

# Explanatory Guide

## Prescribing for the Queensland Community Pharmacy Hormonal Contraception Pilot

### Purpose

This factsheet provides guidance on **prescribing as part of the Queensland Community Pharmacy Hormonal Contraception Pilot** (the Hormonal Contraception Pilot).

Legislation relevant to prescribing for the Hormonal Contraception Pilot includes:

- [The Medicines and Poisons \(Medicines\) Regulation 2021](#) (the Medicines Regulation)
- [Extended Practice Authority – Pharmacists – Part 3 – Queensland Community Pharmacy Hormonal Contraception Pilot](#) (the Pharmacists EPA).

### Scope

Pharmacists who are participating in the Hormonal Contraception Pilot are authorised under the Medicines Regulation to prescribe specified S4 hormonal contraceptives in accordance with the Medicines Regulation and the *Pharmacists EPA*.

### General information

- Prescriptions must be compliant with the Medicines Regulation and the Medicines and Poisons Act 2019. Refer to the [Writing Lawful Prescriptions](#) factsheet.
- Prescriptions for medicines prescribed under the Hormonal Contraception Pilot **must** be generated through the specified pilot clinical information system.
- Participating pharmacists are not authorised to prescribe medicines for 'off-label' use (i.e., using a medicine for a reason not listed as an indication for use on the Australian Register of Therapeutic Goods).

### Pilot prescribing vs usual pharmacy practice

Pharmacists who are authorised for the Hormonal Contraception Pilot **ONLY** (i.e. not authorised for the Queensland Community Pharmacy Scope of Practice Pilot) are not authorised to deliver medications management services (i.e. continued dispensing and therapeutic adaptation/substitution services) available through the Scope of Practice Pilot.

Section 156 of the Medicines and Poisons (Medicines) Regulation 2021 permits any community pharmacist to sell an S4 hormonal contraceptive to support continued treatment. This is part of usual pharmacy practice and is not a pilot service.

If a pharmacist determines that selling an S4 medicine as part of usual pharmacy practice is the most suitable option for the patient, **then details of the service should not be recorded in the pilot clinical information system as this is not a pilot service**. Refer to Example 1 for more guidance on the difference between prescribing and usual pharmacy practice.

## Pilot prescribing process

Prescribing must occur as part of a hormonal contraception consultation that includes a clinical assessment of the patient's contraceptive and sexual health needs and suitability for hormonal contraception that is documented in the specified clinical information system. This includes where the patient is already on hormonal contraception and the consultation outcome results in a prescription to continue the same medicine.

Where pharmacotherapy is required, a participating pharmacist may prescribe a hormonal contraception medicine where the following requirements are met:

- The medicine is being administered as part of a hormonal contraception pilot service, **AND**,
- The medicine is listed in Column 1, Appendix 5 of the *Pharmacists EPA*, subject to any restrictions or conditions listed in Column 2, Appendix 5 of the *Pharmacists EPA*.

The medicine must be prescribed in accordance with the 'Sexual and Reproductive Health: Contraception' section of the current online version of the Therapeutic Guidelines and the Hormonal Contraception Pilot Clinical Practice Guideline.

Other requirements for prescribing a medicine as part of the pilot include that:

- Pharmacists must not prescribe, in one prescription, greater than 12 month's supply of the medicine.
- The pharmacist should prescribe a sufficient quantity of the medicine, including repeats, to cover until the next scheduled clinical review or based on the patient's circumstances (e.g., any barriers that may limit access to a service including planned travel).
- The quantity and repeats prescribed should align with standard quantities issued for medicines (e.g., a standard manufacturer's pack/as outlined on the PBS).
- Where a patient chooses to have a prescription made as part of a pilot service dispensed at the pharmacy providing the pilot service, it is best practice for another pharmacist to dispense the prescription.

## Information for dispensers

- Prescriptions made as part of the Pilot may be dispensed at the pharmacy where the pilot service was delivered, or at another pharmacy, regardless of that pharmacy's participation in the Pilot.
- Prescriptions made as part of the pilot may not be able to be dispensed outside of Queensland. Patients that are planning to travel interstate should be advised to have an appropriate quantity of medicine dispensed prior to departure or to contact a pharmacy in the destination to check if a pilot prescription will be accepted.

## Hormonal Contraception Pilot prescribing examples

### Example 1

A patient wants a repeat supply of Levlen ED<sup>®</sup>. She has presented a prescription which is expired, and she is unable to see her GP.

#### Option 1: Prescribing under the Hormonal Contraception Pilot:

The *Pharmacists EPA* allows for prescribing of all combined oral contraceptive (COC) medications except for medications with 50 micrograms or more of Ethinylestradiol.

