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## CPG OCP1 PRESCRIPTION OF HORMONAL CONTRACEPTIVES

**GUIDELINE STATUS:** FINAL 02/07/2008  
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### SCOPE OF PRACTICE

#### TARGET POPULATION

- Female clients requesting hormonal contraceptive for contraception who are not pregnant and where risk factors do not exceed Category 2 of the eligibility criteria of WHO Medical Eligibility Criteria for contraceptive use.<sup>1</sup>

#### EXCLUSION CRITERIA

Melbourne Sexual Health Centre offers initial prescriptions for the combined oral contraceptive pill (COCP), progestogen only pill (POCP) and intramuscular Depo-Provera. Where there are the following contraindications to prescribing<sup>2,3,4</sup>, the practitioner will refer the client for Medical Officer (MO) review.

- Women who are pregnant
- Women who are less than 6 months post partum
- Women who are breastfeeding
- Women with blood pressure more than 140 mmHg (systolic) or 90 mmHg (diastolic)

### GUIDELINE OBJECTIVES AND ANTICIPATED OUTCOMES

- Appropriate exploration of contraceptive choices and prescription of hormonal contraceptive medication
- Referral to appropriate agency where required
- Identification of individual STI risk and provision of appropriate screening

### BACKGROUND

#### CONDITION DESCRIPTION

Hormonal contraceptives are effective in preventing pregnancy and providing fertility control for women.<sup>2,4,5</sup> There are non-contraceptive benefits associated with certain hormonal contraceptives.<sup>4</sup> These include reduced risks of ovarian and endometrial cancers, benign breast disease and menstrual cycle disorders.<sup>4</sup> Hormonal contraceptives include progestogen only and oestrogen/progestogen formulations which can be administered via different routes: orally; intramuscular injection; per vagina; and intradermally.<sup>4</sup>

#### FACTORS AFFECTING CONTRACEPTIVE CHOICE<sup>2,5</sup>

- Women's choice and lifestyle considerations
- Age, Risk of STIs
- Adherence issues
- Parity, Time frame for returning to fertility
- Suitability when breast feeding
- Smoking history
- Co morbidities including metabolic syndrome, obesity, menstrual disorders, acne
- Risk factors for cardiovascular conditions or cancer
- Regular use of enzyme-inducing drugs or complementary medicines

**CLINICAL ASSESSMENT** <sup>2, 4, 5</sup>

<b>Consider and exclude the risk of pregnancy at time of consult</b>	<ul style="list-style-type: none"><li>Reasonably ensure that the woman is not pregnant if she meets the following criteria and has no symptoms or signs of pregnancy <sup>2, 4, 5</sup>:<ol style="list-style-type: none"><li>Has not had unprotected intercourse since the start of the last normal period</li><li>has been consistently and correctly using a reliable method of contraception</li><li>is within 5 days of the start of a normal period</li><li>is within 4 weeks post partum</li><li>is within 7 days post abortion or post miscarriage</li><li>is fully or nearly fully breastfeeding, amenorrhoeic and &lt; 6 months post partum</li><li>Urine HCG pregnancy test adds weight to excluding pregnancy and is only reliable if 3 weeks have elapsed since the date of last intercourse</li></ol></li></ul>
<b>General History</b>	<ul style="list-style-type: none"><li>Age</li><li>Medications including past hormonal contraceptive use</li><li>Cigarette smoking</li><li>Drug use (over the counter, recreational and complimentary therapies)</li><li>Blood pressure</li><li>Body Mass Index (BMI)</li></ul>
<b>Family History</b>	<ul style="list-style-type: none"><li>Cardiovascular disease, diabetes</li></ul>
<b>Gynaecological History</b>	<ul style="list-style-type: none"><li>Previous episodes of abnormal PV bleeding, investigations, results, diagnosis or differential diagnoses</li><li>Pap test history</li><li>Gynaecological surgery</li><li>Pelvic pain</li><li>Known gynaecological conditions</li></ul>
<b>Obstetric History</b>	<ul style="list-style-type: none"><li>Parity</li><li>Infertility or sub fertility</li></ul>
<b>Menstrual History</b>	<ul style="list-style-type: none"><li>Last normal menstrual period (LNMP)</li><li>Age at menarche, post menopausal bleeding</li><li>Intermenstrual bleed (IMB)</li><li>Cycle length, duration; estimated amount of flow, dates and patterns of last three normal menstrual periods</li><li>Presence of clots</li><li>Premenstrual symptoms</li><li>Colour / character of flow and related signs and symptoms (pain, odour, discharge)</li></ul>
<b>Contraceptive Use History</b>	<ul style="list-style-type: none"><li>Contraceptive use, type,</li><li>length of time used</li><li>side effects and missed pills</li></ul>
<b>Sexual History</b>	<ul style="list-style-type: none"><li>Risk of STI / BBV</li><li>Post coital bleeding (PCI)</li><li>Pain on sex or pelvic pain</li><li>Risk of pregnancy due to unprotected sexual contact</li></ul>

