Health and Social Care in Northern Ireland

NI Medicines Management Formulary

Chapter 7

Contraception, gynaecology and urinary tract disorders

(Adult)

Version 3.0 Draft

7.0

7.1.1 Primary Dysmenorrhoea

Choice	Drug
1st choice	Ibuprofen tablets 200mg, 400mg
	Or
	Naproxen tablets 250mg, 500mg (plain tablets, not e/c)
2nd choice	Paracetamol tablets 500mg

Prescribing Notes

- Prescribe as per NICE CKS: Dysmenorrhoea.
- For optimal effect, regular analgesics should be initiated just before anticipated onset of menstruation.
- If the woman does not wish to conceive, hormonal contraceptives may be considered as alternative first line treatment (see section 7.3.1 *(add jump)*) since they may prevent the pain of dysmenorrhea.
- Refer if symptoms are severe and not responding to initial treatment within 3-6 months, or where symptoms are deteriorating with time, or if there is doubt about the diagnosis.

Cautions

- **Mefenamic acid is not listed as a formulary choice.** There are concerns that mefenamic acid is more likely to cause seizures in overdose than other NSAIDs; mefenamic acid has a narrow therapeutic window which increases the risk of accidental overdose.

7.1.2 Heavy Menstrual Bleeding

Choice	Drug
Formulary choices	**Levonorgestrel 20micrograms/24 hours intrauterine system:** Benilexa one handed 20micrograms/24 hours intrauterine delivery system or Levosert 20micrograms/24 hours intrauterine system or Mirena® 20micrograms/24hours intrauterine device
	Or
	Tranexamic acid 500mg tablets
	Or
	NSAID:
	Ibuprofen tablets 200mg, 400mg
	or
	Naproxen tablets 250mg, 500mg
	Or
	Oral Contraceptive (see 7.3 add jump)

Prescribing Notes

- Prescribe as per NICE NG88, see also NICE CKS: Menorrhagia. Treatments should be tailored to individual choice.
- A levonorgestrel-releasing intrauterine system (LNG-IUS) is the preferred first choice treatment by NICE, provided that long-term contraception is acceptable (anticipated minimum use of 12 months).
- LNG-IUS should always be prescribed by **brand name**. See MHRA for further information.
- IUS insertions should be performed by healthcare staff who are fully trained in the technique, regularly updated and who perform frequent insertions (recommendation is 12 or more per year).
- A NSAID may be preferred to tranexamic acid where dysmenorrhoea is also a factor.

Cautions

- **Mefenamic acid is not listed as a formulary choice.** There are concerns that mefenamic acid is more likely to cause seizures in overdose than other NSAIDs; mefenamic acid has a narrow therapeutic window which increases the risk of accidental overdose.

7.1.3 Endometriosis-related pain

Choice	Drug
Consider a trial of paracetamol 500mg or NSAID (see 10.1.1 add jump) for up to 3 months	
Formulary choices	Combined oral contraceptive (see 7.3.1 add jump)
	Or
	Progestogen-only contraceptives (oral, parenteral, implant, IUS). See 7.3.2 add jump

Prescribing Notes

- Prescribe as per NICE NG73: Endometriosis: diagnosis and management.
- Symptoms, particularly pelvic pain and abnormal uterine bleeding, may be better controlled if the combined oral contraceptive is taken continuously for 90 days.
- GnRH analogues should only be prescribed under the supervision of a gynecologist.

7.1.4 Lichen Sclerosus (adult female) - *if no diagnostic uncertainty*

Choice	Drug
1st choice	Regular ointment based emollient, see 13.2.1 add jump
	Clobetasol propionate ointment 0.05% (Dermovate®)

Prescribing Notes

- Refer to BAD leaflet lichen schlerosis in females for management information including recommended steroid dosing regimen.
- An ointment-based emollient should be used as soap substitute, moisturiser and barrier.

