



BEDFORDSHIRE, LUTON AND MILTON KEYNES AREA PRESCRIBING COMMITTEE (APC)

Contraception Prescribing Guidance for Primary Care

(May 2024)

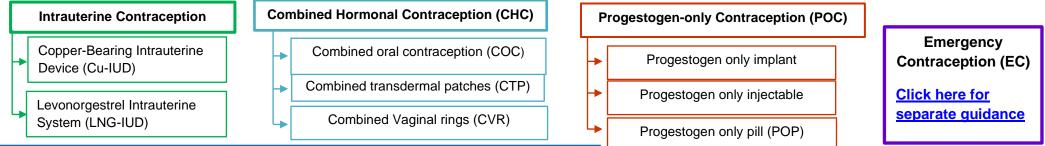
Approved by BLMK APC May 2024

Review date: May 2027

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

BLMK Contraception Prescribing Guidance

This guidance is based on best practice advice, given by the Faculty of Sexual Reproductive Health (FSRH), NICE Clinical Knowledge Summaries (CKS) and may vary from the individual drug SmPCs

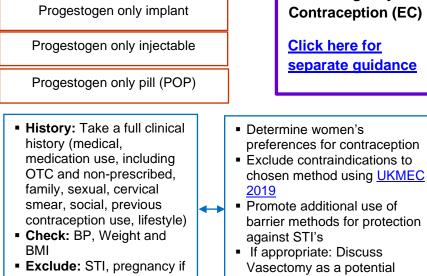


Summary of key messages

This guideline should be read in conjunction with the individual <u>Summaries of Product Characteristics</u> (<u>SmPCs</u>): ,the relevant **FSRH guidance** , **FSRH UK Medical Eligibility criteria for contraceptive** (**UKMEC**) -see <u>FSRH UKMEC criteria (2019)</u>, <u>CKS guidance</u> and the <u>eBNF</u>

<u>UKMEC</u> criteria should be applied to assess a woman's eligibility for use of IUD, CHC or POC.

- Women should be made aware that no method of contraception is 100% effective.
- Women requiring contraception should be given information about and offered a choice of all methods, including long-acting reversible contraception (LARC) methods.
- All currently available LARC methods (intrauterine devices, implants, and injectable contraceptives) are more cost effective than the combined oral contraceptive pill even at 1 year of use. IUDs and implants are more cost effective than injectable contraceptives.
- LARC methods are also the most reliable method of contraception and should be 1st Line choice where possible. Information on effectiveness of the different methods can be found <u>here</u>.
- Combined Oral Contraceptives (COC): choose a preparation with the oestrogen and progestogen combination which gives lowest associated VTE risk, good cycle control and reduced risk of side effects
- If a younger women aged 16 years of age or under requests contraception without parental consent, she should be assessed for her capacity to give informed consent to treatment. It should be documented in the clinical record whether or not <u>Fraser criteria is met</u>. (NB this may have been documented previously).
- Nut and / or soya allergy: Some formulations of both COC and POPs contain ingredients <u>not</u> suitable for women with nut and /or soya allergies If applicable, refer to individuals SmPCs for excipient content select a suitable preparation and continue to prescribe by **brand name**.
- Lactose All oral contraceptives contain lactose. See <u>FSRH advice</u> for further guidance on alternatives for vegans.
- All COCs should be prescribe by brand name.
- POPs can be prescribed generically but should be prescribed by brand in patients with nut and /or soya allergies
- **Emergency contraception** (EC) the copper coil is the most effective EC method: it should be offered to all women seeking emergency contraception (see separate <u>EC guidance).</u>



The UKMEC Categories

appropriate

For each of the personal characteristics or medical conditions considered by the UKMEC a Category 1, 2, 3 or 4 is given. The definitions of the categories are given in Table 1.

