from hospital Discretionary Community Supply;
    - specified short-term medical conditions; and
    - specified chronic diseases and tube feed patients.

    In addition the initial and renewal funding periods will change.
- The diabetic enteral and oral feeds access criteria will be amended to include a criterion relating to "weight loss and malnutrition that requires nutritional support."
- The Standard Supplements (1 kcal/ml powders and 1.5 kcal/ml ready-mixed liquids, with and without fibre) will be added to the Discretionary Community Supply list - DHB hospitals will be able to provide these products to patients living at home for 10 days prior to hospitalisation and 30 days following discharge without a Special Authority authorisation..

Patients who currently have a valid Special Authority will not be affected by these changes until their current Special Authority approval expires.

Background

Standard feeds can be used as a supplement to a patient's normal diet, or as a partial or complete replacement of a patient's normal diet. These products are available in a powder form which is reconstituted with water (1 kcal/ml) or milk (1.5 kcal/ml). They are also available in more expensive ready-mixed liquid forms and enteral feed forms. The powder and the ready-made liquids currently require separate Special Authority approvals for funding to be provided.

Current access to standard feeds is broad due to the inclusion of criteria such as "malnutrition requiring nutrition support", "failure to thrive", and "increased nutritional requirements", and anecdotal evidence suggests that these may be being used as a replacement for first-line approaches to nutritional care.

The UK National Institute for Health and Clinical Excellence (NICE) 2006 guidelines[3] for Oral Nutrition Support include definitions of malnutrition and the risk of malnutrition, in both the hospital and community settings, which incorporate the patient's BMI, their

[3] Nutrition support in adults Oral nutrition support, enteral tube feeding and parenteral nutrition (National Collaborating Centre for Acute Care, February 2006). http://www.nice.org.uk/Guidance/CG32/Guidance/pdf/English

percentage unintentional weight loss, the time over which the nutrient intake has been unintentionally reduced and the likelihood of future impaired nutrient intake.

The Special Foods Subcommittee considers it appropriate that PHARMAC incorporate a malnutrition definition and a requirement for a trial of other dietary measures into the Standard Supplement Special Authority criteria. The intention of this being to ensure that the funding of sip feeds is targeted by providing a clear funding framework for nutritional support.

Details of the decision

This decision will enable patients to switch between the standard 1.0-1.5 kcal/ml powder, ready-mixed liquids and enteral feeds (with and without fibre) without requiring a second Special Authority approval. It will also provide more specific access criteria with patients being able to access funding if they:

- are children;
- are adults who are malnourished and who have tried first-line dietary measures;
- are adults transitioning from hospital Discretionary Community Supply;
- have a specified short-term medical condition; or
- have a specified chronic disease, or require tube feeding.

A major change from the current access criteria is that adults (who do not have one of the specified conditions) are required to be malnourished (according to the NICE definition) and have tried first-line dietary measures such as food fortification prior to being eligible for funding – in addition the initial approval period has been reduced from 12 to 3 months.

To provide a transition from hospital to community care (e.g. for patients requiring nutritional support around certain surgical interventions) we have included oral supplements on the Discretionary Community Supply (DCS) list. This will enable patients who require additional nutrition prior to hospitalisation or where a short course following discharge is considered appropriate to obtain product from the DHB hospital without a Special Authority approval (at the cost/discretion of the relevant hospital).

Some patient groups while not being malnourished are at a higher risk of malnutrition. Access for a number of these patient groups and those requiring tube feeding has been accommodated through access being provided to a number of specified conditions.

From 1 April 2011:

- Standard Supplements will be available under the following Special Authority criteria:

  Initial application – **Children**.
  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. A nutrition goal has been set (eg reach a specific weight or BMI).

Renewal application – **Children**.
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 (e.g. reach a specific weight or BMI).