7.1.6 Premenstrual syndrome

Choice	Drug
All women with PMS	Offer lifestyle advice and treat predominant symptoms
Moderate PMS symptoms	New generation COC e.g. Gedarel® 30/150 (desogestrel 150 micrograms, ethinylestradiol 30 micrograms)
Severe PMS symptoms	Fluoxetine 20mg capsules

Prescribing Notes

- For more information refer to CKS guidance: Premenstrual syndrome.
- The COC can be used cyclically or continuously for premenstrual syndrome, although current data suggest continuous rather than cyclical use.
- Fluoxetine can be considered for women with severe PMS (off-label use), to be taken continuously or just during the luteal phase.

Cautions

- See Caution section for 7.3.1 and 4.3.1 (add jumps)

7.1.7 Polycystic Ovarian Syndrome

General notes

- PCOS consists of a collection of symptoms, some or all of which may not require drug treatment; weight reduction is the first essential line of management for obese patients.

- Refer to NICE CKS: Polycystic ovary syndrome for details on diagnosis, management and when to refer.

7.2 Treatment of vaginal and vulval conditions

7.2.1 Topical HRT for vaginal atrophy

Choice	Drug
1st choice	Estriol 0.1% intravaginal cream
2nd choice	Estradiol 10 micrograms vaginal tablets

Prescribing Notes

- Prescribe as per NG 23 Menopause: diagnosis and Management.
- Offer vaginal oestrogen to women with urogenital atrophy (including those on systemic HRT) and continue treatment for as long as needed to relieve symptoms.
- Consider patient preference and response when selecting the formulation of vaginal oestrogen e.g. cream or tablets.
- For people with a personal history of breast cancer see NICE NG23.
- Women using long-term vaginal oestrogen treatments do not need to add in cyclical progestogen.

7.2.2. Vaginal and Vulval Infections

- See Chapter 5 Genitourinary Tract Infections for information on the management of bacterial vaginosis, candidiasis and chlamydia
- With any genital symptom always consider the possibility of sexually transmitted infection. Consider referral to GUM as appropriate.

7.3 Contraceptives

General Notes

- The Faculty of Sexual and Reproductive Healthcare (FSRH) produce eligibility criteria for contraceptive use, see UKMEC.
- Most contraceptive failures are due to poor compliance which is strongly influenced by acceptability. Women requiring contraception

should be given information about and offered a choice of method including long acting reversible contraception (LARC) methods see NICE CG 30.

- Drug interactions, including enzyme-inducing drugs, should be considered when prescribing contraceptives, see FSRH.

7.3.1. Combined oral contraceptives (COCs)

Containing ethinylestradiol 30micrograms

Choice	Drug
1st choice	Rigevidon® (ethinylestradiol 30micrograms, levonorgestrel 150micrograms)
2nd choice	Gedarel® 30/150 (ethinylestradiol 30micrograms,desogestrel 150micrograms)

Containing ethinylestradiol 20micrograms

Choice	Drug
Formulary choice	Gedarel® 20/150 (ethinylestradiol 20micrograms, desogestrel 150micrograms)

Prescribing Notes

- Combined contraceptive pills should be **prescribed by brand name.**
- Switching pills to a one with different progesterone component is an option for women experiencing progestogenic symptoms such as breast tenderness, low mood or acne. A different progestogen may result in fewer or different, side–effects.
- Gedarel® 20/150 contains a lower dose of oestrogen and may be associated with a better side–effect profile in women complaining of oestrogenic symptoms such as nausea or breast enlargement/mastalgia.
- Tailored regimens offer an acceptable alternative for many women as they can reduce the frequency of withdrawal bleeds and can reduce withdrawal symptoms associated with the hormone-free interval. The

use of tailored regimens is outside the manufacturer's license but is supported by the FRSH, see FSRH.

- COCs containing an ethinylestradiol 30micrograms/drospirenone 3mg combination, e.g. Yasmin®, are **not** first choice contraceptives. They have similar contraceptive effectiveness to other COCs, no significant advantages in adverse event profile and cost significantly more**.** If this combination is deemed necessary, prescribe a less costly brand, e.g. Dretine® or Yacella®.
- Triphasic and biphasic COCs have no real benefits and are more complicated to use.
- It is recommended that COCs are not continued beyond 50 years of age since more suitable alternatives exist, see UKMEC
- FSRH produce eligibility criteria for contraceptive use, see UKMEC.
- Drug interactions, including enzyme-inducing drugs, should be considered when prescribing contraceptives, see FSRH.
- For missed pill guidance, see FSRH.

