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Dear Danae,

Application for a change to the Pharmaceutical Schedule

Thank you for inviting the Royal New Zealand College of General Practitioners (the College) to submit an application in support of widening access to Mirena. We understand that the Family Planning organisation and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) are also submitting applications which support widening funded access to Mirena.

Introduction to general practice and the College

General practice is the specialty that treats patients: with the widest variety of conditions; with the greatest range of severity (from minor to terminal); from the earliest presentation to the end; and with the most inseparable intertwining of the biomedical and the psychosocial. General practitioners (GPs) treat patients of all ages, from neonates to elderly, across the course of their lives.

GPs comprise almost 40 percent of New Zealand's specialist workforce and their professional body, the Royal New Zealand College of General Practitioners (the College), is the largest medical College in the country. The College provides training and ongoing professional development for general GPs and rural hospital generalists, and sets standards for general practice. The College is committed to achieving health equity in New Zealand. To achieve health equity, we advocate for:

- A greater focus on the social determinants of health (including labour, welfare, education and housing).
- A greater focus on measures to reduce smoking and to increase healthy food options for low-income families.
- Health services that are better integrated with other community services.
- A review of the funding model for primary care to ensure that funding is targeted towards the most disadvantaged.
- Free primary health care for low-income families, because health inequities begin early and compound over the life course.

This is the first time that the College has made such an application to PHARMAC.

For some time now our members have been telling us of their frustration that Mirena was not more widely funded, and of the potential health improvements that wider funding could bring. We therefore appreciate having the opportunity to make this application and hope that between the College, RANZCOG and Family Planning we have provided PHARMAC with the information that is needed to support a successful application.

Should you require any further information or clarification please contact the College's policy team at policy@rnzcgp.org.nz.

Yours sincerely,

Michael Thorn
Manager Strategic Policy

Application for a change to the Pharmaceutical Schedule

That the progesterone only long–acting intra-uterine system (LIUS) Mirena is funded for contraception, menorrhagia and endometriosis.

Applicant

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Proposed Pharmaceutical

Chemical: Intrauterine system containing levonorgestrel
Presentation: inserter and intrauterine system containing 52mg levonorgestrel
Brand name: Mirena
Supplier: Bayer New Zealand
Price: $269.50 minus the confidential rebate
Medsafe registration: Yes
Indications licensed by Medsafe: (1)

1. Contraception
2. Treatment of idiopathic menorrhagia provided there is no underlying pathology.
3. Prevention of endometrial hyperplasia during oestrogen replacement therapy

Indications that funding is being sought for:
1. Contraception (Community and Hospital use)
2. Management of heavy menstrual bleeding (Community and Hospital use)
3. Endometriosis and pelvic pain (Community and Hospital use)

Who in New Zealand do you expect would receive this:

1. For Contraception

The preferred option is for Mirena to be available to all women of reproductive age requesting this form of contraception, for whom it is appropriate clinically.

Currently long acting reversible contraceptives (LARCs) are used by less than 10% of women and the majority of these are Jadelles. In the CHOICE study (2), when women were able to choose whatever contraception method they preferred, without barriers of information, cost or availability, almost 47% chose a Mirena.

If PHARMAC is unable to fund Mirena for all women in whom it would be clinically appropriate, then we suggest that women for whom other methods of contraception have

proven to be unsatisfactory or are likely to be unsatisfactory (such as the young, those with a high BMI and those who have difficulty with medication adherence), should be prioritised for funding.

2. For Heavy Menstrual bleeding

The preferred option is for Mirena to be available to all women who self report heavy menstrual bleeding.
An alternative option would be all women who self report menorrhagia and have not responded to other medical management.

3. For Endometriosis and pelvic pain

In primary care this would include those women in whom the cyclical nature of their pelvic pain makes endometriosis a likely diagnosis but who require a trial of medical management before being referred to secondary care for a laporoscopy if medical management fails.

