Hospital Pharmaceuticals Review

PTAC, Hospital Pharmaceuticals Subcommittee & Reproductive and Sexual Health Subcommittee minutes for web publishing

Genito-Urinary System therapeutic group

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

This document contains minutes relevant to the consultation document of 19 November 2012 relating to products in the Genito-Urinary System therapeutic group.

Note that this document is not a complete record of the relevant PTAC and Subcommittee meetings; only the relevant portions of the minutes relating PTAC and its Subcommittees advice on the review of Hospital Pharmaceuticals are included.

Contents

Hospital Pharmaceuticals Subcommittee – 4 October 2011

1 Contraceptives

1.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Contraceptives heading.

1.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Cyproterone acetate with ethinyloestradiol
  - Tab 2 mg with ethinyloestradiol 35 µg
- Ethinyloestradiol with levonorgestrel
  - Tab 30 µg with levonorgestrel 150 µg
  - Tab 50 µg with levonorgestrel 125 µg
- Ethinyloestradiol with norethisterone
  - Tab 35 µg with norethisterone 500 µg
  - Tab 35 µg with norethisterone 1 mg
- Levonorgestrel
  - Tab 1.5 mg
  - Subdermal implant (2 x 75 mg rods)
- Intra-uterine devices
  - Copper - various sizes
- Medroxyprogesterone acetate
  - Inj 150 mg per ml, 1ml
- Norethisterone
  - Tab 350 µg

1.3 The Subcommittee noted that the following pharmaceuticals are also listed in the Pharmaceutical Schedule, and recommended that they be included in a national PML:

- Ethinyloestradiol with desogestrel
  - Tab 20 µg with desogestrel 150 µg
  - Tab 30 µg with desogestrel 150 µg
- Ethinyloestradiol with levonorgestrel
  - Tab 20 µg with levonorgestrel 100 µg
- Norethisterone with mestranol
  - Tab 1 mg with mestranol 50 µg
- Levonorgestrel
  - Tab 30 µg

1.4 The Subcommittee noted that oral contraceptives are generally not used in hospitals, other than for emergency contraception.

1.5 The Subcommittee noted that the following pharmaceuticals are not subsidised in the Pharmaceutical Schedule and, as they do not have a niche use in hospitals, recommended that they not be included in a national PML:

- Drospirenone with ethinyloestradiol
  - Tab 3 mg with ethinyloestradiol 20 µg
  - Tab 3 mg with ethinyloestradiol 30 µg
- Ethinyloestradiol with gestodene
  - Tab 30 µg with gestodene 75 µg
- Nonoxynol-9
  - Jelly 2%
- Desogestrel
  - Tab 75 µg
- Etonogestrel
  - Subdermal implant 68 mg

2 Other Gynaecological Preparations

2.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Other Gynaecological Preparations heading.

2.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Acetic acid with hydroxyquinoline and ricinoleic acid
  - Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate 0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator
- Carboprost trometamol
  - Inj 250 µg per ml, 1 ml
- Dinoprostone
  - Pessaries 10 mg
  - Vaginal gel 1 mg / 2.5 ml
  - Vaginal gel 2 mg / 2.5 ml
- Ergometrine maleate
  - Inj 500 µg per ml, 1 ml
- Mifepristone
  - Tab 200 mg
- Oestriol
  - Crm 1 mg per g with applicator
  - Pessaries 500 µg
- Oxytocin
  - Inj 5 iu per ml, 1 ml
  - Inj 10 iu per ml, 1 ml
- Oxytocin with ergometrine maleate
  - Inj 5 iu with ergometrine maleate 500 µg per ml, 1 ml

2.3 The Subcommittee recommended that at least one preparation of acetic acid solution be included in a national PML, but was unsure of the need for both 3% and 5% solutions, and recommended that the view of obstetricians and gynaecologists be sought on this matter.

2.4 The Subcommittee noted that dinoprost trometamol (5 mg per ml, 1 ml injection) was not widely used in DHB hospitals and considered that it did not need to be included in

a national PML. However, the Subcommittee requested that the view of obstetricians and gynaecologists be sought on its potential exclusion.

2.5 The Subcommittee noted that methylergometrine (200 µg per ml, 1 ml injection) had only been used in DHB hospitals during a period when ergometrine maleate was unavailable, and recommended that it not be included in a national PML.

2.6 The Subcommittee noted that the case of methylergometrine highlighted a need for of a national PML to accommodate use of non-PML pharmaceuticals when equivalent PML pharmaceuticals were out of stock.

2.7 The Subcommittee noted that progesterone 8% gel is used in fertility clinics, and noted that this is not a service covered by DHB hospitals. The Subcommittee recommended that this not be included in a national PML. However, the Subcommittee noted that PHARMAC staff were intending to discuss the issue of fertility treatments with the Ministry of Health.

2.8 The Subcommittee recommended that progesterone capsules not be included in a national PML.

3 Urologicals

3.1 The Subcommittee reviewed the information from DHB hospitals and PHARMAC in relation to products under the Urologicals heading.

3.2 The Subcommittee noted that the following pharmaceuticals are commonly used in DHB hospitals and/or are fully subsidised in the Pharmaceutical Schedule and recommended that they be included in a national preferred medicines list (PML) without need for further prioritisation:

- Finasteride
  - Tab 5 mg
- Tamsulosin
  - Cap 400 µg
- Potassium citrate
  - Oral liq 3 mmol per ml
- Sodium citro-tartrate
  - Grans eff 4 g sachets
- Oxybutynin
  - Tab 5 mg
  - Oral liq 5 mg per 5 ml
- Solifenacin succinate
  - Tab 5 mg
  - Tab 10 mg

3.3 The Subcommittee recommended that the listing of finasteride, tamsulosin, potassium citrate and solifenacin in a national PML be subject to restrictions on their use that are in line with the restrictions for them in the Pharmaceutical Schedule.