Treatment of Acne

- Oral contraceptives are not first line for acne treatment, see section 13.6.1 (*add jump)* for management choices.
- If a person receiving treatment for acne wishes to use hormonal contraception, a COC is preferred over a progestogen-only pill.
- COCs (if not contraindicated) in combination with topical agents can be considered as an alternative to systemic antibiotics in women.
- Co-cyprindiol (Dianette®) or other ethinylestradiol/cyproterone acetate-containing products can only be considered in severe acne where other treatments have failed. Careful discussion of the risks and benefits with the patient is required. Use should be discontinued 3 months after acne has been controlled and prescription guided by the UK MEC for Contraceptive Use and the SPC for the individual product. See MHRA alerts regarding risk of meningioma and information on risk of VTE.

Caution

- The absolute risk of blood clots with all low-dose CHCs is small - there is good evidence that the risk of venous thromboembolism (VTE) may vary between products, depending on the progestogen - CHCs that contain levonorgestrel, norethisterone, or norgestimate have the lowest risk of VTE - 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. For full information see MHRA.

7.3.2 Progestogen-Only Contraceptives

7.3.2.1. Oral Progestogen-Only Contraceptives

Choice	Drug
1st choice	desogestrel 75 microgram

Prescribing Notes

- Progestogen–only pills (POPs) are associated with irregular bleeding in up to 40% of users. Bleeding patterns do not tend to improve with time and are not likely to be any different with a different progestogen.
- The Faculty of Sexual and Reproductive Healthcare (FSRH) produce eligibility criteria for contraceptive use see UKMEC.
- Drug interactions, including enzyme-inducing drugs, should be considered when prescribing contraceptives, see FSRH.
- For missed pill guidance, see FSRH.

7.3.2.2. Parenteral Progestogen-Only Contraceptives

Injection

Choice	Drug
Formulary choices	Medroxyprogesterone 150mg/1ml suspension for injection pre-filled syringes (Depo-Provera®) or Medroxyprogesterone 104mg/0.65ml suspension for injection pre-filled disposable devices (Sayana® Press)

Prescribing Notes

- Progestogen-only injectables can cause menstrual dysfunction and weight gain. By the end of the first year of use, 80% of women will have become amenorrhoeic or have scanty infrequent periods.
- When progestogen-only injectables are stopped, ovarian activity can take up to a year to recover.
- Progestogen-only injectable use should be reviewed after 2 years in women of all ages.
- Sayana® Press is an alternative to Depo-Provera® for patients who wish to self-administer following training. The effectiveness of progestogen-only injectables is unaffected by enzyme-inducing drugs and interval between injections need not be altered.
- The Faculty of Sexual and Reproductive Healthcare (FSRH) produce eligibility criteria for contraceptive use see UKMEC.
- Drug interactions should be considered when prescribing contraceptives, see FSRH.
- For more information see FSRH.

Cautions

- Progestogen-only injectables are associated with a small loss of bone mineral density (BMD), which is usually recovered after discontinuation.

- There has been particular concern about use in women aged <18 years (who have not yet attained their peak bone mass) and among women who are approaching the menopause when additional BMD loss will occur. There is no available evidence on the effect of progestogen-only injectables on long-term fracture risk. Progestogen-only injectables can be used by adolescents who have yet to achieve their peak bone mass **only if other methods are unacceptable or unsuitable.**
- In women with risk factors for osteoporosis, a method of contraception other than progestogen-only injectables should be considered,

Implant

Choice	Drug
1st choice	Etonogestrel 68mg (Nexplanon®)

Prescribing Notes

- Nexplanon® is a low dose long–acting progestogen which suppresses ovulation in all women. Contraceptive effect lasts for 3 years.
- When Nexplanon® is stopped there is no delay in return to fertility.
- No more than 20% of women will experience amenorrhoea; the rest may have unpredictable and sometimes prolonged bleeding. This point should be covered carefully during counselling.
- Nexplanon® insertion and removal requires specialist training.
- The Faculty of Sexual and Reproductive Healthcare (FSRH) produce eligibility criteria for contraceptive use see UKMEC
- Drug interactions, including enzyme-inducing drugs, should be considered when prescribing contraceptives, see FSRH.
- For more information see FSRH.

