Government of **Western Australia**
Department of **Health**

Pharmacist Resupply of Oral Contraceptive Pills Pilot – Western Australian Protocol

This protocol provides a framework for pharmacists authorised to resupply oral contraceptive pills to eligible patients. Patients who have requested the service but are not eligible for resupply should be referred to their regular medical practitioner or health service. This protocol is based upon evidence-based guidelines and pharmacists should read and use it in conjunction with relevant references, see 'Pharmacist assessment'.

Acronyms and Definitions

BMI	Body mass index	**POP**	Progestogen-only contraception
COC	Combined oral contraception	**SASA**	Structured Administration and Supply Arrangement
GP	General Practitioner	**STI**	Sexually transmitted infection
LARC	Long-acting reversible contraception	**UKMEC**	UK Medical Eligibility Criteria
OCP	Oral contraceptive pills	**VTE**	Venous thromboembolism

Program Scope	WA criteria
A. Age range	16-39 years (inclusive)
B. Dosage forms	Combined oral contraception and progestogen-only contraception. Dosage forms other than oral formulations excluded.
C. OCP history	OCP initiated by a General Practitioner or a Nurse Practitioner and has been stabilised for minimum 2 years continuously. Different OCP or hormones excluded on protocol medicines list are not permitted.
D. OCP review	A thorough review of the OCP with a medical practitioner or nurse practitioner. Minimum every 2 years.
E. Transgender and gender diverse people presumed female at birth	Included, and professional obligations apply.
F. Pill break	Maximum 2 weeks continuously.
G. Re-supply quantity	One manufacturer's pack, or maximum up to 12 months.
H. High dose estrogen (50 microg of ethinylestradiol)	Not permitted

Program Scope	WA criteria	
I. Permitted estrogens	Estradiol Ethinylestradiol Excluded – estetrol, mestranol	**See attachment 1**
J. Permitted progestogens	Levonorgestrel Norethisterone Drospirenone Nomegestrol Desogestrel Dienogest Gestodene Excluded - Cyproterone	**See attachment 1**
K. Exclusion criteria: **Including UKMEC Category 3 & 4 contraindications, and conditions that require immediate referral. Refer the patient to their regular GP with a copy of the assessment.** **Breastfeeding and postpartum risks are excluded due to the requirement for continuous OCP history for at least 2 years.** **See also:** UKMEC April 2016 (Amended September 2019) UKMEC April 2016 Summary Sheet (Amended September 2019)	**Combined oral contraception (COC)** • Current or previous history of breast cancer (including carrier of known gene mutations, e.g. BRCA) • Hepatocellular adenoma, or malignant liver tumour • Severe (decompensated) cirrhosis • Potentially pregnant • STI screening is indicated (although OCP may still be resupplied by the pharmacist) • Unexplained and un-investigated vaginal bleeding or acute, severe menstrual bleeding • If drug interactions are identified. For example, prescription/non-prescription medications (CYP 3A4/5 inducers such as carbamazepine, corticosteroids, modafinil, phenobarbital, phenytoin, rifampicin, St John's wort) • Migraine with/without aura • Prolonged immobilisation	**Progestogen-only contraception (POP)** • Current or previous history of breast cancer • Hepatocellular adenoma, or malignant liver tumour • Severe (decompensated) cirrhosis • Potentially pregnant • STI screening is indicated (although OCP may still be resupplied by the pharmacist) • Unexplained and un-investigated vaginal bleeding or acute, severe menstrual bleeding • If drug interactions are identified. For example, prescription/non-prescription medications (CYP 3A4/5 inducers such as carbamazepine, corticosteroids, modafinil, phenobarbital, phenytoin, rifampicin, St John's wort) • Ischaemic heart disease, stroke or transient ischaemic attack (TIA) that develops during use of POP.

Program Scope	WA criteria	
	• Age 35 years or older and current smoker or recently quit smoking in the last 12 months (including nicotine vaping) • History of ischaemic heart disease, stroke, or transient ischaemic attack • Hypertension (systolic blood pressure 140mmHg or higher, diastolic blood pressure 90mmHg or higher), including adequately controlled hypertension • Complicated valvular or congenital heart disease • Cardiomyopathy with impaired cardiac function • Atrial fibrillation • History of VTE or a first-degree relative with a VTE (provoked or unprovoked) under the age of 45 years • Positive antiphospholipid antibodies • Known thrombogenic mutations, e.g. factor V Leiden, prothrombin mutation, Protein S, Protein C, antithrombin deficiencies • Diabetes with nephropathy, retinopathy, neuropathy, or other vascular disease • Gall bladder disease (medically treated or current) • Past COC related cholestasis • Body mass index (BMI) ≥ 35kg/m2	

Explanatory notes

A. Age range

Patients under 16 years, or 40 years and over: Refer these patients confidentially to a GP, sexual health clinic, or health service.