Initial application – **Adults**.
Approvals valid for 3 months for applications meeting the following criteria:
All of the following:
1. Any of the following:
   Patient is Malnourished
   - 1.1 Patient has a body mass index (BMI) of less than 18.5 kg/m2; or
   - 1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
   - 1.3 Patient has a BMI of less than 20 kg/m2 and unintentional weight loss greater than 5% within the last 3-6 months; and
2. Any of the following:
   First-line dietary measures
   Patient has not responded to first-line dietary measures over a 4 week period by:
   - 2.1 increasing their food intake frequency (e.g. snacks between meals); or,
   - 2.2 using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or,
   - 2.3 using over the counter supplements (e.g. Complan),
3. All of the following:
   Nutrition Goal:
   - 3.1 A nutrition goal has been set (e.g. to reach a specific weight or BMI)

Renewal application – **Adults**.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. A nutrition goal has been set (e.g. reach a specific weight or BMI); and,
2. Any of the following:
   Patient is Malnourished
   - 2.1 Patient has a body mass index (BMI) of less than 18.5 kg/m2; or
   - 2.2 Patient has unintentional weight loss greater than 10%within the last 3-6 months; or
   - 2.3 Patient has a BMI of less than 20 kg/m2 and unintentional weight loss greater than 5% within the last 3-6 months; and

Initial application – **Adults transitioning from hospital Discretionary Community Supply**.
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 (e.g. 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; and

Initial application – **Specific medical condition**.
Approvals valid for 1 year for applications meeting the following criteria:
The patient has any of the following:

1. Is being feed via a nasogastric tube or a nasogastric tube is to be inserted for feeding; or
2. Malignancy and is considered likely to develop malnutrition.as a result; or
3. is undergoing a bone marrow transplant; or,
4. Tempomandible joint surgery.

Renewal application – **Specific medical condition**.
Approvals valid for 1 year for applications meeting the following criteria:
The patient has any of the following:

1. Is being fed via a nasogastric tube; or
2. Malignancy and is considered likely to develop malnutrition.as a result; or
3. Has undergone a bone marrow transplant; or,
4. Tempomandible joint surgery.

Initial application – **Chronic disease OR tube feeding**.
Approvals valid without further renewal for applications meeting the following criteria:
The patient has any of the following:

1. Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria) ; or the patient has:
2. Cystic Fibrosis; or
3. Liver disease; or
4. Chronic Renal failure; or
5. Inflammatory bowel disease; or
6. Chronic obstructive pulmonary disease with hypercapnia; or
7. Short bowel syndrome; or
8. Bowel fistula; or
9. Severe chronic neurological conditions

Renewal application – **Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583**.
Approvals valid without further renewal for applications meeting the following criteria:
The patient has any of the following:

1. Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria) ; or the patient has:
2. Cystic Fibrosis; or
3. Liver disease; or
4. Chronic Renal failure; or
5. Inflammatory bowel disease; or
6. Chronic obstructive pulmonary disease with hypercapnia; or
7. Short bowel syndrome; or
8. Bowel fistula; or
9. Severe chronic neurological conditions

Patients who currently have a valid Special Authority will not be affected by this change until their current Special Authority approval expires.

- The diabetic enteral and oral feeds Special Authority criteria will be amended so that those eligible, in addition to being a Type I or II diabetic, will be required to be "suffering weight loss and malnutrition that requires nutritional support":

  Special Authority for Subsidy
  Initial application. Approvals valid for 1 year for patients with Type I or II diabetes who are suffering weight loss and malnutrition that requires nutritional support.

  Renewal. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

1 The treatment remains appropriate and the patient is benefiting from treatment.

- The following Standard Supplement will be added to the Discretionary Community Supply list (Part III of Section H of the Pharmaceutical Schedule) as follows:

SPECIAL FOOD SUPPLEMENT

Oral supplement 1kcal/ml, powder	900 g	Sustagen Hospital Formula
Oral supplement 1kcal/ml, powder	400 g	Ensure
Oral supplement 1kcal/ml, powder	900 g	Ensure
Oral feed 1.5kcal/ml liquid	200 ml	Ensure Plus
Oral feed 1.5kcal/ml liquid	237 ml	Ensure Plus
Oral feed 1.5kcal/ml liquid	200 ml	Fortisip
Oral feed with fibre 1.5kcal/ml liquid	200 ml	Fortisip Multi Fibre

For use in community/non-hospitalised patients for 10 days prior to hospitalisation and 30 days following discharge.