Figure 1 provides a list of the COC medications as outlined in the specified section of the Therapeutic Guidelines. Levlen ED<sup>®</sup> contains 30 micrograms Ethinylestradiol and 150 micrograms of progesterone. Therefore, it is permitted to be prescribed in accordance with the *Pharmacists EPA*.

Figure 1 Pharmacotherapy guidance in the 'Sexual and Reproductive Health: Contraception' section of the Therapeutic Guidelines

Therapeutic Guidelines		Formulations of combined hormonal contraception available in Australia
Estrogen dose (micrograms)	Progestogen dose (micrograms)	Brand name examples [NB1]
<b>monophasic vaginal ring</b>		
ethinylestradiol 2700 (15 micrograms/24 hours over 3 weeks)	etonogestrel 11 700 (120 micrograms/24 hours over 3 weeks)	NuvaRing
<b>monophasic oral</b>		
estetrol 14200	drospirenone 3000	NextStellis
estradiol 1500	norgestrel 2500	Zoely [NB2]
ethinylestradiol 20	levonorgestrel 100	Femme-Tab ED 20/100 [NB3] Lenest 20 ED Loette Microgynon 20 ED Micronelle 20 ED
ethinylestradiol 20	drospirenone 3000	Yaz [NB2]
ethinylestradiol 30	desogestrel 150	Madeline Marvelon
ethinylestradiol 30	dienogest 2000	Valette
ethinylestradiol 30	drospirenone 3000	Petibelle Yasmin
ethinylestradiol 30	gestodene 75	Minulet
ethinylestradiol 30	levonorgestrel 150	Eleanor 150/30 ED [NB3] Evelyn 150/30 ED [NB3] Femme-Tab ED 30/150 [NB3] Lenest 30 ED [NB3] Levlen ED [NB3] Microgynon 30 ED Micronelle 30 ED [NB3] Monofeme [NB3] Nordette Seasonique [NB4]
ethinylestradiol 35	cyproterone 2000 [NB5] [NB6]	Chelsea-35 ED Diane-35 ED Estelle-35 ED Jene-35 ED Juliet-35 ED Laila-35 ED
ethinylestradiol 35	norethisterone 500	Norimin [NB3]
ethinylestradiol 35	norethisterone 1000	Brevinor-1 [NB3] Norimin-1 [NB3]
ethinylestradiol 50 [NB7]	levonorgestrel 125	Microgynon 50 ED
mestranol 50 [NB7]	norethisterone 1000	Norinyl-1

The [Hormonal Contraception Pilot Clinical Practice Guideline](#) places no restrictions on prescribing combined oral contraceptive pills, aside from any applicable patient-specific contraindications (refer to Figure 2).

Figure 2 Pharmacotherapy guidance in the Hormonal Contraception Pilot Clinical Practice Guideline

**Combined oral contraceptive pill**

Refer to: [FSRH Clinical guidance – Combined Hormonal Contraception](#) <sup>(3)</sup>.

**Choice of COC**

- Comparative information about COCs to assist with COC choice is available in the [Australian Medicines Handbook: Combined oral contraceptives](#).
- The COC with the lowest effective dose of estrogen and progestogen that is well tolerated and able to provide acceptable menstrual cycle control for each patient should be chosen as first-line <sup>(9, 21)</sup>.
  - Low-dose estrogen pills (ethinylestradiol 35 micrograms or less) with levonorgestrel or norethisterone are considered the 'gold standard' <sup>(21)</sup>.
  - Newer COCs can be significantly more expensive than other types of COCs and have limited evidence to support any additional benefits over less expensive or PBD listed versions <sup>(21, 22)</sup>.
- Other guiding principles for COC pill selection are safety profile, affordability and additional non-contraceptive benefits if desired <sup>(21)</sup>.
- There have been limited head-to-head trials to guide COC selection; some pills have specific indications and non-contraceptive benefits that may assist with selection use e.g. acne <sup>(22)</sup>.
- Newer progestogens reduce the potential for androgenic, estrogenic and glucocorticoid effects <sup>(21)</sup>.
- The quadriphasic pill is indicated for heavy menstrual bleeding as well as contraception but it has complex instructions for managing a missed pill <sup>(22)</sup>.
- Triphasic pills are no longer commonly used because of a lack of benefits over other types <sup>(22)</sup>.
- COCs with a high estrogen dose (50 micrograms of ethinylestradiol or mestranol) are not routinely recommended for contraception because of the unacceptable risk of venous thromboembolism (VTE) <sup>(22)</sup>. These formulations are not permitted for use in the Hormonal Contraception Pilot.

