**Patient Group Direction (PGD) for the Supply or Administration of Ethinylestradiol 30 Micrograms/Levonorgestrel 150 Micrograms (e.g. Microgynon 30®)**

<table>
<thead>
<tr>
<th>Classification of Document:</th>
<th>Patient Group Direction</th>
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</thead>
<tbody>
<tr>
<td>Purpose:</td>
<td>Supply/administration of ethinylestradiol 30 micrograms / levonorgestrel 150 micrograms tablets (e.g. Microgynon® 30) to clients without prescription under a PGD.</td>
</tr>
<tr>
<td>Document Number:</td>
<td>US-0615/04</td>
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<tr>
<td>Version Number:</td>
<td>2.0</td>
</tr>
<tr>
<td>Controlled Document Sponsor:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Controlled Document Lead:</td>
<td>Lead Consultant Umbrella Service</td>
</tr>
<tr>
<td>Approved By:</td>
<td>MMAG</td>
</tr>
<tr>
<td>On:</td>
<td>20th September 2016</td>
</tr>
<tr>
<td>Review Date:</td>
<td>20th September 2018</td>
</tr>
<tr>
<td>Expiry Date:</td>
<td>20th September 2019</td>
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**Distribution:**

- **Essential Reading for:**
  - All registered pharmacists supplying Ethinylestradiol 30 micrograms / levonorgestrel 150 micrograms tablets (e.g. Microgynon® 30) against this PGD

- **Information for:**
  - All registered healthcare workers working in Sexual Health Services
<table>
<thead>
<tr>
<th>Pharmacy to which the PGD applies.</th>
<th>Pharmacies offering supply of ethinylestradiol 30 micrograms / levonorgestrel 150 micrograms tablets (e.g. Microgynon® 30) under the Umbrella Consortium for Sexual Health Services in Birmingham and Solihull.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of the medication to which the direction applies.</td>
<td>Ethinylestradiol 30 micrograms / levonorgestrel 150 micrograms tablets (e.g. Microgynon® 30)</td>
</tr>
<tr>
<td>Group of professional staff who are authorised to administer/supply under this PGD.</td>
<td>Registered Pharmacists working under the Umbrella Consortium for Sexual Health Services in Birmingham and Solihull who have been accredited by the service following completion of approved training.</td>
</tr>
</tbody>
</table>
| Training and method of assessment of competence. | Registered Pharmacists must have accessed and completed training approved by the Umbrella training department. The mandatory training will consist of:  
- Completion of Centre for Pharmacy Postgraduate Education (CPPE) e-Learning and e-assessment for Contraception.  
- Accessing the Umbrella training as stipulated by the Umbrella training department  

**Continued professional development**  
The Umbrella training department will provide yearly refreshers which will be mandatory for the Pharmacist to access. |
| Clinical situation to which this direction applies. | To prevent pregnancy in women of reproductive age.  
Fraser Competence must be assessed for all patients under 16 years age and recorded on the appropriate pro-forma.  
Women requesting contraception, where after assessment the treatment of choice is a combined oral contraceptive |
### Exclusion criteria

- Under 13 years of age
- Clients aged under 16 if not Fraser Competent
- Pregnant
- Breast feeding or not breast feeding - less than 6 weeks post-partum
- Known hypersensitivity to medroxyprogesterone acetate or any ingredient of the vehicle injection
- Smoking over 35 years of age
- Patients aged 35 years or over who have stopped smoking for less than 1 year.
- BMI 35 or over
- More than one risk factors for cardiovascular disease (such as smoking, diabetes, hypertension, obesity and dyslipidaemias)
- Raised BP systolic BP>140mmHg or diastolic BP>90mmHg or history of hypertension
- History of venous thromboembolism (VTE) or family history – first degree relative aged less than 45 years
- Immobility due to wheelchair use, debilitating illness or major surgery
- Current or previous history of ischaemic heart disease
- Current or previous history of stroke
- Complicated valvular and congenital heart disease
- Cardiomyopathy with impaired cardiac function
- Atrial fibrillation
- Migraine with or without aura at any age
- Breast cancer current or past.
- Diabetes with nephropathy / retinopathy / neuropathy or other vascular disease
- Gall bladder disease – current and medically treated
- History of COC related cholestasis
- Acute or flare of viral hepatitis
- Severe cirrhosis
- Benign and malignant liver tumours
- Systemic Lupus Erythematosus (SLE) with positive antiphospholipid antibodies
- Undiagnosed breast mass / symptoms
- Carriers of gene mutation associated with breast cancer (e.g BRAC 1 / BRAC 2)
- Complicated organ transplant (rejection or graft failure)
- Known thrombogenic mutations (e.g. factor V Leiden and others)
**Drug interactions**