Feedback received during consultation

The proposals consulted upon were to:

- have a single Special Authority form for standard oral supplement powders and standard ready-mixed liquid and enteral feeds so that they could be used interchangeably;
- amend the Special Authority criteria for these products to include a malnutrition requirement and the use of other dietary measures (eg food fortification) prior to patients being eligible for funding – children and tube feed patients were exempt – and to reduce the initial approval periods from 3 years (cystic fibrosis) or 1 year (other) to 3 months;
- add standard 1 kcal/ml powder feeds and standard 1.5 kcal/ml liquid feeds (with and without fibre) to the DCS list; and
- include a requirement that the patient is experiencing "weight loss and malnutrition that requires nutritional support" to the Diabetic Products Special Authority criteria.

As a result of the consultation feedback a number of changes to the proposals were made. These changes include:

- altering the first-line dietary measures requirements so that patients are required to have increased their intake frequency OR used high-energy foods OR used over the counter supplements (the initial proposal required all to have occurred);
- the removal of the requirement that malnourished adults who have used other dietary measures also have a specific medical condition; and
- the provision of subsidy to the following three additional patient groups:
    - patients transitioning from hospital Discretionary Community Supply;
    - patients with a specific short-term medical condition; and
    - patients with a chronic disease or tube feeding.

The feedback received raised a number of issues in relation to the proposal. We would like to note these issues and provide the following responses:

Themes
Support - There was strong support for the proposal to merge the oral supplement and adult product standard sections of the Pharmaceutical Schedule as it would enable patients to easily switch between the powdered and ready-made liquid feeds without clinicians having to complete two Special Authority applications which may have renewals at different times.
Measurement of height and weight - If the malnutrition definition requires a height measurement then this may not be possible in many people (particularly the frail, old and those with physical disabilities) and therefore alternative measurements will need to be used (ulna, knee height or demi span) to estimate height. It is uncommon for height to be measured even in aged care hospitals. **PHARMAC response** - We acknowledge that it can sometimes be difficult to determine a patient's height and consider it appropriate for a height approximation to be used in such cases.
Malnutrition definition - There was strong support for the use of a standardised malnutrition protocol including the use of dietary measures as the first-line treatment option. However opinion was split as to whether a malnutrition screening or assessment tool should be used, and, given that they are validated in different patient groups (some are validated in older populations and general medicine while others are validated for acute care) which specific tool(s) should be used. A malnutrition definition including weight loss or a BMI is not always considered appropriate especially in patients with high energy requirements or where there is a high risk of malnutrition/weight loss in the acute setting. For example in cystic fibrosis, surgery, renal, liver disease, complex gastrointestinal problems, obstructive gastric tumours, head and neck cancer, short bowel syndrome. It was suggested that to ensure a validated tool is available for all patient populations a number of options could be included (for example: Malnutrition Screening Tool, Malnutrition Universal Screening Tool, MNA-SF, Subjective Global Assessment, Mini-Nutritional Assessment). **PHARMAC response** - While we considered these suggestions we have used NICE's definition of malnutrition to determine those eligible for subsidy. We acknowledge that the malnutrition definition adopted may not be appropriate for all patient groups especially those with high risk/need. We have therefore provided provision for higher risk/need patient groups (including acute patients) to be able to access subsidy on the basis of their disease state rather than actual or potential malnutrition status. This has been done through the addition of criteria specific to the patients transitioning from hospital Discretionary Community Supply, those with a specific short-term medical condition, and those with a chronic disease or being tube feed. Practitioners will still be able to use any assessment/screening tool that they wish; however eligibility for funding is according to the Special Authority eligibility criteria.
List of funded medical conditions - Some respondents considered that the list of medical conditions that would be funded should the patient be malnourished and have failed on other dietary measures is too restrictive and that it should be extended to include older adults with non-disease related malnutrition eating disorders and mental health conditions causing weight loss as they will experience similar negative health effects and burden the health system as those with disease related malnutrition. **PHARMAC response** - We have removed the requirement for the patient to have a specified medical condition as well as being malnourished and have tried first-line dietary measures.
Approval periods - Some respondents supported the proposed reduction in the initial Special Authority approval period from 12 or 36 months to 3 months as it would encourage timely review and would reflect best-practice, as well as reducing waste by preventing additional prescriptions for patients who no longer require a ready-made feed due to non-compliance or they have achieved their nutrition goals. Other respondents considered that the 3 months renewal would create an additional and excessive workload/administrative burden which had the potential to delay appropriate intervention. It was noted that prescriptions should be 3 monthly not Special Authority applications. Some responders considered that there should be a yearly renewal or even no renewal (lifetime Special Authorities) for chronic conditions, and others considered 2 years to be appropriate for people in residential care. **PHARMAC response** - We consider that a review at 3 month is appropriate for those with malnutrition as it is standard practice. However we consider that longer renewal periods are appropriate for those transitioning from hospital Discretionary Community Supply (6 months), patients with certain short-term medical conditions (1 year) and patients with a chronic disease or tube feeding (lifetime) to avoid excessive administration requirements.