method of contraception

Table 1: Definition of UKMEC categories

UKMEC	DEFINITION OF CATEGORY
Category 1	A condition for which there is no restriction for the use of the method
Category 2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks
Category 3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method. The provision of a method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable
Category 4	A condition which represents an unacceptable health risk if the method is used

CHOICE OF CONTRACEPTION

Offer and discuss Long-Acting **Reversible Contraception (LARC) as** 1st Line option

If LARCS declined, contraindicated / intolerance Offer and discuss shortacting hormonal methods of contraception

1st line choice contraception – Long- Acting Reversible Contraception (LARC)

Intrauterine Devices (IUDs)

Copper-Bearing Intrauterine Device (380 mm² Cu-IUD

- Cu-IUDs are licensed for either 5 or 10 years of use (see BNF for details)
- A Cu-IUD containing ≥300 mm2 copper inserted at or after age 40 years can be used for contraception until menopause. (FSRH recommendation, off label) Formulary Choices: 1st line choice : framed copper banded (Framed, copper stem only devices should only be used if banded products cannot be obtained)

Levonorgestrel intrauterine devices (LNG-IUD) (available as 52mg, 19.5mg or 13.5mg strengths)

- A 52 mg LNG-IUD has additional potential gynaecological benefits including management of heavy menstrual bleeding (HMB) and dysmenorrhoea.
- All 52 mg LNG-IUDs can be used for 6 years for contraception if the user is <45 years old at • the time of insertion. Individuals ≥45 years old can use the device for contraception until age 55 years after which time contraception is no longer required. (FSRH recommendation, off label use); in addition, Mirena 52mg has recently been licensed for up to 8 years for contraception.
- Any 52 mg LNG-IUD for up to 5 years for endometrial protection in individuals using oestrogen as part of hormone replacement therapy (HRT) (FSRH recommendation, off label use) (See FSRH IUD guidance).
- 13.5mg and 19.5mg LNG-IUD are licenced for contraception only 13.5mg can be used for 3 years; 19.5mg can be used for 5 years.

Formulary options: 1st line options:-

- Levosert® 52mg (Has a slightly wider applicator diameter than Mirena®) 0
- Mirena® 52mg 0
- Benilexa® 52mg 0
- Kyleena® 19.5mg (NB Kyleena is licensed for contraception only) 0

2nd line: -

Jaydess® 13.5mg (NB Jaydess is licensed for contraception only - to be 0 used if progestogenic side effects unacceptable

Progestogen only implant and Progestogen only injection

Progestogen-only subdermal implant

• Etonogestrel (ENG-IMP):- Nexplanon® 68mg (3vear licence)

Progestogen Only injections (containing medroxyprogesterone acetate)

Formulary options:

- Depo-Provera (13 Weekly intramuscular injection) FSRH recommendation, Off label use)
- Sayana Press (13 Weekly Subcutaneous Injection) • - Women can self-administer after adequate training. Women wishing to do so can be referred to Sexual Health services for training.

Associated with small loss of bone mineral density (BMD), which is usually recovered after discontinuation. risks and benefits should be re-assessed every 2 years.

Combined oral Contraception

• Advise women that taking the pill regularly at the same time of the day will aid adherence.

FSRH recommendations:

- Women should be given information about both standard and tailored CHC regimens to broaden contraceptive choice.
- Women should be advised that use of tailored CHC regimens is outside the manufacturer's licence but is supported by the Faculty of Sexual & Reproductive Healthcare (FSRH).
- Women should have access to clear information (either written or digital) to support tailored CHC use.

Tailored CHC Regimens

- Tailored regimens are as safe as and may be more effective for contraception than the standard 21/7 regimen and therefore should be actively promoted (NICE, FSRH guidance, off-label use). See FSRH CHC guidance
- Consider tailored regimens to broaden contraception choice and support compliance.
- Details of tailored regimens are available on CKS website CKS advice on tailored regimens
- Traditional use of combined hormonal contraceptives (CHCs) is 21 days of active pills or one ring, or three patches, followed by a 7-day hormonefree interval (HFI).