The College's preference is that PHARMAC fund Mirena for all women in whom it is clinically indicated for the above uses and conditions. However, being aware of PHARMACs need to limit expenditure, should there be insufficient funds to allow this we would welcome the opportunity to discuss options with PHARMAC as to how the available funding could be best targeted.

Duration of treatment: The maximum duration is 5 years but the device can be removed any time prior to this if a pregnancy is desired. If a pregnancy is not planned the Mirena can be removed at 5 years and a new device inserted.
Setting for use: Community and Hospital use.

Treatment initiation

Starting treatment: Ensure the women is not pregnant, has no symptoms of intermenstrual or post coital bleeding or history suggestive of other pathology, and a normal physical examination**.**
Tests required: Swabs can be performed at the time of insertion if necessary.

Treatment continuation

If the Mirena is inserted in the first seven days of the menstrual cycle it is effective immediately as a contraception. Good counselling prior to insertion is important so woman are aware that the bleeding pattern may be initially more irregular before settling to be lighter or amenorrhoeic.

Prescribing and dispensing

Initiation of therapy: Practitioners caring for women of reproductive age need to be well informed on all forms of contraception, and specifically on the benefits of LARC, so they can prescribe appropriately.

The insertion of the LIUS needs to be by practitioners skilled in this. It is envisaged and recommended that not all practitioners will be LARC inserters as practitioners need to perform a minimum number of insertions annually to ensure competency.

Timely and appropriate access to skilled inserters needs to be available within each region. The use of Health Pathways to disseminate the availability of inserters is being used in Christchurch and is being considered for the Auckland region.

Training and ongoing competency of inserters needs to be considered. Bayer provides education on models and clinical experience is gained in a collegial fashion. The Goodfellow unit is looking at providing a theoretical training platform.

Health need

This is discussed in relation to each of the three indications for which increased access is sought.

A: Contraception

Overview

The provision of Mirena for contraception should be seen in the context of the movement towards LARC as the appropriate form of contraception for the majority of women. LARC has a failure rate lower than sterilisation, is not user dependent and is fully reversible.

The funding of Mirena was recommended in the "Inquiry into Improving Child Health Outcomes" - November 2013:

> *We recommend to the Government that it provide funding for free or low-cost access to a wider range of long-acting reversible contraceptives, including the Mirena device or its equivalent, for all women of childbearing age, and ensure that health workforce planning provides for delivery*.(3)

Increasing funded access to Mirena is consistent with the action areas of the 2016 New Zealand Health strategy (4). In particular the provision of Mirena is people powered in that it expands choice for women in contraception; it is closer to home as it is provided in the community and is about investing in the life of the whanau; and it adds value by reducing inequities since it is a method very suited to women with complex chaotic lives. In addition it encourages a team approach as the provision of timely and appropriate contraception to all women requires cooperation between general practice, maternity

services, secondary care, school based clinics, sexual health clinics, mental health facilities and family planning.

The opportunity for general practice to intervene in the provision of contraception for young people was demonstrated in a study reported in the BMJ in 2000 showing that young people do attend their GP prior to becoming pregnant, (5). The BEACH study in Australia in 2012 concluded that Australian general practice has not embraced the prescribing of LARC as recommended in clinical guidelines (6). In New Zealand in 2016 a Kaupapa Māori study of 14-19 year olds demonstrated multiple missed opportunities to promote contraception and stressed the need to move to more LARC (7). The need to have available appropriate contraception that is acceptable to our young people, and other vulnerable groups in our society, has been highlighted for over a decade now and this recent Wellington study is an indictment as to how much we are failing our women.

Unmet need for contraception

The Growing up in New Zealand study demonstrated that 40 % of pregnancies in New Zealand are unintended.(8) While unintended does not mean unwanted it does mean that women have been denied a choice; an opportunity to plan their pregnancy, to space their children, to recover from one pregnancy before beginning another - with the myriad of health benefits that are associated with such planning, for example starting folic acid when the LARC is removed, advice and assistance if necessary to stop smoking and avoid alcohol and maintaining breast feeding for longer and restoring iron stores before beginning a further pregnancy .

