NSW PHARMACIST PRACTICE STANDARDS FOR THE CONTINUATION OF HORMONAL CONTRACEPTION

A. APPROVED MEDICINES

Approved Medicines are listed in the Authority (dated 30 January 2025), applies to single or combined oral forms of:

a. ethinyloestadiol (40μg or less)
b. levonorgestrel
c. norethisterone
d. drospirenone (single ingredient preparations only)

B. GENERAL REQUIREMENTS

Pharmacists must hold general registration under the Health Practitioner Regulation National Law and have successfully completed the training requirements detailed in the Authority (dated 30 January 2025).

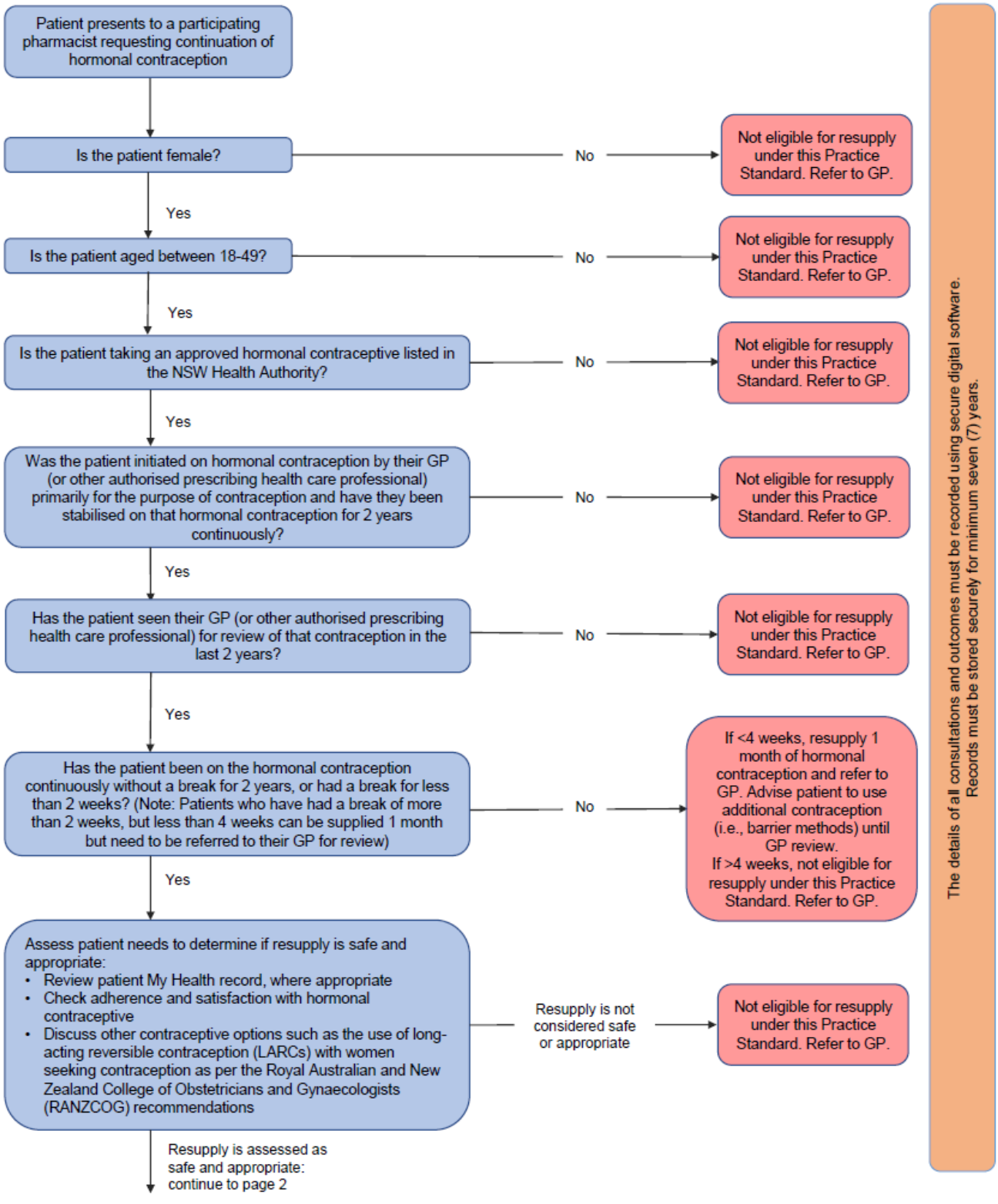
C. ADVERSE EVENTS

If the treating pharmacist becomes aware of an uncommon, unexpected or serious adverse event following treatment with an Approved Medicine, this should be reported to the Therapeutic Goods Administration. This should be conducted via the usual processes, by reporting online at https://aems.tga.gov.au/.