## CONTRACEPTIVE CHOICE

### FACILITATING CONTRACEPTIVE CHOICE<sup>6</sup>

- How the method works
- Effectiveness
- Advantages and disadvantages
- Side effects
- How to use
- Clinical follow up required
- What to do if the method is not used correctly or fails

Table OCP1.1 Contraceptive Choice<sup>2 3 4</sup>

- A monophasic Combined Oral Contraceptive (COC) containing 30 µg ethinylestradiol (EE) with levonorgestrel or norethisterone is a suitable first prescription of COC.<sup>2 4</sup>
- Norethisterone and levonorgestrel COCs have a lower risk of VTE than COCs containing desogestrel and gestodene.<sup>2 4</sup>
- There is no evidence to support the use of biphasic or triphasic COCs as suitable for the first prescription of COCs.<sup>2 4</sup>

However other considerations including lifestyle factors should be accounted for in determining the individual's choices other than the OCP.

## EXCLUSION CRITERIA

### Medical History<sup>2 3 4</sup>

- Women with current diagnosis of migraine, ischaemic heart disease (IHD), venous-thromboembolic event (VTE) or any cardiovascular disease or cerebrovascular accident (CVA)
- Women with a personal history of, or risk factors for deep vein thrombosis (DVT); pulmonary embolism (PE) or recent prolonged immobilization or major surgery
- Women with a personal history of hypertension, diabetes, hyperlipidaemia; liver disease or cholestasis associated with OCP; malabsorption syndrome including cystic fibrosis
- Women on drugs affecting liver enzymes including rifampicin, griseofulvin, phenytoin, carbamazepine, barbiturates, primidone or St Johns Wort or any other medication likely to impact on the efficacy of hormonal contraception
- Women with a history of previous allergy or hypersensitivity to OCP

### Risk Factors<sup>2 3 4</sup>

- Women age between 35 and menopause and who are smokers and obese (BMI > 30)

### Family History<sup>2 3 4</sup>

- Women with a family history (first degree relative) of cardiovascular disease at an early age (<50 years)

### Women with Cardiovascular Risk<sup>2 4</sup>

Cardiovascular risk is an important consideration in choosing an appropriate hormonal contraceptive. Combined oral contraceptives increase cardiovascular risk in women who have one or more cardiovascular risk factors

- Smoking in women over 35 years
- Obesity; body mass index >30kg/m<sup>3</sup>
- Uncontrolled hypertension, hyperlipidaemia or diabetes with vascular disease
- Family history of cardiovascular disease before age 50

### **Adolescents** <sup>2 4</sup>

Discuss potential side effects including reduced premenstrual symptoms, regular and reduced volume of menstruation, weight gain, and headaches

- Consider a low dose (30 microgram ethinylloestradiol) monophasic combined oral contraceptive
- Consider an implant or vaginal ring if compliance is an issue.

### **Women over 35** <sup>2 4</sup>

For women over 35, consider non-hormonal or progestogen only methods first if there are cardiovascular risk factors.