In some communities the unplanned pregnancy rate is much higher, with an unpublished survey of women attending a Jadelle insertion clinic in South Auckland reporting an 80% unplanned pregnancy rate.

The economic benefits of preventing unplanned pregnancies from a social and health perspective have been well documented (9,10), as has the evidence for LARCs as the most cost effective method of achieving this (11, 12, 13).

Populations with higher needs

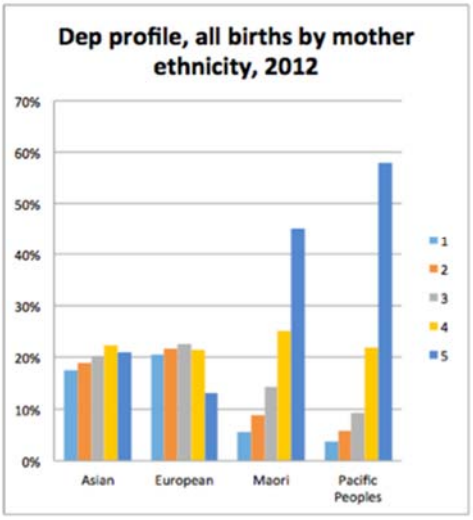
(i) Women 25-44: According to the 2011-12 New Zealand Health Survey of adults, women aged between 25 and 44 were much more likely than any other age group to have unmet primary care needs (14). Women in this age group are busy, frequently juggling full time work with running a household and caring for children. While they may attend primary care for their children they are less likely to present with their own medical needs.

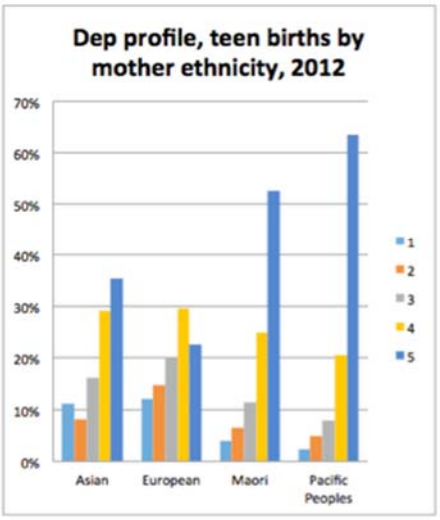
(ii) High Deprivation: Women from areas of high deprivation use contraception significantly less than women from low deprivation areas – 45% cf 65 % (15). This may be due to a variety of barriers which could include:

a) Ability to afford health care
b) reduced health literacy regarding contraception
c) reduced access to medical advice
d) complex chaotic lives.

(iii) Youth: Young people have difficulty accessing effective contraception and this is further exacerbated if the young people are from high deprivation schools (40% not using contraception) versus low deprivation schools (15% not using contraception) (16).

(iv) Māori and Pacific: Māori and Pacific women from a decile 5 area group have a much higher pregnancy rate than other ethnicities and this is even more marked for teen births, as illustrated in the graphs below (15).





Why Mirena?

When women were able to choose whatever contraception method they preferred, without barriers of information, cost or availability, 67% choose a LARC, with 47% choosing a Mirena (2). This clearly shows women's preference. In similar circumstances at New Zealand abortion clinics where women are well informed on contraception and there is no cost barrier to their choice, 49% of women are choosing LARC (17). Currently in New Zealand only women who can afford to purchase the Mirena for themselves are able to use it for contraception - an inequitable situation.

