

Special Foods Subcommittee teleconference meeting held

Wednesday 26 September 2012

(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.

Some material has been withheld, in accordance with the Official Information Act 1982 (OIA) in order to protect the privacy of natural persons (section 9(2)(a)).

These Subcommittee minutes were reviewed by PTAC at its meeting on 9 & 10 May 2013, the record of which is available on the PHARMAC website.

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1 Heparon Junior as a replacement for Generaid Plus

Application

- 1.1 The Subcommittee reviewed an application from Nutricia to list Heparon Junior on the Pharmaceutical Schedule as a replacement for Generaid Plus for the treatment of infants (0 to 1 years old) and children (1 to 10 years old) with liver disease (acute and chronic).

Recommendation

- 1.2 The Subcommittee **recommended** that Heparon Junior is listed on the Pharmaceutical Schedule as a replacement for Generaid Plus for the treatment of children with liver disease with a high priority.
- 1.3 The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Discussion

- 1.4 The Subcommittee reviewed an application from Nutricia seeking to delist Generaid Plus and replace it with Heparon Junior for infants (0 to 1 years old) and children (1 to 10 years old) with liver disease (acute and chronic) due to the worldwide discontinuation of Generaid Plus.
- 1.5 The Subcommittee noted that currently Pepti Junior and Generaid Plus are being used in infants and children with liver disease with the transition from Pepti Junior to Generaid Plus occurring at around 4 to 6 months even though Generaid Plus is not recommended for use for children under 1 year of age.
- 1.6 The Subcommittee noted that Heparon Junior is a specific liver disease formulation for infants and children.
- 1.7 The Subcommittee compared Heparon Junior to Generaid Plus. The Subcommittee noted that both products had branched chain amino acids (BCAA) and were low in sodium. The Subcommittee also noted that Heparon Junior had increased fat soluble vitamins and minerals which would remove/reduce the need for additional vitamin and mineral supplementation.
- 1.8 The Subcommittee noted that there was only one study supplied supporting the safety and efficacy of Heparon Junior (Houchin et al, Safety and efficacy of Heparon Junior in infants with cholestatic liver disease, JPGN 2010 (50) suppl 7: E53).
- 1.9 However the Subcommittee considered that some comfort is provided in that the nutritional profile of Heparon Junior is essentially equivalent to Generaid Plus but with nutritional advantages in its fat soluble vitamin and mineral content and that reports from the United Kingdom indicate that Heparon Junior is a useful product.
- 1.10 The Subcommittee considered that Pepti Junior would still be used in patients under 1 year of age.

- 1.11 The Subcommittee noted that the proposed price of Heparon Junior was the same as the current price of Generaid Plus and therefore considered the proposal cost-neutral to the Pharmaceutical Budget.
- 1.12 The Subcommittee recommended the listing of Heparon Junior with a high priority given the discontinuation of Generaid Plus.
- 1.13 The Subcommittee noted that other products potentially available that could be used in this patient group included Hepatamine and Hepatical. The Subcommittee noted that Hepatamine is a supplement which is available in Australia and that Hepatical is a full feed which is available in the United Kingdom. The Subcommittee considered that a full feed is more appropriate than a supplement. The Subcommittee considered that Heparon Junior was appropriate for children but was open to considering another product for adolescents and possibly adults.
- 1.14 The Subcommittee noted that the current Generaid Plus Special Authority only included patients on the liver transplant list but not patients with end-stage liver disease whose condition required a liver transplant but who were not on the waiting list. The Subcommittee recommended that the Special Authority criteria is amended as follows (changes in bold and strikethrough):

1.14.1 Approvals valid for 3 years where the patient is a child (up to 18 years) who ~~is awaiting liver transplant~~ **fits the medical criteria for a liver transplant.**

2 Fortisip Compact Protein

Application

- 2.1 The Subcommittee reviewed an application from Nutrica for the listing of its 2.4 kcal/ml liquid oral feed with 18g of protein (Fortisip Compact Protein) on the Pharmaceutical Schedule.