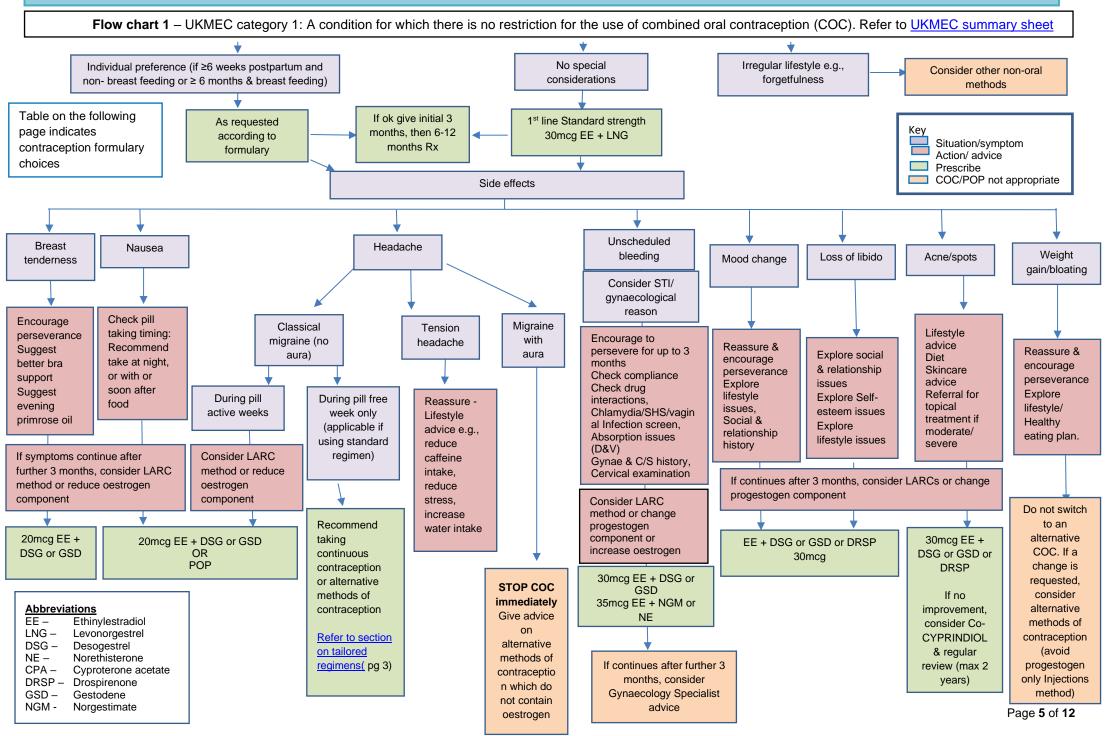
Tailored (non-standard) CHC regimens:

- > Reduce the frequency of the Hormone free interval (HFI) (extended regimens), abolish the HFI (continuous regimens) and/or shorten the HFI
- > May reduce or avoid HFI-associated symptoms.
- There is potentially a reduced risk of escape ovulation and resulting contraceptive failure with tailored regimens compared to traditional 21/7 regimens.

Follow-up and review of oral combined hormonal contraception:

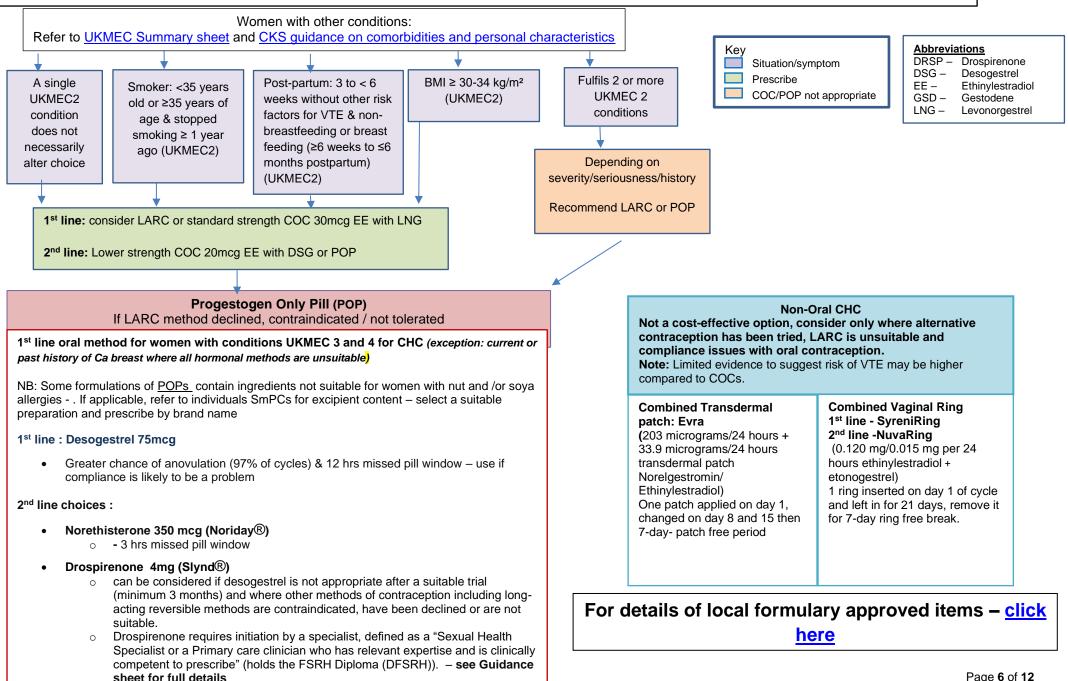
- Arrange a follow up review 10–12 weeks after starting oral contraception.
- Re-check blood pressure and body mass index.
- Assess the woman for any new risk factors e.g. migraine that means her current method is no longer suitable (UKMEC guidance)
- If the woman is experiencing troublesome side effects, give advice for managing side effects using Flow chart 1 or change contraceptive method.
- Offer advice and information on considering LARCs, where there are no contraindications to use.
- Check compliance: Ensure the pill is being taken consistently and correctly and that the women understands the missed or late pill taking and drug interaction advice.
- Review annually thereafter (or sooner if anything changes).

Combined Hormonal Contraception (CHC) - If LARC is declined or contraindicated or intolerance



Combined Hormonal Contraception (CHC) continued

Flow chart 2 - UKMEC category 2: A condition where the advantages of using combined oral contraception generally outweigh the theoretical or proven risks



Additional Information

Missed pills

Combines Oral Contraceptive (COC)- see Missed pill advice from CKSProgestogen Only Pill (POP)- See Missed pill advice from CKS

Drug interactions

Liver enzyme inducing drugs (e.g., some antibiotics, antiepileptics, antiretrovirals, St John's Wort, may reduce the efficacy of the COC and POP)

- Refer to the relevant drug's SmPC and eBNF for advice on managing the interaction and also for advice on if additional or alternative contraception methods should be used.
- Drug Interaction information is also available via SystmOne at point of prescribing.
- See also FSRH advice on interacting drugs that could reduce contraceptive effectiveness.
- If a woman is taking a teratogenic drug(s) or drug(s) with potential teratogenic effects see below.

Contraception for women using a known teratogenic drugs or drugs with potential teratogenic effects NB This advice also applies to women whose partner is using a known teratogenic drugs or drugs with potential teratogenic effects.

