Attach Patient Banda Label here

Coventry & Warwickshire Area Prescribing Committee

Shared Care Agreement

Apomorphine: *for the treatment of parkinson's disease*

prescribe by BRAND

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE: This shared care agreement (SCA) outlines suggested ways in which the responsibilities for managing the prescribing of **Apomorphine** can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so.

In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.
If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Specialist Responsibilities

1. Discuss the benefits and side effects of treatment with the patient. Advise the patient prior to starting apomorphine treatment that they could experience nausea, vomiting and local indurations/nodules at injection sites. Other adverse events include neuropsychiatric disturbances, transient sedation and hypotension. In some patients, dyskinetic episodes may occur which can be severe.
2. Initiate treatment and stabilise patient on maintenance dose.
3. Ask the GP whether he or she is willing to participate in shared care by emailing the shared care request letter, (continue to prescribe until GP has agreed to take over prescribing).
4. Communicate promptly with the GP when treatment is changed or needs to be changed by GP.
6. Ensure that there is a mechanism in place to receive rapid referral of a patient from GP in the event of adverse effects or deteriorating clinical condition.
7. Review the patient's condition, monitor the response to treatment and review medication on a defined regular basis.
8. Advise GP on how to stop treatment.
9. Report adverse events to the MHRA on a yellow card form and to the GP.
10. Ensure clear backup arrangements exist for GPs for advice and support.

Report adverse events to the MHRA on a Yellow Card www.mhra.gov.uk/yellowcard, and to the GP and appropriate Medicines Optimisation team

General Practitioner Responsibilities

1. Reply to the request for shared care as soon as practicable, preferably within 5 working days, by emailing back the shared care letter. Confirm that the patient has been cautioned not to drive if they experience adverse effects.
2. Prescribe apomorphine at the dose recommended from the agreed date, by the brand defined by the consultant, as applicable.
3. Adjust the dose as advised by the specialist.
4. Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
5. Refer back to specialist if patient's condition deteriorates, or if there are concerns over patient compliance.
6. Stop treatment on the advice of the specialist or implement withdrawal if an urgent need to stop treatment arises.

Report adverse events to the MHRA on a Yellow Card www.mhra.gov.uk/yellowcard and to the specialist and appropriate Medicines Optimisation team.

Patient/carer's Role

1. Attend all appointments with GP and specialist.
2. Report to the specialist or GP if s/he does not have a clear understanding of the treatment. Take on advice regarding incidence of adverse events and their impact on lifestyle.
3. Share any concerns in relation to treatment with apomorphine.
4. Alert GP or specialist of any changes in circumstances that could affect drug treatment.
5. Report any adverse effects or warning symptoms to the specialist or GP.

The patient may also choose to report any adverse drug reaction direct to the MHRA on a Yellow Card , available at pharmacies, GP surgeries or from the Yellow Card hotline (freephone 0808 100 3352 during business hours). The form can also be downloaded from www.mhra.gov.uk/yellowcard

SUPPORTING INFORMATION:

<table>
<tr><td>Indications:</td><td colspan="2">Licensed for the treatment of of disabling motor fluctuations in patients with Parkinson’s disease which persist after treatment with levodopa (with a peripheral decarboxylase inhibitor) and/or other dopaminergic medications.
Apomorphine should be initiated in the controlled environment of a specialist clinic. The patient’s treatment with levodopa and/or other dopaminergic medications should be optimised before starting apomorphine treatment.</td></tr>
<tr><td>Dose and Administration:</td><td colspan="2">Apomorphine is administered by the subcutaneous (SC) route. It can be delivered either as continuous SC infusion via a pump (APO-go® pre-filled syringe 50 mg/10 ml solution for infusion; Dacepton® vials 100 mg/20 ml solution for infusion) or as an intermittent SC pen injection (APO-go® PEN 30 mg/3ml solution for injection; Dacepton® cartridge 30 mg/3 ml solution for injection).
For full details of initiating treatment: refer to the Summary of product Characteristics (SPC).
The optimum dose of apomorphine needs to be determined on an individual patient basis. During treatment with a pen-injector, the daily dose varies widely between patients and is typically within the range of 3 – 30 mg, with each dose administered at the start of an ‘off’ episode. Individual bolus injections and the total daily dose should not exceed 10 mg and 100 mg respectively.
For patients whose overall control remains unsatisfactory using intermittent injections, or who require many and frequent injections (> 6 per day), apomorphine can be administered as a continuous SC infusion via pump. Maximum daily apomorphine dose should not exceed 100 mg.
Patients selected for a pen-injector should be able to recognise the onset of their ‘off’ symptoms and be capable of injecting themselves, or have a responsible carer able to inject for them when required.</td></tr>
<tr><td>Monitoring:</td><td>Hospital team/PDNS
• Monitoring /evaluation of adverse drug reactions
• Monitoring /evaluation of symptomatic response
• Communication of results / treatment changes to primary care team
• Check full blood count, Coombs test and LFT 4-6 months</td><td>Primary care team
• Monitor general health / well being
• Prescribe ongoing drug therapy as recommended by hospital team
• Inform hospital team if side effects or complications
• Inform hospital is shared care is declined</td></tr>
<tr><td>Contra-indications:</td><td colspan="2">• Neuropsychiatric problems / dementia
• Hepatic impairment
• Respiratory or CNS depression
• Not for use in under 18 years</td></tr>
<tr><td>Cautions:</td><td colspan="2">• Pregnancy / breast feeding
• Pulmonary / cardiovascular disease/ endocrine disease
• Renal disease
• Postural hypotension
• Prolonged QT interval avoid if high risk of torsades de pointes arrhythmia
• Elderly
Haemolytic anaemia in patients with apomorphine and levodopa reported. Coombs test and LFT needed at 4-6 monthly intervals</td></tr>
<tr><td>Side effects:</td><td colspan="2">Nausea, vomiting and local induration/nodules at SC injection sites are the most common side effects. The local SC effects may be reduced in some cases by rotation of injection sites.
Dyskinesias can occur during ‘on’ periods, which can be severe, leading to withdrawal of treatment in some patients. Other adverse effects include neuropsychiatric disturbances, transient sedation and hypotension.
Impulse control disorders have been described in patients taking dopamine agonists including apomorphine. Patients assessed by specialist team before initiation. Somnolence. Care needed with driving and machinery.

Apomorphine does not have black triangle (▼) status. All serious suspected adverse reactions (even well recognised or causal link uncertain) should be reported to the MHRA.</td></tr>
<tr><td>Drug interactions:</td><td colspan="2">(see also above under cautions): Significant interactions stated as outlined in BNF, see BNF and SPC for more detail
Patients selected for treatment with apomorphine HCl are almost certain to be taking concomitant medications for their Parkinson's disease. In the initial stages of apomorphine HCl therapy, the patient should be monitored for unusual side effects or signs of potentiation of effect.
Neuroleptic medicinal products may have an antagonistic effect if used with apomorphine. There is a potential interaction between clozapine and apomorphine; however, clozapine may also be used to reduce the symptoms of neuropsychiatric complications.
If neuroleptic medicinal products have to be used in patients with Parkinson's disease treated by dopamine agonists, a gradual reduction in apomorphine dose may be considered when administration is by minipump and/or syringe-driver (symptoms suggestive of neuroleptic malignant syndrome have been reported rarely with abrupt withdrawal of dopaminergic therapy).
It is recommended to avoid the administration of apomorphine with other drugs known to prolong the QT interval</td></tr>
</table>

Cost:	The current brands of apomorphine available are listed below: **APO-go®**[1] Injection, apomorphine hydrochloride 10 mg/mL, net price 5-mL amp = £14.62. Injection **(APO-go® Pen)**, apomorphine hydrochloride 10 mg/mL, net price 3-mL pen injector = £24.78. Injection **(APO-go® PFS)**, apomorphine hydrochloride 5 mg/mL, net price 10-mL prefilled syringe = £14.62. **Dacepton®**[2] Injection cartridges (D-mine- Pen®)**,** apomorphine hydrochloride hemihydrate 10 mg/mL, net price 3-mL cartridge = £24.60 Infusion vials **(Dacepton®)**, apomorphine hydrochloride hemihydrate 5 mg/mL, net price 20mL vial = £29.00. **Note:** Dacepton® brand of apomorphine pre-filled cartridges has chemical and physical stability for 15 days after first opening , compared to 48 hours for the APO-go® Pen. Dacepton® brand of vials of apomorphine solution for infusion has chemical and physical stability for 7 days after first opening , compared to 24 hours for the APO-go® Pen.
Back-up advice and support:	See shared care request letter at the end of this agreement, and patient clinical summary letter for contact details of clinician(s) initiating and stabilising patient prior to request for shared care.

