University Hospital of North Staffordshire NHS Trust

North Staffordshire Combined Healthcare NHS Trust

Staffordshire and Stoke on Trent Partnership NHS Trust

NHS North Staffordshire Clinical Commissioning Group

NHS Stoke-on-Trent Clinical Commissioning Group

Effective Shared Care Agreement for the treatment of severe motor complications in people with Parkinson Disease with apomorphine (APO-go®)

This shared care agreement outlines the ways in which the responsibilities for managing the prescribing of apomorphine will be shared between the specialist and general practitioner (GP). 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 will remain with the specialist. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practical.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor 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.

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RESPONSIBILITIES and ROLES

Specialist responsibilities

- Patient selection and arranging day case admission for apomorphine challenge.
- Conduct any necessary baseline assessments to determine suitability.
- Ensure arrangements for continued prescribing are in place and that the GP is willing to continue treatment.
- Ensure that the patient/ carer understand the treatment (including provision of information) and plan for follow-up care.
- Initiation of either intermittent apomorphine injection or continuous infusion driver and optimisation of antiparkinsonian drug therapy.
- Supply the initial 28 days of apomorphine and equipment to the patient on discharge.
- Advise the GP of the dose preparation (e.g. pen, pre-filled syringe or ampoules), and any equipment/consumables that need to be prescribed.
- Monitoring and evaluation of adverse drug reactions, disease and drug response.
- Provision of telephone contact for patients, carers and health professionals, with clear arrangements for back-up advice and support should further assistance be required.
- Discontinuation of treatment when considered to be no longer efficacious or if side-effects outweigh benefits, and advice to GPs on when to stop treatment or alter dose.
- Arrangement of review dates at clinically relevant time intervals.
- Perform a full blood count at 3-6 monthly intervals.
- BP monitoring at 3-6 monthly intervals.
- Prompt communication with GP of any changes in treatment or dose requirements, results of monitoring undertaken and assessment of adverse events.
- Confirmation of apomorphine and equipment supply arrangements with relevant community pharmacy / dispensing surgery.
- To facilitate the co-ordination of on-going patient care within the community and home environment.

General Practitioner responsibilities

- To inform the specialist team of any significant developments, or deterioration, such as the occurrence of side effects or an inability to administer apomorphine.
- Prescribe on-going apomorphine therapy, equipment/consumables and domperidone if required, as recommended by the specialist team.

Patient's / Carer's role

- Report any adverse effects to their GP and/or specialist regarding their treatment.
- Ensure that they have a clear understanding of their treatment.
- Ensure they attend for monitoring requirements as per shared care guideline.
- Take prescriptions to the pharmacy / dispensing surgery as soon as possible so that they have adequate time to obtain supplies of the medicine (unless home care delivery).

Monitoring requirements

GP or Consultant	Baseline	Every 3-6 months & after dose change
Consultant	Undertake any baseline assessments including motor function and ECG (if necessary for domperidone treatment) Monitor blood pressure (e.g. standing and sitting) during initiation and any dose titration phase Monitor therapy and evaluate adverse drug reactions	Perform a full blood count Monitor blood pressure Monitor therapy and evaluate adverse drug reactions
GP	No requirement to monitor	No requirement to monitor

Administration equipment requirements

Patients prescribed the APO-go® PEN will receive needles FOC with the pens.

Patients prescribed the APO-go® PFS and APO-go® AMPOULES will be provided with a pump on-loan, syringes and connectors FOC. The Specialist will advise the GP of the infusion lines that are to be prescribed, these will usually be Neria lines (Unomedical) which are listed in the drug tariff and available on prescription, however the line length and gauge may vary depending on the needs of the patient. All patients have access to the APO-go® helpline should they have any queries or experience any problems with their equipment.

SUPPORTING INFORMATION EFFECTIVE SHARED CARE AGREEMENT

This information should be read in conjunction with the Summary of Product Characteristics for apomorphine available from www.medicines.org.uk

Licensed indications

Treatment of motor fluctuations (“on-off” phenomena) in patients with Parkinson's Disease which are not sufficiently controlled by oral anti-Parkinson medication.

Dosage and Administration

It is essential that the patient is established on domperidone, usually 10(-20) mg three times daily, for at least two days prior to initiation of therapy. Once treatment has been established, domperidone may be gradually reduced in some patients but successfully eliminated only in a few, without any vomiting or hypotension.

Apomorphine should be initiated in the controlled environment of a specialist clinic under the supervision of a physician experienced in the treatment of PD. The patient's treatment with levodopa, with or without dopamine agonists, should be optimised before starting apomorphine treatment.

Apomorphine must not be given via the intravenous route. The solution should be inspected visually prior to use and must be discarded if it has turned green. Only clear, colourless and particle free solution should be used.