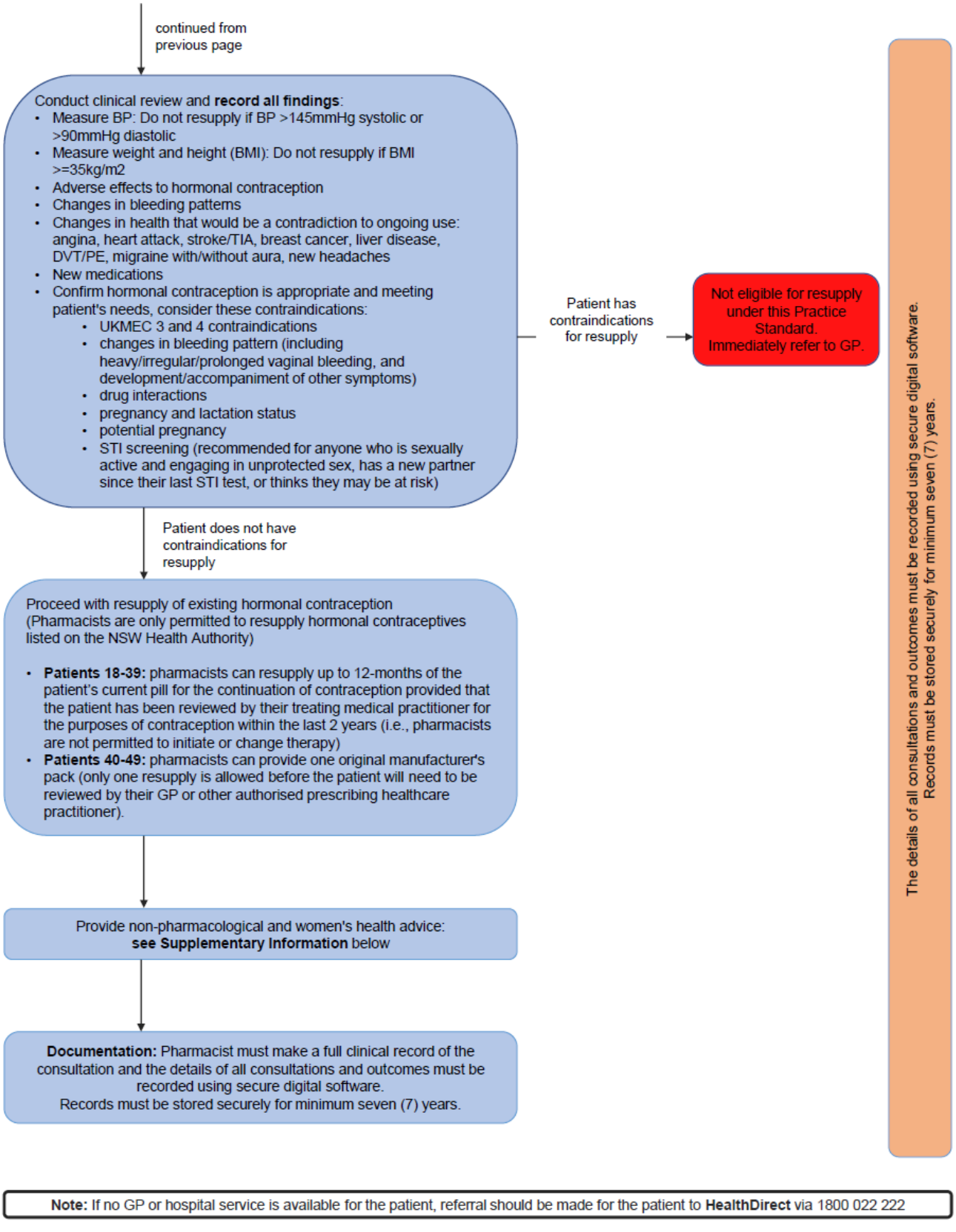
Additionally, you must notify the patient's usual general practitioner (if they have one).

