Hormone and Contraceptive Subcommittee of PTAC meeting held 26 May 2009

(minutes for web publishing)

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Note that this document is not necessarily a complete record of the Hormone and Contraceptive Subcommittee meeting; only the relevant portions of the minutes relating to Hormone and Contraceptive Subcommittee discussions about an application that contain a recommendation are published.

The Hormone and Contraceptive 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.

Contents

1 Long Acting Reversible Contraception

1.1 The Subcommittee considered that Long Acting Reversible Contraception (LARC) encompassed any form of contraception that required administration less than once a month. Members noted that currently PHARMAC subsidises medroxyprogesterone acetate injection (Depo-Provera) and a copper Intra-Uterine Device (IUD) for this use.

1.2 The Subcommittee considered that Depo-Provera was an effective LARC but had a high failure rate due to compliance issues. Members considered that the 3 monthly dosing, and the difficulty in remembering to attend for a dose, was the main cause of non-compliance. The Subcommittee considered that this issue explained the difference in failure rates between typical and perfect use.

1.3 The Subcommittee considered that the copper IUD was an effective LARC. Members noted that heavy menstrual bleeding meant that it was not clinically acceptable for some patients, and switching patients to levonorgestrel intra-Uterine System (IUS), Mirena, was the preferred treatment option.

1.4 The Subcommittee noted that a new copper 380A IUD was available in other countries which could be inserted for use for up to 10 years. The Subcommittee **recommended** that PHARMAC should investigate funding the copper 380A IUD as this provided longer protection than the currently funded Multiload Cu 375 IUD.

1.5 The Subcommittee considered that the levonorgestrel IUS provided benefits additional to contraception and noted endometrial protection in Polycystic Ovary Syndrome (PCOS), an alternative to oral progestins for women with a uterus using oestrogen replacement, and conservation of iron. Members also noted that the levonorgestrel IUS was an effective LARC and noted it may be slightly more effective than tubal ligation, although there was no direct evidence to support this.

1.6 The Subcommittee noted that there was a mild increase in the risk of sexually transmitted infections (STIs) when copper IUDs and levonorgestrel IUS were compared to other LARC.

1.7 The Subcommittee noted there were two implants available in New Zealand; currently one implant is registered (Jadelle) and one implant is likely to be registered soon (Implanon). Members noted that one Jadelle insertion is effective for up to 5 years and one Implanon insertion is effective for up to 3 years. Members considered the both implants were effective LARC methods and **recommended** the funding on the Pharmaceutical Schedule of either implant with a high priority.

1.8 The Subcommittee noted that there was less dysmenorrhagia associated with implants than the copper IUD, but that implants did affect bleeding patterns (irregular bleeding and amenorrhoea) with moderate rates of removal for this reason. Members noted that younger women at particularly high risk of unplanned pregnancies for whom other contraceptive methods (including combined oral contraceptives, progestogen only pills and injections and IUDs/IUSs) are unsuitable might be a target population.

1.9 The Subcommittee noted that both the levonorgestrel IUS and implants had to be inserted within 7 days of menstruation. The Subcommittee considered that the window of

opportunity to insert a copper IUD was longer due to its use as an emergency contraceptive. Members noted that implants were potentially easier to insert (30 minute appointment and 5 minute insertion time) than levonorgestrel IUS and copper IUDs on completion of appropriate training and experience.

1.10 The Subcommittee discussed the number of visits to a clinician a patient would require for the various LARC and noted the following amounts would be adequate for the majority of patients:

	Oral Contraceptive	medroxyprogesterone acetate injection	IUS/IUD	Implant
GP visits	6 monthly	2 years	6 weeks post insertion	Once only for insertion
Nurse	-	12 weekly	-	-

Members noted that there would be an appointment for removal for IUS/IUD and the implant and considered that the appointment for removal of the implant would be longer.

1.11 Members noted that approximately 10% of levonorgestrel IUS and copper IUDs move or are expelled and require reinsertion within the 5 year period.

1.12 The Subcommittee considered that the copper IUD should be considered the first line agent for LARC unless excessive menstrual bleeding made this clinically inappropriate. Members noted that excessive menstrual bleeding was dependent upon an individual's perception and for this reason difficult to quantify.

1.13 The Subcommittee considered that if access was widened to include LARC approximately 10% (maximum 20%) of patients using the copper IUD would switch to levonorgestrel IUS. The members estimated that about 10% of patients on Depo-Provera and 10% of patients on an oral contraceptive would choose to use an implant if one was funded. Approximately a total of 30% of contraceptive users would switch to implants and levonorgestrel IUS if access was widened.

1.14 The Subcommittee **recommended** the listing of a hormonal LARC on the Community Pharmaceutical Schedule with a high priority and no restrictions; and noted that any of the currently available forms of hormonal LARC would be acceptable.

The Decision Criteria particularly relevant to this recommendation are:

(i)The health needs of all eligible people within New Zealand; (ii)The particular health needs of Maori and Pacific peoples; (iii)The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv)The clinical benefits and risks of pharmaceuticals; (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; (vii) The direct cost to health service users;

2 Goserelin for Uterine Fibroids

2.1 The Subcommittee considered a submission from AstraZeneca for the funding of goserelin 3.6mg (Zoladex) implant for the indication of Uterine Fibroids. Members noted that this application had been considered previously by PTAC and had been referred to the Subcommittee for review.

2.2 The Subcommittee considered that the evidence provided in support of this application was of moderate quality.

2.3 Members noted that leuprorelin 3.75mg (Lucrin) was also indicated for uterine fibroids.

2.4 The Subcommittee noted the Farquhar et el study (BJOG Nov 2002, Vol 109; 1273-1280) and considered that GnRH analogues reduced the frequency of abdominal incisions in the case of hysterectomy and vertical incisions in the case of myomectomy.

2.5 The Subcommittee noted that GnRH analogues administered pre-operatively reduced the size of uterine fibroids. Members considered that patients who had received GnRH analogues pre-operatively had a shorter surgical time (6 minute reduction) and reduced blood loss.

2.6 The Subcommittee noted there are currently funded alternatives that could be used for uterine fibroids, these included aromatase inhibitors such as letrozole and anastrozole, or medroxyprogesterone. Members considered that goserelin was unlikely to be cost-effective for this use.

2.7 The Subcommittee considered there may be a benefit to a particular sub-population of women with uterine fibroids > 18 weeks in size; or who have preoperative anaemia defined as serum ferritin level < 16 mg/l or haemoglobin level < 120 g/l; or for women who wish to get pregnant in the future (myomectomies).

2.8 Members **recommended** amending the goserelin 3.6mg Special Authority restriction to include uterine fibroids for the above indications with a low priority.

The Decision Criteria particularly relevant to this recommendation are:

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