3.4 The Subcommittee noted that the following pharmaceuticals are not subsidised in the Pharmaceutical Schedule and, as they do not have a niche use in hospitals, recommended that they not be included in a national PML:

- Tamsulosin
  - Tab long-acting 400 µg
- Potassium citrate
  - Tab 540 mg
- Oxybutynin
  - Patch 36 mg
- Tolterodine
  - Tab 1 mg
  - Tab 2 mg
- Alprostadil
  - Inj 10 µg
  - Inj 20 µg

4 Hospital Pharmaceuticals

4.1 The Subcommittee reviewed a series of recommendations by the Hospital Pharmaceuticals Subcommittee in regards to which pharmaceuticals relevant to reproduction and sexual health should be included on a national Preferred Medicines List (PML).

Contraceptives

4.2 The Subcommittee noted the recommendations of the Hospital Pharmaceuticals Subcommittee in regard to levonorgestrel IUDs. The Subcommittee recommended that PHARMAC evaluate the viability of using the CPAC grading score for the use of levonorgestrel intra-uterine device as an alternative to surgery including, but not restricted to, hysterectomies and endometrial ablation.

Other obstetric and gynaecological preparations

4.3 The Subcommittee recommended terbutaline subcutaneous 250 mg injection be listed in a national PML, as it is used in acute hyperstimulation in labour or when it may be necessary to turn the baby.

4.4 The Subcommittee recommended that Lugol's iodine and methylene blue be listed in the PML as they are both used as diagnostic agents in colposcopy.

4.5 The Subcommittee recommended that both 3% and 5% strengths of acetic acid be included in a national PML.

4.6 The Subcommittee noted that the Hospital Pharmaceuticals Subcommittee had sought advice on the presentations of ferric subsulfate that should be included in a national PML. Members noted that solution and gel formulations were currently in use, and considered that both should remain available.

4.7 The Subcommittee recommended that atosiban be listed in a national PML as it is used to delay pre-term birth. Members noted that atosiban is only used when other tocolytics are contraindicated.

4.8 The Subcommittee recommended that dinoprost trometamol not be included in a national PML. Members noted that this has largely been superceded by mifepristone. However, the Subcommittee recommended consulting with maternal foetal medicines specialists on its potential exclusion.

5 Review of Genito-Urinary System Recommendations

Contraceptives

5.1 The Subcommittee noted the advice from the Reproductive and Sexual Health Subcommittee in relation to prescribing criteria for levonorgestrel-releasing intra-uterine devices. The Subcommittee considered that further work was required to define the prescribing restrictions for this agent in DHB hospitals, and noted that the criteria in the community would likely need to change as a result, to ensure continuity of care. The Subcommittee recommended that any proposed changes be reviewed by PTAC.

Other Gynaecological and Obstetric Preparations

5.2 The Subcommittee noted that the Reproductive and Sexual Health Subcommittee had recommended that both the 3% and 5% presentations of acetic acid be included in a national PML.

5.3 Members noted that the Reproductive and Sexual Health Subcommittee had recommended that PHARMAC seek advice from maternal-foetal medicine specialists in relation to the need for dinoprost in a national PML.

5.4 The Subcommittee noted that the Reproductive and Sexual Health Subcommittee had recommended that terbutaline injection be included in a national PML. The Subcommittee recommended that this be restricted to recommendation by obstetricians and gynaecologists.

5.5 The Subcommittee noted that the Reproductive and Sexual Health Subcommittee had recommended that atosiban be included in a national PML. Members considered that this may require further consideration by PTAC.

Pharmacology and Therapeutic Advisory Committee – 8 & 9 November 2012

6 Genito-Urinary System

6.1 The Committee considered a list of pharmaceuticals under consideration for use in DHB hospitals under the Genito-Urinary System heading, including advice from the Hospital Pharmaceuticals Subcommittee and the Reproductive and Sexual Health Subcommittee. Except where indicated, the Committee agreed with the recommendations by the subcommittees.

6.2 The Committee noted that the subcommittees had considered options for widening access to levonorgestrel intra-uterine devices to include indications other than heavy menstrual bleeding.

6.3 The Committee considered that there is a lack of evidence in support of extending funded use to patients with endometriosis or delay or prevent hysterectomy in patients with endometrial hyperplasia.

6.4 The Committee recommended that prescribing restrictions for levonorgestrel intra-uterine device in DHB hospitals be aligned with the Special Authority restriction in the Pharmaceutical Schedule.

6.5 The Committee recommended that PHARMAC seek an application from the College of Obstetricians and Gynaecologists to widen access to levonorgestrel intra-uterine device.

6.6 The Committee noted that the Reproductive and Sexual Health Subcommittee had recommended that atosiban be included in a national PML for use in prevention of pre-term birth when other agents are contraindicated. The Committee noted that the latest Cochrane review on the topic (Papatsonis D et al, Cochrane Database Syst Rev. 2009 Jan 21;(1)) found no evidence for superiority of atosiban over placebo, and some data suggested an increase in infant mortality with its use.

6.7 The Committee noted that further evidence may be available in support of atoisban since the publication of the Cochrane review, and considered that PHARMAC should seek a funding application for this agent.