Recommendation

- 2.2 The Subcommittee **recommended** that Fortisip Compact only be listed on the Pharmaceutical Schedule if cost-neutral to the Pharmaceutical Schedule.
- 2.3 The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Discussion

- 2.4 The Subcommittee noted that the application was for a 2.4 kcal/ml liquid oral feed (Fortisip Compact Protein) which provided 300 kcal and 18g of protein in a 125 ml bottle.
- 2.5 The Subcommittee noted that it had reviewed an application for Fortisip Compact at its 2010 meeting. The Subcommittee noted that the current application was for this

product but with a higher protein content (18g versus 12g per bottle). The Subcommittee noted that in considering Fortisip Compact in 2010 that it had noted that there was no evidence provided that indicated that Fortisip Compact provided a health benefit over currently available products, that there was no unmet clinical need for Fortisip Compact, and that it had recommended that Fortisip Compact be listed only if cost-neutral. The Subcommittee noted that Nutricia had not sought to progress the funding of Fortisip Compact at the time of the present application.

- 2.6 The Subcommittee noted that currently a number of standard liquid feeds are funded including 1.5 kcal/ml Fortisip and Ensure Plus products which provide 300 to 355 kcal's with 12 to 13 g of protein in 200 ml to 237 ml packs, 2.0 kcal/ml Two Cal HN which provides 474 kcal's with 19.9 g of protein in a 237 ml pack, and the 2.0 kcal/ml ready to hang Two Cal HN and Nutrison Concentrated products. The Subcommittee noted that the ready to hang products are fully funded and that the oral feeds are referenced priced to the powder alternatives on a price per kcal basis but that they are fully funded for patients being tube fed.
- 2.7 The Subcommittee considered that Two Cal HN as an oral feed and Nutrison Concentrated and Two Cal HN RTH as enteral feeds are the most appropriate comparators for Fortisip Compact and Fortisip Compact Protein.
- 2.8 The Subcommittee noted that the application indicated that Fortisip Compact Protein is not intended to be used as a sole source of nutrition and that the recommended intake is 1 to 2 bottles per day.
- 2.9 The Subcommittee noted that Fortisip Compact Protein was a concentrated oral feed which provided a high energy and protein content.
- 2.10 The Subcommittee considered that in addition to energy and protein patients also require hydration to meet their fluid requirements. The Subcommittee considered that Fortisip Compact Protein would not meet a patient's hydration needs and therefore an alternative would be to use less concentrated products which would also provide additional fluid.
- 2.11 The Subcommittee noted that the only trial presented in the application was "A pilot study investigating compliance and efficacy of a novel low volume energy dense (2.4 kcal/ml) multi-nutrient supplement in malnourished community patients (Hubbard, G.P., Holdaway, A. and Stratton, R - ESPEN 2009 Poster) where 31 community-based patients at risk of malnutrition (52% medium risk and 48% high risk using MUST) were offered two bottles of Fortisip Compact daily in addition to diet for 4 weeks. The Subcommittee noted that after the 4 week period the mean weight and BMI of the patients had increased from 52.1 kg to 53.0 kg ($p=0.009$) and 20.3 kg/m^2 to 20.6 kg/m^2 ($p=0.004$) respectively. However, the Subcommittee noted that the application is for Fortisip Compact Protein while the study used Fortisip Compact, and the study did not compare the effectiveness of Fortisip Compact with the currently funded products. The Subcommittee therefore considered that the study provided no information as to whether Fortisip Compact Protein would result in better health outcomes or even a gain in weight/BMI when compared to the currently funded products such as Two Cal HN.
- 2.12 The Subcommittee noted that the application referred to the following systematic reviews and meta-analysis, although these were not provided.
- 2.13 The Subcommittee noted that the publications by Milne, AC. Potter, J. Vivanti, A. and Avenell, A. (Protein and energy supplementation in elderly people at risk from

malnutrition. Cochrane Database Syst Rev 2009;(2): CD 003288); Milne, AC. Avenell, A. and Potter, J. (Meta-analysis:protein and energy supplementation in older people. Ann Intern Med 2006; 144 (1):37-48); and Stang, I. Bartram, M. Liao, Y. Poschl, K. Stehle, P. Sieber, CC. and Volkert, D. (Low-volume, energy and nutrient dense oral nutritional supplement improves nutritional status of nursing home residents. Geriatrics II PP035-Mon :127) provided little information as the trials compared oral nutritional supplements with placebo or standard care, rather than Fortisip Compact Protein with the currently funded treatment options.