Themes
Oncology - Oncology patients should be exempt from a 4 week trial of food fortification and over the counter supplements. Special Authorities should be valid for at least 1 year as it is the length of prescribing not the length of time of the Special Authority approval that is the issue. Most oncology patients, if they require ready-made liquid feeds require them during their treatment, in the recovery phase or to support their palliation which would be periods longer than 3 months. Head and neck cancer patients can need them for more than a year due to the degree of oral disability. **PHARMAC Response –** The Special Authority criteria exempts these patients from the need for food fortification, with an approval period of one year.
Diabetic Products Special Authority Criteria - It was suggested that the Special Authority be amended so that it has the same criteria as the standard powder and ready made liquid feeds. **PHARMAC Response** - We will review the criteria for the more specialised oral supplement products, including the diabetic products, once the access changes for the standard products have been implemented for a period of time, and we have been able to review their impact.
Discretionary Community Supply (DCS) - Including standard powder and ready-made liquid feeds on the DCS list was supported. Some respondents had concerns that some, or all DHBs, may not cover the cost and this may result in inequitable access. Some respondents considered that DCS listings should only occur if there is an agreement on how the cost shift from PHARMAC to DHBs would work. There were a number of suggestions of additional products (or in some instances all Special Foods) that could be put on the DCS list allowing a one month trial period. Particular products suggested included – the ready made milk-based liquid feeds (with and without fibre), the oral supplement powders, Monogen, Fortimel, Arginine-containing products, diabetic oral supplements, juice-based supplements, infant formula's, low LCT feed for post surgical chylothorax and paediatric patients requiring short term nutritional supplementation following surgery or acute illness. **PHARMAC Response** - The Discretionary Community Supply (DCS) list contains products that can be provided to patients for use in the community at the discretionary of the relevant DHB hospital – the DHB hospital would be paying for the product. As such any decision on what products, if any, will be provided by a DHB hospital is at its discretion. We may consider listing additional products on the DCS list, should these initial listings prove useful.
Cystic Fibrosis - The Australian Clinical Practice guidelines recommend the use of oral nutritional supplements in cystic fibrosis patients with a BMI < 20 or wt < 45 kg or if a > 5% weight loss has occurred over 2 months. **PHARMAC Response** - Cystic fibrosis is included in the chronic disease criterion, therefore all cystic fibrosis patients will be eligible for subsidy.
Children - There was support for the criteria for children. It was also noted that in paediatrics BMI percentile is a more appropriate measure for growth monitoring than a specific BMI and that the renewal for children should include an additional prerequisite that "supplements are required to maintain current nutritional status and/or weight, height and BMI percentiles". **PHARMAC Response** - We note the support for the proposed criteria for children.
Implementation - There were a number of comments regarding the implementation of any new Special Authority criteria. These noted the importance of providing enough education so that prescribers are able to diagnose and treat patients appropriately. Some responders considered that ideally patients would be assessed by a registered dietitian who could then advise on a patients requirements, although it was noted that if this was to occur there would be workforce issues. **PHARMAC Response** - We consider the provision of additional educational opportunities important and are providing a number of educational opportunities for practitioners – these are listed in the introduction to these changes.

Themes
Suggestions - The following suggestions were made: • Enable only 1 month of product to be dispensed at once – this would reduce wastage. • Improve prescribing practices so that patients are asked what flavours they like, realistic volumes are prescribed and there is a review prior to any additional prescriptions. **PHARMAC Response** - Given the range of clinical circumstances, there is a wide range of appropriate volumes. PHARMAC has less influence over dispensing frequency/quantity than it does over funding provision (through Special Authority). This makes managing volume through restrictions challenging. We also note that restricting the dispensing quantity would increase the number of dispensing fees. Once the impact of the proposed changes is known we would be able to assess the dispensing frequency and quantities and consider the suggested changes as appropriate. The provision of products on DCS will enable patients to indicate what flavours they like. We will consider inclusion of the above points in any educational materials.