- Combined oral contraceptives can be used by women over 35 without cardiovascular risk factors

### **Metabolic Syndrome or Diabetes** <sup>2 4</sup>

- Consider non-hormonal contraceptives first in women with metabolic syndrome due to cardiovascular risk factors
- Hormonal contraceptives may be prescribed in non smokers who have diabetes without nephropathy, retinopathy or neuropathy.

### **Smokers** <sup>2 4</sup>

- Combined oral contraceptive use in heavy smokers substantially increases cardiovascular risk.

### **Venous Thromboembolic Event (VTE)** <sup>2 4</sup>

Combined oral contraceptive users have a higher than baseline risk of venous thromboembolic event. But this is rare among reproductive aged women.

#### **Risk of venous thromboembolism** <sup>2 4</sup>

- Age
- Obesity
- High oestrogen dose
- Smoking
- Prothrombotic conditions
- Family history of venous thromboembolism

Table OCP1.2 DVT risk<sup>2 3 4</sup>

### **Risk of Cancer** <sup>2 4</sup>

- There is continuing debate as to the COC increasing the relative risk of breast cancer (RR 1.24 in current COC users) A family history of breast cancer is classified as Category 1 for COC users.
- There is a small increase in the risk of cervical cancer in long-term COC users
- There is a 4 fold increase in the risk of liver cancer in long term COC users
- COC reduces the risk of endometrial and ovarian cancer

### **Use of Enzyme Inducing Drugs** <sup>2 4</sup>

Hepatic enzyme –inducing drugs can interact with hormonal contraceptives and reduce their efficacy.

- Phenobarbitone
- Phenytoin
- Carbamazepine
- Oxcarbazepine
- Topiramate
- Rifampicin
- Griseofulvin
- St Johns Wort

## Menstrual Disorders (Menorrhagia / dysmenorrhoea) <sup>2,4</sup>

- Initiate therapy with a monophasic combined oral contraceptive. If menorrhagia or dysmenorrhoea remains uncontrolled, tri-cycle pills to reduce the frequency of withdrawal bleeding.
- The levonorgestrel – releasing IUD is an alternative for managing menorrhagia.

## COMBINED CONTRACEPTIVE PILL (COC) <sup>2,4,11</sup>

### BACKGROUND

- Combined oral contraceptives (COC) are preparations of synthetic oestrogen and progestogen. Women take 21 days of hormone pills followed by 7 days placebo.<sup>4</sup>
- Monophasic formulations contain the same oestrogen and progestogen dose throughout the full 21 days of the course.<sup>4</sup>
- Triphasic formulations which alter the dose of oestrogen in the middle of the cycle reduce the potential for breakthrough bleeding. The progesterone component increases at 2 stages throughout the cycle.<sup>4</sup>

### MECHANISM OF ACTION <sup>2,4,11</sup>

- Inhibition of ovulation
- Cervical mucous thickening
- Prevention of implantation should fertilization occur

### ADVANTAGES OF COMBINED ORAL CONTRACEPTIVES <sup>2,4,11</sup>

- Highly effective with correct use
- Easily reversible
- Predictable withdrawal bleeds
- Manipulation cycles
- Improve acne
- Reduction in the risk of endometrial and ovarian cancer
- Reduction in benign breast disease, ovarian cysts
- Management of PMS, polycystic syndrome

