BSW Primary Care Guidelines for the Pharmacological Management of Overactive Bladder (OAB) Disease in Adults

Based on NICE NG123: https://www.nice.org.uk/guidance/ng123

NHS Bath and North East Somerset, Swindon and Wiltshire Integrated Care Board

1.) **INITIAL ASSESSMENT OF PATIENT TO ENSURE DIAGNOSIS IS CORRECT**:
- Include PV examination, bladder palpitation, urine dipstick (for blood), urinalysis, medication review, functional ability.

2.) **CONSERVATIVE MANAGEMENT**:
- Fluid management, bladder retraining, pelvic floor exercises, weight loss if BMI>30, smoking cessation, intravaginal oestrogens (in postmenopausal women with vaginal atrophy, see BSW HRT Treatment Options).
- Offer trial of supervised pelvic floor muscle training of at least 3 months duration as 1st line treatment to women with stress or mixed urinary incontinence via the continence team.

3.) **ASSESS PATIENT'S ANTICHOLINERGIC BURDEN:** http://www.acbcalc.com/

4.) **CONSIDER DRUG OPTIONS:** Before drug treatment starts, discuss:
- That there is increasing evidence of long-term harm from anticholinergic medicines on cognitive function and so a discussion of risks versus benefits for each patient must be undertaken and documented in their notes.
- If a patient wishes to try an OAB medication they should only use it for as short a time as possible to reduce likelihood of long-term side-effects. Also supply a patient information leaflet and support them to be informed about the risks.
- The likelihood of success and associated common adverse effects. Note that the side-effects can contribute to falls risk.
- The frequency and route of administration.
- That some adverse effects such as dry mouth and constipation 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.
- That treatment should be changed or stopped if ineffective after 6-8 weeks.
- Anecdotally, some patients might prefer to use an OAB medication when required (PRN) when going out rather than regularly. This is not evidence-based but may offer a suitable balance between efficacy and side-effects.

LOW RISK PATIENTS: ANTI-MUSCARINICS

USE THESE DRUGS WITH CAUTION in those with autonomic neuropathy and in those susceptible to angle-closure glaucoma (*see page 2) and in hiatus hernia with reflux oesophagitis.

Anti-muscarinics can worsen hyperthyroidism, coronary artery disease, congestive heart failure, hypertension, arrhythmias and tachycardia.

CONTRA-INDICATIONS: myasthenia gravis, urinary retention, severe ulcerative colitis, toxic megacolon, GI obstruction or intestinal atony.

FIRST LINE: SOLIFENACIN

DOSE: ADULT 5mg daily. *Consider increase to 10mg daily if tolerated but looking for greater efficacy.*

REVIEW by 8 weeks

SECOND-LINE: TOLTERODINE

DOSE: ADULT 2mg BD (IR) OR 4mg OD if using Tolterodine XL.

REVIEW by 8 weeks

HIGH RISK PATIENTS: FALLS or CONTRA-INDICATIONS to ANTI-MUSCARINICS (e.g. elderly, frail, dementia, Parkinson's, previous deliriums, multiple comorbidities)

REVIEW by 8 weeks

MIRABEGRON as per NICE TA290

DOSE: 25mg daily. Increase to 50mg after 1-2 weeks if tolerated. Monitor BP. See MHRA safety update October 2015.

or

VIBEGRON (Obgemsa®) as per NICE TA999

DOSE: 75mg daily. Vibegron works in a similar way to mirabegron. The licensed dose of vibegron (75mg) has not been directly compared to mirabegron in a clinical trial, but an indirect treatment comparison suggests it is likely to work as well. Also see more prescribing info on next page.

Review ALL patients on long-term medicine every 12 months, or every 6 months if >75yrs.

SECOND-LINE: TROSPIUM DOSE: ADULT 20mg BD (IR) *(increase to TDS if tolerated, but needing greater efficacy) OR Trospium XL 60mg OD.*

If it hasn't worked

REVIEW by 8 weeks

THIRD LINE (1st and 2nd line *anti-muscarinics ineffective or not tolerated*):

MIRABEGRON as per NICE TA290 DOSE: 25mg daily. Increase to 50mg after 1-2 weeks if tolerating. Monitor BP.

or

VIBEGRON as per NICE TA999 DOSE: 75mg daily. Vibegron works in a similar way to mirabegron (see info above and on next page).

