NHS Bassetlaw Clinical Commissioning Group

NHS Doncaster Clinical Commissioning Group

Doncaster and Bassetlaw Area Prescribing Committee Amber-G Prescribing Guidance for the use of Midodrine in patients with Postural Hypotension

1.0 Introduction

This document sets out guidelines for the assessment and treatment of patients who require medication for the treatment of Postural Hypotension (otherwise known as orthostatic intolerance).

Prescribing guidelines are intended to provide clear guidance to General Practitioners (GPs) and hospital prescribers regarding the procedures to be adopted when clinical (and therefore prescribing and financial) responsibility for a patient's treatment is transferred from secondary to primary care.

GPs, as independent contractors, have the right to decline to take clinical and prescribing responsibilities for a patient on their medical list who is being treated elsewhere. However the reason for this action must be documented. In the view of the Doncaster & Bassetlaw APC, it would be the exception for a GP to refuse to take clinical and prescribing responsibilities for an individual drug, where Amber-G prescribing guidelines for that drug have become common practice and where prescribing guidelines include adequate support, education, and information as approved by the Doncaster & Bassetlaw APC.

If a specialist asks a GP to prescribe in relation to this disease the GP should reply to this request as soon as practicable. The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequence of its use.

This prescribing guideline applies only for the indication for which the drugs are stated to be used for. It should not be used for other indications listed on the Doncaster & Bassetlaw APC traffic light system or for other unlicensed indications for the drug.

2.0 Background Information

Postural Hypotension is diagnosed when, within two to five minutes of quiet standing (after a five minute period of supine rest), one or more of the following is present:

- At least a 20 mmHg fall in systolic pressure
- At least a 10 mmHg fall in diastolic pressure

It is more common in the elderly due at least in part to impaired baroreflex sensitivity.

Although Postural Hypotension in older people is common, treatment is not always necessary, particularly in the absence of symptoms, for example, falls or dizziness on standing.

For those patients who have been reviewed by a specialist in falls, after other causes have been excluded – for example, inappropriate use of antihypertensives, dehydration, symptomatic anaemia, hypoadrenalism, Midodrine can be a useful adjunct to treatment.

Midodrine is a direct-acting sympathomimetic with selective alpha-agonist activity. It enhances smooth muscle tone leading to peripheral vasoconstriction. It has no direct cardiac stimulatory effects. Midodrine slightly decreases cardiac output and renal blood flow. It increases the tone of the internal bladder sphincter and delays the emptying of the bladder. Midodrine is a pro-drug, the active metabolite is deglymidodrine.

Midodrine should be initiated by a specialist. This should be a Consultant Geriatrician, or deputy, or via the falls clinic specialists. These guidelines apply only to midodrine initiated by a specialist.

3.0 Diagnosis & Investigations

Postural Hypotension is diagnosed when, within two to five minutes of quiet standing (after a five minute period of supine rest), one or more of the following is present:

- At least a 20 mmHg fall in systolic pressure
- At least a 10 mmHg fall in diastolic pressure

Symptomatic Postural Hypotension exists where the above changes in blood pressure are associated with symptoms, in particular falls or loss of consciousness.

4.0 Drug Treatment

For contraindications or further information please see the current Martindale: The Complete Drug Reference or summary of product characteristics for the individual drug http://www.medicines.org.uk/

