BHR CCGs GPs and ACUTE NHS Trust Shared Care Guidelines

Apo-go Shared Care Guidelines for patients with Complex Parkinsons Disease

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AS AND FILED IN NOTES

Patient Name: **Date of Birth:** **NHS No:**

Name of Referring Consultant: **Contact number:**

INTRODUCTION – Indication and Licensing

This protocol provides information on the use of Apomorphine treatment for the shared care of therapy between the Neurology specialist team in secondary care and the GP concerned once the Apomorphine has been initiated. Follow up care will be monitored either with the Specialist Nurse in APO-go or the Specialist Parkinson's Nurse in Primary care or the Neurologist as appropriate.

The complex nature of Apomorphine administration necessitates that it should be initiated by the Movement Disorder Team in the hospital environment. An individual care plan will be provided in writing to the GP following initiation of Apomorphine either subcutaneously or intermittently.

Disabling motor fluctuations are a common complication of idiopathic Parkinson's disease. Some of these patients may benefit from the use of Apomorphine.

Apomorphine is a directly acting dopamine agonist with **no** opiate or addictive properties. Apomorphine is not used orally because it undergoes extensive first pass metabolism to an inactive metabolite. Treatment with Apomorphine is usually either by intermittent subcutaneous (s/c) injection or continuous s/c infusion. Following a single s/c dose, apomorphine has an onset of action of between 5-15 minutes. The effect lasts between 40-60 minutes. The aim of treatment is to optimise the delicate balance between optimal response and minimal side-effects.

Once the patient's condition is stable and the patient is demonstrably benefiting from the treatment and is free from any significant side effects, the prescribing of Apomorphine for the patient will be transferred to the GP. GPs should only take on the prescribing when they are confident in the agreed care plan advised by the specialist team. Contingency plans must be in place to enable the patient to receive the recommended treatment, should the GP decline to prescribe.

PATIENT PATHWAY- *INITIATED IN SECONDARY CARE*

Clinical Speciality / Indication	Prescribing Initiated by	Prescribing Continued by *(detail when suitable for transfer to occur)*	Monitored by *(detail when suitable for transfer to occur IF APPROPRIATE)*	Duration of treatment
Movement Disorders Specialist Neurologist and Parkinsons Disease Specialist Nurse	Consultant or Parkinsons Disease Specialist Nurse	GP	After initiation patient will be monitored by the Specialist Nurse in APO-go in the community. Any blood tests/ECG monitoring needed will be organised by secondary care	ongoing

Original Guideline written by: Kirsten Turner PD Nurse Specialist R.G.N. BSc, Hons, PGDip Edits MSc .Non-Medical Prescriber and Kamaljit Takhar, Deputy Chief Pharmacist, NELFT NHS Foundation Trust
Consulted with Dr Anjum Misbahuddin and Dr John McAuley, Consultant Neurologists
Approved by: BHRUT Medicines Optimisation Group & BHR CCGs Area Prescribing sub-Committees June 2018
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PRIOR TO INITIATION OF TREATMENT

Premedication with oral domperidone 10mg three times a day starting 72hours prior to initiation of therapy is essential. Baseline ECG and rationalization of medication which can prolong QT interval will be required prior to initiation due to potential issues with conduction abnormalities including QT prolongation. If this cannot be achieved, the specialist team would consider the use of ondansetron (off label) in discussion with the patient.

DOSE AND ADMINISTRATION

The route of administration will either be subcutaneous intermittent injection or continuous subcutaneous infusion, depending on patient requirements. The Specialist Nurse in APO-go will teach the patients and their family members safe techniques for administering the apomorphine.

Intermittent subcutaneous injection:
Administered subcutaneously, to the outside of the thighs or abdomen, using a multi-dose APO-go disposable pen injector comes with a pack of 100 dedicated needles as part of the prescription and is included in the price in the BNF.

Continuous subcutaneous infusion:
Administered using an APO-go PFS 5mg/ml pre-filled syringe via an APO-go pump

OR

Administered using an APO-go® POD 5mg/ml solution for infusion in cartridge.
1 ml of solution contains 5mg apomorphine hydrochloride hemihydrate. Each 20ml cartridge contains 100mg apomorphine hydrochloride hemihydrate. (APO-go POD SmPC, 2022)

APO-go pumps
Are available on permanent loan from Britannia Pharmaceuticals Ltd.

The APO-go® POD is designed to be used with a pump (the Crono® APO-go III Infusion Pump or the Crono® PAR4 20 Infusion Pump) and the CronoBell Sleeve. These are CE marked medical devices. (APO-go POD SmPC, 2022

The injection site should be covered using a suitable dressing e.g. tegaderm and to minimise local irritation at the site of administration, injection site should be rotated daily.

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The Neria Infusion Sets are recommended for the delivery of Apomorphine continuous subcutaneous infusion for a variety of reasons. Reduction of subcutaneous nodules, easy for the patients and carers to insert the needle and accuracy of inserting the needle into the subcutaneous layer and comfort as the needles are so fine.