- FSRH guidance advises that women of reproductive age who are taking known teratogenic drugs or drugs with potential teratogenic effects should always be advised to use highly effective contraception both during treatment and for the recommended timeframe after discontinuation to avoid unintended pregnancy.
- Women should be made aware that no method of contraception is 100% effective.
- Women should seek advice from a specialist, who will carry out a pregnancy risk assessment and provide evidence-based advice on the most suitable method for them.
- MHRA have published advice on teratogenic drugs including pregnancy testing requirements <u>click here</u>

If using a method of contraception which is considered 'highly effective'

- E.g. long-acting reversible contraceptives (LARC) copper intrauterine device (Cu-IUD), levonorgestrel intrauterine device (LNG-IUD), progestogen-only implant and male and female sterilisation, additional contraceptive haveprecautions (e.g. condoms or a second effective contraceptive method) are not required.
- Use of condoms should be advised for protection against sexually transmitted infections.
- NB women using progestogen only implant must not take any interacting drugs that could reduce contraceptive effectiveness.

If using Combined hormonal Contraception (CHC) or Progestogen-only pill (POP) or Progestogen-only Injections

The typical use failure rate of combined hormonal contraception (CHC) and the progestogen-only pill (POP) is 9%; for progestogen-only injectables eg depot medroxyprogesterone acetate (DMPA) it is 6%).

- If pills, patches, vaginal rings or injectables are used then an <u>additional barrier contraception, such as condoms, are advised</u> and <u>regular</u> pregnancy testing considered.
- NB women using CHC or POP must not take any interacting drugs that could reduce contraceptive effectiveness.
- Use of barrier methods, withdrawal and fertility awareness methods alone is not recommended.

Risk of Venous Thromboembolism

- Evidence from observational studies suggest that current use of CHC is associated with a 3- to 3.5-fold increase in VTE risk compared with non-use of CHC.
- Despite this increased risk, the number of VTE events in women using CHC remains very small. See figures below.
- VTE risk is lower when taking CHC than during pregnancy and the postpartum period.
- VTE risk is highest in the months immediately after initiation of CHC or when restarting after a break of at least 1 month. The risk then reduces over the first year of use and remains stable thereafter. The frequent stopping and restarting of CHC is discouraged.
- The European Medicines Agency (EMA) review published estimated figures for absolute risk of VTE in users of CHC evidence to suggest that the risk of VTE associated with different CHC was influenced by progestogen type:-

Estimated incidence (per 10 000 women per year of use)

- Not using CHC and not pregnant: ~ 2
- CHC with levonorgestrel, norgestimate or norethisterone: ~ 5-7
- CHC with etonogestrel or norelgestromin: ~ 6-12
- CHC with gestodene, desogestrel or drospirenone and co-pyrindiol: ~ 9-12
- Due to limited evidence; it is difficult to compare the effect of Ethinylestradiol dose on VTE risk.
- Safety data for new formulations containing estradiol valerate, estradiol hemihydrate, dienogest, and nomegestrol acetate is limited. Preparations containing these formulations are nonformulary.
- Combined transdermal patch and vaginal ring: Long-term data on VTE risk with the patch or ring are limited and conflicting.
- The benefits of any CHC far outweigh the risk of serious side effects - prescribers and women should be aware of the major risk factors for thromboembolism, and of the key signs and symptoms.

Contraception in women over 40 years

In women (aged over 40 and ≤50 years of age, all intrauterine and hormonal methods of contraception can be considered provided there are no contraindications. (see <u>UKMEC, FSRH</u> <u>guidance</u>)