Funding of Standard Adult Oral Feeds (Ready-Mixed Liquids and Powders)

Decision

From 1 April 2011:

- The standard powder oral feeds will be fully funded, while the subsidy for standard ready-made liquid feeds will be reduced to match the powder formulations.
- Ready-mixed liquid formulations will incur a part-charge unless suppliers reduce their prices to the level of the powders.

Background

Standard feeds can be used as a supplement to a patient's normal diet or as a partial or complete replacement of a patient's normal diet.

These products are available in a powder form which then needs to be reconstituted with water (1 kcal/ml) or milk (1.5 kcal/ml). They are also available in more expensive ready-made liquid forms (1.5 kcal/ml and 2.0 kcal/ml).

The Special Foods Subcommittee considered the powder and ready-mixed liquid feeds to have the same, or a similar, therapeutic effect. It also noted that the ready-mixed liquid feeds are preferred over the powders for a variety of reasons including convenience and portability.

Given the similarity in funding availability, usage and resulting expenditure on the ready-mixed liquids is much higher than the powders (in 2008/09 expenditure was $5.9 million versus $70,000).

Details of the decision

From 1 April 2011 the standard oral ready-made feeds 1.5 kcal/ml (with and without fibre) and standard oral ready-made feeds 2.0 kcal/ml liquid will be reference priced to the oral feed 1 kcal/ml powder on the basis of a cost of $0.0024 per ml of 1 kcal reconstituted liquid (with water) as follows:

Brand	Flavours	Pack size	Current Price	Current Subsidy	New Subsidy
Powder formulations					
Sustagen Hospital Formula	Chocolate, vanilla	900 g OP	$10.22	$10.22	$10.22
Ensure	Chocolate, strawberry, vanilla	400 g OP	$4.22	$4.22	$4.22
Ensure	Chocolate, vanilla	900 g OP	$9.50	$9.50	$9.50
Ready-mixed liquid formulations					
Fortisip	Banana, chocolate, strawberry, toffee, tropical fruit, vanilla	200 ml OP	$1.12	$1.12	$0.72
Ensure Plus	Banana, chocolate, fruit of the forest, strawberry, vanilla	200 ml OP	$1.45	$1.12	$0.72
Ensure Plus	Chocolate, coffee latte, strawberry, vanilla	237 ml OP	$1.33	$1.33	$0.85
Fortisip Multi Fibre	Chocolate, strawberry, vanilla	200 ml OP	$1.12	$1.12	$0.72
2 Cal HN	Vanilla	237 ml OP	$2.25	$2.25	$1.14

In the event that patients prefer the ready-mixed liquids, or find them more convenient, then they will be funded to the level of the powders. In the event that the suppliers do not reduce their prices, those choosing the ready-mixed products for some or all of their requirements would have to meet the additional costs.

Consultation

The change that has been adopted is consistent with the proposal consulted upon.

There was support for the proposal on the basis that patients contributing to the cost of the ready-made liquids may result in patients valuing the products and therefore reduce wastage and potentially improve compliance. There was also opposition to the proposal.

The feedback received raised a number of issues in relation to the proposal. We would like to provide the following responses to these issues as follows:

Issue	PHARMAC Response
Reference pricing is inappropriate - There was widespread disagreement with the proposal to reference price the ready-made liquid feeds to the powders on the basis that: ▪ The powders do not contain a full range of nutrients and may be low in fat or high in vitamin A when made up with milk. ▪ The powders can not be used in lactose intolerant patients. ▪ The calorie density is not comparable. ▪ Patients may not have the ability to take the required volume. ▪ Compliance may be an issue due to flavour fatigue, ease of use and convenience. ▪ Preparation errors and poor food hygiene may occur with the powdered products.	Both the powders and ready-mixed products are "concentrated" nutritional supplements containing essentially the same food benefit and having the same therapeutic effect. The powders are indicated as a complete diet and can be mixed with full fat milk or water. Lactose free powders are subsidised. The products can be modified through the use of additional powder, high calorie foods and full fat milk. The taste can be modified through the use of flavouring, flavoured milk or additives such as fruit. The potential for preparation errors and poor food hygiene occur with all foods. We acknowledge that the powders are not as easy to use/convenient as the ready-made liquids. If a patient prefers a ready-made liquid on this basis, the patient can receive the subsidy benefit applied to the powders, and make a contribution towards the extra cost of the ready-mixed products.
Financial effect - a part-charge on ready-made liquid feeds could place financial pressure on vulnerable patients especially the elderly, sick, those with a low income and those on a disability allowance or the sickness or unemployment benefits.	We acknowledge that a patient surcharge on ready-made liquid feeds would result in an additional cost to patients. However the powdered alternatives would be available fully funded.
Bolus feeding – bolus feeding in patients being tube feed requires ready-made liquids as these are available in smaller volume sealed containers and are more practical and convenient than decanting volumes out of enteral feed packs due to the requirement to warm the product, the risk of bacterial growth, decanting can be messy, and there is less wastage.	These concerns are largely as a result of patients needing a more convenient, smaller enteral feed pack size. Previously only a larger volume was subsidised. We have recently fully funded some smaller packs of enteral feeds that can be used as bolus feeds which should address this concern.

Issue	PHARMAC Response
Anorexia - making up a powder is not realistic for patients with anorexia	It is not clear that compliance would be any poorer with a reconstitutable powder than with ready-made products. We are always open to considering clinical evidence that may demonstrate different benefits between groups of people, and re-considering the funding provided as a result.
Crohn's Disease - the first line treatment is enteral nutrition – i.e. 6-8 packs of 1.5 kcal/ml adult ready made liquid feeds per day for 6-8 weeks (equals $60-$80 per week) - with the hope of inducing remission. As the patients must only take supplementary feeds, to have the best chance of inducing remission, it is preferable that they are fully funded. The alternative treatment is corticosteroids (i.e. prednisone) which have significant adverse effects in children including growth restriction and decreased bone mineral density – 15 to 20 patients per year).	The powders would be available fully subsidised for these patients. The powder products can be modified and enhanced, as described elsewhere in this document. If a ready-made liquid is preferred the subsidy benefit applied to the powders can be obtained, with a contribution towards the extra cost of the ready-mixed products.
Cystic Fibrosis - Cystic fibrosis patients require about 1.5 to 1.8 times the recommended dietary allowances of energy and protein in addition to a greater intake of all other nutrients. 2 to 6 packs of Fortisip/Ensure Plus ready-made liquid feeds are usually prescribed, this would equate to $10.64 to $38.22 per week. 2.0 kcal/ml products should be fully funded for patients with cystic fibrosis or intestinal failure.	
Children (8 to 18 yrs old) - Standard adult ready-made liquid feeds should be fully funded for children as: • growing children with disease related malnutrition, have greater requirements and are at increased risk of malnutrition – they often need 120-150% of normal requirements i.e. cystic fibrosis patients – therefore if the family can't afford the cost of sip feeds then the child would be hospitalised; and • long term use of ready-made liquid feeds are unlikely as children are monitored by dietitians.	

Additional Comments
• There has been an increase in the use of enteral feeds due to its increased use, children with enteral feeding moving to adult formula, and the cessation of "home-made" enteral feeds i.e. pureed home cooked foods. • Special Foods are not always used in place of foods, but often in addition to foods due to increased requirements. Thus patients using ready-made liquid feeds on a complete diet do not incur lower food costs than those in the general population. • Comparing the cost of food (based on a food cost survey) in a well population and an unwell

population is a gross over simplification.

- We acknowledge that it may be necessary to introduce a part charge.
- Minimise the part charge on ready-made liquid feeds by extending it to include patients using enteral feeds or tube feeds (the food costs for these patients are lower).
- If reference pricing is to occur, the reference price holder for 2.0 kcal/ml products should be the 1.5 kcal/ml ready made liquid feeds not Sustagen.
- Have a capped part charge for all products to prevent discrimination against high volume products i.e. $1 to $2 per product (ready made liquid feeds, powder, enteral) to a maximum of $8 per day.
- Apply the following co-payments:
    - powders - $4 per 900g (about $4 per week)
    - ready made liquid feeds - $0.75 per 200ml (about $10.50 per week)
    - enteral feeds - $2.50 per litre (about $26.25 per week).
- Fully fund adult ready made liquid feeds for children aged 10-18 years.