All sets in this range have been tested for compatibility with Apomorphine

The range comprises the following options:

Code	Needle Guage	Tubing Length	Needle Length
78-060-2738	27g	60cm	8mm
78-110-2738	27g	110cm	8mm
78-110-2731	27g	110cm	10mm
78-060-2938	29g	60cm	8mm
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ADVERSE EFFECTS

Apomorphine is highly emetogenic. Tolerance to this effect develops in many patients allowing eventual withdrawal of domperidone. However, most patients require pre-treatment with domperidone (see above), and will need to continue on this treatment for many weeks after apomorphine initiation. If domperidone is unsuitable, the specialist team would consider the use of ondansetron (off label in discussion with the patient)

Postural hypotension may be experienced on initiating treatment. This is transitory and should not persist after discharge.

Apomorphine has been associated with somnolence and/or sudden sleep onset episodes, see cautions section for further advice.

Apomorphine therapy can be associated with psychological and psychosexual disturbances. These effects occur particularly in patients who have previously experienced psychiatric disturbances with other dopamine agonists.

Apomorphine has been implicated in a few cases of haemolytic anaemia with a positive direct Coombs' test and thrombocytopenia. Routine haematology tests are advised.

Subcutaneous administration of Apomorphine can cause necrosis, inflammation and formation of nodules at the injection site.

CONTRAINDICATIONS

Apomorphine HCl treatment must not be administered to patients who have an 'on' response to levodopa which is marred by severe dyskinesia or dystonia

APO-go should not be administered to patients who have a known hypersensitivity to apomorphine or any excipients of the medicinal product

APO-go is contraindicated for children and adolescents under 18 years of age.

Apomorphine is contra-indicated in patients with any respiratory depression, dementia, psychotic diseases* or hepatic insufficiency. Apomorphine should not be administered to anyone with known hypersensitivity to Apomorphine or any of the excipients

*Apomorphine is contra-indicated in patients with pre-existing psychiatric problems unless a full specialist assessment has been undertaken

CAUTIONS

Apomorphine HCl should be given with caution to patients with renal, pulmonary, or cardiovascular disease and persons prone to nausea and vomiting.

Extra caution is recommended during initiation of therapy in elderly and/or debilitated patients.

Since apomorphine may produce hypotension, even when given with domperidone pre-treatment, care should be exercised in patients with pre-existing cardiac disease or in patients taking vasoactive medicinal products such as anti-hypertensives, and especially in patients with pre-existing postural

hypotension.

Since apomorphine, especially at high dose, may have the potential for QT prolongation, caution should be exercised when treating patients at risk for torsades de pointes arrhythmia.

Apomorphine has been associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with apomorphine. Patients who have experienced somnolence must refrain from driving or operating machines. Furthermore, a reduction of dosage or termination of therapy may be considered necessary.

Neuropsychiatric problems co-exist in many patients with advanced Parkinson's disease. There is evidence that for some patients, neuropsychiatric disturbances may be exacerbated by apomorphine. Special care should be exercised when apomorphine is used in these patients.

Patients should be regularly monitored for the development of impulse control disorders which can occur with apomorphine.

PREGNANCY AND BREASTFEEDING

Due to the age of the treated population, the occurrence of pregnancy is improbable; however, the effects of apomorphine in pregnancy are unknown, and apomorphine should be avoided in pregnant and breast-feeding mothers. Advice from tertiary specialist centre would be sought in this scenario.

DRUG INTERACTIONS

Patients selected for treatment with apomorphine 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

Caution is advised when combining apomorphine with other medicinal products, especially those with a narrow therapeutic range.

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.

Even when co-administered with domperidone, apomorphine may potentiate the antihypertensive effects of antihypertensive drugs (see caution section above)

It is recommended to avoid the administration of apomorphine with other drugs known to prolong the QT interval (see caution section above)

ROUTINE MONITORING

Periodic clinical evaluation and monitoring of hepatic, haemopoietic (including direct Coombs test), renal and cardiovascular function is advised every 6-12 months.
The Neurology team will request routine bloods when the patient attends hospital clinic appointments.

STORAGE

All forms of Apomorphine should be stored at room temperature (no greater than 25ºC) and protected from light. Solution for injection which has turned green should not be used.

APO-go pens have a 48-hour expiry once in use. Pre-filled syringes should be discarded after 24 hours.

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APO-go POD comes in a 20ml pre-filled cartridge, it has a longer in use stability than the APO-go PFS, 48 hours versus 24 hours.

SHARED CARE

Shared care guideline: document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital consultant or nurse specialist, GP and the patient, and also sets out responsibilities for each party. The intention for shared care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a system of communication and cooperation in the management of patients. The doctor/nurse who prescribed the medicine has the clinical responsibility for the drug and the consequence of its use.