Apomorphine injections

Selection of patients suitable for APO-go® injections

Patients should be able to recognise the onset of their 'off' symptoms and be capable of injecting themselves or else have a responsible carer able to inject for them when required.

Determination of the threshold dose

The appropriate dose for each patient is established by incremental dosing schedules. The following schedule is suggested:

1mg of apomorphine (approx. 15-20mcg/kg) may be injected subcutaneously during a hypokinetic or 'off' period and the patient is observed over 30 min for a motor response. If no or inadequate response a second dose of 2mg of apomorphine is injected and the patient observed for an adequate response for a further 30 min. The dosage may be increased by incremental injections with at least a 40 min interval between succeeding injections, until a satisfactory motor response is obtained.

Establishment of treatment

Once the appropriate dose is determined, a single subcutaneous injection may be given into the lower abdomen or outer thigh at the first signs of an 'off' episode. It cannot be excluded that absorption may differ with different injection sites within a single individual. Accordingly, the patient should then be observed for the next hour to assess the quality of their response to treatment. Alterations in dosage may be made according to the patient's response. The optimal dosage of apomorphine varies between individuals but, once established, remains relatively constant for each patient.

Continuous apomorphine infusion

Patients who have shown a good 'on' period response during the initiation stage, but whose overall control remains unsatisfactory using intermittent injections, or who require many and frequent injections (>10/day), may be commenced on or transferred to continuous subcutaneous infusion by minipump and/or syringe driver as follows:

Continuous infusion is started at a rate of 1mg/hour then increased according to the individual response. Increases in the infusion rate should not exceed 0.5mg/hour at intervals of not less than 4 hours. Hourly infusion rates may range between 1mg and 4mg. Infusions should run for waking hours only. Unless the patient is experiencing severe night-time problems, 24-hour infusions are not advised. Tolerance to the therapy does not seem to occur as long as there is an overnight period

without treatment of at least 4 hours. In any event, the infusion site should be changed every 12 hours.

Patients may need to supplement their continuous infusion with intermittent bolus boosts, as necessary, and as directed by their physician.

A reduction in dosage of other dopamine agonists may be considered during continuous infusion.

Precautions on continuing treatment

The daily dose of APO-go® varies widely between patients, typically within the range of 3-30mg, given as continuous infusion or as 1-10 injections and sometimes as many as 12 separate injections per day. It is recommended that the total daily dose of apomorphine should not exceed 100mg and that individual bolus injections should not exceed 10mg.

Elderly

The elderly are well represented in the population of PD patients and constitute a high proportion of those studied in clinical trials of APO-go®. Their management has not differed from that of younger patients. However, extra caution is recommended during initiation of therapy because of the risk of postural hypotension.

Contraindications

In patients with respiratory depression, dementia, psychotic diseases or hepatic insufficiency; avoid if 'on' response to levodopa which is marred by severe dyskinesia or dystonia.

Side Effects

Respiratory depression, dementia, psychotic diseases or hepatic insufficiency; 'on' response to levodopa which is marred by severe dyskinesia or dystonia

Drug Interactions

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).

The possible effects of apomorphine on the plasma concentrations of other medicinal products have not been studied. Therefore caution is advised when combining apomorphine with other medicinal products, especially those with a narrow therapeutic range.

Antihypertensive and Cardiac Active Medicinal Products

Even when co-administered with domperidone, apomorphine may potentiate the antihypertensive effects of these medicinal products.

It is recommended to avoid the administration of apomorphine with other drugs known to prolong the QT interval**.**

Primary Care Costs

Product	**Pack size**	**Primary Care cost ex VAT**
APO-go® PFS 5mg/ml Solution for Infusion in Pre-filled Syringe	5x10ml PFS	£73.10
APO-go® PEN 10mg/ml Solution for Injection	5x3ml pens	£123.90
APO-go® AMPOULES 10mg/ml solution for injection or infusion	5x5ml ampoules	£73.10

References

APO-go PFS 5mg/ml Solution for Infusion in Pre-filled Syringe. Genus Pharmaceuticals. Summary of Product Characteristics. Date of revision of the text January 2013. Accessed via www.medicines.org 04/06/13.

APO-go Pen 10mg/ml Solution for Injection. Genus Pharmaceuticals. Summary of Product Characteristics. Date of revision of the text January 2013. Accessed via www.medicines.org 04/06/13.

APO-go Pen AMPOULES 10mg/ml Solution for Injection or Infusion. Genus Pharmaceuticals. Summary of Product Characteristics. Date of revision of the text January 2013. Accessed via www.medicines.org 04/06/13.

British National Formulary No 64 (September 2012). BMJ and Pharmaceutical Press: London.

BACK-UP ADVICE AND SUPPORT

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