Patients aged 16-17 years: These patients can have up to 4 months resupplied as an extension to their original prescription, provided other protocol conditions are met. Given the potential health and social risk factors, these patients should have more frequent contraception reviews and be encouraged to engage regularly with a GP. A thorough review is essential, and a new prescription must be issued for subsequent supplies.

Patients aged 18-39 years: These patients can have up to 12 months of OCP resupplied at once, guided by the patient's preference and the pharmacist's assessment. Other conditions must be considered when determining the quantity. For instance, a patient turning 40 years-of-age in a month should not be given a full 12-month resupply. Instead, resupplying one manufacturer's pack of OCP is acceptable, but the patient should be referred for a medical review.

B. Dosage forms

Only oral forms of contraception are eligible for resupply. However, pharmacists should consider discussing the use of Long-Acting Reversible Contraception (LARCs) with patients when appropriate, following the recommendations of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG).

Further information: Long Acting Reversible Contraception (LARC) - Consensus Statement (ranzcog.edu.au)

C. OCP history

The patient must have a stable history of using the requested OCP for at least 2 years. This requirement ensures that:

- The patient has undergone at least one medical review since starting the OCP.
- The OCP is well-tolerated by the patient.
- The patient demonstrates good adherence to the OCP regimen.

D. OCP review

Patients on OCP should have a medical review at least every 2 years. Before resupplying, pharmacists should verify the previous prescription by sighting it or through other physical or electronic records (e.g., My Health Records, dispensing records). The review date must be considered during resupply, ensuring that the quantity resupplied only allows for the continuation of OCP within the 2-year period.

E. Transgender and gender diverse (TGD) people presumed female at birth

Pharmacists providing contraception and sexual health advice for TGD individuals presumed female at birth must ensure the service is safe and accessible. It's important to verify that TGD individuals seeking contraceptive care are actively engaged with appropriate sexual health services as needed. The resupply of OCP is permitted for TGD individuals, provided all other protocol conditions are met.

Further information can be found here: FSRH CEU Statement: Contraceptive Choices and Sexual Health for Transgender and Non-Binary People (October 2017)

F. Pill break

Pill breaks should not exceed 2 weeks consecutively, with inactive pills not considered part of the pill break in this context. The total duration of pill breaks should not surpass 4 weeks within a 12-month period. If a patient frequently takes pill breaks, pharmacists should exercise their professional judgement and consider referring the patient to explore alternative contraception options.

Pharmacist assessment

- **Confidentiality**: Consultations must be conducted in a private room to maintain confidentiality, it should not be seen or heard by a person not involved in the consultation.
- **Consent**: Documented informed consent must be obtained from the patient. This can include financial consent (costs to the patient), consent to access medical records, and consent for referral.
- **Clinical Measurements**: For COC, measure the patient's blood pressure and BMI.
- **Risk Assessment**: Assess the patient's adherence, smoking status, adverse effects to OCP, changes in bleeding pattern, changes in health, new medications, and potential pregnancy.
- **References**: Refer to UKMEC, Therapeutic Guidelines, Australian Medicines Handbook (AMH), product information, and other relevant references.
- **Risk Categories**: Patients with UKMEC category 3 and 4 risks are considered high risk and must be referred. Category 2 risks can be considered, and pharmacists should exercise professional judgement when multiple category 2 conditions are present.
- **Social and Sexual Health Discussion**: Discuss social and sexual health issues as appropriate. Refer confidentially when required.
- **Adherence and Satisfaction Check**: Check the patient's adherence and satisfaction with OCP. Offer contraceptive counselling to explore other options as appropriate, e.g., LARCs.

Documentation and communication

The pharmacist must create and maintain a comprehensive clinical record of the consultation. The record must include:

- Patient identifiers and consent given.
- Date of consultation and name of pharmacist who undertook the consultation.
- Clinical information relevant to the resupply, e.g., medical and OCP history, BMI, BP, pregnancy status, STI risks.
- Clinical opinion reached by the pharmacist, as well as the actions and management plan.
- Details of the OCP supplied (generic name, strength, and quantity).
- Counselling and advice given to the patient.
- Any referrals made to another healthcare professional with patient's consent.

Practitioners' obligations in managing health records can be found here.

A copy of this record should be provided to the patient and, if necessary, their regular medical practitioner. Record keeping of supply must be kept for at least 2 years, in accordance with Part 12 of the Medicines and Poisons Regulations 2016.