Responsibilities of the Hospital Consultant

1.Assessing suitability of patients for treatment.
2. Initiating treatment with Apomorphine, including initial supply of the necessary equipment will be arranged by the Neurology Team in Secondary care.
3. Giving patients a full explanation of the treatment plan and supplying them with a booklet explaining the therapy in full.
4. Ensuring patient understanding of the treatment, monitoring and follow-up that will be required
5. Organising training of patient and carers to administer Apomorphine as appropriate. Training to be arranged by specialist nurse in APO-go from Britannia Pharmaceuticals.
6. Arranging support from District Nurses if required to administer and/or prepare Apomorphine for continuous infusion.
7. Liaison with GP to agree to share the patients care.
8. Gradual withdrawal of Domperidone according to response (or ondansetron if Domperidone was unsuitable)
9. To monitor and evaluate the response to antiparkinsonian therapy and initiate changes to therapy.
10. To monitor for and evaluate abnormal test results and any adverse drug reactions.
11. Send a letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated.
12. Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
13. Inform GP of patients who do not attend clinic appointments.
14. Counsel the patient on contraception and what to do if pregnancy occurs. Document in the healthcare record.
15. Hospital consultant to issue first prescription of Apomorphine,

Responsibilities of the GP

1.The GP will arrange for an ECG and bloods and a prescription of Domperidone 10mg TDS for 72hours prior to Apomorphine being commenced
2. The GP will prescribe subcutaneous infusion sets, Tegaderm dressings if required and sharps bin.
3. The GP will be responsible for the prescribing of APO-go, needles/infusion lines on an ongoing basis once the patient is stable and when the GP formally agrees to shared care.
4.To inform the consultant or specialist nurse of changes in the patient's condition which may be related to treatment with apomorphine
5. Report any adverse events to the consultant/specialist nurse, where appropriate.
6. Report any adverse events to the MHRA via the yellow card scheme at https://yellowcard.mhra.gov.uk/ where appropriate.

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7. Monitor patient's overall health and well-being
8. Assist in the monitoring of the progression of the disease and report to the consultant/nurse specialist
9. To treat local skin problems such as infection or fibrosis with advice from the specialist Nurse.

Patient's/Carer's/Guardian's role

1. Report to the specialist consultant, specialist nurse or GP if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment.
3. Report any adverse effects to the specialist Nurse / Consultant or GP.
4. If wishing to self-administer, will agree to appropriate training and to protocols for the safe disposal of sharps

Cost of injection (excluding VAT):

APO-go 5 x 3ml disposable pens each containing apomorphine 30mg/3ml, includes - 100 dedicated needles £123.91

Cost of pre-filled syringe (excluding VAT)

APO-go PFS 5 x 10ml prefilled syringes containing 50mg/10ml £73.11

Cost of APO-go POD cartridges (excluding VAT)

APO-go® POD cartridges contain apomorphine hydrochloride 5mg/ml, as 100mg in 20ml, basic NHS cost £146.22 per 5 cartridges.

RESOURCES AVAILABLE

CONTACT DETAILS	
BHRuT Consultant/Team via switchboard	01708 435000 ext 2644 (Neurology secretary)
Specialist Nurse employed by Brittania Pharmaceutical on honorary contract with BHRUT	07834 177072
Apo-go 24/7 Help Line	08440881327 ww.apo-go.com

References

CG35 Parkinson's disease: full guideline - NICE
https://www.**nice**.org.uk/guidance/cg35/evidence/full-**guideline**-194930029

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Other useful references

Apomorphine- summary of product characteristics http://www.medicines.org.uk/emc/medicine/12942
UCL Apomorphine Shared Care Guidelines 5th Edition 2005
APO-go® POD (apomorphine hydrochloride) 5 mg/ml solution for infusion in cartridge formulary pack
UK-POD-2200021 Date of preparation: January 2023
Summary of Product Characteristics Updated 07 September 2022 / Britannia Pharmaceuticals Ltd revision of text 19/5/22
www.Apo-go.co.uk

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Appendix 1 **Shared Care Guidance for Apomorphine**

TAKING PRIDE IN OUR CARE TOGETHER

Barking, Havering and Redbridge NHS University Hospitals NHS Trust

SHARED CARE AGREEMENT LETTER

Name of GP …….

Address …….

Dear GP

Re: Patient's Name……

Date of Birth……

Hospital Number…….

Indication for ……

Route: Intermittent subcutaneous / Continuous subcutaneous)- DELETE AS APPROPRIATE

Dose…….mg per week.

All sets in this range have been tested for compatibility with - Apomorphine
The range comprises the following options, I have underlined the set that would be appropriate for ……

Code	Needle Guage	Tubing Length	Needle Length
78-060-2738	27g	60cm	8mm
78-110-2738	27g	110cm	8mm
78-110-2731	27g	110cm	10mm
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Enclosed is a copy of the shared care guidelines for apomorphine to be retained in the patient's notes.

Should you agree to shared care, we will send a letter containing the details of the patient's treatment plan, the dose to be prescribed and all relevant blood results.

Please sign below and return this letter to the hospital consultant/specialist nurse if you agree to the shared care arrangements for this patient.

Many thanks

Consultant GP

Signature…….. Signature……..

Name …….. Name ……..

Date…….. Date……..

If you are not taking on shared care for this patient, please state the reason why and return this letter to the Hospital Specialist.

……
……

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