NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

19 March 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 September 2012.

These decisions establish a further four (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. These groups: Alimentary Tract and Metabolism, Infections, Respiratory System and Allergies, and Sensory Organs primarily relate to pharmaceuticals used in gastroenterology, infectious diseases, respiratory medicine, ophthalmology and otolaryngology.

All of the consultation letters relevant to this work are available on PHARMAC's website (note that the link is updated from that used in previous documents):

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

Details of the decision

Following consultation, some changes were made to the proposal. Significant changes are:

- The prescribing restrictions for infliximab in gastroenterology have been amended as a result of feedback that we received.
- We have included sodium phosphate with phosphoric acid oral liquid (Fleet Phospha-Soda)
- We have not listed L-ornithine L-aspartate in the community Schedule as we are currently reviewing rifaximin for hepatic encephalopathy.
- We have amended the prescriber restrictions for itraconazole and ketoconazole to include a wider range of prescribers.
- We have delayed the changes to the prescribing restrictions for norfloxacin.
- Olopatadine eye drops will be listed in the Schedule without prescribing restrictions.

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

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 29 October 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:

Theme	Comment
Alimentary Tract and Metabolism	
Respondents requested changes to that separate criteria be used for infliximab for use in paediatric Crohn's disease.	We have now included specific paediatric criteria for Crohn's disease.
Gastroenterologists noted that the requirement for patients with fistulising Crohn's disease to undergo a four month treatment period with conventional agents before accessing infliximab will not be appropriate in all cases, noting that some patients experience rapid deterioration, and consider that access to infliximab should be immediate for such cases. Respondents also noted that methotrexate is not registered for use in fistulising Crohn's disease, and requested that this be removed as a required pre-treatment. One respondent considered that azathioprine is not useful for fistulising disease, and the requirement to use this may lead to delays in in commencing an effective treatment.	We have amended the criteria for infliximab in fistulising Crohn's disease to accommodate immediate use in patients with rapid deterioration, and have removed methotrexate as one of the treatment options to have been considered prior to infliximab commencement. We understand that the use of thiopurines, which includes azathioprine and mercaptopurine are common treatments in fistulising disease, and consider it appropriate for this requirement to remain for non-urgent cases.
Respondents suggested that the requirement for intravenous corticosteroids to be used in acute severe fulminant ulcerative colitis prior to infliximab be removed in cases where patients had already received high doses of oral corticosteroids.	We agree with this suggestion, and have amended the criteria accordingly.
Several gastroenterologists recommended that the definitions relating to ulcerative colitis in the infliximab restrictions be tightened to reduce the risk of inappropriate prescribing, and the Simple Clinical Colitis Activity Index was suggested for use in the criteria.	We have amended the criteria to include SCCAI scores for commencement and continuation, and included the requirement that the ulcerative colitis be endoscopically proven.

Theme	Comment
Respondents noted that an increased frequency of infliximab dosing is used to regain control of disease in inflammatory bowel disease	We have included the option to escalate the dose of infliximab for secondary non-response to treatment. This would allow 3 additional doses of infliximab to be administered during a 16 week period.
Respondents requested that adalimumab also be made available for ulcerative colitis.	We consider this to be a community-led funding decision. We note that adalimumab is not currently registered for this indication.
Respondents requested that ursodeoxycholic acid (UDCA) be available for a number of additional indications, such as: • TPN-induced cholestasis; • children with intestinal failure-associated liver disease; • acute drug induced liver disease; • palliation of cholestasis related pruritis (intractable pruritis); • progressive familial intrahepatic cholestasis (PFIC); • Alagille syndrome; and • intestinal failure associated liver disease.	Our view is that the prescribing criteria for UCDA in hospitals should be aligned with the community funding criteria. However, we are currently considering options for widening the Special Authority criteria for UCDA, and may be consulting on such changes in the near future.
Respondents noted that we had proposed not to include Fleet Phospha-soda oral liquid in Section H on safety grounds, but considered that it should be included, and that its safety concerns have been over-stated.	Fleet Phospha-soda oral liquid has now been included in Section H.
Respondents requested wider access to macrogol 3350 with electrolytes (Lax-Sachets, Movicol) in DHB hospitals. They noted that lactulose is not considered to be a suitable first-line treatment option in all cases.	Our view is that the prescribing criteria for macrogol 3350 with electrolytes should be aligned with the community funding criteria. However, we are currently considering options for widening the Special Authority criteria for this, and may be consulting on such changes in the near future.
Respondents requested that additional laxatives be included in Section H, such as: • paraffin oral liquid (Parachoc); • macrogol 3350 without electrolytes (Clearlax); and • sodium picosulphate (Dulcolax).	We are currently considering the listing of a macrogol-only product in the Schedule for paediatric use, and would welcome a funding application for any other products.

