### Changes to version 1.0

The pathway has been updated with the following additions:

- Advice on management of overactive bladder in men based on NICE CG97
- Change of title to ‘Management of overactive bladder in adults’
- Initial assessment in primary care and red flag symptoms
- Drugs which can contribute to development of overactive bladder
- Advice on prescribing OAB drugs for frail and elderly patients
- Patient information leaflet regarding review of the OAB medicines

### Approvals

This document must be approved by the following before distribution:

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<tr>
<th>NAME</th>
<th>TITLE</th>
<th>DATE OF ISSUE</th>
<th>VERSION</th>
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<td>GMMMG</td>
<td>Treatment of Overactive Bladder in Women</td>
<td>01/11/2015</td>
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<td>PaGDSG</td>
<td>Management of overactive bladder in adults</td>
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<td>Management of overactive bladder in adults</td>
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The most up to date version of this guideline can be found online at [http://gmmmg.nhs.uk/](http://gmmmg.nhs.uk/)
1 Introduction

Overactive bladder syndrome (OAB) is urgency with or without urge incontinence, usually with frequency and nocturia.\(^1\) It is often but not always associated with detrusor muscle overactivity. The prevalence of OAB increases with age and can have a significant impact on quality of life. OAB may be associated with Parkinson’s disease, spinal cord injury, diabetic neuropathy, multiple sclerosis, dementia or stroke; however most cases have no specific cause. In men, urge incontinence may be due to neurological disease or enlarged prostate.\(^2\)

This document aims in providing advice on management of OAB in primary and secondary care. It applies to adult patients presenting with OAB both in outpatient and inpatient settings.

The National Institute for Health and Care Excellence (NICE) has published clinical guidelines regarding management of overactive bladder in women (NG123) and men (CG97).

NICE recommend non-surgical treatment as the mainstay of therapy for OAB including conservative treatment (first-line) and pharmacological treatment (second line).

OAB in neurological disease is outside the scope of this pathway. This is covered in NICE CG148.

2 Background

- Majority of the drugs used in OAB are antimuscarinic (anticholinergic) drugs – e.g. darifenacin, fesoterodine, oxybutynin, propiverine, solifenacin, tolterodine, and trosopium. They reduce symptoms of urgency and urge incontinence and increase bladder capacity. Side effects are quite common with these medications but are often minor and tolerable. The most common side effect of antimuscarinic drugs is a dry mouth.\(^3\)
- Caution should be taken when prescribing pharmacological treatment in patients with cognitive impairment or decline, or in the elderly. For those patients trosopium could be considered as a preferred option as it does not penetrate the central nervous system.
- Fesoterodine is a pro-drug which is hydrolysed to the same active metabolite as tolterodine, having similar side effects, and has not been shown to be more effective than the other antimuscarinic agents.
- The recently produced NICE guideline (NG123, 2019) concludes that the anticholinergic medicine with the lowest acquisition cost should be offered to treat OAB. More expensive OAB drugs do NOT confer sufficient additional benefit to justify the higher cost.
- NICE TA290 recommends mirabegron as an alternative option for patients who cannot tolerate anticholinergic drugs or in whom they are contraindicated or ineffective.
- Mirabegron stimulates beta-3 receptors in the bladder. This has the effect of relaxing the bladder muscles. Mirabegron side effects can include a fast heartbeat, headache, diarrhoea and increased tendency to urine infections.\(^4\)
- In addition to current individual drug costs, approaching loss of exclusivity and availability of generic preparations should be considered when prescribing OAB treatment. Solifenacin patent is due to expire in June 2019. Patents for fesoterodine and mirabegron are due to expire respectively in 2022 and 2027.
Initial assessment and 1st line (non-pharmacological) treatment for OAB

**Initial assessment in PRIMARY CARE:**
- Full medical history
- Full drug history to identify drugs which may contribute to the problem (see below for further details)
- Physical examination and urinalysis
- Measurement of post-void residue (optional)
- **Bladder diary** - minimum of 3 days to cover both work and leisure

**Men**
- Examination of abdomen, external genitalia and digital rectal examination (DRE)
- Optional prostate-specific antigen (PSA) test, flow rate measurement, serum creatinine test (only if renal impairment suspected)
- Referral to a Prostate Assessment Clinic should be considered

**Women**
- Assessment of pelvic floor
- Examination for vaginal atrophy
- Assessment of prolapse

**CONSERVATIVE MANAGEMENT IN PRIMARY CARE (should be reviewed after 3 months)**
- All patients should receive conservative treatment prior commencement of pharmacological therapy or referral to secondary care
- Consider referral to Community Continence Service for assessment and conservative treatment
- Offer conservative treatment which should include patient education, lifestyle advice, **bladder retraining** (for at least 6 weeks) and pelvic floor exercises (women / men) (for at least 3 months)