- Antiretroviral therapy
- Anticonvulsant therapy (phenytoin, carbamezepine, barbiturates, primidone, topiramate, oxcarbazepine)
- Enzyme inducing antibiotics such as rifampicin or rifabutin therapy
- Herbal remedy, St John’s Wort. See Appendix 1 of the current BNF for the full list

If the client is receiving any concomitant medication or treatment it is the responsibility of the Registered Pharmacist to ensure that treatment with the drug detailed in this PGD is appropriate. This information must be sought from a parent or carer if necessary. In case of any further doubt advice must be sought from an appropriate health professional and documented.

<table>
<thead>
<tr>
<th>Action to be taken when a patient is excluded from treatment according to the PGD.</th>
<th>The Registered Pharmacist will discuss reasons for exclusion and refer to the Umbrella Sexual health service</th>
</tr>
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<tbody>
<tr>
<td>Document action taken.</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Treatment to be supplied/ administered under the PGD.</th>
<th>Ethinylestradiol 30 micrograms/levonorgestrel 150 micrograms tablets</th>
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<tr>
<th>Security, storage and labelling of medicines.</th>
<th>Do not store above 25°C.</th>
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<tr>
<td>Store in a locked cupboard in the original packaging.</td>
<td></td>
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<tr>
<td>Must be labelled as per usual labelling requirements for dispensed medicines under the Medicines Act 1968.</td>
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<tr>
<th>Route of administration and method.</th>
<th>To be taken orally</th>
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<tr>
<th>Dose to be administered.</th>
<th>One tablet</th>
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| Frequency of administration. | At the same time each day for 21 consecutive days followed by a break of 7 tablet free days. |
**PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OR ADMINISTRATION OF ETHINYLESTRADIOL 30 MICROGRAMS/LEVONERGESTREL 150 MICROGRAMS**

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<table>
<thead>
<tr>
<th>Maximum dosage &amp; minimum/maximum period over which the drug may be administered.</th>
<th>Maximum of one tablet each day. Three month’s supply in the manufacturer’s original pack, appropriately labelled.</th>
</tr>
</thead>
</table>
| Special considerations/ Additional information | Consider offering the patient additional services:  
- Condom distribution  
- STI kit ordering |
| Warnings & potential adverse reactions. | Nausea, break-through bleeding breast tenderness, headaches, mood changes, weight gain, dizziness and fatigue.  
Refer to manufacturer’s PIL, Summary of Product Characteristics (SPC) and current BNF. |
| Follow up - circumstances under which further advice should be sought and arrangements for referral. | Patients should be directed to their GP or Umbrella Sexual Health services for ongoing supply of pills.  
Further supply can be given within the pharmacy and effectiveness, concordance and client satisfaction must be ascertained. |
| Written or verbal advice to be given to patients or carers before, during or after treatment. | • Start taking on day 1 to day 5 of her period and no other contraceptive precautions are necessary.  
• If not commencing pill use on day 1 to day 5 of period, or 1st day post termination or 21st day post-partum, then additional precautions i.e. a barrier method should be used for 7 days.  
• Take one tablet a day for 21 days.  
• Each new packet should be started on the same day every month.  
• If more than 24 hours late take the missed pill and follow missed pill advice |
In the case of vomiting within 2 hrs of taking pill barrier methods should be used for the next 7 days. • using liver enzyme-inducing medications short term should be advised to use condoms in addition to combined oral contraceptive pills and for at least 4 weeks after the liver enzyme-inducer is stopped