7.3.2.3. Intra-uterine progestogen-only systems (LNG IUS)

Choice	Drug
Formulary choices	**Levonorgestrel 20micrograms/24 hours intrauterine device:**
	Benilexa one handed 20micrograms/24 hours intrauterine delivery system
	or
	Levosert 20micrograms/24 hours intrauterine system
	or
	Mirena® 20micrograms/24hours intrauterine device
	Or
	Levonorgestrel 19.5mg intrauterine device:
	Kyleena® (levonorgestrel 19.5mg intrauterine device)

Prescribing Notes

- Refer to NICE Guidance CG 30 Long Acting Reversible Contraception and FSRH guidance.
- LNG IUS should always be prescribed by **brand name**, see MHRA**.**
- LNG IUS products are highly effective methods of contraception.
- Many women experience quite frequent and prolonged spotting for the first 3–6 months; thereafter amenorrhoea is common. Patients should be counselled accordingly.
- See 7.1.2 (*add jump)* for LNG-IUS options for the treatment of heavy menstrual bleeding.
- Kyleena® is licensed for contraception only (not recommended for endometrial protection as part of HRT or for heavy menstrua bleeding). The narrower introducer and smaller device makes Kyleena® more suitable for nulliparous or young women.
- IUS insertions should be performed by healthcare staff who are fully trained in the technique, regularly updated and who perform frequent insertions (recommendation is 12 or more per year).
- The Faculty of Sexual and Reproductive Healthcare (FSRH) produce eligibility criteria for contraceptive use see UKMEC.

- The MHRA have issued advice on the risk factors for uterine perforation with intra-uterine contraception, including copper intra-uterine devices and LNG IUS, see MHRA.

7.3.4 Contraceptive devices

Intrauterine Devices

Choice	Drug
1st choice	T-Safe® 380A QL
	Or
	TT380® Slimline
2nd choice	Nova-T® 380

Prescribing Notes

- Refer to NICE Guidance CG 30 Long Acting Reversible Contraception and FSRH guidance.
- Copper IUDs provide long–acting highly effective contraception for at least 5 years.
- Return to fertility after removal is rapid.
- Copper IUDs are associated with an increase in menstrual blood loss and intermenstrual bleeding, menstrual bleeding often decreases over time however intermenstrual bleeding is less likely to do so.
- Fertility declines with age and therefore a copper intra-uterine device which is fitted in a woman over the age of 40, may remain in the uterus until menopause.
- Technically it may only be possible to fit a Nova-T®380 (narrower device) in some women. It may be useful for emergency contraception in nulliparous women.
- IUS insertions should be performed by healthcare staff who are fully trained in the technique, regularly updated and who perform frequent insertions (recommendation is 12 or more per year).
- The Faculty of Sexual and Reproductive Healthcare (FSRH) produce eligibility criteria for contraceptive use see UKMEC.

- The MHRA have issued advice on the risk factors for uterine perforation with intra-uterine contraception, including copper intra-uterine devices and levonorgestrel-releasing intra-uterine systems, see MHRA.

7.3.5 Emergency contraception

Choice	Drug	Dosage
Refer to Prescribing notes below		
1st choices	**Copper IUD** (within 120 hours of UPSI or up to 5 days after predicted day of ovulation)	see section 7.3.4 (add link)
	Or	
	Ulipristal 30mg tablet (within 120 hours of UPSI)	30mg to be taken as soon as possible following UPSI, but no later than 120 hours ***Note: hormonal contraception should be avoided for 5 days after ulipristal 30mg***
	Or	
2nd choice	**Levonorgestrel 1.5 mg tablet** (within 72 hours of UPSI)	1.5mg to be taken as soon as possible following UPSI, preferably within 12 hours but no later than after 72 hours Consider double dose (3mg) if -BMI>26 kg/m2/weight >70kg or -taking an enzyme inducer, see DSU *(add jump)*