**Lifestyle advice**
- Advise on modification of high or low fluid intake, ideally drinking 1.5 litres/day
- Treat contributory factors such as constipation / chronic cough
- Advise on smoking cessation, weight loss (especially if BMI >30) and reduction of caffeine intake

**RED FLAG SYMPTOMS which require referral to SECONDARY CARE SPECIALIST SERVICE**
- Symptomatic prolapse visible at or below the vaginal introitus
- Palpable bladder on examination after voiding
- Symptomatic non-visible haematuria with no UTI (any age)
- Asymptomatic non-visible haematuria in all patients aged 40 years or older
- Associated faecal incontinence
- Previous continence / pelvic cancer surgery
- Previous pelvic radiation therapy or chemotherapy
- Visible haematuria
- Recurrent UTI
- Persisting bladder or urethral pain
- Suspected urogenital fistulae
- Suspected urological cancer
- Suspected neurological disease
- Clinically benign pelvic masses
- Symptoms of voiding difficulty

**Drugs which can contribute to development of overactive bladder**
- Diuretics such as hydrochlorothiazide, furosemide, bumetanide
- Muscle relaxants and sedatives such as diazepam, chlordiazepoxide, lorazepam
- Opioids such as oxycodone, morphine
- Antihistamines such as diphenhydramine
- Alpha-adrenergic antagonists such as terazosin, doxazosin
- Angiotensin converting enzyme inhibitors
- Hormone replacement therapy
- Some antidepressants and antipsychotics
4.1 **Introduction of pharmacological treatment**

 If symptoms of OAB do not improve after a trial of conservative management, pharmacological treatment should be considered at the lowest recommended dose.

4.2 **When offering antimuscarinic drugs to treat OAB always consider the following:**

- Coexisting conditions (e.g. poor bladder emptying, constipation, glaucoma, Myasthenia gravis, Sjogren’s syndrome)
- Risk of adverse effects including cognitive impairment

4.3 **Before starting OAB drugs discuss with patients:**

- Associated common adverse effects, including potential cognitive impairment
- Frequency and route of administration
- That some adverse effects such as dry mouth and constipation may indicate that treatment is starting to have an effect
- That they may not see the full benefits until they have been taking the treatment for 4 weeks

4.4 **Elderly and/or frail patients – consider the following:**

- Antimuscarinic drugs may affect cognitive function in frail and/or elderly patients hence every effort should be made to employ non-pharmacological treatment first
- In older people who are being prescribed antimuscarinic drugs for control of urinary incontinence, anticholinergic burden score should be calculated and risk of cognitive dysfunction estimated

4.5 **Treatment review**

- Offer face-to-face or telephone review 4 weeks after the start of each new OAB drug treatment
- Offer review before 4 weeks if the adverse events of OAB drug treatment are intolerable
- Offer referral to secondary care if patient does not want to try another drug, but would like to consider further treatment
- Review patients every 6 months to assess whether treatment is still needed and only continue treatment for as long as benefit is maintained
- For all patients who have been taking an antimuscarinic drug for at least 6 months **OFFER** a trial without treatment for a maximum of 4 weeks (exclusions include patients with neurological conditions such as multiple sclerosis or difficult social circumstances). The improvement of symptoms may continue after treatment withdrawal.

A patient information leaflet and assessment chart is available (see appendix 1).
5. Choice of pharmacological treatment in OAB

1\textsuperscript{st} line pharmacological treatment (antimuscarinic)
- Tolterodine (IR) 2 mg twice daily; reduce to 1mg twice daily if necessary to minimise side effects (or if GFR ≤30 mL/min), OR
- Oxybutynin (IR) initially 5 mg two to three times daily (AVOID PRESCRIBING OXYBUTYNIN IN FRAIL +/- ELDERLY)

Review at 4 weeks. Continue if treatment well tolerated and effective. If not, discontinue and consider other 1\textsuperscript{st} line option or move to 2\textsuperscript{nd} line treatment.

2\textsuperscript{nd} line pharmacological treatment (antimuscarinic)
- Darifenacin (MR) 7.5mg once a day; increase if necessary after 2 weeks to 15mg once a day
- Trospium (IR) 20mg twice a day; if GFR 10-30mL/min reduce to 20mg once daily or on alternate days

Review at 4 weeks. Continue if treatment well tolerated and effective. If not, discontinue and consider other 2\textsuperscript{nd} line option or move to 3\textsuperscript{rd} line treatment.

For patients unable to tolerate oral treatment offer transdermal oxybutynin 36mg (releasing 3.9mg/24 hours) twice weekly. Continue if treatment well tolerated and effective. If not, discontinue and refer to secondary care.