- 2.14 The Subcommittee noted that the systematic review and meta-analysis by Cawood, AL. Elia, M. and Stratton, RJ. (Systematic review and meta-analysis of the effects of high protein oral nutritional supplements. Ageing Research Reviews 11 2012: 278-296) included an analysis of three trials of standard oral nutritional supplementation (<20% energy from protein) with high protein oral nutritional supplementation (>20% energy from protein) which found that most outcomes were not significantly different and concluded that there was inadequate information to compare standard oral nutritional supplements with high protein oral nutritional supplements.
- 2.15 The Subcommittee considered that there was no evidence provided that indicated that Fortisip Compact Protein provided a health benefit over the currently funded products. The Subcommittee also considered that patients' liquid requirements would not be met with more concentrated nutritional supplements such as Fortisip Compact and Fortisip Compact Protein.
- 2.16 The Subcommittee noted that the current funding is on a cost per kcal basis and that on this basis Fortisip Compact Protein is a cost over the currently funded options such as Two Cal HN.

3 Food Thickeners

Application

- 3.1 The Subcommittee reviewed a PHARMAC staff memorandum regarding the funding of food thickeners in the Community and Hospital for the treatment of dysphagia and gastro-oesophageal reflux in premature hospitalised babies.

Recommendation

- 3.2 The Subcommittee deferred making a decision on the funding of food thickeners until it had the opportunity to consider the opinions, and any additional evidence provided by, other relevant clinical groups including Speech Language Therapists, Geriatricians, and Neurologists.

Discussion

- 3.3 The Subcommittee noted that currently food thickeners are only funded in the Community for patients with motor neurone disease with a swallowing disorder with the funded option being limited to Karicare Food Thickener. The Subcommittee noted that in the hospital setting food thickeners were being used for additional patient groups and that this including both powders and pre-thickened drinks.
- 3.4 The Subcommittee noted that standards for the provision of thickened fluids (mildly thick, moderately thick, and extremely thick) and texture modified foods (soft, minced

and moist, and smooth pureed) have recently been developed and are becoming a routine part of the assessment and management of feeding and swallowing difficulties.

