Special Foods Subcommittee meeting held 14 October 2009

(minutes for web publishing)

Special Foods Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Special Foods Subcommittee meeting; only the relevant portions of the minutes relating to Special Foods Subcommittee discussions about an application or PHARMAC staff proposal that contain a recommendation are published.

The Special Foods Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 25 & 26 February 2010, the record of which is available on the PHARMAC website.

Contents

1 Infant formula for gastrointestinal and other malabsorption problems Special Authority and Sole Supply

Application

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

Recommendation

1.2 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 malsorption
- 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 oesopagitis 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

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

1.4 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.

1.5 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.

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

1.7 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.

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

1.9 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.

1.10 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.

1.11 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.

1.12 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.

1.13 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.

2 Special Foods Funding Arrangements

Application

2.1 The Subcommittee considered whether the philosophy that a patient should incur no more or no less financial burden for purchasing more specialised and expensive Special Food products, as a result of their medical condition, than the general population in terms of food costs should be applied more consistently within the Special Foods therapeutic group.

Recommendation

2.2 The Subcommittee **recommended** that PHARMAC staff should apply across all Special Food therapeutic groups, the philosophy that a patient should incur no more or no less financial burden for purchasing more specialised and expensive Special Food products, as a result of their medical condition, than the general population in terms of food costs.

Discussion

2.3 The Subcommittee noted that this philosophy is applied to most infant formula's, PKU food/pasta and gluten free foods resulting in a patient part-charge (equivalent to the price differential of the subsidised Special Food and a equivalent product in a supermarket), but that it is not applied to some infant formula and all oral/enteral feeds which are fully funded.

2.4 The Subcommittee considered that patients should contribute up to the cost of food incurred in a normal diet when Special Foods are used as a total diet or when they are used to replace food within a total diet. The Subcommittee

considered that in these situations a patient's contribution could be in the form of a part-charge or another mechanism if administratively appropriate.

2.5 The Subcommittee considered that it would be appropriate for patients to receive subsided Special Foods when they are used as a supplement to a total diet.

2.6 The Subcommittee considered that PHARMAC staff should seek the advice of surgeons in determining which patients require an increased calorific requirement. However the Subcommittee noted that this would likely include patients such as those with inflammatory bowel disease, poor absorption, inflammation, infection and cystic fibrosis.

2.7 The Subcommittee considered that generally patients would accept the concept that they should not have the equivalent of their food cost subsidised.

2.8 The Subcommittee considered that more difficult patient groups to implement the policy in would include:

2.8.1 Infants who can not be breast feed and require enteral tube feeding.

2.8.2 Coeliac patients where the alternative is considered to be solely rice, corn, some grains and potatoes.