Prescribing Notes

- Refer to FSRH guidance: Emergency Contraception and FSRH decision making algorithms (see algorithms 1 and 2).Copper IUD is the **most effective** method of EC and should be offered first line (20x more effective than oral EC).
- If IUD insertion is not available locally then consider referral to a service which can provide insertion of IUD. Oral emergency contraception should be provided in the interim.
- **Patients should be informed that oral ECs are ineffective if taken after ovulation.**

- Ulipristal is first line oral EC as it is more effective than levonorgestrel for most people.
- Oral emergency contraceptives are available under the Pharmacy First service for women and young people aged 13 years and over, from participating pharmacies, see Pharmacy First service provider list.
- If EC is required in women already using hormonal contraception, see FSRH.
- The MHRA have issued advice on the risk factors for uterine perforation with intra-uterine contraception, including copper intra-uterine devices and levonorgestrel-releasing intra-uterine systems, see MHRA.

7.3.6

Delaying menstruation

Patients already taking COCs

- Menstruation can be delayed by skipping the pill free break (for monophasic 21-day pills) [off label]. Advice differs for other pill types.

For patients not taking hormonal contraception

- Norethisterone 5mg three times daily, started 3 days before the expected menses can be prescribed. Menstruation will occur 2-3 days after stopping taking the norethisterone. Norethisterone is partially metabolised to ethinylestradiol and a daily dose of 10-20mg of norethisterone is estimated to be equivalent to taking a 20-30microgram COC pill. It should be avoided in women at increased risk of VTE. There is some limited evidence to suggest medroxyprogesterone acetate 10mg three times a day may offer a safer alternative for high risk women (off label prescribing).

7.4 Drugs for Genito-Urinary Disorders

7.4.1. Drugs for Voiding (Obstructive) Symptoms in Men

General notes

- Refer to NICE Guidance CG97, Lower Urinary Tract Symptoms.

- Uncomplicated lower urinary symptoms in males should initially be managed with conservative measures, specifically providing information and reassurance, and advice on lifestyle interventions (such as changes to fluid intake). To be effective, conservative care needs to be tailored, see CKS.

7.4.1 (i) Alpha blockers

Choice	Drug
1st choice	Tamsulosin 400 micrograms M/R capsules *NB - tamsulosin tablets are expensive, prescribe capsules*
2nd choices	Alfuzosin 2.5mg tablets or Doxazosin 1mg, 2mg, 4mg, 8mg tablets (immediate release)

Prescribing Notes

- Refer to NICE Guidance CG97, Lower Urinary Tract Symptoms.
- Uncomplicated lower urinary symptoms in males should initially be managed with conservative measures, specifically providing information and reassurance, and advice on lifestyle interventions (such as changes to fluid intake). To be effective, conservative care needs to be tailored, see CG97.
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Caution

- Alpha–blockers reduce blood pressure and first doses may cause drowsiness and dizziness. Patients receiving antihypertensives may need lower doses and supervision.
- Patients already prescribed doxazosin for hypertension should not be prescribed another alpha blocker such as tamsulosin.
- Alpha-blockers should be avoided in patients with a history of postural hypotension and micturition syncope.

- Caution is required in the elderly and in patients undergoing cataract surgery (risk of intra-operative floppy iris syndrome).

7.4.1 (ii) 5 alpha-reductase inhibitors

Choice	Drug
1st choice	Finasteride 5mg tablets

Prescribing Notes

- Refer to NICE Guidance CG97, Lower Urinary Tract Symptoms.
- Uncomplicated lower urinary symptoms in males should initially be managed with conservative measures, specifically providing information and reassurance, and advice on lifestyle interventions (such as changes to fluid intake). To be effective, conservative care needs to be tailored, see CG97.5 alpha-reductase inhibitors can be considered for men with lower urinary symptoms who have prostates estimated to be larger than 30 g or a PSA level greater than 1.4ng/ml and who are considered high risk of progression, e.g. older men. Response to treatment should be reviewed after 3-6 months.

Caution

- A patient alert card is being introduced for men taking finasteride to help raise awareness of the risk of psychiatric side effects and sexual dysfunction, including the potential for sexual dysfunction to persist after treatment has stopped. Healthcare professionals are reminded to monitor patients for both psychiatric and sexual side effects. See MHRA.

