NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

16 May 2013

Decisions relating to hospital medicines funding

PHARMAC is pleased to announce that a further decision has been made to establish a nationally-consistent list of medicines to be funded within DHB hospitals. This decision relates to a consultation letter dated 25 February 2013.

These decisions establish the final six (of sixteen) 'therapeutic groups' that will make up the list of medicines to be funded in DHB hospitals, which will be contained in Section H of the Pharmaceutical Schedule: Blood and Blood Forming Organs, Extemporaneously Compounded Preparations, Oncology Agents and Immunosuppressants, Special Foods, Vaccines and Various.

All of the consultation letters relevant to this work are available on PHARMAC's website:

www.pharmac.health.nz/medicines/hospital-pharmaceuticals

Details of the decision

Following consultation, some changes were made to the proposal. Additional items to be listed in Section H include:

- alpha tocopheryl acetate;
- zinc oral drops;
- oral magnesium presentations;
- citrate locks;
- polidocanol;
- additional presentations of glucose/carbohydrates for hypoglycaemic episodes;
- additional intravenous fluids;
- defibrotide;
- citrate hemofiltration bags;
- electrolyte cold storage solution;
- pediasure powder;
- aspartate-glutamate; and
- thrombin powder.

Other than these changes, the decision broadly reflects what was proposed in the consultation document.

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Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received were considered in their entirety in making a decision on the proposal. The following key issues were raised in relation to specific aspects of the proposal:

Feedback	Discussion
Blood and Blood Forming Organs	
Responders requested that ferric carboxymaltose be included, as it allows for a more rapid administration of iron.	PTAC has recommended that this should only be listed in the Schedule if it was cost-neutral compared with iron polymaltose.
Responders requested that potassium iodate tablets be included.	We note that these were excluded from the consultation document in error, as they are subsidised in the community. These have been included in the proposed list.
Respondents noted that abciximab is currently used for intra-cranial interventions.	We have amended the prescribing restrictions to accommodate this use.
One responder requested that Centrum or a similar general multivitamin/mineral product be included for adults.	We consider that this should be a community-led funding decision, and we would welcome a funding application for this.
A respondent requested that prescribing restrictions for bivalirudin, danaparoid and fondaparinux be extended to cover patients with heparin intolerance or heparin resistance.	We have amended the restrictions to cover these situations.
One responder suggested that a multivitamin product for patients with chronic kidney disease be included.	We consider that this should be a community-led funding decision. We note that a funding application has been reviewed by PTAC and recommended with a medium priority for a population of people with CKD.
Responders noted that the proposal was to exclude pegfilgrastim, and requested that this be included, noting a preference for this over filgrastim.	We note that we have recently negotiated an agreement with Roche for the inclusion of pegfilgrastim in Section H, and consultation on this proposal has recently closed.
Wairarapa DHB requested that a 75 mg presentation of aspirin be included.	A 100 mg aspirin is subsidised in the community, and we consider that a 75 mg presentation should only be available in Section H if it becomes subsidised in the community.

Feedback	Discussion
Some responders questioned the proposed prescriber-type restriction for filgrastim.	We note that other prescribers would be able to prescribe filgrastim, providing that they are operating within an established protocol, or following recommendation by an oncologist or haematologist.
A responder requested that tinzaparin be included, as they consider it to be the preferred low molecular weight heparin in obstetrics.	Our clinical advice has been to exclude tinzaparin from Section H, as enoxaparin and dalteparin are considered to be appropriate for use, and having a third LMWH product would result in increased risks.
A responder suggested that the short-term use of prasugrel following STEMI be extended to provide on-going funding for patients following discharge.	This short-term use of prasugrel is in line with the clinical advice we have received. We would welcome a further funding application for the extended use of prasugrel in this setting.
A responder requested that IV ascorbic acid be included.	We would welcome a funding application for the inclusion of IV ascorbic acid.
A responder requested that tirofiban be included.	The Cardiovascular Subcommittee recommended that tirofiban only be included in Section H if it was cost-neutral compared with eptifibatide; we remain open to including it in the future.
A responder considered that it would be useful to have alteplase syringes available.	We would be willing to consider listing this presentation should it gain regulatory consent.
Responders requested that additional products for metabolic patients be included, such as co-enzyme Q10 and pantothenic acid.	We consider that these should only be included if they are subsidised in the community, and we would welcome a funding application for these.
Oncology Agents and Immunosuppressants	
Responders noted that gefitinib had been excluded from the consultation document, although it is subsidised in the community.	We note that this was excluded from the consultation document in error, and has now been included.
A responder requested that etanercept be available for use in graft vs. host disease.	We would welcome a funding application for this use.
Paediatric gastroenterologists requested that the indications for mycophenolate be extended to include a range of autoimmune conditions.	We would welcome a funding application for such an expansion of access.