- 3.5 The Subcommittee noted that food thickeners are promoted on their ability to make consuming liquids and foods easier and that they provide a clinical benefit by enhancing swallowing ability and therefore reducing aspiration of food and liquids thus reducing any consequential aspiration pneumonia.
- 3.6 The Subcommittee noted that while it had previously discussed the funding of food thickeners a number of times; including the role of cornstarch, the lack of equitable access, the use of disease state to determine access rather than swallowing ability, the use, need for, and availability of Speech Language Therapist review, and the cost implications; it had never reviewed the evidence base to determine whether food thickeners result in clinically beneficial outcomes such as reduced aspiration pneumonia.
- 3.7 The Subcommittee noted a number of papers provided by PHARMAC staff and concluded that while these promote the use of food thickeners there is little evidence of a clinically beneficial effect.
- 3.8 The Subcommittee noted a review by Campbell-Taylor (Oropharyngeal Dysphagia in Long-Term Care: Misperceptions of Treatment Efficacy" JAMDA September 2008). The Subcommittee noted that the review maintained: there is a paucity of high quality evidence for the efficacy of food thickeners in preventing aspiration and that food thickeners often create risk of dehydration in older patients; aspiration of thickened fluids does occur with a resulting risk of pneumonia; aspiration of saliva is a risk factor for aspiration pneumonia due to its microbial content and it's postulated that following aspiration of thickened fluids, the cilia of the lungs are incapable of moving the solid material.
- 3.9 The Subcommittee noted an editorial on the Campbell-Taylor article by Thomas (Hard to Swallow: Management of Dysphagia in Nursing Home Residents" JAMDA September 2008). The Subcommittee noted that the editorial maintained: that while the article is controversial the conclusions are consistent with other previously published reviews; that while the data supporting dietary modification and thickened liquids are not overwhelming dietary modification would seem reasonable if it did no harm, however the data suggest that diet modification is not very effective in reducing aspiration or pneumonia and may lead to inadequate intake of nutrients and fluids.
- 3.10 The Subcommittee considered the use of food thickeners in the treatment of gastro-oesophageal reflux in paediatric patients with particular consideration of including these in the hospital formulary for premature hospitalised babies.
- 3.11 The Subcommittee noted a review and meta-analysis by Horvath et al ("The Effect of Thickened-Feed Interventions on Gastroesophageal Reflux in Infants: Systematic Review and Meta-analysis of Randomised, Controlled Trials" Pediatrics 2008) which evaluated the efficacy and safety of thickened feeds in the treatment of gastro-oesophageal reflux in healthy infants from 14 randomized, controlled trials. The Subcommittee noted that this concluded that while some outcomes were statistically significant, the effect may be of questionable clinical significance and that more data are needed.
- 3.12 The Subcommittee also noted a 2009 Cochrane Review by Huang et al (Feed thickener for newborn infants with gastro-oesophageal reflux) which evaluated the

use of feed thickeners in reducing signs and symptoms of GOR, acid episodes on pH monitoring and histological evidence of oesophagitis in neonates which found that there is no current evidence to support or refute the use of feed thickeners in treating newborn babies with gastro-oesophageal reflux.

- 3.13 Overall the Subcommittee considered that from the information that it had reviewed there was insufficient evidence to support the use and funding of food thickeners in dysphagia or in the neonatal/paediatric setting.
- 3.14 The Subcommittee considered that it would be appropriate to obtain opinion on these conclusions from other clinical specialities.
- 3.15 The Subcommittee noted that PHARMAC staff had sought an opinion from the New Zealand Speech Language Association but that this was not available at the time of the meeting. The Subcommittee noted a previous opinion from the Association, and other feedback from the Speech Language Sector, supporting wider access, more funded options and greater involvement of Speech Language therapists. The Subcommittee noted that reference was made to food thickeners resulting in reduced hospitalisations for illnesses such as aspiration pneumonia.
- 3.16 The Subcommittee noted that Speech Language Therapists were often involved in determining the need and type of food thickener and that Speech Language Therapist assessment may, or may not, involve the use of video fluoroscopy. The Subcommittee noted that a limitation of video fluoroscopy is that it is resource intensive and does not account for changes in the condition of the patient over time.
- 3.17 The Subcommittee noted that there is a disparity in the use of free water for dysphagia in the South Island with it being used in Canterbury and Southland but not being used in Dunedin and Nelson.
- 3.18 The Subcommittee considered that PHARMAC should ask the New Zealand Speech Language Association to provide evidence indicating whether food thickeners provide clinically beneficial outcomes such as reduced aspiration pneumonia.
- 3.19 The Subcommittee concluded that on the basis of the evidence that it had reviewed that it would be appropriate for food thickeners not to be funded in the Community. The Subcommittee also concluded that at this time the evidence did not support the use of food thickeners in hospitals but that this may be appropriate for a short period (not more than one year) in acute patients.
- 3.20 The Subcommittee considered that prior to any decision being made that PHARMAC staff should obtain opinions, which include how food thickeners are currently being used and a review of the relevant evidence, from Speech Language Therapists, Geriatricians, and Neurologists.
- 3.21 The Subcommittee also considered that the opinion of a senior lecturer in speech language therapy should also be obtained.