Health and Social Care Board

Directorate of Integrated Care
12-22 Linenhall Street
BELFAST
BT2 8BS

Tel : 028 9536 3926
Fax : 028 9536 3126
www.hscboard.hscni.net

To:
Trust Chief Executives
GPs & General Practice Pharmacists
Out-of-hours Medical Services
Community Pharmacists

25th March 2021

Dear Colleague

NORTHERN IRELAND FORMULARY, UPDATED PRESCRIBING NOTES RE: ORAL EMERGENCY CONTRACEPTION

Following a number of cases of patients presenting to Early Medical Abortion clinics with apparent Levonorgestrel failure, Chapter 7 of the Northern Ireland Formulary has been updated. The purpose of this letter is to advise Health Care Professionals, who undertake consultations for Emergency Contraception (EC), on this update.

The formulary now reflects the evidence that suggests Ulipristal is more effective than Levonorgestrel (even on day 1 after intercourse and has sustained efficacy to day 5).

Oral EC provides women with a means of reducing the risk of conception following unprotected sexual intercourse (UPSI). It is intended for occasional emergency use and should not be considered a substitute for effective regular contraception. There are two choices of oral EC in the NI formulary:

- **Ulipristal (ellaOne®) 30mg tablet:** 1 tablet to be taken as soon as possible following UPSI, but no later than 120 hours

  Or

- **Levonorgestrel 1.5 mg tablet:** 1 tablet to be taken as soon as possible following UPSI, preferably within 12 hours but no later than 72 hours.
  *The Faculty of Sexual and Reproductive Health's (FSRH) recommends that a higher **unlicensed** dose of 3mg (i.e. 2 x 1.5mg tablets) should be considered (by prescribers) for patients with body-weight over 70 kg or BMI over 26 kg/m^2.*

Oral EC is also available to purchase over the counter from community pharmacists. The following products are available: ellaOne® 30mg Tablet, Levonelle® One Step or Levonorgestrel 1.5mg Tablet.

ADVICE FOR WOMEN REQUESTING ORAL EC

Health Care Professionals providing EC should refer to the **Faculty of Sexual and Reproductive Health's (FSRH) Emergency Contraception Guideline**. This guideline provides an algorithm to inform on the most suitable choice of oral EC (i.e. ulipristal or levonorgestrel) for a particular patient. Additional factors influencing the choice of oral EC are provided in Appendix 1. FSRH recommends that EC providers advise all women as follows:

1. **Copper Intra-Uterine Device (Cu-IUD):**
   - The Cu-IUD is the most effective method of EC
   - It should be considered by all women who have had UPSI and do not want to conceive
   - However, as services providing Cu-IUD insertion may not be readily accessible or acceptable to a woman, oral EC should be offered as soon as possible after UPSI.

2. **Ulipristal:**
   - Ulipristal has been demonstrated to be more effective than levonorgestrel
   - Ulipristal has been demonstrated to be effective for EC up to 120 hours after UPSI
   - Oral EC is unlikely to be effective if taken >120 hours after the last UPSI.

3. **Levonorgestrel:**
   - Levonorgestrel EC is licensed for EC up to 72 hours after UPSI
   - Evidence suggests that levonorgestrel is ineffective if taken more than 96 hours after UPSI.

A consultation for emergency contraception should also include advice on the importance of ongoing contraception and the methods of contraception that are available. Risk assessment for a sexually transmitted infection should also be considered.

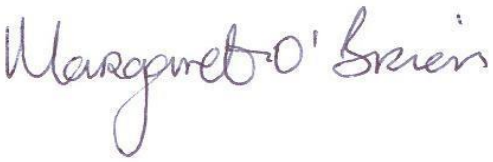
ACTION FOR HEALTH CARE PROFESSIONALS

- **Community Pharmacy** – review any proforma / aide memoir / protocol used by pharmacists undertaking consultations for oral emergency contraception. Please note, NICPLD is hosting a webinar for pharmacists on emergency contraception at 7.30pm on Wednesday 30th March, details available at https://www.nicpld.org/

- **GP practices / OOH medical service providers** – prescribers should be aware that NI formulary has been updated. If necessary, amend defaults on prescribing systems so both choices of oral EC are available for

selection. OOHs medical service providers should maintain appropriate stock levels of both choices of oral EC.

Yours sincerely



Joe Brogan
Assistant Director of Integrated Care
Head of Pharmacy and Medicines Management

Dr Margaret O'Brien
Assistant Director of Integrated Care
Head of GMS

Enc.

Appendix 1

Additional information to consider regarding the most appropriate choice of oral EC:

Ovulation	• **The available evidence suggests that oral EC taken after ovulation is ineffective** • Ulipristal inhibits or postpones ovulation. If ovulation has already occurred, ulipristal is no longer effective • Levonorgestrel is thought to work mainly by preventing ovulation and fertilisation if UPSI has taken place in the preovulatory phase. Levonorgestrel is not effective once the process of implantation has begun • However there is large variability in ovulation and most women will have no way of knowing when it has occurred, so oral EC should be taken as soon as possible after UPSI to prevent or postpone ovulation.
Commencing / restarting oral contraceptive pill following UPSI	• If UPSI is likely to have taken place during the 5 days prior to ovulation, risk of pregnancy is very high. As ulipristal is more effective than levonorgestrel, it should be considered the first-line choice of oral EC • However, the ability of **ulipristal** to delay ovulation is reduced if progestogen (contained within an oral contraceptive pill) is taken in the following 120 hours. **Hormonal contraception should not be started until 5 days after taking ulipristal** • If pregnancy risk from UPSI is low, it may be appropriate to prioritise immediate quick start of hormonal contraception (oral contraceptive pill), so that pregnancy risk from further UPSI is reduced. **Levonorgestrel with immediate start of oral contraception pill could be considered in this situation. Hormonal contraception can be started immediately after taking levonorgestrel.**
Recent use of progestogen	• The effectiveness of **ulipristal** could theoretically be reduced if a woman has recently taken a progestogen (e.g. if she requires EC because of missed oral contraceptive pill). • It is unknown whether **ulipristal** taken when there may still be circulating progestogen is more or less effective than **levonorgestrel**.

BMI / body weight	• The effectiveness of **levonorgestrel** could be reduced if a woman has a BMI >26 kg/m^2 or weight >70 kg • The FSRH recommends that either **ulipristal** or a double dose (3 mg) of **levonorgestrel** is given in this situation. It is unknown which is more effective • ***Pharmacists are advised that the higher 3mg dose of levonorgestrel is not in line with the Product Licence (PL) of Levonelle® One Step. In this situation Pharmacists may consider it appropriate to recommend ellaOne® is purchased over the counter.***
Enzyme-inducing drugs	• The effectiveness of both **ulipristal** and **levonorgestrel** could be reduced if a woman is taking an enzyme inducer medicine (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, primidone, St John's wort) • It is not known whether either choice is effective in preventing pregnancy in this situation • It is recommended that a double dose (3 mg) of **levonorgestrel** can be used, but effectiveness (and how this compares to **ulipristal**) is unknown. See note above re: PL of Levonelle® One Step • Use of double-dose **ulipristal** is not currently recommended.
Severe asthma treated by oral glucocorticoid	• **Ulipristal** use in women with severe asthma treated by oral glucocorticoid is not recommended
Pregnancy	• Oral EC does not cause abortion or harm in very early pregnancy • Both **ulipristal** and **levonorgestrel** can therefore be used if there is any possibility the woman might already be pregnant.
Further use of oral EC within same cycle	• Both **ulipristal** and **levonorgestrel** can be used more than once in the same cycle if this is indicated by further UPSI.