7.4.2. Drugs for Urinary Frequency and Incontinence

Urinary Frequency Due to Overactive Bladder (symptoms)

Choice	Drug
1st choice	Solifenacin 5mg, 10mg tablets
2nd choices	Fesoterodine modified release 4mg, 8mg tablets or
	Tolterodine 1mg, 2mg tablets (immediate release)

Prescribing Notes

- Refer to NICE CG97 Lower Urinary Tract Symptoms and NICE NG123 Urinary incontinence and pelvic organ prolapse in women.
- **Conservative management is the first line treatment**, such as bladder training, supervised pelvic floor muscle training and lifestyle advice.
- Pharmacotherapy as above confers a high anticholinergic burden score. As well as the known side effects of dry mouth, constipation, blurred vision, confusion and falls there is increasing evidence that a high anticholinergic burden is associated with worsening cognition, an increased risk of dementia, major adverse cardiovascular events and all-cause mortality. The decision to start anticholinergics should be considered carefully (especially in older and vulnerable patients), taking into account co-existing conditions and total anticholinergic burden. The lowest effective dose should be used, on-going treatment should be reviewed regularly and drug holidays sought where possible. A number of risk scales and calculators are available to assess and review anticholinergic burden e.g. ACB calculator Mirabegron is only recommended as an option for treating the symptoms of overactive bladder in people for whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects. See NICE TA 290.

Cautions

- Pharmacotherapy as above confers a high anticholinergic burden score. As well as the known side effects of dry mouth, constipation,

blurred vision, confusion and falls there is increasing evidence that a high anticholinergic burden is associated with worsening cognition, an increased risk of dementia, major adverse cardiovascular events and all-cause mortality. The decision to start anticholinergics should be considered carefully (especially in older and vulnerable patients), taking into account co-existing conditions and total anticholinergic burden. The lowest effective dose should be used, on-going treatment should be reviewed regularly and drug holidays sought where possible. A number of risk scales and calculators are available to assess and review anticholinergic burden e.g. ACB calculatorThere is risk of severe hypertension and associated cerebrovascular and cardiac events with mirabegron. For further details see MHRA..

7.4.5 Drugs for Erectile Dysfunction

General Notes

- Drug treatments for erectile dysfunction may only be prescribed on HSC prescription under certain circumstances. These are:
  - men who have diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, severe pelvic injury, single gene neurological disease, spina bifida, or spinal cord injury
  - men who are receiving dialysis for renal failure
  - men who have had radical pelvic surgery, prostatectomy (including transurethral resection of the prostate) or kidney transplant
  - men who were receiving Caverject®, Erecnos®, MUSE®, Viagra® or Viridal® for erectile dysfunction, at the expense of the NHS, on 14th Sept 1998
- The prescription must be endorsed "SLS".
- GPs can issue private prescriptions for patients on their list, that don't meet SLS criteria, but cannot charge patients for issuing a private prescription.
- Men suffering from severe distress as a result of impotence should be referred for assessment by specialist in secondary care. In Northern Ireland, treatments for impotence leading to severe distress are classified as **red** drugs; supply is via hospital pharmacies. For full details on the red/amber list, visit http://www.ipnsm.hscni.net/red-amber/

Drugs for erectile dysfunction

Choice	Drug
1st choice	Sildenafil tablets 50mg,100mg
2nd choice	Tadalafil tablets 10mg, 20mg

Prescribing Notes

- Refer to NICE CKS Erectile dysfunction for further information on management. Note NHS prescription criteria in Northern Ireland differ – refer to general notes [add jump].
- Presentation with erectile dysfunction should prompt assessment and screening for cardiovascular disease.
- There is not enough evidence to routinely recommend tadalafil 'once daily' (2.5mg, 5mg) preparations for erectile dysfunction.
- It may take time to work, 6 attempts with a particular drug, at a maximal dose with optimum timing and stimulation is recommended before considering treatment failure; if continued failure try switching to an alternative PDE5i.
- Sildenafil and tadalafil are now available to purchase from pharmacies for suitable patients.

Editorial note: on conclusion of chapter review complete summary sheet and tagging updates.