

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Apomorphine (APO-go or Dacepton) in the treatment of Parkinson's disease
Prescribe by brand (products are not interchangeable)

1. REFERRAL CRITERIA

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP that the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring
- Patients will only be referred to the GP once the GP has agreed in each individual case, subject to receiving the relevant clinical information.
- Once stable the patient will be given a supply of Apomorphine sufficient for 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

GP responsibilities	Specialist responsibilities
<ol style="list-style-type: none"> 1. Reply to the request for shared care as soon as practicable. 2. Prescribe apomorphine at the dose recommended by the specialist 3. Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment. Particularly any significant development or deterioration in the following areas: motor performance, hallucinations, confusional states, psychosis, depression or an inability to administer apomorphine 4. The GP may adjust the dose of domperidone, if necessary, but should not adjust the dose of apomorphine unless under the instruction of the specialist team 5. GP to be aware of drugs which prolong QT interval (concomitant domperidone and apomorphine). As per MHRA drug safety update, April 2016 advice. 6. The specialist should be informed if any patient is found to be anaemic through opportunistic testing 7. report any adverse effects to the referring specialist and the MHRA yellow card scheme 8. Stop treatment on advice of specialist 	<ol style="list-style-type: none"> 1. Discuss the possible benefits and side effects of treatment with the patient. 2. Perform initial full blood count (FBC). FBC should also be performed at 6-12 monthly intervals and results should be appropriately actioned. Coombs Test is to be undertaken if patient is found to be anaemic. Perform an ECG prior to using domperidone – see MHRA drug safety update (May 2014) 3. The total daily dose should not exceed 100mg (doses in excess of 100mg should be discussed with the GP prior to handover) 4. Provide training/instruction to the patient or carer regarding method and frequency of administration, preparation, dosage of apomorphine 5. Prescribe the apomorphine until the patient is stable 6. Review the patient's condition and monitor response to treatment regularly. 7. Provide clear written information to the GP about the recommended dose, strength and form of apomorphine to be used. As there are different strengths of apomorphine available it is important to refer to mg/hr when communicating information about dosing 8. Provide clear written information to the GP about the recommended ancillary equipment to allow GP to continue to prescribe. (e.g. state specific type/code of Neria infusion lines) 9. Before starting treatment, carefully consider whether the benefits of concomitant apomorphine and domperidone treatment outweigh the small increased risk of cardiac side effects. (MHRA drug safety update, April 2016) 10. Check the QT-interval before starting domperidone, during the apomorphine initiation phase and if clinically indicated thereafter (e.g. if a QT - prolonging or interacting drug is started or if symptoms of cardiac side effects are reported) 11. Provide clear written information to the GP about the recommended dose and length of treatment for domperidone. 12. Ensure that clear backup arrangements exist for GPs to obtain advice and support 13. Report adverse events to MHRA yellow card scheme and GP.
Patient responsibilities	
<ul style="list-style-type: none"> • Report any adverse effects to the specialist or GP whilst taking apomorphine • Share any concerns in relation to treatment with apomorphine • Report to the specialist or GP if they do not have a clear understanding of their treatment • Report any changes that could increase the risk of arrhythmia to the specialist or GP, such as: <ul style="list-style-type: none"> o Symptoms of cardiac or hepatic disorders o Conditions that could cause electrolyte disturbances (e.g. gastroenteritis or starting a diuretic) o Starting any other medicines 	

3. COMMUNICATION AND SUPPORT

i. Hospital contacts:	ii. Out of hours contacts and procedures:
Chesterfield Royal Hospital NHS FT Dr R Genever – 01246 513659 Dr J Russell – 01246 513659 Christine Smith, PD Nurse Specialist – 01246 515719	On call Medic for Parkinson's Disease via switchboard: 01246 277271
University Hospitals of Derby and Burton NHS FT Dr L Jarman – 01332 785328 Dr R Skelly – 01332 785447 L Brown/S Filon, PD Specialist Nurses – 01332 783535	On call Pharmacist: 01332 340131 Bleep 1395
iii. Local arrangements for referral- As outlined in the GP and consultant/specialist areas of responsibility	