Gluten Free Food

Decisions

From 1 April 2011:

- The funding of gluten-free foods will no longer be actively managed by PHARMAC (i.e. no access, product or subsidy changes will occur).

Background

A gluten free diet is recommended for those with coeliac disease and dermatitis herpetiformis. There are two types of gluten-free foods that are available for those requiring a gluten free diet:

- **naturally gluten-free foods** - foods that naturally do not contain gluten (e.g. fruits, vegetables, beef, poultry, fish, nuts, eggs, rice and potatoes)
- **gluten-free substitute foods** - foods that have been developed by manufacturers as alternatives to products that naturally contain gluten (e.g. breads, pasta).

In response to increasing interest in gluten-free products by consumers, a growing number of gluten-free alternatives are being developed.

Currently a number of gluten-free substitute foods are subsidised (i.e. flour, bread mix, baking mix and pasta) although none are fully funded. The ability of pharmacies to mark-up the unfunded portion of the cost means that the part-funding philosophy of funding costs additional to usual food cannot be delivered. Consequently, the use of these subsidised listings is very low, and almost non-existent in some areas. Gluten free foods, and gluten free substitutes, are widely available through retail outlets and in some cases may be less expensive than obtaining the subsidised product.

Details of the decision

From 1 April 2011 the following note will be added under the Gluten Free Foods heading in Section D of the Pharmaceutical Schedule:

> *The funding of gluten free foods is no longer being actively managed by PHARMAC from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten-free options are available through retail outlets.*

As we are ceasing active management of the subsidies for these listings (as opposed to delisting these products) - there would, in effect, be an extended transition to cessation of subsidies. This approach will minimise disruption to the direct-distribution model presently operating in some locations, and enable ongoing work by DHBs and PHARMAC that relates to national approaches to distribution of Special Foods to be completed.

Feedback received during consultation

The proposal consulted upon was to cease active management of gluten free foods. No changes to the original proposal have been made.

The feedback received raised a number of issues in relation to the proposal. We would like to provide the following responses to these issues as follows:

Themes
Health effects - Consultation responders noted that there are a number of adverse health outcomes that patients with Coeliac disease or dermatitis herpetiformis may get if they do not consume a gluten-free diet. These include osteoporosis, infertility, miscarriages, depression, dental enamel defects, diabetes, cancer, arthritis, depression, pancreatic disease, central and peripheral nervous system disease, vitamin K deficiency, disorders of the gall bladder, liver and spleen, thyroid disease and increased risk of gastrointestinal and oesophageal carcinoma. **Cost of gluten free foods** - The cost to patients if they want to adhere to a gluten free diet is much higher (usually 3 to 4 times but could be more) than the cost of normal (non-gluten free) foods and this is one of the reasons that Coeliacs struggle to maintain a gluten-free diet (e.g. standard canned spaghetti is $0.99 while gluten free spaghetti is $5 plus). Therefore if patients can't access subsidies they won't stay on a gluten free diet, especially if they have fixed and limited incomes. This would result in declining health ultimately further burdening the health system – these additional health sector costs should be considered in any decision. **PHARMAC Response** - Gluten free foods, and gluten free substitutes, are widely available through retail outlets and in some cases may be less expensive than obtaining the subsidised product. Given the range of options that are generally available we have decided that, over time, the range of subsidies for gluten free substitutes would reduce. The cost of food would therefore be borne by people out of their own income/means. This decision would not be expected to immediately alter the current situation in terms of out of pocket expenses, for most patients.
Alternative proposals/suggestions - The following suggestions were made by responders: ▪ The list of prescription gluten free foods should be extended rather than reduced with breakfast cereals being added at a minimum. ▪ PHARMAC should annually review gluten free subsidies so that they keep pace with the price of the products. ▪ PHARMAC should pay every Coeliac patient, diagnosed via biopsy, an annual set fee to purchase gluten free food from a supplier of their choice.

Foods and Supplements for Inborn Errors of Metabolism

Decisions

From 1 April 2011:

- Patients with inborn errors of metabolism will be eligible for lifetime Special Authority approval for supplements and low protein baking mix and pasta.
- Low protein baking mix and pasta will be fully funded.