Table OCP1.3 OCP Advantages <sup>2,4,11</sup>

POTENTIAL SIDE EFFECTS COC <sup>2,4,5,11</sup>	MANAGEMENT OF SIDE EFFECTS (Refer to MO)*
Headache	<ul style="list-style-type: none"> <li>• Medical evaluation of headache*</li> <li>• ↓ dose of <b>EE</b></li> <li>• oestrogen supplement in pill free week (if headaches occur in pill free week)</li> </ul>
Nausea	<ul style="list-style-type: none"> <li>• ↓ dose of EE*</li> <li>• Take pills at night</li> </ul>
Breast tenderness	<ul style="list-style-type: none"> <li>• Decrease dose</li> <li>• May be oestrogen or progestogen effect, may be benefit in changing pills*</li> </ul>
Acne	<ul style="list-style-type: none"> <li>• COCs generally improve acne</li> </ul>
Lowered Libido and mood changes	<ul style="list-style-type: none"> <li>• No evidence for management; individual response to pills; trying a change</li> </ul>
Weight gain	<ul style="list-style-type: none"> <li>• Lower dose</li> <li>• Try drospirenone containing pill – has diuretic effect*</li> </ul>
Chloasma	<ul style="list-style-type: none"> <li>• Change to POP</li> </ul>
Bloating	<ul style="list-style-type: none"> <li>• Lower dose or try drospirenone*</li> </ul>

Break through bleeding	<ul style="list-style-type: none"> <li>• Exclude pregnancy, STI, missed pills</li> <li>• ↑ oestrogen</li> <li>• change progestogen to either 1 mg norethisterone COC or to desogestrel or gestodene containing COC*</li> </ul>
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## COC - CLIENT INFORMATION

### Travel involving time-zone changes <sup>2, 4</sup>

- No intervention if individual is happy to take regular pill at the same 24 hour interval as the home time-zone
- To change to a preferred time, shorten the interval between two COCs but not lengthen it – may mean taking an extra active pill and starting the next active pack a day earlier

### Skipping periods <sup>2, 4</sup>

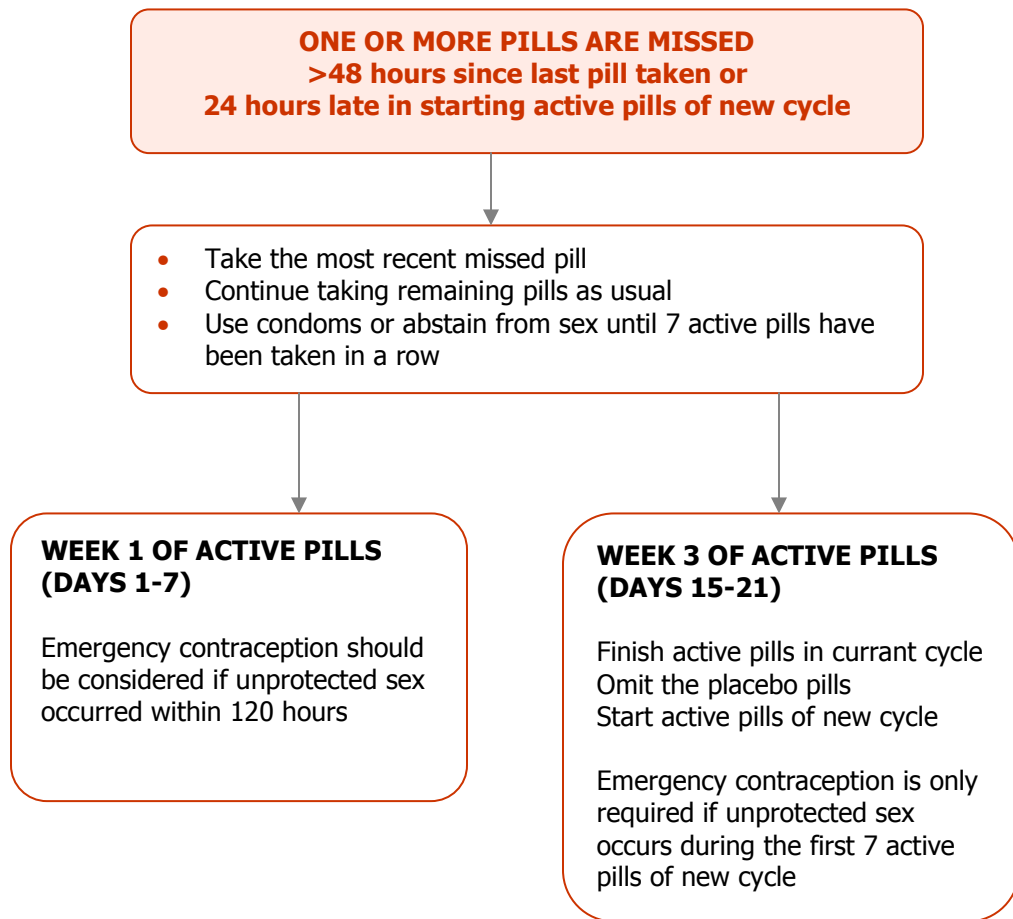
- Go straight to last active pill in the cycle to the first active pill in the next cycle