See MHRA safety update Oct 2015 and general info on B3-adrenergic receptor agonists on P2

REVIEW 8 weeks

If INEFFECTIVE or NOT TOLERATED and possible invasive treatment are sought consider referral to urology for treatments such as botulinum toxin (see NHS BSW ICB policy here).

BSW ICB Medicines Optimisation bswicb.prescribing@nhs.net

First approved Oct 2020. Minor update Feb 2022 to include MR preps of tolterodine and trospium. Update Sep 2024 to include vibegron as per NICE TA999.

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General Information on B3-adrenergic receptor agonists (mirabegron and vibegron)

Mirabegron – Adult dose is 50mg daily (reduce to 25mg if eGFR 15–29ml/minute/1.73m² and avoid if eGFR < 15 ml/minute/1.73m²). Manufacturer advises using 25mg once daily in those concomitantly receiving strong CYP3A inhibitors e.g. itraconazole, ketoconazole, ritonavir and clarithromycin. Caution if history of QT-interval prolongation; concomitant use with drugs that prolong the QT interval. **Regular monitoring of blood pressure is important, especially in patients with pre-existing hypertension. See MHRA DSU Oct 2015. SmPC for mirabegron.**
Note: 25mg and 50mg tablets are the same price, so don't prescribe as 2 x 25mg.

Vibegron – Adult dose 75mg daily. **Tablets may also be crushed/mixed with soft food** for administration.
No dose adjustment required in mild/moderate/severe renal impairment or in mild/moderate hepatic impairment but manufacturer notes vibegron has not been studied in end-stage renal disease (GFR < 15 mL/min with or without haemodialysis) or in severe hepatic impairment (Child-Pugh C) so is not recommended in these patient groups. Urinary retention has been reported in patients taking vibegron; monitor signs and symptoms of urinary retention particularly in patients with clinically significant bladder outlet obstruction, conditions predisposing for bladder outlet obstruction, and if taking muscarinic antagonist medicinal product concomitantly with vibegron**. The vibegron SPC does not list hypertension as a contraindication or make recommendations for blood pressure monitoring, but hypertension was a commonly reported event in a pivotal extension study (NICE TA999) so we suggest caution until there is more experience of use**. As a recently launched medicine in the UK, long-term clinical trial and real-world data is limited. Vibegron is subject to additional monitoring▼. Report suspected adverse reactions yellow card

COMBINATION USE OF MIRABEGRON PLUS SOLIFENACIN (AMBER): This regimen is not licensed in the UK but might be recommended by a urology specialist after a patient has had urodynamics with proven detrusor over-activity. Such use may be taken on by a GP if they are happy to take on the prescribing responsibility. A review of the evidence base for such use can be found here.

¥Note about Glaucoma when considering anti-muscarinics; advice from *Journal of Obstetrics and Gynaecology* 2005; 25(5): 419 – 421 1:

1. Establish whether the patient has glaucoma or a family history of glaucoma.
2. Patients with **open-angle glaucoma** can be treated safely. Patients with **known angle-closure glaucoma** should be under hospital review by an ophthalmologist and are likely to have been treated by laser or surgery. Such patients are almost certainly safe to treat with anti- cholinergic agents, but liaison with an ophthalmologist is advised.
3. If the patient is **not known to have glaucoma**, determine whether he/she is at significant risk of developing 'angle-closure' because of systemic anticholinergic treatment. For practical purposes, this can be achieved by history taking to identify the risk factors such as female sex, being long-sighted, Hispanic or Asian race and having a family history of angle closure glaucoma.

NOTE: Oxybutynin is not included in this primary care guidance. It is highly anticholinergic and mainly used for paediatric patients and spinal/neurogenic bladder patients. In BSW it is assigned an AMBER traffic light status for use only after specialist initiation or recommendation.

References

1. NICE NG123 Urinary incontinence and pelvic organ prolapse in women: management (Updated June 2019) https://www.nice.org.uk/guidance/ng123
2. NICE TA290 Mirabegron for treating symptoms of overactive bladder (June 2013) https://www.nice.org.uk/guidance/ta290
3. NICE TA999 Vibegron for treating symptoms of overactive bladder syndrome (Sept 2024) Overview | Vibegron for treating symptoms of overactive bladder syndrome | Guidance | NICE
4. MHRA Drug Safety Update October 2015: Mirabegron (Betmiga): risk of severe hypertension and associated cerebrovascular and cardiac events https://www.gov.uk/drug-safety-update/mirabegron-betmiga-risk-of-severe-hypertension-and-associated-cerebrovascular-and-cardiac-events