Clinical Practice Guideline – Hormonal Contraception. Printed copies uncontrolled. Page 8  
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- The COCs available in Australia and for use in the Hormonal Contraception Pilot are listed in the [Therapeutic Guidelines: Formulations of combined hormonal contraception](#) table. **NB: This table does contain high estrogen COCs (50 micrograms of ethinylestradiol or mestranol) which are NOT permitted for use in the Hormonal Contraception Pilot.**

**Outcome:** it is within scope of the Hormonal Contraception Pilot to prescribe Levlen ED<sup>®</sup> providing:

- A consultation is carried out that includes a clinical assessment of the patient that is documented in the specified clinical information system.
- A prescription for the medicine is generated through the specified pilot clinical information system.
- In one prescription, no greater than 12 months' supply is prescribed.

**Option 2: Supply of medicine under Section 156 'Selling S4 oral hormonal contraceptives' of the Medicines and Poisons (Medicines) Regulation 2021.**

If it is determined that selling an S4 hormonal contraceptive to support continued treatment is the most appropriate option for the patient, then section 156 of the *Medicines and Poisons Regulation 2021* applies to this service. **It is not a pilot service, or a prescribing event.**

**Outcome:** should you choose this option, please **do not** record this service within the pilot clinical information system. Selling an S4 hormonal contraceptive is considered usual pharmacy practice and does not fall within the scope of the Hormonal Contraception Pilot.

## Example 2

A patient would like to try a new contraceptive option and has specifically requested Microgynon 50ED. She would like you to prescribe this for her.

The Pharmacists EPA details the following:

Figure 3: Excerpt of the Pharmacists EPA

Medicines for the Contraception Pilot	
Column 1 - Scheduled substance	Column 2 - Restrictions/Conditions
Combined hormonal contraception - combined oral contraceptives (COCs) and the contraceptive vaginal ring	<ul style="list-style-type: none"><li>The medicine must be prescribed in accordance with the current online version of the section of the Therapeutic Guidelines titled "Sexual and Reproductive Health: Contraception".</li><li>Excluding those with high estrogen dose (Formulations containing 50 micrograms or more of ethinylestradiol, or formulations containing mestranol are not permitted).</li></ul>
Progesterone-only contraceptive pill	<ul style="list-style-type: none"><li>The medicine must be prescribed in accordance with the current online version of the section of the Therapeutic Guidelines titled "Sexual and Reproductive Health: Contraception".</li></ul>
Depot medroxyprogesterone (injection)	<ul style="list-style-type: none"><li>The medicine must be prescribed in accordance with the current online version of the section of the Therapeutic Guidelines titled "Sexual and Reproductive Health: Contraception".</li></ul>

**Outcome:** the Pharmacists EPA prohibits the prescribing of medications with 50 micrograms or more of Ethinylestradiol, so in this case the pharmacist should discuss other appropriate contraceptive options or refer the patient to their usual care provider.

### Example 3

A 36-year-old female presents for a consultation and would like to commence hormonal contraception. She is 12 weeks post-partum. Following a consultation, you recommend that the patient commence Drospirone 4mg.

The Pharmacists EPA allows for prescribing of all progesterone-only contraceptives, provided they are prescribed in accordance with the 'Sexual and Reproductive Health: Contraception' section of the current online version of the Therapeutic Guidelines (refer to Figure 3 and Figure 4).

In Figure 5 you can see the Hormonal Contraception Pilot Clinical Practice Guideline places no restrictions on prescribing progesterone-only contraceptives, aside from any applicable patient-specific contraindications.

**Outcome:** prescribing Drospirone 4mg is within scope of the Hormonal Contraception Pilot, providing:

- A consultation is carried out that includes a clinical assessment of the patient that is documented in the specified clinical information system.
- A prescription for the medicine is generated through the specified pilot clinical information system.
- In one prescription, no greater than 12 months' supply is prescribed.

Figure 4: Pharmacotherapy guidance in the 'Sexual and Reproductive Health: Contraception' section of the Therapeutic Guidelines

#### Starting a POP containing drospirenone

If a POP containing drospirenone is preferred, use:

drospirenone 4 mg orally, once daily.

Advise users of a drospirenone POP:

- which pill to start on, and the difference between active and inactive pills; the hormone-free interval is advised because scheduled withdrawal bleeding may reduce the risk of unscheduled bleeding at other times in the cycle
- what to do if a [pill is missed](#)
- that poor absorption or some [drug interactions](#) can reduce the effectiveness of the POP, requiring use of an additional method of contraception.

Figure 5: Pharmacotherapy guidance in the Hormonal Contraception Pilot Clinical Practice Guideline

### Progestogen-only contraceptive pill

Refer to: [FSRH Clinical guidance – Progestogen-only Pills](#) <sup>(2)</sup>.

#### Choice of PoP

For patients who have a contraindication to estrogen in COC pills or have a preference for estrogen free contraception, POPs can be considered <sup>(2)</sup>. A new POP containing 4mg of drospirenone is available for use in Australia however not listed on the PBS and is significantly more expensive than the older POPs<sup>(24)</sup>.