NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

17 June 2013

Approval of proposal to amend the listing of various products in the infections group

PHARMAC is pleased to announce the approval of a proposal to amend the listing of a number of products in the Infections Group of the Pharmaceutical Schedule from 1 July 2013. This was the subject of a consultation letter dated 4 April 2013 http://www.pharmac.health.nz/news/item/proposal-to-amend-the-listing-of-various-pharmaceuticals-in-the-infections-group

All proposals included in the consultation letter were approved as proposed apart from the following changes:

- Cefazolin: the dialysis indication has not been removed as was initially consulted upon. The restriction will now be as follows:

  Only if prescribed for dialysis or cellulitis in accordance with a DHB approved protocol and the prescription is endorsed accordingly.

- Gentamicin sulphate: the indication for cystic fibrosis has not been removed as initially consulted upon. The restriction will now be as follows:

  Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection, and the prescription is endorsed accordingly.

- Moxifloxacin: an additional indication, prophylaxis following a penetrating eye injury, has been included. The wording with respect to confirmed mycoplasma genitalium has been amended to require nucleic acid amplification tests rather than polymerase chain reaction identification. The new Special Authority Restrictions will be as follows:

  Initial application - (Mycoplasma genitalium) from any relevant practitioner. Approvals valid for 1 month for applications meeting the following criteria:
  Any of the following:
  1. Has nucleic acid amplification test (NAAT) confirmed Mycoplasma genitalium; and
  2. has tried and failed to clear infection using azithromycin; and
  3. treatment is only for 7 days.

  Initial application – (Penetrating eye injury) only from an ophthalmologist. Approvals valid for 1 month where the patient requires prophylaxis following a penetrating eye injury and treatment is only for 5 days.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 18 April 2013 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

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Theme	Comment
Suggested that the wording "polymerase chain reaction (PCR)" be replaced with "nucleic acid amplification test (NAAT)". Advised that this is a more generic term which would be preferable as not all laboratories testing for Mycoplasma genitalium in the future will be using a PCR test – some will use other NAATs which are equivalent to PCR.	The Special Authority has been changed in line with this feedback.
Lamivudine should be available for patients with inflammatory arthritis who are receiving Methotrexate or Leflunomide and are Hepatitis B S Ag positive. The following groups should have access: • a patient who is HBcAb positive (+/- HBV DNA positive but HBsAg negative) and who is to receive alemtuzumab with high-dose methylprednisolone • a patient who is HBcAb positive (+/- HBV DNA positive but HBsAg negative), and who is to receive an allogeneic stem cell transplantation • a patient who is HBcAb positive and who is to receive rituximab with fludarabine and cyclophosphamide [this protocol is considered significantly more immunosuppressive than the R-CHOP listed, but does not include high-dose steroids].	We sought rapid clinical advice from the Anti-Infective Subcommittee regarding the requested changes and, based on this, have not changed the Special Authority criteria to reflect this feedback. The advice was as follows: None of the scenarios sought are recognised to carry a significant risk of reactivation of HBV. Methotrexate and lefludomide are not associated with risk of HBsAg reactivation. These patients should be treated with entecavir according to current criteria for CHB, based on HBV DNA, ALT, and/or stage of fibrosis. Rituximab plus CHOP is a risk in HBsAg negative, anti-HBcore positive patients (15% reactivate) because of (i) the specific effect of anti-CD20 on humoral immunity (not the level of global immunosuppression) combined with (ii) high dose steroids (which have a specific direct effect on HBV replication through activation of the Glucocorticoid responsive element on the HBV genome). Hence, the only indication for prophylaxis in Anti-HBcore positive patients is R-CHOP. We would consider funding applications for these indications.
Cephazolin is used to treat gram positive infections in patients undergoing peritoneal dialysis and this should be retained.	The Special Authority has been changed to reflect this feedback and cephazolin will continue to be available for use in dialysis patients.

Theme	Comment
Gentamycin is used preferentially as a nebuliser, in young patients living with cystic fibrosis with less resistant pseudomonas.	The changes to the Special Authority reflect this feedback and gentamycin will remain available for the cystic fibrosis indication.
Support the changes to antiretrovirals.	
With respect to anti-retrovirals - would recommend that the wording be changed from "Patient has had non-consensual intercourse …" to "Patient has had non-consensual sexual contact" as this is the more accepted phrasing	We consider that, for the purposes of funding criteria, the requirement for penetration (and hence relationship to possible mucosal trauma) should be stipulated. We appreciate that this is not the accepted phrasing for discussions with patients.
Minocycline – notes that minocycline is used for other indications including bullous disorders (bullous pemphigoid, pemphigus) and pyoderma gangrenosum. Requests that consideration is given to widening access for these other indications.	We will seek the advice of the Dermatology Subcommittee as requested.
Considers that the Special Authority for valaciclovir should include herpes simplex in immunocompromised patients for sites other than the genitals.	We will seek further advice from the Anti-Infective Subcommittee regarding this request.

More information

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