4. CLINICAL INFORMATION

i. Prescribed indications	The treatment of disabling motor fluctuations in patients with PD which persist despite individually titrated treatment with L- dopa and/or dopamine agonists
ii. Therapeutic summary	<p>Apomorphine is a directly acting dopaminergic agonist, licensed for use in patients with Parkinson's Disease who have frequent and/or severe akinesia ("off periods") not controlled by levodopa or other dopamine agonists. Research has shown that apomorphine reduces the daily "off" period time by up to 50% in patients with late-stage Parkinson's disease associated with refractory on-off oscillations.</p> <p>Treatment is by intermittent sub-cutaneous injection at the onset of an "off" period; or by continuous sub-cutaneous infusion usually over 12 hours. Following a single dose, apomorphine has an onset of action of 5-15 minutes and lasts for 45-90 minutes.</p> <p>Candidates for apomorphine therapy are those capable of recognising and anticipating "off" episodes. They must also be capable and motivated in order to use the treatment properly.</p> <p>Although apomorphine is not commonly used, it is a relatively safe drug.</p>
iii. Dose & Route of administration	<p>These will be determined and adjusted by the specialist team.</p> <p>The total daily dose should not exceed 100mg (doses in excess of 100mg should be discussed with the GP prior to handover)</p> <p>BNF SC injection usual dose 3-30mg daily (max. per dose 10mg) SC infusion usual dose 1-4mg/hour or 15-60micrograms/kg/hour</p> <p>Change infusion site every 12 hours and give during waking hours only (tolerance may occur unless there is a 4-hour treatment-free period at night—24-hour infusions not recommended unless severe night time symptoms)</p> <p><u>Use by subcutaneous infusion</u> This is a common method of administration and is delivered via a sub-cutaneous needle attached to a syringe driver. The patient and their carers will be instructed in the use of this system and patient held information will be provided for their own use and to support Primary Care personnel who may be involved in problems with the infusion system.</p> <p><u>Apomorphine is available as:</u></p> <ol style="list-style-type: none"> 1. APO-Go (Britannia) <ul style="list-style-type: none"> • Ampoules containing 50mg/5ml (10mg/ml, APO-go) • Pre-filled syringes- each 10ml pre-filled syringe contains 50mg apomorphine hydrochloride (5mg/ml, APO-go PFS) • Disposable multiple dose pen injector system 30mg/3ml (10mg/ml, APO-go Pen) 2. Dacepton (Ever Pharma) <ul style="list-style-type: none"> • Vial 100mg in 20ml (5mg/ml) solution for infusion • D-Mine Pump reservoir • Cartridge 30mg in 3ml (10mg/ml, for use in the D-mine pen) <p>As there are different strengths available it is important to refer to mg/hr when communicating information about dosing.</p> <p>Pre-treatment and associated co-treatment with domperidone is essential (see section vi).</p>
iv. Duration of treatment	Indefinite