The dispensing record for resupply must not list the previous medical practitioner or nurse practitioner in the 'prescriber' field. Instead, the name of the pharmacist who undertook the consultation must be used. Additionally, their Healthcare Provider Identifier-Individual (HPI-I) number must be included in the dispensing record, alongside with other critical information (e.g. patient's IHI) for My Health Record transmission.

The pharmacy dispensing software must be configured to enable the details of the supply to be uploaded to My Health Record, refer to your software vendor for comprehensive guidance on the requirements. As My Health Record is consumer

controlled, the patient can request to withhold the transmission of the dispensing record. The request must be documented, and such a request serves as a justifiable reason for not meeting condition *4(m)* of the SASA.

A referral should be initiated only with the patient's consent. Where practical, it should be directed to the patient's regular GP or another GP within the same practice. This approach helps maintain the continuity of care for the patient.

Non-pharmacological and self-care advice

Pharmacist should provide Consumer Medicines Information and/or a Self-Care Fact Card, and appropriate counselling on the OCP supplied. This includes:

- **Instructions**: How to take the OCP and recognise active/inactive pills.
- **Side Effects**: What side effects to expect, potential drug interactions. Signs of VTE and what to do if it is suspected.
- **Missed Pill**: What to do in the event of a missed pill, with instructions specific to the OCP resupplied. Additionally, emergency contraception options available if required.
- **Adherence**: Reiterate the importance of adherence and avoiding starting/stopping the pill.
- **Blood Pressure Monitoring**: The patient's blood pressure should be monitored at least at 12 monthly intervals.
- **GP Review**: Patients should engage with a regular GP and be reviewed at least every two years.
- **Cervical Screening**: Cervical screening is available for women from the age of 25 and is recommended every 5 years.
- **Breast Checks**: Breast checks are recommended for women who have a personal or family history of breast cancer. Patients should seek GP advice regarding the frequency and type of screening.
- **STI Screening**: STI screening is recommended for anyone who is sexually active and engaging in unprotected sex. Guidance and information on how to take a sexual history is available at: Sexual history | STI Guidelines Australia

Fees and charges

Pharmacists may charge a consultation fee for the service, in addition to the cost of OCP supplied. Pharmacists should make sure that the patient understood the costs involved when offering the service and inform them that free consultations are available through bulk-billing general practitioners.

Attachment 1: Summary table for OCP

Brand name examples	Estrogen	Progestogen
Progestogen only contraception		
Slinda		drospirenone 4 mg
Microlut		levonorgestrel 30 mcg
Noriday 28-day		norethisterone 350 mcg
Monophasic combined oral contraception		
Low estrogen dose		
Bella, Brooke, Rosie, Yana, Yaz	ethinylestradiol 20 mcg	drospirenone 3 mg
Femme-Tab 20/100, Lenest 20, Loette, Microgynon 20, Micronelle 20		levonorgestrel 100 mcg
Zoely	estradiol 1.5 mg	nomegestrol 2.5 mg
Standard estrogen dose		
Madeline, Marvelon	ethinylestradiol 30 mcg	desogestrel 150 mcg
Valette		dienogest 2mg
Brooklynn, Isabelle, Petibelle, Rosalee, Yasmin, Yelena		drospirenone 3 mg
Minulet		gestodene 75 mcg
Eleanor 150/30, Evelyn 150/30, Femme-Tab 30/150, Lenest 30, Levlen, Microgynon 30, Micronelle 30, Monofeme, Seasonique		levonorgestrel 150 mcg
Brenda-35, Diane-35, Estelle-35, Jene-35, Juliet-35 **NOT PERMITTED**		cyproterone 2 mg
Norimin, Brevinor	ethinylestradiol 35 mcg	norethisterone 0.5 mg
Norimin-1, Brevinor-1		norethisterone 1 mg
High estrogen dose		
Microgynon 50 **NOT PERMITTED**	ethinylestradiol 50 mcg	levonorgestrel 125 mcg
Norinyl-1 **NOT PERMITTED**	mestranol 50 mcg	norethisterone 1 mg
Unclassified estrogen dose		
Nextstellis **NOT PERMITTED**	estetrol 14.2 mg	drospirenone 3 mg
Multiphasic combined oral contraception		
Logynon, Trifeme, Triquilar, Triphasil	ethinylestradiol 30 mcg/40 mcg/30 mcg	levonorgestrel 50 mcg/75 mcg/125 mcg
Qlaira	estradiol 3 mg/2 mg/2 mg/1 mg	dienogest nil/2 mg/3 mg/nil