Feedback	Discussion
Responders noted that alemtuzumab is currently used by some patients under a compassionate supply programme, and queried whether this would be affected.	We note that use of alemtuzumab under such programmes will remain available. Existing patients would be covered by a 'grand-parenting' provision in the Section H rules, and future patients would be managed through NPPA.
Paediatricians noted that the list excluded a number of products used in paediatric cancer centres.	The funding exemption that currently applies to the use of PCTs in paediatrics will still be in effect from 1 July, so their use of these products will be unchanged. We do intend to review this exemption the future, and anticipate that this will likely occur over the next 6-12 months.
A responder queried whether the current situation for accessing pemetrexed through ACC and NPPA would be affected.	Access to pemetrexed would be unchanged by this decision.
A responder noted that crisantaspase (Erwinase) is the agent of choice for patients who are allergic to pegaspargase.	We note that crisantaspase is currently funded for some patients through NPPA, as it is a cancer treatment, and that this would remain available from July. We expect however to consider the listing of crisantaspase further in the next few months.
Responders noted additional indications for rituximab, such as in haemophilia, graft vs. host disease, transplants and and nephrotic syndrome.	We have included use in haemophilia in the prescribing criteria for rituximab, and we will be working with clinicians to determine prescribing criteria for other indications over the coming months. In the meantime, clinicians would be able to apply for its use under NPPA.
A responder considered that teniposide should be available for multiple myeloma patients.	We note that teniposide was discontinued by the supplier in 2010, however use under NPPA remains an option provided it can be sourced, and we would welcome a funding application for its relisting.
Special Foods	
Responders requested that additional products, such as Scandishake, Pediasure Fibre, Fortisip Compact, Calogen Extra Plus and Forticreme be included in Section H.	To ensure continuity of care, we consider that these products should only be included in Section H if they are also subsidised in the community.

Feedback	Discussion
Responders requested that prescribing criteria for elemental and semi-elemental feeds be widened to include use in any type of eosinophilic enteritis, not just oesophagitis, for patients with multiple food allergies who require enteral feeding, and to accommodate use in acute pancreatitis.	We have amended the prescribing restrictions in line with these suggestions.
Responder requested that additional food/fluid thickeners be included, and that pre-thickened drinks be included.	We have included 'Instant Thick' and 'Easy Thick' in Section H, alongside the other thickeners. We are still working through a number of issues in relation these products, and in the meantime, although we have not included pre-thickened drinks in Section H, DHB hospitals will continue to be able to use pre-thickened fluids beyond 1 July.
Respondents noted that some there may be a need for some patients to have a higher protein intake without increasing calorific intake.	We have amended the criteria for high protein oral feed (Fortimel Regular) to accommodate this.
Responders noted that some proposed products may not be available in New Zealand.	We have excluded products where we have been notified of discontinuation by the supplier, and will follow up on the supply of other items over the coming months.
Responders noted that there may be a number of circumstances requiring wider access to diabetic feeds in hospitals.	We have widened the hospital prescribing restrictions for diabetic feeds to be more in line with the restrictions for standard supplements.
Responders requested that prescribing restrictions for fat modules be extended to cover patients with chyle leaks, ascites or with increased energy requirements.	We have amended the criteria in line with this suggestion.
Responders requested that additional presentations of ready-to-hang products be included in Section H.	We have included several additional products, such as Jevity Plus RTH, Nutrini Energy Multifibre RTH and Jevity HiCal RTH. We would welcome a funding application for any additional products.
Responders requested that Oral Impact be included in Section H.	We would welcome a funding application for this product.
Responders requested that additional products for metabolic patients be included, such as Energivit powder, Phlexy-Vits and PKU Anamix Junior powder.	We are currently considering funding proposals for the listing of these products. In the meantime, applications would be able to be made under NPPA.

Feedback	Discussion
Responders requested wider prescribing criteria in hospitals and in the community for a number of products, including: • carbohydrate and fat supplement; • diabetic products, for dairy free patients; • elemental products, for patients who have not tolerated standard feeds; • standard supplements, for patients with disabilities; and • paediatric products, for children with oral motor difficulties. Responders also requested that the prescribing criteria for in-hospital use of high calorie products be extended.	We will be seeking further advice from the Special Foods Subcommittee on these matters at its next meeting, later this year.
Responders requested that additional flavours of products be included in Section H.	Section H will not, restrict the range of flavours from 1 July; therefore we have not specified them all. We note that flavours were mentioned in the consultation letter, but this was only for illustrative purposes when different flavours have different nutritional profiles, such as with Neocate Advance.
Responders expressed concern about the ability to use modular products as an additive to food.	We note that the criterion “for use as a modular feed” in the consultation document was intended to also permit use in a modular feed, in addition to use as an additive. We have reworded the criteria to improve its clarity.
A number of responder requested that the surgical product, preOp, be included, noting that this can be used in Enhanced Recovery after Surgery (ERAS) programmes.	We have not included preOp in Section H at this time. Advice from the Special Foods Subcommittee did not support its listing, however we remain open to reconsidering its listing, should we receive clinical data supporting its use over other carbohydrate supplementation, or subject to reaching an acceptable commercial agreement with the supplier.
Responders requested the addition of the Flavour Creations Recover (high protein) range of products and the Flavour Creations Formulated Meal Replacement range of products to Section H.	These have not been included in Section H at this time. However, we intend to review these further over the coming months.