Drug, dose & TLS listing	Adverse effects	Therapeutic monitoring	Consultant / GP	Clinically relevant drug interactions
1.				
1.1 Midodrine [Amber G]				
Treatment of postural hypotension • The usual starting dose is 2.5mg 2 – 3 times daily • The dose is titrated in small increments at intervals of 3 – 7 days until an optimal response is obtained. • Maximum dose is 30mg daily in divided doses • Doses should be taken in the morning, noon and in the late afternoon. • It is recommended that doses are not given after the evening meal to avoid the risk of supine hypertension • The duration of treatment depends upon the progression of disease and a patient's functional status	• Cardiovascular system ○ Palpitations ○ Tachycardia ○ Reflex bradycardia ○ Supine hypertension ○ Arrythmias • Skin ○ Paraesthesia ○ Pruritus of the scalp ○ Flushing ○ Rash • Gastro-intestinal ○ Nausea ○ Vomiting • Urinary ○ Urinary retention or urgency • Central nervous system ○ Headache ○ Confusion ○ Anxiety or nervousness ○ Drowsiness ○ Dizziness	Baseline and initiation • Lying and standing BP • Renal Function • Heart Rate • Liver Function Tests • CXR Ongoing • Side Effects • Symptom control • Report any adverse reactions to the specialist and CSM	Consultant	• Cardiac Glycosides- Midodrine may potentiate reflex bradycardia or other kinds of conduction disorders and arrhythmia • Alpha and beta adrenergic blocking drugs- The blood pressure raising effects of midodrine may be antagonised by alpha blockers. The heart rate reducing effect of beta blockers may be increased. • Atropine- may enhance the blood pressure raising effect of atropine • Tricyclic antidepressants, sympathomimetic agents, thyroid hormones, MAO-inhibitors, corticosteroids- may increase sympathomimetic effect
			GP • Annual wellbeing check of supine / sitting blood pressure, U&E, pulse (be aware of any **symptomatic** bradycardia <60bpm) • Side effects • Symptom control • Adverse Reactions	

5.0 Amber-G Prescribing guidelines for the management of postural hypotension arrangements

Once a stable medication regime has been established (usually 3 months but not exceptionally), physical monitoring and prescribing of Amber G category drugs can be transferred to primary care with agreement.

5.1 Aspects of care for which Secondary Care Team is responsible

- Patient selection, diagnosis and assessment of Postural Hypotension
- Medication review (e.g. contributing medication / interacting medication)
- Initiation of prescription of Postural Hypotension by specialist service
- Initial quantity supplied will be 1-3 months depending upon clinical response
- Ensure patient is fully informed of potential benefits and side effects of treatment
- Ensure that Amber-G prescribing guidance is followed before transfer of treatment
    - That the patient/carer is clear what is being monitored and by whom
    - That the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP)
- Writing to the GP after clinic detailing whether the medication regime should remain the same, be changed or be stopped. Specify any dose or frequency changes.
- Specify BP range to consider review of treatment based on the individuals co-morbidities.
- Monitor side effects of medication.
- Report adverse events via the Yellow Card reporting system in the BNF or at www. Yellowcard.gov.uk

5.2 Aspects of care for which Primary Care Team is responsible

- Ensure that Amber-G prescribing guidance is followed before transfer of treatment
    - That the patient/carer is clear what is being monitored and by whom
    - That the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP)
- Prescribe Midodrine once a patient is clinically stable.

- Amend prescription as per requests from secondary care for dose changes in patients on established treatment
- Seek specialist advice promptly as advised in the prescribing guidelines or if signs/symptom changes occur
- Stop treatment on advice of specialist, or immediately if intolerable side effects occur provided that it is safer to do so than to continue this therapy
- Annual monitoring of supine or sitting blood pressure. If a patient is no longer able to comply with this assessment (e.g. because of weakness or frailty) then this might trigger a discussion with the specialist either via telephone conversation or letter and consideration to discontinue treatment as part of advanced care planning. Accept BP <160mmHg unless specified otherwise by specialist in handover letter.
- Annual check of renal function
- Treatment is usually long-term. However if patients would like to discontinue treatment seek specialist advice
- Treatment can be reviewed as part of advanced care planning
- Report adverse events via the Yellow Card reporting system in the BNF or at www. Yellowcard.gov.uk and to the consultant sharing the care of the patient

6.0 PROCEDURE FOR ADOPTING Amber-G prescribing

6.1 General Procedure:

The specialist will send the GP a letter handing over prescribing responsibilities. This should specify BP range and when to consider review of treatment. Accept BP <160mmHg unless specified otherwise by specialist in handover letter.
The patient will be asked to make arrangements with their GP for continued supply.

7 .0 REFERENCES

- Summary of Product Characteristics: Bramox 2.5mg and 5mg Tablets. Brancaster Pharma December 2016
- Summary of Product Characteristics: Midon Tablets 2.5mg. Takeda Products, Ireland October 2010
- Patient Information Leaflet: Gutron Tablets 5mg. Nycomed Austria GmbH July 2010

8.0 Guidance Development

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