References:

1. Britannia Pharmaceuticals Limited. Summary of Product Characteristics APO-go ampoules 10mg/ml, APO-go Pen 10mg/ml Solution for Injection, APO-go PFS 5mg/ml Solution for Infusion in Pre-filled Syringe, updated 03 Jul 2018.
2. Ever Pharma UK Limited. Summary of Product Characteristics Dacepton 10mg/ml solution for injection in cartridge and Dacepton 5mg/ml solution for infusion, updated 19 Nov 2018.
3. BNF on Formulary Complete. University Hospitals Coventry and Warwickshire NHS Trust. 2018. Available from: https://www.formularycomplete.com/ Date accessed: 19 Sept 2019

Pathway for Referral for Apomorphine Therapy in Parkinson's disease

Patients should be referred to a Movement Disorder clinic if it is felt apomorphine might be a suitable therapeutic option.

Referral to movement disorder clinic has the advantage of joint review by consultant and PD Nurse Specialist (PDNS).

Patient suitable for apomorphine therapy

Neurologist:

- Provide information to patient/carer
- Provide information and shared care agreement to primary care team
- Baseline ECG and blood tests (FBC, LFT, Coombs test)
- Liaise with UHCW Hospital PDNS re: date of assessment and order apomorphine from pharmacy

UHCW Hospital PDNS:

- Arrange day case attendance for apomorphine assessment
- Arrange prescription for domperidone 10 mg t.i.d for 3 days prior to and including morning of test

GP:

- Agree prescription of medication when dose stable
- Report adverse events to PDNS / hospital team

Neurologist/PDNS/day case staff: Morning Appointment

Apo Response Test:

- Obtain patient's written consent
- Omit morning Parkinson's medication
- Baseline UPDRS part 3, 6 metre timed walk and postural blood pressures.
- Give single injection of apomorphine once per 30 minutes and re-test until a response is seen (1 mg, 3 mg, 5 mg, 6 mg, 7 mg, 10 mg). If no response at 10 mg, patient is a non-responder.
- Observe for side effects (lying and standing BP, nausea etc)
- Once response is seen, repeat UPDRS part 3, 6 metre timed walk and postural blood pressure

Positive Challenge

- Patient notices good response
- Decrease in UPDRS motor score by >20%

Review (Neurologist/PDNS):

- Relatively short "off period" <6 times/day: intermittent apomorphine sc injections.
- >6 injections required per day: consider switching to apomorphine pump sc infusion

Negative Challenge

- Patient feels no change
- No improvement in UPDRS or patient develops side effects

Review in Clinic

- consider other therapeutic options
- consider palliative options

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Shared Care Drug Information	
Date:	
Patient name:	
NHS number:	
Drug:	

Provider Trust Logo here

Dear Dr

Request to continue prescribing of a shared care drug

I have started this patient on the above drug that has been deemed as appropriate for shared care by the Coventry and Warwickshire Area Prescribing Committee (APC).

The last prescription for a month's supply was issued on_____. The dose is_____ _____*(include strength and frequency).*

I would be grateful if you could consider participating in shared care. I am sending you a copy of the shared care agreement *(previous pages to this document)* locally approved by the APC.

If you are agreeable, please could you complete the section below and return it to me by email as soon as possible but at the latest within 5 working days If you wish to discuss this with me, please contact me via my secretary. *(see telephone below).*

On receipt of your agreement to participate, I will write to the patient to inform them that they will be able to order the medication from your surgery. That letter will be used as the written request for the medication. It states that patients DO NOT need to make an appointment to see their GP to request the medication.

Yours sincerely,

Specialist name: _____

Telephone number: _____

NHS.net Email Address: _____

For completion by GP: (complete section below and send back to the Specialist within 5 working days)						
I agree to prescribe *(tick as appropriate)*	**Yes**		**No**		**I would like to discuss further:**	
Reasons if "No"						
Prescriber name:						
Signature:						