If antimuscarinic drugs are contraindicated or clinically ineffective or have unacceptable side effects, omit 1\textsuperscript{st} and 2\textsuperscript{nd} line treatments and offer 3\textsuperscript{rd} line option, beta-3-adrenoceptor (mirabegron). Prescribing should be in accordance with NICE TA 290.

3\textsuperscript{rd} line pharmacological treatment
- Mirabegron (MR) 50mg once daily; if GFR 15-29mL/min, reduce to 25mg once daily

Review at 4 weeks. Continue if treatment well tolerated and effective. If not, discontinue and refer to secondary care.

Mirabegron is contraindicated in patients with severe uncontrolled hypertension (SBP≥180mmHg or DBP≥110mmHg, or both).
BP should be measured before starting treatment and monitored regularly during treatment, especially in patients with hypertension (MHRA drug update).

Offer intravaginal oestrogens for the treatment of OAB symptoms in post-menopausal women with pelvic organ prolapse and signs of vaginal atrophy (NICE NG123, 2019), e.g. estriol 0.01% intravaginal cream, Gynest® or estradiol 10microgram vaginal tablets, Vagifem®.
6 Invasive procedures for OAB(botulinum toxin A)

6.1 If patient wishes to discuss the options for further management (non-therapeutic interventions and invasive therapy) then ensure referral to multidisciplinary team (MDT) to arrange urodynamic investigation.

6.2 Botulinum toxin type A can be used intravesically in patients with overactive bladder who:

- Have urodynamically confirmed detrusor over activity and have received and not responded to a trial of conservative management and pharmacological treatments (unless contraindicated or not tolerated)
- In whom urodynamic investigation has not demonstrated detrusor overactivity, if the symptoms have not responded to non-surgical management and the patient does not wish to have other invasive treatments (women)
- Are willing and able to self-catheterise
- The clinical suitability was determined by MDT on basis of symptom severity (patient completed bladder diary over at least 3 days).

For further details please refer to the GMMMG’s Greater Manchester botulinum toxin policy, section 37a.

6.3 Do not offer botulinum toxin B for proven detrusor overactivity.

7 References

2 Knott L, Overactive Bladder, Patient [online], 2015. Available at: https://patient.info/doctor/overactive-bladder [Accessed on 07/12/18]
9 Trial of stopping your Overactive bladder drug, NHS Oxfordshire CCG [online], 2015, Available at http://www.oxfordshireccg.nhs.uk/professional-resources/documents/clinical-guidelines/gynaecology/leaflet-for-trial-of-stopping-OAB-drugs.pdf [Accessed on 21/09/18]
Appendix 1

Trial of stopping overactive bladder drug

You are currently taking a type of medicine called an anticholinergic to treat your overactive bladder symptoms.

Why stop?

- Some people find the improvement in symptoms continues off treatment so it is important to have a break every six months to see if you still need the medicine.
- Anticholinergic drugs can cause side effects, for example a dry mouth and constipation so it is good to check that the medicine is having more benefits than side effects.
- Anticholinergic drugs may be linked with an increased risk of developing dementia (a 1.5x increased risk of dementia in those who had been taking the drug daily for 3 years).

What should I do?

- As advised by your doctor, stop your overactive bladder medicine for four weeks.
- If you are taking more than one medicine your pharmacist will be able to help you identify which tablet to stop.
- Record how you feel when you are taking the tablets and then how you feel without them. The form available on the next page will help you assess if the medicine is helping you.
- Let your GP know how you got on and whether you want to restart the medicine. You can do this at your next medication review

What else can I do to help my symptoms?

- Cutting out caffeine, commonly found in coffee, tea and fizzy drinks, may help improve symptoms.
- Drinking normal quantities of fluids. Limiting fluids may make symptoms worse.
- Going to the toilet only when you need to, as this allows the bladder to get used to being full.
- Bladder training may also help to control symptoms. If you would like more information please ask your GP, nurse or pharmacist.
### Patient overactive bladder questionnaire

#### Before stopping the tablets (fill this table on one occasion):

<table>
<thead>
<tr>
<th>Symptoms over the last week</th>
<th>Not at all</th>
<th>Occasionally</th>
<th>Often</th>
<th>Very often</th>
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<tr>
<td>Uncomfortable or sudden urge to urinate</td>
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<td></td>
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</tr>
<tr>
<td>Accidental loss of small amounts of urine</td>
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<tr>
<td>Waking up at night to go to the toilet</td>
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<tr>
<td>Urine loss associated with a strong urge to urinate</td>
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<tr>
<td>Side effects from the tablets e.g. dry mouth, constipation, blurred vision, drowsiness</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My bladder problem stopped me doing what I wanted to do</td>
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</table>

#### Four weeks after stopping the tablets (fill this table on one occasion):

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<th>Symptoms over the last week</th>
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