Alternative Treatments

1. Jadelle: The Hormone and Contraception Subcommittee of PTAC in May 2009 recognised the importance of LARC and recommended the listing of a hormonal LARC on the Community Pharmaceutical Schedule with a high priority and no restrictions (18). Jadelle was subsequently added to the Pharmaceutical schedule as the sole subsidised hormonal LARC from 1/8/2010 until 31/12/13. A report on the experience of New Zealand women during their first year of use of Jadelle found that 18% had their implant removed; and for more than half of those cases it was because of the bleeding pattern (19). The College is aware of an anecdotal report that Jadelle has gained a reputation as a "tramp stamp" which is easily palpable by men when they hold a women's arm, and glows under fluorescent lighting found at discos. While Jadelle is a very effective LARC there are issues around its use that that make it unacceptable to a significant proportion of women.

2. Copper IUCD: The Hormone and Contraception Subcommittee of PTAC also noted that while the copper IUD was an effective LARC the heavy menstrual bleeding associated with its use was not clinically acceptable for some patients and switching to Mirena is the preferred treatment option (18). After counselling about the various forms of LARC women are often reluctant to accept a method that is likely to make their periods heavier.

3. Depo Provera: Depo Provera is sometimes considered a LARC as it lasts for 3 months and is reversible, but the requirement to present for ongoing injections every 12 weeks means the user failure rate of 6% is less acceptable. The large dose of hormone in Depo Provera is responsible for more side effects: weight gain, and acne causing the most concern.

4. Sterilisation: Sterilisation carries a similar success rate to LARCs but even in women who have opted for permanent loss of fertility there is a significant likelihood of regret that is inversely related to the age at sterilisation (20). In addition this is very expensive when done privately and there can be a long wait to have this done in the public system.

5. Oral contraception: Contraception methods that require daily compliance have a higher failure rate than LARC. The combined pill is not recommended for women with a high BMI.

Other Health benefits

1. Prevention of Endometrial Hyperplasia

Endometrial hyperplasia, which is classified as simple, complex or atypical, can progress to endometrial cancer. Mirena causes endometrial growth suppression that is more effective than systemic levonorgestrel and occurs within three months of its insertion.

A Cochrane review in 2013 confirmed that Mirena is a safe and effective treatment for non-atypical endometrial hyperplasia but further investigation is required to ascertain whether Mirena is an alternative to hysterectomy for atypical endometrial hyperplasia (21).

A high BMI significantly increases the risk of endometrial cancer due to the stimulatory effects of additional oestrogen from adipose tissue and the accompanying progesterone deficiency leading to endometrial proliferation, hyperplasia and endometrial cancer (22). Populations at risk are those with a higher BMI; Māori females being twice as likely to be obese as non-Māori females and Pacific females have a significantly higher mean BMI than non-Pacific females (23).

An audit of women in South Auckland being managed in general practice on the abnormal uterine bleeding pathway, with a pipelle and ultrasound, found that fifty percent of the women required a referral to secondary care because of abnormal results (24). The provision of Mirena earlier in the natural history of this condition may prevent its progression, reduce the pathology in the community and the expense on the health system from having to manage these patients at a later stage in their illness.

2. Anaemia

It is estimated that 20% of women of reproductive age in New Zealand are iron deficient due to the demands of pregnancy and blood loss during menstruation, causing significant morbidity such as fatigue, weakness, reduced ability to fight infections, difficulty concentrating, headaches, shortness of breath and angina (25).This is consistent for all women of childbearing age regardless of their ethnicity (23). Mirena reduces menstrual blood loss by at least 60% thereby increasing the concentration of ferritin and haemoglobin and reducing the incidence of anaemia (1).

One GP working in practice in a deprived area with a high Pacific population reported having approached mothers in the waiting room on occasion because they appeared so pale. They had come to bring their children to the doctor rather than for themselves. When a history was taken the woman reported feeling tired and struggling with their jobs and their children. They frequently wore nappies rather than pads to try to contain the volume of their menstrual loss. They have not sought contraception, help for their heavy periods or for their tiredness and anaemia.