D. PATIENT CONSENT, ELIGIBILITY AND RECORDS

The following flow chart should be used in consultations to assess the eligibility, identity and govern supply of suitable treatments, and guide associated referral requirements.



Note: If no GP or hospital service is available for the patient, referral should be made for the patient to **HealthDirect** via 1800 022 222



Note: If no GP or hospital service is available for the patient, referral should be made for the patient to **HealthDirect** via 1800 022 222

E. SUPPLEMENTARY INFORMATION AND NOTES

This supplementary information provides additional guidance and information for pharmacists delivering the Community Pharmacy Hormonal Contraception Continuation (Resupply) Service. It is to be used together with the flowchart and training modules and other resources provided by education providers.

Key points

- The Community Pharmacy Hormonal Contraception Continuation (Resupply) Service Practice Standard provides a framework for appropriately trained authorised pharmacists to resupply hormonal contraception to eligible patients as part of the NSW Health Authority (dated 23 September 2024).
- To receive a resupply of hormonal contraception, the patient must fulfill the eligibility requirements of the Practice Standard. Patients who have requested the service but are not eligible for resupply should be referred to their regular medical practitioner or health service.
- Pharmacists can resupply up to 12-months[1] of the patient's current hormonal contraception that has been prescribed primarily for the purpose of contraception provided that the patient has been reviewed by their treating medical practitioner or health service for the purposes of contraception within the last 2 years (i.e., pharmacists are not permitted to initiate or change therapy).
- Pharmacists must only resupply formulations listed in the Authority.
- Patients must be physically present in the pharmacy to be eligible for resupply.
- Patients are required to have a pharmacist consultation, including blood pressure monitoring, before a hormonal contraceptive method may be resupplied.
- Pharmacists must make a full clinical record of the consultation and the details of all consultations and outcomes must be recorded using secure digital software. Records must be stored securely for minimum seven (7) years.

CLINICAL DOCUMENATION AND COMMUNICATION

- The pharmacist must make an electronic clinical record, and a record in a pharmacy dispensing system regarding the supply of any hormonal contraceptives under these services, in accordance with the Authority.
- Where a patient has a My Health Record, the pharmacist must ensure the details of the hormonal contraception supply are uploaded to My Health Record, unless requested otherwise by the patient.

[1] For patients aged 40-49: pharmacists can only provide one original manufacturer's pack (only one resupply is allowed before the patient will need to be reviewed by their GP or other authorising prescribing healthcare practitioner).

PATIENT HISTORY

- Sufficient information must be obtained from the patient to assess the safety and appropriateness of resupply of the hormonal contraception. The My Health Record should be reviewed where appropriate and available.
- The patient history should include:
    - Age
    - Pregnancy and breastfeeding status
    - Underlying medical conditions, including new or recently diagnosed medical conditions (see UK Medical Eligibility Criteria [UKMEC] 3 and 4) [1], which may:
        - Be a contraindication to hormonal contraception e.g. migraine with aura (patients with a UKMEC category 3 or 4 condition are not eligible for resupply and require a referral)
        - Impact on contraceptive effectiveness and choice
    - Current medications, including adherence and satisfaction with hormonal contraception
        - Pharmacists must ascertain whether use of hormonal contraception has been continuous and can resupply according to the Practice Standard.
        - If a patient frequently takes pill breaks, pharmacists should use professional judgement and consider referring the patient to explore alternative contraception options e.g. long-acting reversible contraception (LARCs).
    - Drug allergies/adverse effects, including any adverse effects of hormonal contraception
    - Prior use of contraceptives, tolerability, and adverse effects
    - Smoking status, including vaping
        - There is an increased risk of using hormonal contraception in smokers over 35 years.[2]
    - Any unexplained and un-investigated vaginal bleeding or acute, severe menstrual bleeding
    - Any headaches indicative of migraines
    - Last Cervical Screening Test[3] and Breast check
    - HPV vaccination status

Sexual and social history

- In addition to a standard patient history, pharmacists must also consider taking a brief sexual history from the patient to inform shared decision making/appropriateness of hormonal contraception resupply.

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[2] Family Planning Alliance Australia recommends: 'Until further evidence is available, vaping with nicotine is considered equivalent to cigarette smoking in relation to the MEC for contraceptive use. As it is not possible to determine equivalency of exposure between vaping and smoking, any vaping in those aged 35 years and older will be MEC 4 (i.e. absolutely contraindicated) for use of combined hormonal contraception.' [13]

[3] All patients seeking contraception who have not had a cervical screening test (CST) in the previous 5 years should be advised to see a medical practitioner for a CST, and a referral provided if the patient consents. They are still eligible for the hormonal contraception resupply service.

- The following issues may be considered but may not be relevant to all people: previous use and experiences with contraception, current relationship status and risk factors for STIs (including STI history of current and/or recent partner if applicable). Guidance and information on how to take a sexual history is available at: https://sti.guidelines.org.au/sexual-history/. [2]

Sexually transmitted infection (STI) screening

- STI screening is recommended for anyone who is sexually active and engaging in unprotected sex, has a new partner since their last STI test, or thinks they may be at risk.
- Pharmacists should recommend STI testing for individuals who may be at risk even if the individual does not report any symptoms.
- Presence of genitourinary symptoms that might suggest a STI: changes in vaginal or urethral discharge; vulval, genital skin problems or symptoms; lower abdominal pain; dysuria.
- Aboriginal and Torres Strait Islander People are disproportionally affected by STIs. Consider the Australian Consensus STI Testing Guideline for Aboriginal and Torres Strait Islander People for priority populations testing and frequency or recommendations on STI screening. [3]

Bleeding pattern and menstrual history

- Any changes in vaginal bleeding and the development or accompaniment of other symptoms may indicate underlying pathology. This requires referral to a medical practitioner or health service for further investigation and management.
- Changes in bleeding pattern may include abnormalities in frequency (e.g. heavy bleeding), irregular bleeding, prolonged menstrual bleeding, abnormalities in volume, intermenstrual bleeding, and post-coital bleeding.
- Development or accompaniment of other symptoms may include dysmenorrhea (pain and cramping with bleeding), vaginal discharge, dyspareunia (pain with intercourse), changes in bladder or bowel function, weight gain or loss, headaches, visual disturbances, hirsutism, and acne.

Women over 40

- Despite a natural decline in fertility, women over 40 require ongoing contraception until they reach menopause if they wish to avoid unplanned pregnancy.
- As per the Faculty of Sexual and Reproductive (FSRH), women over 40 have an age-related increased background risk of cardiovascular disease, obesity, breast cancer and most gynaecological cancers. [4] As a result, choice of contraceptive method needs to be reviewed with their medical practitioner or health service.
- Women over 35 who smoke should be advised to stop combined hormonal contraception as the risk of mortality associated with smoking becomes clinically significant at this point. [5]

- Women over 50, should be advised to no longer use combined hormonal contraception as there are safer methods of contraception at this stage.

EXAMINATION

- The pharmacist should measure blood pressure (BP) and the patient's height and weight to calculate BMI to determine the patient's suitability for continuing their OCP and record this information in their clinical software program.
- Note that a single elevated BP reading is not enough to classify an individual as hypertensive (note that activity immediately prior to consultation should also be taken into consideration) and a second BP reading should be taken at the end of the consultation. If BP remains elevated, the patient should be referred to a medical practitioner or health service for further assessment and selection of an appropriate contraceptive method.
- BP should be monitored and recorded every 12 months.
- BMI should be calculated on the first presentation, and professional judgement exercised regarding whether BMI needs to be recalculated on subsequent presentations (i.e., consider length of time between presentations, changes in body weight).

SEXUAL AND REPRODUCTIVE HEALTH COUNSELLING

Sexual and domestic abuse

- Pharmacists must be aware of the possibility that a woman seeking contraception may be and/or has been subjected to sexual violence or abuse (assault or sexual coercion), either within a relationship or outside of a relationship.
- If the pharmacist becomes aware of this during the consultation, they should provide appropriate support and assistance, including referral to support options depending on the patient circumstances:
    - Referral options include to the local hospital, sexual health clinic and/or community-based sexual violence support services. A list of family violence statewide support services including confidential crisis support, information and counselling in NSW is available at NSW Government domestic, family and sexual violence [6]
- If required, emergency contraception may be supplied as per standard pharmacy care, or the person may be referred to an appropriate medical practitioner or health service for another method of emergency contraception e.g. insertion of a copper intrauterine device.