- Potential and temporary nuisance effects
- Risks discussed:
  - Risk of venous thromboembolism (VTE) is doubled compared to non users – but the absolute risk is very low.
  - Signs and symptoms of VTE to look out for and what to do if they develop
  - Small increase risk of cervical cancer (related to duration of use) – advice regarding cervical cytology screening - remaining up to date
  - Small risk of breast cancer which will reduce with time after stopping
  - Seek professional advice if any other abnormal symptoms occur
  - Discuss “safer sex” and encourage concurrent condom use, teaching this method if necessary.
  - Patients should be informed that this medicine is being issued under a PGD and is not prescribed
  - The manufacturer’s PIL must be handed to the patient.

Record keeping.
The Registered Pharmacist must record all significant information accurately and appropriately including assessment of Fraser Competence for clients less than 16 years.

- Complete ‘PharmOutcomes’ Ethinylestradiol/Levonorgestrel 30/150 (COC) service
- Accurately record consultation outcome
- A record of the drug supplied, batch number and expiry dates must be documented.
- The date and time of supply.

Names of professionals who are authorised to administer/supply drug according to the PGD.

A list of the Registered Pharmacists who have undertaken and submitted confirmation they have accessed approved training will be kept by Pinnacle Health Partnership LLP (PharmOutcomes) and accessible by Umbrella.
PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OR ADMINISTRATION OF ETHINYLESTRADIOL 30 MICROGRAMS/LEVONERGESTREL 150 MICROGRAMS
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### Professional with responsibility for ensuring review of the PGD takes place.

A Consultant in Reproductive and Sexual Health and the Senior Nurse for the Umbrella Consortium for Sexual Health Services in Birmingham will be responsible for review of the PGD.

### Staff responsible for Review of this PGD.

- Chief Pharmacist UHB
- Lead Consultant for Umbrella Service
- Senior Nurse for the Umbrella Consortium for Sexual Health Services in Birmingham

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**References**

1. UK Medical eligibility criteria for contraceptive use UKMEC 2009

2. Faculty of Sexual & Reproductive Health Care Clinical Guideline : Combined Hormonal Contraception CEU 2011

3. Drug interactions with hormonal contraception FSRH January 2011(Updated January 2012)

4. Nursing and Midwifery Council Record Keeping April 2010

5. Quick starting Contraception CEU September 2010.

6. Spotting the Signs April 2014
   - A National proforma for identifying risk of child exploitation in Sexual Health Services
   - [http://www.brook.org.uk/attachments/Spotting-the-signs-CSE-_a_national_proforma_April_2014_online.pdf](http://www.brook.org.uk/attachments/Spotting-the-signs-CSE-_a_national_proforma_April_2014_online.pdf)

7. Unscheduled bleeding May 2009
## Patient group direction approved by:

<table>
<thead>
<tr>
<th>Role</th>
<th>Signature</th>
<th>Name</th>
<th>Designation</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Clinician</td>
<td></td>
<td>Jonathan Ross</td>
<td>Professor of Sexual Health and HIV</td>
<td>06/10/16</td>
</tr>
<tr>
<td>Senior Pharmacist (Head of Professional Group)</td>
<td></td>
<td>Inderjit Singh</td>
<td>Chief Pharmacist</td>
<td>29/4/16</td>
</tr>
<tr>
<td>Medical Director (Head of Governance and Executive Director for Organisation)</td>
<td></td>
<td>David Reeser</td>
<td>Executive Medical Director (Deputy)</td>
<td>26/10/16</td>
</tr>
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</table>

### Date direction comes into force
- 20th September 2016

### Date direction expires
- 20th September 2019