### Late and missed pills <sup>2, 4</sup>

- A late pill is defined as being up to 24 hours late
- A missed pill is defined as one that is more than 24 hours late
- Missing the active pill closest to the placebo pill prolong the pill free interval and increase the chance of break through ovulation
- Seven consecutive active pills are sufficient to suppress ovulation after which seven pill free days are needed for ovulation to occur
- A back up method of contraception, or abstinence, should be used if a pill is more than 24 hours late until the seven consecutive active pills have been taken.
- If the missed pills are in week three (day 15-21 of active pills) omit the pill free interval

### GI disturbance and antibiotics <sup>2, 4</sup>

- Pills should be taken as normal



**MEDICATION FORMULARY** <sup>2,4,5, 11</sup>

DRUG	INDICATIONS	ROUTE	DOSE	FREQUENCY	THERAPEUTIC CLASS/ Poisons Schedule	CONTRAINDICATIONS/ INTERACTIONS	PRECAUTIONS/ ADVERSE EFFECTS
<b>Ethinylloestradiol levonorgestrel</b>	Contraception	oral	30/150 mg	28 tablets continuously	B3 S4	<p><b>Absolute</b> Pregnancy, breast or gynecological malignancy, undiagnosed genital bleeding, women who wish to conceive within one year. Bleeding or coagulation disorder that precludes IMI</p> <p><b>Relative</b> Cerebrovascular or coronary artery disease, diabetes with vascular disease, severe cirrhosis, acute liver disease history of depression</p>	<p>Bone mineral density loss Attainment of peak bone mineral density in adolescents may be compromised with Depo usage.</p>
						<p>Possible liver enzyme inducer. Clients on liver enzyme inducing medications should have an MO review Aminoglutethimide</p>	<p>Menstrual cycle changes Weight changes Headache, Dizziness Rash, nausea, breast tenderness, infertility, BMD loss, anaphylactoid, Thromboembolic disease, ocular effects, Hirsutism, alopecia, abdominal pain, breast and cervical changes, cushingoid symptoms, sweating, Adrenal disturbance</p>

## PROGESTOGEN ONLY PILL (POP) <sup>2,4,5,12</sup>

### BACKGROUND

- Contains progestogen only
- All 28 pills contain same dosage
- One pill taken at same time every day, without a break

### MECHANISM OF ACTION <sup>6</sup>

- Cervical mucous thickening (primary mechanism)
- Prevention of implantation

### ADVANTAGES OF COMBINED ORAL CONTRACEPTIVES <sup>2,4,5,12</sup>

Progesterone only pill (POP) is a suitable alternative to the combined contraceptive pill for the following clients

- Previous VTE
- Side effects or contraindication with use of oestrogen
- Women over 35 years of age who are smokers
- Women who are lactating
- Women with hypertension, migraine, liver disease
- Women who have sickle cell disease
- Women who prolonged immobilization
- Diabetic women with cardiovascular disease
- Women who want to take a lower dose of hormones

### POP - CLIENT INFORMATION <sup>2,4,5</sup>

- Once a pill is > 3 hours late, it is considered a missed pill
- Clients are advised to recommence taking pill ASAP but use condoms for contraception for 48 hrs (i.e. until 3 consecutive pill have been taken).
- Consider emergency contraception pill for any acts of unprotected sex until 3 consecutive pills have been taken.