Feedback	Discussion
Respondents requested additional criteria in the hospital prescribing restrictions for standard supplements, to cover situations such as dysphagia, malignancy, paediatric Crohn's disease and a low residue diet.	Our view is that these situations will be covered under the in-hospital prescribing restrictions for standard supplements, which are much wider than the community criteria; however we welcome further feedback on this point.
Several responders requested that addition of standard infant formulas including soy and goat milk formula, and others requested that the Loprofin range of low protein foods be included.	We consider that standard, soy and goat milk infant formulas fall outside the scope of Part II of Section H, and therefore DHB hospitals will retain local discretion regarding their use. This is also the case for low-protein and gluten-free foods.
A responder queried what impacts would be for patients transferring from hospitals to the community, noting that standard supplements are currently included in the Discretionary Community Supply list.	Although the DCS list will be removed from 1 July, DHB hospitals would continue to be able to provide standard supplements for patients transitioning back into the community, under rule 8 of the new Section H rules.
A number of responders requested that high arginine products, e.g. Cubitan and Resource Arginaid, be included for patients with chronic or large non-healing wounds/ulcers.	We note that the Special Foods Subcommittee considered that a further review of the evidence for these products should occur, and we would welcome a funding application for any of these products.
A responder requested that glutamine be added to the list, and noted that current guidelines support its use in selected patient groups.	We intend to consider this further over the coming months.
Some responders requested that fibre supplements, such as Stimulance, be included, noting that these are useful products for healthy bowel function.	Our advice from the Special Foods Subcommittee was not to include fibre supplements, however we would welcome a funding application for their inclusion in Section H, and for subsidisation in the community.
Several responders queried whether the HML would release them from their current contractual relationships with Special Foods suppliers.	We note that DHBs may have contracts for special foods that have been excluded from Section H, and DHBs would be expected to cease using these, other than through NPPA or another of the exceptions provisions in the Section H rules. Other than this, we do not expect current contracts to be affected; however we would be happy to have further discussions on specific points with DHBs or special foods suppliers.

Feedback	Discussion
Vaccines	
Responders requested changes to cover the provision of tetanus toxoid for tetanus prone wounds.	We have amended the criteria for the diphtheria and tetanus vaccine to cover this use. We note some requests to include a standalone tetanus toxoid injection, although we understand that this is not currently in use in DHB hospitals and is not currently registered. However, we would be willing to consider this at a later time.
Responders noted that the proposal would result in wider criteria than in the community for some vaccines.	We are currently undertaking a review of the community eligibility for the Immunisation Schedule and will be considering community access following this review process. At this time access to vaccines in the hospital is wider than that in the community.
Responders recommended changes to the criteria for varicella vaccine to clarify that this is not to be used while a patient is immunosuppressed, and requested that household contacts also be covered.	We have incorporated these suggestions in the criteria.
A responder questioned whether hospitals would be able to provide the regular immunisation on the Immunisation Schedule for long stay patients.	The restrictions should enable DHBs to provide all regular vaccinations under the Immunisation Schedule.
A responder considered that front line health care workers should be provided immunisations for certain vaccine preventable illnesses.	DHB hospitals would retain discretion over the use of vaccines for their staff.
A responder requested that restrictions applying to the hepatitis A vaccine should be widened to include patients with hepatitis B or C or for post-exposure prophylaxis.	We intend to seek further clinical advice on this issue from the Immunisation Subcommittee.
A responder requested that the conjugate meningococcal vaccines be included beneficial for children aged under 2 years, as the polysaccharide vaccine is not licensed for this population.	We have included conjugate meningococcal quadrivalent (A, C, Y and W-135) and monovalent meningococcal C conjugate vaccine.
Responders requested that restrictions be expanded to include use of various vaccines following immunosuppression.	We have included “revaccination following immunosuppression” as a criterion for a number of vaccines.

Feedback	Discussion
Various	
Responders suggested changes to the presentations of sodium thiosulphate and for ethanol with glucose to be listed.	We have incorporated these changes in the list.
A responder requested that fuller's earth be included for the treatment of paraquat poisoning.	Our understanding is that activated charcoal is an appropriate alternative to fuller's earth in the management of paraquat poisoning, and that it is not be necessary for hospitals to hold both products.
A responder requested the addition of sterile paraffin liquid.	We consider that this is already encompassed by the listing of paraffin liquid.
A responder requested the addition of mouthwash tablets.	We consider that these are not within scope of the list, and so DHBs retain discretion over their use.
Responders requested that glucarpidase be included for methotrexate toxicity.	We will be considering this further in the coming months. In the meantime, applications can be considered via NPPA.

More information

A list of all products considered under these four therapeutic groups, and under those groups previously notified, is available on our website, and will be updated as further decisions are notified:

www.pharmac.health.nz/medicines/hospital-pharmaceuticals

If you have any questions about these decisions, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.

If you would like to submit a funding application for anything raised in this document, or for any matter, information on this process can be found on our website at:

www.pharmac.health.nz/medicines/how-medicines-are-funded/new-funding-applications