Theme	Comment
Respondents requested a wider range of phosphate binders, such as sevelamer and various presentations of calcium carbonate and calcium acetate.	We have received a funding application for sevelamer, which we have started to evaluate and will be considering further over the coming months. We have also recently listed a liquid calcium carbonate product suitable for paediatric patients on the Pharmaceutical Schedule from December, and will consider funding applications for any additional products that are submitted to us.
Respondents suggested that additional metabolic products, such as individual amino acids, be included.	We are considering listing a number of additional metabolic products in the Schedule, and will consult on such changes when we are in a position to do so. In the interim applications under NPPA remain an option.
Respondent queried whether Fleet phosphate enema and Novomix 30 Flexpen would be included.	We note that both of these products were proposed for inclusion (and will be included in Section H), however we note that their inclusion may not have been clear from the product descriptions.
A respondent noted that there is a need for a non-enteric coated formulation of pancreatic enzyme.	We have included pancreatic enzyme powder, which is a non-EC formulation, however we understand that supply of this presentation is not certain. We will be happy to consider any other non-EC formulations of pancreatic enzymes that become available.
Respondents requested that additional oral liquid presentations, such as diazoxide, omeprazole, magnesium hydroxide and ursodeoxycholic acid.	We note that oral liquid forms of these agents are able be compounded from other forms that are to be included in Section H – diazoxide capsules, omeprazole powder, magnesium hydroxide paste and UCDA capsules. We are aware that there have been some issues with compounding the new brand of UCDA capsules, and we are working with compounding pharmacists on this issue.
Some respondents considered that omeprazole dispersible tablets should be available for paediatric use, not just patients who are tube fed.	We note that omeprazole capsules can be sprinkled on soft food for paediatric patients who require a dose of 10 mg or greater. Extemporaneously compounded omeprazole oral suspension (from powder or capsules) can be used for patients who require smaller, liquid doses.

Theme	Comment
A respondent requested that a steroid mouthwash be included.	We note that although there is not a proprietary steroid mouthwash listed in the Schedule, two suitable steroid options remain available – prednisolone liquid and triamcinolone oral paste. However, we would be willing to consider a funding application for a proprietary product, should one be available.
Respondents that additional products such as niacinamide, pantothenic acid, a combination benzydamine/chlorhexidine mouthwash (Difflam C), peppermint oil capsules and exenatide be included.	Our view is that treatments such as these should only be included in Section H if they are also funded in Section B. That is, the funding decision should be led by the community, and we would welcome funding applications for them.
Infections	
A larger number of responses relating to antimicrobial products identified that many products were currently used by clinicians who were not included in the restrictions. Many responders noted that the products were used in standard treatments such as piperacillin with tazobactam in febrile neutropenia.	As these products are already part of standard treatments it is likely they would be included in hospital protocols or antimicrobial guidelines, therefore the prescribers would be able to continue to use these products. If no written protocol exists one could be developed, and clinicians could develop these guidelines for consideration in DHB hospitals. DHBs may also adopt protocols or guidelines from other centres. We have made some changes to the prescriber restrictions where we considered that protocols or guidelines would not be an appropriate mechanism for access. This includes adding dermatologists to the restriction for itraconazole, and adding dermatologists, endocrinologists and oncologists to the restriction for ketoconazole.
Respondents were concerned at having to use IV erythromycin due to its potential for venous irritation and vessel trauma and wondered if clarithromycin IV would be more appropriate.	We will be considering this request further over the next few months.