Transgender, gender diverse and non-binary people

- These services are inclusive of transgender, gender diverse, intersex or non-binary people assigned and/or presumed female at birth - current gender identity does not impose any restrictions on methods of contraception that may be used; the same considerations apply for choosing safe and effective

contraception, including personal characteristics, existing medical conditions and current medicines.
- Pharmacists may refer individuals assigned and/or presumed female at birth who are at risk of pregnancy to a general practitioner or specialist sexual health services, if not already engaging with these services, to ensure that they receive comprehensive and culturally safe sexual healthcare that is tailored to their individual needs.

Aboriginal and Torres Strait Islander people

- Sexual health is often not openly discussed in Aboriginal and Torres Strait Islander cultures and 'shame' (a deeply internalised feeling of inadequacy, self-doubt or ostracism) may be a strong barrier to First Nations people seeking sexual health care or contraception, especially in the community pharmacy setting in smaller communities.
- All health care providers must be cognisant of causing additional 'shame' to Aboriginal and Torres Strait Islander people while providing reproductive counselling or advice.
- It may be necessary (but not always) and beneficial to refer Aboriginal and Torres Strait Islander people seeking contraception to a medical practitioner or health service where the person has an existing relationship (if the person consents).

Provision of non-pharmacological and women's health advice

- Offering comprehensive counselling that covers adverse effects, instructions for use and patient expectations where this is required assists to promote effective and ongoing contraceptive use.
- Comprehensive advice and counselling (including supporting written information when required) as per the Therapeutic Guidelines, Australian Medicines Handbook, UKMEC, and other relevant resources, should be provided to the patient:
    - Consumer Medicines Information and/or other resources/handouts endorsed by relevant organisations.
    - Appropriate counselling on the hormonal contraception supplied, (i.e., how to take, side effects to expect/how to manage side effects, when the OC is less effective, what to do in the event of a missed pill, reiterate the importance of adherence and avoiding starting/stopping the pill)
    - Educate patients on the importance of getting regular women's health and sexual/reproductive health checks
- If patients have a concern with the type of hormonal contraception they are using, encourage them to speak with their medical practitioner or health service and make appropriate referrals.
- Presentations to the community pharmacy for contraceptive resupply provide an important opportunity to engage patients in preventative healthcare, such as screening, education, vaccination, and referral to a medical practitioner or

health service where appropriate. Patients should be provided information about and be encouraged to make an appointment for the following screening:

- Cervical screening – routine screening is available for people from the age of 25 and is recommended every five years
- Breast checks – people who have a personal or family history of breast cancer, should be advised to see their medical practitioner or health service for advice regarding frequency and type of screening
- STI screening – recommended for anyone who is sexually active and engaging in unprotected sex, has a new partner since their last STI test, or thinks they may be at risk.
- Pharmacists may also discuss the use of LARCs with patients when appropriate, as per the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) recommendations. See Long Acting Reversible Contraception (LARC) - Consensus Statement for further information.[7]

CONTRAINDICATIONS TO HORMONAL CONTRACEPTION

1. The Therapeutic Guidelines - Contraception indicates a range of contraindications and precautions for combined hormonal contraception and progestogen-only oral contraception.[9] These are based on the UK Medical Eligibility Criteria (UKMEC) and include conditions in Table 1 and 2 (not an exhaustive list).
2. For a full list of UKMEC 3 and UKMEC 4 classified conditions, see:
    - FSRH Guideline Combined Hormonal Contraception [10]
    - FSRH Clinical Guideline: Progestogen-only Pills [11]
    - FSRH UK Medical Eligibility Criteria for Contraceptive Use [1]
    - FSRH Progestogen-only Injectable Contraception [12]
    - RANZCOG Contraception Clinical Guideline [4]

Table 1: Contraindications to resupply of combined hormonal contraceptives

UKMEC Category 3 and 4 contraindications, and other conditions that require immediate referral
• Current or previous history of breast cancer (including carriers of known gene mutations associated with breast cancer) • Migraine with/without aura • Current or past history of ischaemic heart disease, stroke or transient ischaemic attack • Aged 35 years or older and current smoker or recently quit smoking (including nicotine vaping*) in the last 12 months • Hypertension (systolic blood pressure 140 mmHg or higher, or diastolic blood pressure 90 mmHg or higher), including adequately controlled hypertension • Hypertension, with vascular disease • Complicated valvular or congenital heart disease • Cardiomyopathy with impaired cardiac function • Atrial fibrillation • Current or past 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 • Prolonged immobilisation • Severe (decompensated) cirrhosis • Hepatocellular adenoma or malignant liver tumour • Body mass index (BMI) 35 kg/m2 or more • Diabetes with nephropathy, retinopathy, neuropathy or other vascular disease • Gall bladder disease (medically treated or current) • Undiagnosed mass/breast symptoms (only if the condition is pre-existing and the COCP is initiated) • Multiple risk factors for cardiovascular disease (such as smoking, diabetes, hypertension, obesity, and dyslipidaemias) • Past COC related cholestasis • Organ transplant - Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy • Acute viral hepatitis, or flare (only if the condition is pre-existing and the COC is initiated)
*As per Australian consensus guidelines