Background

Inborn errors of metabolism (IEM) are genetic conditions which disrupt specific amino acid pathways. These can, depending upon the amino acid, result in mental retardation, progressive neurological degeneration, higher risks of strokes and other debilitating symptoms.

IEM are life-long and life-threatening conditions which require patients to have very strict and complex diet regimens. These include low protein food and specific amino acid supplements – although some conditions do not require the specific supplements (e.g. urea cycle disorders). Patients therefore often have very restricted dietary options with alternate food options/supplements not being readily available through retail outlets, and being very costly.

Currently patients are required to demonstrate compliance to the diet prior to being able to access subsidy for the foods and supplements. 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 show compliance, through low phenylalanine blood concentrations, without having access to the foods and supplements in the first place. The cost of these is prohibitively high, with the average patient cost being more than $20,000 per annum. In addition, it is important that women do not have high phenylalanine levels during pregnancy and the current requirements create barriers to access for these patients.

Details of the decision

From 1 April 2011:

- The current Prescribing Guideline and Special Authorities (SA0732, SA0733 and SA0962) that apply to Foods and Supplements for Inborn Errors of Metabolism (Other and PKU) will be removed.
- The headings “Foods and Supplements For Inborn Errors Of Metabolism – Other” and “Foods and Supplements For Inborn Errors Of Metabolism – PKU” will be deleted with all products being listed under a new heading “Foods and Supplements For Inborn Errors Of Metabolism”.
- All the currently listed products will be listed under the new “Foods and Supplements For Inborn Errors Of Metabolism” heading and patients eligible under the following Special Authority will be funded for any of these products:

  Special Authority for Subsidy

  Approvals valid without further renewal unless notified for applications meeting the following criteria:

  Any of the following:

  1 Dietary management of homocystinuria; or

  2 Dietary management of maple syrup urine disease; or

  3 Dietary management of phenylketonuria (PKU); or

  4 For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy.

- Phenyl free baking mix and phenyl free pasta will be renamed low protein baking mix and low protein pasta, in addition these products will be fully funded as follows:

Form	Brand	Pack size	Price	Current Subsidy	New Subsidy
Low protein baking mix					
Powder	Loprofin Mix	500 g OP	$8.22	$6.70	$8.22
Low protein pasta					
Animal Shapes	Loprofin	500 g OP	$11.91	$10.65	$11.91
Lasagne	Loprofin	250 g OP	$5.95	$5.32	$5.95
Low protein rice pasta	Loprofin	500 g OP	$11.91	$10.65	$11.91
Macaroni	Loprofin	250 g OP	$5.95	$5.32	$5.95
Penne	Loprofin	500 g OP	$11.91	$10.65	$11.91
Spaghetti	Loprofin	500 g OP	$11.91	$10.65	$11.91
Spirals	Loprofin	500 g OP	$11.91	$10.65	$11.91

Feedback received during consultation

The proposal consulted upon was to:

- remove the Special Authority requirement for PKU foods (it would remain for PKU supplements); and
- remove the requirement that pregnant women and patients under 16 have to demonstrate compliance to a PKU diet for 12 months in order to access subsidies for PKU supplements.

Following careful consideration of the consultation responses, including suggestions put forward, changes to the proposals were made.

These changes included maintaining the specific supplements and foods (low protein baking mix and pasta) under the same Special Authority criteria, fully funding these products for all patients with inborn errors of metabolism, and removing the renewal requirement.

The feedback received raised a number of issues in relation to the proposal. We would like to note these issues and provide the following responses:

Themes
In addition to exempting pregnant women from having to show dietary compliance to the low amino acid diet, those planning a pregnancy should also be exempt. Patients with inborn errors of metabolism (including PKU, homocystinuria, maple syrup disease, organic acidaemias and urea cycle disorders) should be prescribed both low protein foods and specific low amino acid supplements (with the exception of urea cycle disorders where only low protein foods may be appropriate), therefore a single Special Authority for both the low protein foods and the specific supplements would be appropriate – low protein foods should not be used alone as this can lead to neurological stroke as a result of developing a B12 deficiency and amino acid supplements would not be used by other patients due to the unusual and unpleasant taste. Rename the foods for inborn errors of metabolism from phenyl free baking mix and pasta to low protein baking mix pasta. Remove the renewal requirement that applies to the Special Authorities.
PHARMAC Response
We have included all of these suggestions in the new Special Authority criteria.