<p>v. Pregnancy, paternal exposure and breastfeeding</p>	<p><u>Pregnancy</u> There is no experience of apomorphine usage in pregnant women. Animal reproduction studies do not indicate any teratogenic effects, but doses given to rats which are toxic to the mother can lead to failure to breathe in the newborn. The potential risk for humans is unknown. APO-go should not be used during pregnancy unless clearly necessary.</p> <p><u>Breastfeeding</u> It is not known whether apomorphine is excreted in breast milk. A decision on whether to continue/discontinue breastfeeding or to continue/discontinue therapy with APO-go should be made taking into account the benefit of breast-feeding to the child and the benefit of APO-go to the woman.</p>
<p>vi. Adverse effects</p>	<p>Apomorphine is usually highly emetogenic, so all patients are treated with domperidone 10mg TDS starting at least 3 days prior to initiation of therapy. Domperidone will be gradually withdrawn. Domperidone should be avoided in patients who are taking concomitant medication known to cause QT prolongation, an ECG should be performed prior to using domperidone and the decision to use made by the specialist. It is sometimes possible to withdraw this after a couple of months. The domperidone may also prevent/reduce postural hypotension. See MHRA drug safety update (May 2014)</p> <p>Impulse control disorders Treatment with dopamine-receptor agonists are associated with impulse control disorders, including pathological gambling, binge eating, and hypersexuality. Patients and their carers should be informed about the risk of impulse control disorders. Ergot- and non-ergot-derived dopamine-receptor agonists do not differ in their propensity to cause impulse control disorders, so switching between dopamine-receptor agonists will not control these side-effects. MHRA drug safety update (December 2014)</p> <p>Apomorphine may provoke;</p> <ul style="list-style-type: none"> • nausea and vomiting • postural hypotension – usually only transient on initiation of treatment • Neuro-psychiatric disturbances, e.g. hallucinations, delusions and confusional states. • Inflammation and formation of nodules at injection sites. • dyskinesias (abnormal involuntary movements) • eosinophilia in up to 10% of patients • Coomb's reaction in 6% of patients • haemolytic anaemia and thrombocytopenia
<p>vii. Monitoring Requirements</p>	<p>Specialist: For benefits and ADRs. Haematology tests: FBC to be undertaken at 6 – 12 monthly intervals by the consultant. Coombs test to be undertaken if patient is found to be anaemic Perform an ECG prior using domperidone– see MHRA drug safety update (May 2014)</p>
<p>viii. Clinically relevant drug interactions</p>	<p>Neuroleptic medicinal products may have an antagonistic effect if used with apomorphine these include: -</p> <ul style="list-style-type: none"> • haloperidol • chlorpromazine • promazine • trifluoperazine
<p>ix. Contraindications</p>	<ul style="list-style-type: none"> • Respiratory depression • Dementia • Psychotic diseases • Hypersensitivity to opioids • Not suitable if 'on' response to levodopa marred by severe dyskinesia, hypotonia or psychiatric effects • Hepatic impairment
<p>x. Additional information</p>	<p>Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.</p>

<p>xi. Supply of ancillary equipment e.g. syringe drivers, tubing</p> <p>Specialist to provide clear written information to the GP about the recommended ancillary equipment to allow GP to continue to prescribe. (e.g. state specific type/code of Neria infusion lines)</p>	<p>APO-go Pens The patient will usually have been given a pen by the hospital. GP to continue prescribe in multiples of 5. This is a disposable multiple dose pen injector system incorporating a clear glass cartridge. The company provides needles FOC with the pack of pens, and thereafter, as and when required by the patient. Needles supplied are 8mm (30G)</p> <p>APO-go ampoules and Pre-filled syringes These are for use with a syringe driver for continuous sub- cutaneous infusion. GP to prescribe ancillary equipment which include sodium chloride 0.9% injection for dilution and subcutaneous infusion lines (Neria lines-1 per day). Syringe drivers are supplied by Britannia.</p> <p>Dacepton cartridges The patient will have been given a D-minepen and an initial supply of cartridges by the hospital. GP to continue prescribe in multiples of 5. The company provides needles Free of Charge and thereafter, as and when required by the patient. Needles supplied are 8mm (30G)</p> <p>Dacepton solution for infusion and pump reservoirs This is for use without dilution for subcutaneous infusion via D-Mine infusion pump. The 20ml vial and infusion reservoir are prescribable on FP10. The patient will have been given an initial supply with the D-Mine infusion pump by the hospital. GP to continue prescribe in multiples of 5 (D-mine Pump Reservoir comes in pack of 10). Subcutaneous infusion lines are supplied Free Of Charge by the Company. Individual clinician decides lines appropriate to the patient need.</p>
<p>xii. Supply, storage and reconstitution instructions</p>	<p>APO-go is prescribable on FP10 but is not available from local wholesalers, only direct from the manufacturers: Britannia Pharmaceuticals Limited, 200 Longwater Avenue, Green Park, Reading. RG2 6GP Tel: 0118-920-9500 Fax: 0118-920-9594</p> <p>The community pharmacist will therefore require a few days notice to obtain apomorphine. If ordered before noon, delivery is next working day.</p> <p><u>Ampoules</u> APO-go ampoules do not contain a preservative, once an ampoule is opened any unused portion should be discarded after 24 hours. Filled syringes can be stored in the fridge for 24 hours. The ampoule should be used in the most economic way possible.</p> <p><u>Pen system</u> Store in a cool dry place (below 25C) but not in the refrigerator. Each pen should be discarded 48 hours after first use. Do not use the solution if it has turned green.</p> <p>Dacepton cartridges, infusion solution and pump reservoirs are prescribable on FP10 and available via community pharmacy or via Pharmaxo The community pharmacist will require a few days' notice to obtain apomorphine.</p> <p>Dacepton cartridges can be used for up to 15 days after first opening</p>
<p>xiii. To be read in conjunction with the following documents</p>	<ul style="list-style-type: none"> • SPC APO-go; Dacepton • RMOC Shared Care Guidance • NHSE - Responsibility for prescribing between Primary & Secondary/Tertiary Care
<p>xiv. Original documents prepared by</p> <p>Reviewed by</p>	<p>Peter Burrill, Specialist in Pharmaceutical Public Health North Derbyshire Public Health Dr Pippa Medcalf, Consultant Physician, Chesterfield & North Derbyshire Royal Hospital</p> <p>Derbyshire Medicines Management Guidelines & Shared Care Group Dr R Skelly, Consultant Physician, Derby Hospitals NHS Foundation Trust Dr R Genever, Parkinson's Disease Consultant, Chesterfield Royal Hospital Lisa Brown, Parkinson's Disease Nurse Specialist, Derby Hospitals NHS Foundation Trust</p>