Table 2: Contraindications to resupply of the progesterone only pill

UKMEC Category 3 and 4 contraindications, and other conditions that require immediate referral
• Current or previous history of breast cancer • Unexplained vaginal bleeding (suspicious for a serious condition) before investigation for the cause • Severe (decompensated) cirrhosis • Hepatocellular adenoma or malignant liver tumour • Ischaemic heart disease, stroke or transient ischaemic attack (TIA) that develops during use

References

[1] Faculty of Sexual and Reproductive (FSRH), “UK Meical Eligibility Criteria for Contraceptive Use,” 2016, amended September 2019. [Online]. Available: https://www.fsrh.org/Common/Uploaded%20files/Standards-and-Guidance/fsrh-ukmec-full-book-2019.pdf.

[2] ASHM, “Australian STI Management Guidelines for use in Primary Care,” 2024. [Online]. Available: https://sti.guidelines.org.au/sexual-history/.

[3] ASHM, “Australian Consensus STI Testing Guideline For Aboriginal And Torres Strait Islander People,” April 2022. [Online]. Available: https://ashm.org.au/resources/australian-consensus-sti-testing-guidelines-for-aboriginal-and-torres-strait-islander-people/.

[4] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), “Contraception Clinical Guideline,” August 2024. [Online]. Available: https://ranzcog.edu.au/wp-content/uploads/Contraception-Clinical-Guideline.pdf.

[5] Faculty of Sexual and Reproductive (FSRH), “Guideline: Contraception for Women Aged Over 40 Years,” August 2017, amended July 2023. [Online]. Available: https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-guideline-contraception-for-women-aged-over-40-years-august-2017-amended-july-2023-.pdf.

[6] NSW Government Communities and Justice, “Domestic, family and sexual violence,” August 2023. [Online]. Available: https://dcj.nsw.gov.au/children-and-families/family-domestic-and-sexual-violence.html.

[7] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), “Consensus Statement: Reducing Unintended Pregnancy for Australian Women Through Increased Access to Long-acting Reversible Contraceptive Methods,” July 2017. [Online]. Available: https://ranzcog.edu.au/wp-content/uploads/2022/05/Long-Acting-Reversible-Contraception-LARC-Consensus-Statement.pdf.

[8] Pharmaceutical Society of Australia (PSA), “Guidelines for pharmacists administering medicines by injection,” November 2020. [Online]. Available: https://my.psa.org.au/servlet/fileField?entityId=ka10o000000QN7DAAW&field=P.

[9] Therapeutic Guidelines, “Sexual and Reproductive Health,” 2023. [Online]. Available: https://tgldcdp.tg.org.au.acs.hcn.com.au/topicTeaser?guidelinePage=Sexual%20and%20Reproductive%20Health&etgAccess=true.

[10] Faculty of Sexual and Reproductive (FSRH), “Guideline: Combined Hormonal Contraception,” January 2019, amended October 2023. [Online]. Available: https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-guideline-combined-hormonal-contraception-october-2023.pdf.

[11] Faculty of Sexual and Reproductive (FSRH), “Guideline: Progestogen-only Pills,” August 2022, amended July 2023. [Online]. Available: https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-ceu-clinical-guideline-progestogen-only-pills-aug22-amended-11july-2023-.pdf.

[12] Faculty of Sexual and Reproductive (FSRH), “Guideline: Progestogen-only Injectables,” December 2014, Amended July 2023. [Online]. Available: https://www.fsrh.org/Common/Uploaded%20files/documents/progestogen-only-injectable-december-2014-amended-11july2023.pdf.

[13] Family Planning Alliance Australia, “Vaping and medical eligibility for hormonal contraception,” January 2020. [Online]. Available: https://shvic.org.au/assets/img/content/Vaping-and-medical-eligibility-for-hormonal-contraception_Dec20.pdf.

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