- Advise that hormone replacement therapy (HRT) does not provide contraception.
- Advise that a woman is potentially fertile for 2 years after her last menstrual period if she is under 50 years of age, and for 1 year after her last period if she is 50 years of age or over. (NB fertility is difficult to determine if woman using HRT or contraception)
- Advise that, in general, women require contraception until the age of 55 years. From 55 years of age natural loss of fertility can be assumed for most women.
- All progestogen-only methods of contraception are safe to use alongside HRT.
- The FSRH IUD guideline supports the use of any 52 mg LNG-IUD for up to 5 years for endometrial protection in individuals using oestrogen as part of hormone replacement therapy (HRT).(FSRH recommendation, off label use) (See FSRH IUD guidance)'
- CHC can be used in eligible women ≤ 50 years of age as an alternative to HRT for relief of menopausal symptoms and prevention of loss of BMD provided there are no contraindications.
- COC with 30mcg EE and levonorgestrel or norethisterone should be considered 1st choice COC for women over 40 years due to risks of VTE, cardiovascular disease and stroke.
- When aged 50 or over advise women using CHC to stop and use a safer contraception method e.g. IUD, progestogen only implant, POP

Method	Health Benefits
Cu-IUD	May be associated with reduced risk of endometrial and cervical cancer
LNG-IUD	Reduced bleeding and pain associated with primary dysmenorrhoea, endometriosis and adenomyosis, management of HMB
Progestogen	Reduced bleeding or amenorrhoea is common
injection	May reduce pain associated with endometriosis
Progestogen implant	Improvement in dysmenorrhoea and endometriosis-associated pain
CHC	May increase BMD (depot medroxyprogesterone can reduce BMD)
	Improved bleeding – regular, lighter, less painful
	Significant reduction in risk of endometrial and ovarian cancer Reduced risk of colorectal cancer
	Improve acne, hirsutism and PCOS symptoms, reduce PMS symptoms
POP	Reduced menstrual pain

Formulary choices of Combined Oral Contraceptive (COC)

 Some formulations of <u>COC</u> pills contain ingredients not suitable for women with nut and /or soya allergies - If applicable, refer to individual SmPCs for excipient content and select a suitable preparation.

Standard strength preparations	Preferred brands (based on cost effectiveness)
Ethinylestradiol 30mcg / Levonorgestrel 150mcg	Rigevidon®, Maexeni®, Levest®
Lower oestrogen with alternative progestogen	
preparations	
Ethinylestradiol 20mcg / Desogestrel 150mcg	Bimizza®, Gedarel® (20/150)
Ethinylestradiol 20mcg / Gestodene 75mcg	Millinette® (20/75), Sunya®
Standard strength oestrogen with alternative	
progestogen preparations	
Ethinylestradiol 30mcg / Desogestrel 150mcg	Cimizt ®, Gedarel ® (30/150)
Ethinylestradiol 30mcg / Gestodene 75mcg	Millinette® 30/75, Katya ®
Ethinylestradiol 30mcg / Drospirenone 3mg	Yacella® (0.03mg/3mg), Dretine® (0.03mg/3mg)
Higher strength oestrogen	
Ethinylestradiol 35mcg / Norethisterone 500mcg	Brevinor®
Ethinylestradiol 35mcg / Norethisterone 1mg	Norimin® (1mg/0.035mg)
Ethinylestradiol 35mcg / Norgestimate 250mcg	Cilique®, Lizinna®

This guideline is based in part on the recommendation of the FSRH, CKS guidance, the Mid and South Essex Contraception guidance (used with permission) and has been adapted to reflect local practises.

CONTACT DETAILS FOR LOCALLY AV iCaSH Bedfordshire (2 Clinic hubs) website:- iCaSH Bedfordshire	VAILABLE SERVICES: iCaSH Milton Keynes Website:- <u>iCaSH Milton Keynes</u>
Tele: 0300 300 3030	Tele: 0300 300 3030
Addresses:-	Address:-
 Kings Brook Clinic, 5 St Johns Street Bedford, MK42 OAH Grove View Integrated Health and Care Hub, Court Drive, Dunstable, LU5 4JD. Luton Sexual Health Clinic Website:- Luton Sexual Health Tele: 01582 497070 Address:- 1st Floor Arndale House, The Mall, Luton, LU1 2LJ 	 624 South Fifth Street, Milton Keynes Buckinghamshire, MK9 2FX

References

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- British National Formulary online https://bnf.nice.org.uk/

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