### POTENTIAL SIDE EFFECTS POP <sup>2,4,5</sup>

- irregular bleeding
- amenorrhea
- breast tenderness
- headaches
- pregnancy

**MEDICATION FORMULARY** 2,4, 5, 12

DRUG	INDICATIONS	ROUTE	DOSE	FREQUENCY	THERAPEUTIC CLASS/ Poisons Schedule	CONTRAINDICATIONS/ INTERACTIONS	PRECAUTIONS/ ADVERSE EFFECTS
<b>Levonorgestrel</b>	Progestogen only Hormonal contraception	oral	30mcg	Daily continuous	B3 S4	<p><b>Absolute</b> Severe arterial wall disease, active trophoblastic disease, Active thrombophlebitis or thromboembolic disorders Pregnancy, abnormal PV bleeding</p> <p><b>Relative</b> Undiagnosed vaginal bleeding , past history of ectopic pregnancy, breast and steroid dependent cancer, polycystic ovarian disease, functional ovarian cysts, liver disease, weight greater than 70kg Medications that interact with POP</p> <p>liver enzyme inducer medications</p>	<p>Menstrual cycle changes Headache, breast tenderness, increase in functional ovarian cysts</p>

**BACKGROUND**

Depo Medroxyprogestrone (DMPA) or Depo Ralovera is a long acting contraceptive administered every three months to women with adequate endogenous oestrogen.

- The effectiveness of DMPA is dependant on the women returning every three months for re-injection.
- Women with lower bodyweights conceive sooner than women with higher bodyweights after discontinuation of DMPA.
- Following injection levels medroxyprogesterone increase for approximately three weeks.

**MECHANISM OF ACTION** <sup>2,4,5,9</sup>

- It transforms proliferate endometrium into secretory endometrium.
- DMPA inhibits gonadotropin production which in turn prevents follicular maturation and ovulation.
- DMPA's long action is a result of its slow absorption from the injection site. Levels decrease exponentially until they are undetectable between 120-200 days following injection.

**CLINICAL INDICATORS** <sup>2,4,5,9</sup>

- Women requesting long acting contraception
- Women with contraindications to oestrogen
- Women who are lactating and require contraception
- Menstrual irregularities that have been investigated such as endometriosis
- Compliance issues with other methods of contraception

**CLIENT EDUCATION** <sup>2,4,5,9</sup>

- Injection due every 12 weeks (3 months)
- Discuss likelihood of bleeding irregularities and delay in return to fertility
- On cessation of Depo amenorrhea may last for up to 14 weeks
- Discuss bone mineral density issues and long term use

**LATE ADMINISTRATION** <sup>2,4,5,9</sup>

If more than 14 weeks have elapsed between injection (>2 weeks overdue) then pregnancy must be excluded before administering the next injection.