Theme	Comment
Respondents noted the restrictions for some antifungal agents include the requirement for an infectious diseases physician or a clinical microbiologist to be involved in prescribing these agents for possible invasive fungal infection, and disagreed with the need for this requirement.	The proposed prescribing restriction reflects the advice that we have received from the Anti-Infective Subcommittee, which includes both infectious disease and haematology perspectives. We note that the restriction relates only to *possible* invasive fungal infection, not to *proven* or *probable* infection, and reflects the view of the Subcommittee that a multi-disciplinary approach should be used for these more complex cases; we also understand that this represents current practice in a number of centres.
An ophthalmologist requested that the criteria for moxifloxacin be extended to include endophalmitis, as moxifloxacin is better at penetrating the blood-eye barrier than other agents.	We will be considering this request further over the next few months.
A respondent considered that all 3rd and 4th generation cephalosporins should have a restriction to infectious disease specialists and clinical microbiologists.	The advice that we have received from the Anti-Infective Subcommittee is that there is not a need to apply a restriction to cefotaxime or ceftriaxone, however we will revisit this issue in the future if needed.
The supplier of norfloxacin noted that the proposed changes to community restrictions could have a marked impact on usage, and that this product is currently supplied under Tender.	We have decided to delay the introduction of a new restriction for norfloxacin until 1 July 2014, the end of the current Tender period.
Respiratory System and Allergies	
A respondent requested that infliximab be made available for sarcoidosis of other organs, not just pulmonary sarcoidosis.	We would be happy to consider a funding application for other forms of sarcoidosis. In the meantime, applications would be able to be made for individual patients under the NPPA process.
Respondents noted the use of dornase alfa for acute exacerbations of cystic fibrosis, as well as for other respiratory illnesses.	We are still considering this issue, and will issue further consultation if necessary in the coming months.
One respondent requested that adrenaline auto-injectors be included.	Our view is that treatments such as this should only be included in Section H if they are also funded in Section B. That is, the funding decision should be led by the community.

Theme	Comment
One respondent considered that the Steritalc brand of talc should be included.	We note that the proposed listing of talc will not specify a brand, and would encompass this product.
Sensory Organs	
Several respondents requested that that aflibercept should be included for macular degeneration.	We note that aflibercept has recently been registered by Medsafe, and would welcome a formal funding application for this agent.
Ophthalmologists responded requesting a range of long-term treatments such as: • preservative-free glaucoma treatments; • combination prostaglandin/timolol; eye drops and • preservative-free dry eye products.	Our view is that these should only be included in Section H if they are also funded in Section B of the Schedule. That is, the funding decision should be led by the community. We note that preservative-free dry eye products were included in a Request for Proposals in November 2012 and we expect this to be resolved in the coming months, which may alter the funding of such products.
Respondents queried the prescriber restriction and the age limit proposed for the funding of olopatadine.	We have decided to list olopatadine without restriction.
Respondents noted that proxymetacaine is registered and considered that it should be included.	We will be considering this product further over the next few months, and will issue subsequent consultation if we intent to include it in the Schedule.
Respondents suggested that triamcinolone ophthalmic injection be included.	We will be considering this product further over the next few months, and will issue subsequent consultation if we intent to include it in the Schedule.
Respondents noted that hypromellose 0.3% was not being considered for inclusion.	Hypromellose 0.3% will remain listed (in combination with dextran 0.1%) in Section H. However, we note that there is an outstanding Request for Proposals relating to dry eye products, which may alter the funding of such products.

Theme	Comment
A respondent requested that the prescribing restrictions for ranibizumab be extended to include additional indications.	The Ophthalmology Subcommittee considered that there was good evidence for the use of bevacizumab for exudative diabetic maculopathy. The Subcommittee also considered that a second line treatment for choroidal neovascularisation in patient with age related macular degeneration in the form of ranivizumab was appropriate. We would be happy to consider funding applications for wider access to this product.
A clinician requested that adalimumab and interferon alpha also be made available for uveitis.	Interferon alpha will not have prescribing restrictions in Section H, so it would be available for uveitis in the hospital setting. We have also amended the community restrictions to include ophthalmologists in the prescriber restriction. At this time we are not aware of evidence to support the use of adalimumab for the treatment of uveitis, however we will seek further advice from the Ophthalmology Subcommittee on the effectiveness of adalimumab in this setting.
A respondent noted that Ocuvis (hypromellose) was used routinely in eye theatres.	We have decided to include this product in Section H.
One DHB noted that its ophthalmologists use silicone oil and purified perflouro-n-octane in the surgical setting for detached retinas.	We consider at this stage that that these two products are not within the definition of 'Hospital Pharmaceutical' that we are using for this work, and so their use would remain a local decision.
Ophthalmologists requested the addition of several compounded antibiotic eye drops.	Hospitals would be able to compound antibiotic eye drops from injections, as they currently do, provided they meet any restriction applying to the antibiotic.

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.