This does not replace the SPC, which should be read in conjunction with it.

Date Approved: September 2014 Updated: August 2021

Review Date: July 2024

Hospital No: «HOSPITAL_NUMBER»
 NHS No: «NHS_NUMBER»

{Insert date}

PRIVATE & CONFIDENTIAL

«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
 «GP_ADDRESS_1»
 «GP_ADDRESS_2»
 «GP_ADDRESS_3»
 «GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»
 «CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_ADDRESS_3»
 «CURRENT_ADDRESS_4» «CURRENT_POSTCODE»

Your patient was seen on {Insert date} with a diagnosis of {Insert diagnosis}. I have initiated the following medication {Insert drug name} and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

Dose Regimen	Date {Insert medicine name} started	Date for GP to start prescribing {Insert medicine name} from
The baseline test results are (if applicable): See overleaf for initiation criteria.		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
<i>The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:</i>	
<i>Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory</i>	Yes / No
<i>The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care</i>	Yes / No
<i>The risks and benefits of treatment have been explained to the patient</i>	Yes / No
<i>The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed</i>	Yes / No
<i>The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments</i>	Yes / No
<i>I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)</i>	Yes / No
<i>I have included with the letter copies of the information the patient has received</i>	Yes / No
<i>I have provided the patient with sufficient medication to last until</i>	
<i>I have arranged a follow up with this patient in the following timescale</i>	

If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely
{Consultant name}

GP RESPONSE TO SHARED CARE (only complete & send if **NOT** participating in shared care)

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

		Tick which apply
1.	<p>The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care</p> <p>As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because <i>[insert reason]</i>. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice.</p> <p>I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.</p>	
2.	<p>The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement</p> <p>As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.</p> <p>Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you</p>	
3.	<p>A minimum duration of supply by the initiating clinician</p> <p>As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.</p>	
4.	<p>Initiation and optimisation by the initiating specialist</p> <p>As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.</p>	
5.	<p>Shared Care Protocol not received</p> <p>As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed.</p> <p>For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.</p>	
6.	<p>Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)</p>	

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

Yours sincerely

{GP name}

{Surgery}

Please send a copy of this response to:

1. The specialist/consultant requesting shared care
2. **AN ANONYMISED COPY OF THIS FORM ONLY** to the Medicines Management and Clinical Policies and Decisions Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: ddccg.medicinesmanagement@nhs.net

(Sending a copy of this form to the Medicines Management and Clinical Policies and Decisions Team will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).