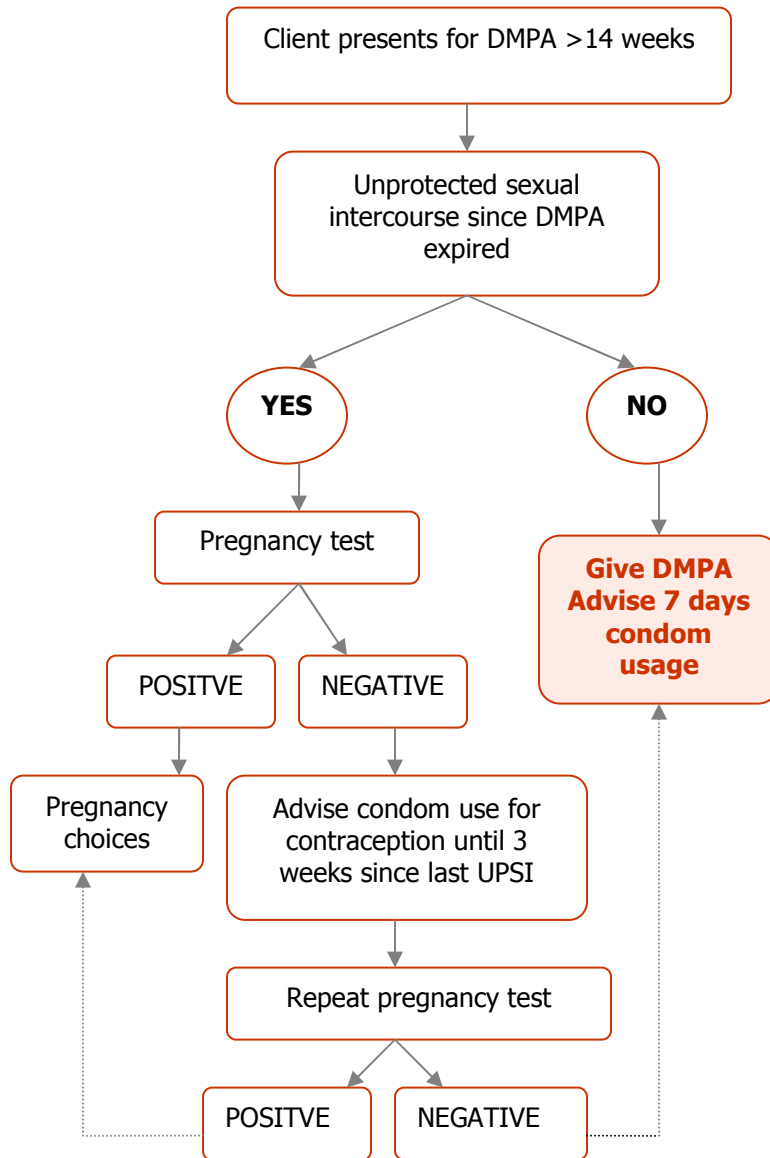
- If unprotected sexual intercourse (UPSI) has occurred within the past 2 weeks then condoms should be used and the client should return in two weeks for pregnancy test
- If pregnancy test is negative at two weeks and no further UPSI has occurred then Depo Ralovera can be administered
- Advise to use additional contraception for seven days following injection

**BONE MINERAL DENSITY CHANGES IN ADULT WOMEN** <sup>2,4,5,9</sup>

In a controlled clinical study adult women using DMPA for up to five years for contraception showed spine and hip mean bone density decreases of 5-6% when compared to the control group. Bone mineral density is more pronounced during the first two years of use with smaller declines in subsequent years. After stopping this form of contraception there was partial recovery of bone mineral density towards baseline. A longer duration of treatment is associated with a slower rate of bone mineral density recovery. Women under the age of 18 years may be at risk of failing to achieve their predicted peak bone mineral density.

**MO REVIEW**

- Abnormal bleeding patterns
- Unwanted side effects
- Provide written consumer medication information



**MEDICATION FORMULARY** <sup>2,4,5,9</sup>

DRUG	INDICATIONS	ROUTE	DOSE	FREQUENCY	THERAPEUTIC CLASS/ Poisons Schedule	CONTRAINDICATIONS/ INTERACTIONS	PRECAUTIONS/ ADVERSE EFFECTS
<b>Depo Medoxyprogesterone Acetate</b>	Progestogen only Hormonal contraception	IMI (Gluteal muscle)	150mg/ mL	Every 12 weeks	D S4	<p><b>Absolute</b> Pregnancy, breast or gynecological malignancy, undiagnosed genital bleeding, women who wish to conceive within one year. Bleeding or coagulation disorder that precludes IMI</p> <p><b>Relative</b> Cerebrovascular or coronary artery disease, diabetes with vascular disease, severe cirrhosis, acute liver disease history of depression</p>	Bone mineral density loss Attainment of peak bone mineral density in adolescents may be compromised with Depo usage.
						<p>Possible liver enzyme inducer. Clients on liver enzyme inducing medications should have an MO review Aminoglutethimide</p>	Menstrual cycle changes Weight changes Headache, Dizziness Rash, nausea, breast tenderness, infertility, BMD loss, anaphylactoid, Thromboembolic disease, ocular effects, Hirsutism, alopecia, abdominal pain, breast and cervical changes, cushingoid symptoms, sweating, Adrenal disturbance

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