B: Management of Heavy Menstrual Bleeding

The primary focus of the management of menorrhagia should be the impact that heavy menstrual bleeding has on the quality of life of the woman. Menorrhagia previously was defined as menstrual blood loss greater than 80mls and attempts made to quantify the blood loss directly or indirectly. This way of measuring menorrhagia may only capture half of the women whose lives are affected by their menstrual bleeding (20). In the U.K. NICE guidelines now recognise that it is the woman herself who determines whether the blood loss is a problem since she is the one whose physical, social, emotional or material quality of life is being affected (26).

Menorrhagia primarily impacts on women in the working age group. The National Health Interview Survey in the United States in 1999 was used to look at the effect of menorrhagia on employment and found a 6.9% reduction in work hours associated with heavy bleeding (27).

Mirena has been shown to not only be a cost–effective option for heavy menstrual bleeding across a variety of settings and a variety of countries but to also improve health related quality of life measures and maintain this improvement over 5 years (20).

The NICE guidelines, acknowledging the central focus of the women in the management of menorrhagia, recommend that if Pharmaceutical treatment is appropriate, Mirena should be the first line treatment (26). This contrasts with the special authority guideline that is currently in place in New Zealand that limits the eligibility for funding for Mirena in primary care to women with heavy menstrual bleeding with a haemoglobin below 120 or a ferritin below 16 in the last 12 months. The College has heard of women being advised to stop their iron tablets in order to become sufficiently anaemic to meet these criteria. One DHB, recognising the role of Mirena, is supplying these to their GPs on a case by case basis for women not meeting the PHARMAC criteria, providing a pipelle and ultrasound has been performed.

C: Endometriosis and Pelvic Pain

Although endometriosis can only be diagnosed by laparoscopy, if it is suspected in a women with pelvic pain of a cyclical nature, and providing there are no other concerning features such as dyschezia or deep dyspareunia, a pelvic mass or desired fertility, Mirena is an appropriate hormonal treatment. Only if there is a failed response to treatment is a referral to secondary care necessary (28). Initiating an effective treatment earlier in the course of this condition not only is more responsive to the women's suffering and the anguish of her family but it may reduce the time she needs off work, prevent a referral to secondary care and the costs involved with surgery.

Summary

The needs of women of reproductive age are not being met. There are huge unmet needs for contraception; more pronounced for the young, Māori and Pacific, and those from high deprivation areas. Unintended pregnancy places stress and financial cost on woman and their whanau. Increasingly stressed families are a cost to society.

The health system has costs associated with terminations of pregnancy, with maternity services - including increasingly complicated births - and particular costs associated with youth pregnancy.

Mirena is ideally suited to provide contraception as it is the preferred option of the majority of women and provides contraception this is reversible and yet not user dependent. This makes it an ideal option for disadvantaged women many of whom lead complex and chaotic lives with resulting poor adherence to other methods.

Contraception that is reliable and can also reduce the risk of anaemia and endometrial cancer provides health benefits that can improve the lives of women and their whanau, and reduce the demands on, and the costs of the health system overall.

Mirena's other benefits in the management of heavy menstrual bleeding and pelvic pain likewise have significant benefits to the individual, their whanau, and the health system. It is inequitable that these benefits are currently only available to women and whanau with the financial resources to afford the high initial outlay necessary to purchase the device.

"The Factors for Consideration" replaced PHARMAC's previous decision criteria in July 2016. They can be grouped into;

- Need
- Health Benefits
- Costs and savings
- Suitability.

As we have demonstrated, funding Mirena for contraception and widening access to funding for the management of heavy menstrual bleeding and pelvic pain, would provide significant Health Benefits, produce Cost Savings, be a Suitable option for many women for whom other options are not appropriate, and meet a huge Need. Most importantly funding Mirena would impact on the health of population groups already experiencing health disparities, in particular Māori, Pacific and the socioeconomically disadvantaged.

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