This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the supply of

Combined Oral Hormonal Contraception (COC)

By registered health care professionals for

Contraception

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 142

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021
2	PGD's 142, 146, 148, 149 and 151 combined and minor word changes	January 2023

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Interim Executive Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGD's
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Contraception
Inclusion criteria	• Individual (age from menarche up to 50 years) requesting contraception • Consent given • A recent, accurate blood pressure recording and BMI should be recorded for all individuals prior to first supply of COC and repeated for each subsequent supply
Exclusion criteria	• Any UKMEC level 3 or 4 • Anyone with 2 or more UKMEC level 2s • Consent not given • Individual under 16 years of age and assessed as not competent using Fraser guidelines • Individuals 16 years and over and assessed as lacking capacity to consent • Known or suspected pregnancy • Known hypersensitivity to the active ingredient or to any constituent of the product, see Summary of Product Characteristics • Less than 21 days after childbirth for deliveries over 24 weeks gestation • Breast feeding and less than 6 weeks postpartum • Not breast feeding and less than 6 weeks post-partum for individuals with other risk factors for venous thromboembolism • Individuals age 50 years and over • Unexplained vaginal bleeding **Cardiovascular Disease** • Individuals age 35 years and over and a smoker or stopped smoking less than 1 year ago (this includes vaping and the use of e-cigarettes) • BMI equal or greater than 35 • Blood pressure greater than 140/90 or controlled hypertension • Multiple risk factors for cardiovascular disease • Current or a past history of ischaemic heart disease, vascular disease, stroke or a transient ischaemic attack • Current or past history of venous thromboembolism • Complicated valvular or congenital heart disease • First degree relative with venous thromboembolism under the age of 45 years • Known thrombogenic mutations • Cardiomyopathy with impaired cardiac function • Atrial fibrillation • Significant or prolonged mobility

	• Imminent planned surgery (COC should be stopped at least 4 weeks prior to planned major surgery or expected period of limited mobility) **Neurological Conditions** • Current or a past history of migraine with neurological symptoms, including aura at any age • Migraine without aura, first attack when on method of contraception containing an oestrogen **Cancers** • Past or current history of breast cancer • Carrier of known gene mutations associated with breast cancer • Malignant liver tumour **Gastrointestinal Conditions** • Viral hepatitis, acute or flare up (for initiation only) • Severe decompensated cirrhosis • Gall bladder disease, symptomatic, medically treated • Gall bladder disease, currently symptomatic • Any bariatric or other surgery resulting in malabsorption • Cholestasis (related to past use of COC) • Benign liver tumour **Other Conditions** • Undiagnosed breast mass (for initiation of method only) • Diabetes with end organ disease • Hyperprolactinaemia • Personal or family history of hypertriglyceridemia • Positive antiphospholipid antibodies (with or without systemic lupus erythematosus) • Organ transplant, with complications • Individuals using enzyme inducing drugs/herbal products or within 4 weeks of stopping them • Known severe renal impairment or acute renal failure • Acute porphyria • Active trophoblastic disease • Sickle cell disease Individuals taking lamotrigine, seek medical advise Interacting medicines see BNF, or individual product SPC
Cautions (including any relevant action to be taken)	• If the individual is less than 13 years of age, the healthcare practitioner must speak to the local safeguarding lead and follow local safeguarding policy • Discuss with a doctor any medical condition that the healthcare professional is not sure or uncertain of

	• Current disease status of those with severe malabsorption syndromes as it could affect the effectiveness of the COC • Medications that induce diarrhoea or vomiting e.g. laxatives, orlistat could reduce the effectiveness of COC • Strongly advise LARCS to all individuals with medical conditions in whom pregnancy is an unacceptable risk, or who are taking medication that is known to be harmful in pregnancy
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated

8. Details of the medicine

Name, form and strength of medicine	• This is a list of the generic monophasic pills that Manx Care Integrated Sexual health Service stock. • The PGD does not restrict which brands can be prescribed. • COC containing ≤30micrograms ethinylestradiol in combination with levonorgestrel or noethisterone is a reasonable first-line choice to minimise cardiovascular risk • **Monophasic** • Ethinylestradiol 30micrograms and levonorgestrel 150micrograms • Ethinylestradiol 30micrograms and desogestrel 150micrograms • Ethinylestradiol 30micrograms and drospirenone 3mg • Ethinylestradiol 35micrograms and norethisterone 500micrograms • Ethinylestradiol 35micrograms and norgestimate 250micrograms • Ethinylestradiol 20micrograms and desogestrel 150micrograms • Ethinylestradiol 20micrograms and gestodene 75micrograms **Monophasic everyday** • Ethinylestradiol 30micrograms and levonorgestrel 150microgram + 7 inactive • Ethinylestradiol 30micrograms and gestodene 75micrograms + 7 inactive

Legal category	Prescription Only Medication (POM)
Indicate any <u>off-label use</u> (if relevant)	Quick start and tailored regimens Best practice is given by the FSRH and is used for guidance in this PGD and may vary from Summary of Product Characteristics (SPC) This PGD includes inclusion criteria, exclusion criteria and dosage regimen which are outside the market authorisation for many of the available products but which are included within the FSRH guidance. Specifically the use of tailored COC regimen is outside the manufacturers licence but is supported by the FSRH.
Route/method of administration	Oral
Dose and frequency	Standard or tailored regimen, refer to FSRH guidance
Quantity to supplied	**Minimum**: 1 box (3 months) **Maximum**: 4 boxes (12 months)
Maximum or minimum treatment period	**Minimum**: 1 box (3 months) **Maximum**: 4 boxes (12 months)
Storage	Room temperature, locked cupboard
Adverse effects	A detailed list of adverse reaction is available in the individual products SPC, available at the electronic medicines compendium website The following possible adverse effects are commonly reported with COC: • Acne • Breast tenderness • Change in Mood • Fluid retention • Headache • Nausea • Temporary disturbance of bleeding patterns • Weight gain Serious adverse effects are less common but the risks should be discussed with the individual: • Arterial thromboembolic events • Hypertension • Venous thromboembolic events
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

10. Appendix A

References
1. British National Formulary (BNF) available online: https://bnf.nice.org.uk 2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk 3. Current Health Care Professions Council standards of practice 4. General Pharmaceutical Council standards 5. The General Optical Council 6. Electronic medicines compendium available online: https://www.medicines.org.uk 7. Faculty of Sexual and Reproductive Healthcare Combined Hormonal Contraception Guideline https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/ 8. UKMEC https://www.fsrh.org/documents/ukmec-2016/

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves