Royal Cornwall Hospitals
NHS Trust

Apomorphine for Treatment of Parkinson's Disease Shared Care Guideline

V5.0

November 2023

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of apomorphine when used in Parkinson's Disease.

1.2. This shared care guideline sets out details for the sharing of care of adult patients prescribed apomorphine. These guidelines provide additional limited information necessary to aid in the treatment these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, ABPI summary of product characteristics and do not replace them.

1.3. This version supersedes any previous versions of this document.

2. The Guidance

2.1. Parkinson's disease (PD) is a common neurodegenerative disorder with a prevalence of about 145,000 in the UK; typical age of onset is between 50-65 years. This is roughly one person in every 350 people.

Motor symptoms (bradykinesia, rigidity and tremor) dominate the clinical picture. The aetiology of PD is unknown but motor symptoms are believed to be caused by a dopamine deficit in the striatum due to progressive loss of dopaminergic neurons that project to the striatum from the substantia nigra.

Drug therapy with levodopa (a precursor to dopamine) and oral dopamine agonists usually provide good symptomatic relief without significant side effects in early disease. However, after some years of treatment many patients develop motor complications which include fluctuations in motor control and dyskinesias. As the disease progresses, the motor fluctuations often cause increasing disability.

Disabling motor fluctuations include unpleasant "off" periods. "Off" periods can be associated with dystonia, depression, pain, sleep dysfunction, bladder dysfunction and swallowing difficulties. With disease progression 'off' periods can occur suddenly rendering someone immobile in a matter of minutes. Apomorphine is a dopamine agonist, which acts directly on D1 and D2 receptors, stimulating areas of the brain where dopamine works. It produces a similar effect to levodopa, that is, the ability to prevent and reverse disabling "off" periods. However optimizing treatment can be difficult and complex for many patients.

2.2. Apomorphine (as APO-go® or APO-go® POD or Dacepton®) is licensed for use in patients with disabling motor fluctuations who are inadequately controlled with levodopa or dopamine agonists. The license covers both subcutaneous intermittent injections and continuous subcutaneous infusions. Despite its name it has no opiate or addictive properties. Apomorphine cannot be used orally because it undergoes extensive first pass metabolism to an inactive metabolite; for this reason it is administered subcutaneously.

2.3. Preparations, Dosages and Administration

2.3.1. This shared care guideline describes the use of both APO-go® and Dacepton® brands of apomorphine. Prescribe by branded name.

2.3.2. Apomorphine may be administered as a “rescue therapy” with intermittent subcutaneous bolus injections given via prefilled APO-go® PEN or D-mine® Pens to give a ‘boost’ in dopaminergic stimulation when needed. Pens can provide a means of rescue within 10 minutes of administration, thereby regaining mobility and independence. The effect usually lasts for about an hour.

2.3.3. For those patients who experience more complex motor fluctuations, including dyskinesias, a continuous subcutaneous infusion using APO-go® or Dacepton® via an ambulatory pump may be used.

2.3.4. Patients and caregivers must receive detailed instructions in the preparation and injection of doses, with particular attention paid to the correct use of the required dosing pen or pump. There are differences in the dosing for each apomorphine product on the market. Therefore, when a patient has received a particular pen/pump and is trained on it, a switch to a different product should be accompanied by re-training under the supervision of a health care professional.

2.3.5. The dose of apomorphine is carefully titrated on an individual basis and can range from a few milligrams daily by intermittent subcutaneous injections, up to 100mg daily by either (or combined routes). In rare cases it may be necessary to give higher doses.

2.3.6. Doses will be determined and adjusted by the specialist team. The total daily dose should not exceed 100mg (doses in excess of 100mg should be discussed with the GP prior to handover).

2.3.7. BNF SC injection usual dose 3-30mg daily (max. per dose 10mg).

2.3.8. Continuous subcutaneous infusion would usually be considered if the patient experiences so many ‘off’ periods that repeated bolus injections are inappropriate (> 10 per day). – SC infusion usual dose 1-4mg/hour or 15-60micrograms/kg/hour.

2.3.9. Use by subcutaneous infusion - 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.

2.3.10. The responsibility of initiating or switching patients to APO-go® POD cartridge will be with the specialist. APO-go nurses will work with specialists to identify and support patients to transfer from the pre-filled syringes to the APO-go® POD cartridge. They will also provide device training for patient, carers or other healthcare professionals as well as ongoing support in the community.

2.3.11. Patients selected for treatment with APO-go® POD should be capable of setting up an infusion system themselves or else have a responsible carer able to set up an infusion system for them when required.

2.3.12. Apomorphine is available as:

1. APO-go® (Britannia)

- Ampoules of 10mg/1ml solution for injection or infusion available as 50mg/5ml ampoule (APO-go). Rarely used due to additional risks of dilution.

- APO-go® PFS: Pre–filled syringes of apomorphine 5mg/ml, each 10ml pre-filled syringe contains 50mg apomorphine hydrochloride. Being phased out and replaced with APO-go® POD 5 mg/ml solution for infusion in cartridge.

- APO-go® POD: Cartridge containing 5mg/ml solution for infusion Each 20ml cartridge contains 100mg apomorphine hydrochloride.

  This is a different concentration to APO-go® and APO-go® PEN.

- APO-go® PEN: Disposable multiple dose pen injector system containing 30mg/3ml.

2. Dacepton (Ever Pharma)

- Vial 100mg in 20ml solution for infusion

- D-Mine Pump reservoir

- Cartridge 30mg in 3ml (for use in the D-mine pen)

2.3.13. As there are different strengths available it is important to refer to mg/hr when communicating information about dosing.

2.4. Obtaining supply

2.4.1. APO-go® PEN - these are prescribable on FP 10. The patient will usually have been given one by the hospital. Please prescribe in multiples of 5 pens per box. This is a disposable multiple dose pen injector system incorporating a clear glass cartridge. The company provides the first box of pens and needles free of charge for the challenge and for use thereafter (30G).

2.4.2. APO-go® PFS - these are prescribable on FP 10. Please prescribe in multiples of 5 pre-filled syringes per box. Ancillaries of reservoir syringe and connectors are supplied free of charge as part of the prescription. APO-go® PFS is a pre-diluted solution intended for use without dilution as a continuous subcutaneous infusion by ambulatory pump. APO-go® PFS is designed to be used with either the Crono® APO-go III Infusion Pump or the Crono PAR4 20 Infusion. These are CE marked medical devices. Subcutaneous infusion line (Neria lines-1 per day) should be prescribed on FP10.

2.4.3. APO-go® POD cartridges - these are prescribable on FP10. Please prescribe in multiples of 5 cartridges per box. Ancillaries of CronoBell sleeve are supplied free of charge as part of the prescription. APO-go® POD is a pre-diluted solution intended for use without dilution as a continuous subcutaneous infusion by ambulatory pump. APO-go® POD is designed to be used with either the Crono® APO-go III Infusion Pump or the Crono PAR4 20 Infusion Pump. These are CE marked medical devices. Subcutaneous infusion line (Neria lines-1 per day) should be prescribed on FP10.

2.4.4. Dacepton cartridges - these are prescribable on FP10. The patient will have been given a D-minepen and an initial supply of cartridges by the hospital. Please 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).

2.4.5. 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. Please prescribe in multiples of five. Subcutaneous infusion lines are supplied Free of Charge by the Company.

2.4.6. Apomorphine is prescribable on FP10 but is not available from local wholesalers, only direct from the manufacturers:

APO-go® Britannia Pharmaceuticals, 200 Longwater Avenue, Green Park, Reading, Berkshire, RG2 6GP.

Orderline: 0844 8801326.

E-mail: customerservices@britannia-pharm.com

Dacepton® Ever Pharma UK Limited, Suite 2, 38 The Green, South Bar Street, Banbury, OX16 9AE.

Stock availability: +44 (0) 1225 302188.

Customer care direct line: 0800 254 0175.

E-mail: wholesale@pharmaxo.com

2.5. Contraindications and Precautions

Contraindications are:

- Hypersensitivity to the active substance or to any of the excipients (sodium metabisulphite, hydrochloric acid, sodium hydroxide.
- Patients with respiratory depression, dementia, psychotic diseases or hepatic insufficiency.
- Hypersensitivity to opioids.

- Not suitable if ‘on’ response to levodopa marred by severe dyskinesia, hypotonia or psychiatric effects.
- Children and adolescents under 18 years of age.

Caution in:

- Patients with renal, pulmonary or cardiovascular disease.
- Elderly and/or debilitated patients.
- Patients with neuropsychiatric disturbances - may be exacerbated by apomorphine.
- Patients at risk for torsades de pointes arrhythmia; due to potential for QT prolongation when apomorphine is given at high doses.
- Patients with postural hypotension or those taking antihypertensives.

2.6. Monitoring - SPECIALIST TEAM

Undertake any baseline assessments including ECG. If this is not possible to undertake, an ECG and routine bloods will be requested for general practice, with the ECG returned to Specialist Team for review. Monitoring therapy and evaluation of adverse drug reactions. BP monitoring (eg standing and sitting) during initiation and any dose titration phase.

2.7. Monitoring - GENERAL PRACTICE

Perform a full blood count at 4-6 monthly intervals. BP monitoring at 4-6 monthly intervals. If patient remains on domperidone therapy long term, undertake ECG monitoring if clinically indicated (ie if a QT-prolonging or interacting drug is started or if symptoms of cardiac side effects are reported).

2.8. Side Effects

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).

Apomorphine may provoke:

- 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.

2.9. Significant Drug Interactions

Neuroleptic medicinal products may have an antagonistic effect if used with apomorphine these include:

- Haloperidol.
- Chlorpromazine.
- Promazine.
- Trifluoperazine.

2.10. Shelf life, storage & disposal

2.10.1. **APO-go®**

2.10.1.1. APO-go® PFS. Prefilled syringes of APO-go® should be stored at room temperature (at or below 25ºC) and protected from light. Once opened, they should be used immediately. No antimicrobial preservative is included in the formulation so prepared syringes should be used within 24 hours. The solution must not be used if it is green or discoloured.

2.10.1.2. APO-go® Pens should be stored in a cool dry place, but not in a fridge and discarded 48hrs after opening.

2.10.1.3. APO-go® stains green on contact so care should be taken to avoid spillages. Lemon juice may prevent green colouring from developing if used immediately. Bleach may help reduce stains on kitchen surfaces.

2.10.2. **APO-go® POD**

2.10.2.1. APO-go® POD cartridge containing 5mg/ml solution for infusion. Each 20ml cartridge contains 100mg apomorphine hydrochloride.

2.10.2.2. Store in a cool dry place, but not in a fridge.

2.10.2.3. Once opened APO-go® POD should be used immediately. Any unused solution should be discarded after 48 hours and a new cartridge used.

2.10.3. **Dacepton® 10mg/ml solution for injection in cartridge (D-Mine® pen)**

2.10.3.1. Dacepton® 10mg/ml solution for injection cartridges should be stored at room temperature (at or below 25ºC). It should not be refrigerated or frozen. Keep in the outer carton in order to protect from light. The product should be stored at the same conditions after opening and between withdrawals.

2.10.3.2. Shelf-life (unopened) is 2 years. After first opening, the product has a shelf-life of 15 days when kept at 25ºC. From a microbiological point of view, unless the method of opening and further handling precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

2.10.3.3. Do not use if the solution has turned green. Only clear, colourless to slightly yellow solutions free of particles in undamaged containers should be used.

2.10.3.4. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

2.10.3.5. Discard each cartridge with unused content not later than 15 days after first opening.

2.10.3.6. Patients should be advised how to safely discard the needle after each injection.

2.10.4. **Dacepton® 5mg/ml solution for infusion**

2.10.4.1. Dacepton® 5mg/ml solution for infusion vials should be kept in the outer carton to protect from light. It should not be refrigerated or frozen.

2.10.4.2. Shelf-life (unopened) is 30 months. After opening and filling the drug product into syringes attached with infusion sets, chemical and physical in-use stability has been demonstrated for 7 days at 25ºC. From a microbial point of view, unless the method of opening and further handling precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

2.10.4.3. Single use only.

2.10.4.4. Discard any unused contents.

2.10.4.5. Do not use if the solution has turned green. Only clear, colourless to slightly yellow solutions free of particles in undamaged containers should be used.

2.10.4.6. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

2.11. Areas of Responsibility for the Sharing of Care

2.10.5. These are suggested ways in which the responsibilities for the management of adult patients with who are prescribed **apomorphine** can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. 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 and be accepted by them.

2.10.6. **In the NHSE guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.**

2.10.7. **Specialist:**

- Patient selection and conduct any necessary baseline assessments to determine suitability.
- Agreement to initiate treatment reached between patient, GP and Specialist Team (under Shared Care Guideline) using the suggested wording template (Appendix 4).
- Liaison (including provision of information) with patient, spouse, carers and Primary Care Teams.
- Start domperidone 10 mg** three times daily three days prior to apomorphine challenge (See Appendix 3 for Challenge instructions) and arrange day case admission for apomorphine challenge.** Domperidone is contraindicated in people with underlying cardiac conditions and other risk factors, including those who take concomitant medication known to cause QT prolongation or potent CYP3A4 inhibitors (such as ketoconazole and erythromycin); and in people with severe hepatic impairment. Once apomorphine treatment is established, the domperidone dose should be gradually reduced to the lowest effective dose and discontinued as soon as possible
- Specialist team to initiate either intermittent apomorphine injection or continuous infusion driver and optimise anti-parkinsonian drug therapy.
- Monitoring and evaluation of adverse drug reactions.

- Telephone contact for patients, carers and health professionals, providing the GP with relevant contact information with clear arrangements for back-up advice and support should further assistance be required relating to this drug.

- The Consultant / Specialist Team will be responsible for disease and drug response monitoring; this will be undertaken in the out-patient setting, and where necessary, the patient's home.

- Discontinue treatment when considered to be no longer efficacious or if side-effects outweigh benefit.

- Specify review dates at clinically relevant time intervals for both the GP and the consultant.

- Prompt communication with GP of any changes in treatment or dose requirements, results of monitoring undertaken and assessment of adverse events.

- The Specialist Team will inform the relevant community pharmacy / dispensing surgery of supply arrangements for apomorphine and consumables.

2.10.8. **General Practitioner:**

- To respond to the shared care request from the consultant in writing without delay.

- To inform the specialist team of any significant developments, or deterioration, such as the occurrence of side effects or an inability to administer apomorphine.

- Be aware that domperidone may be associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death, and hence is contraindicated in those with underlying cardiac conditions and other risk factors.

- Perform a full blood count at 4-6 monthly intervals.

- BP monitoring at 4-6 monthly intervals.

- For patients remaining on domperidone therapy long term, ECG monitoring if clinically indicated.

- Following initiation to prescribe on-going drug therapy as recommended by the specialist team including a 7 litre sharps box (unless Homecare Service is initiated).

- To facilitate the co-ordination of on-going patient care within the community and home environment, liaising with the Specialist Team when necessary.

2.10.9. **Patient / parent / guardian / carer:**

- Report any adverse effects to their GP and/or specialist regarding their treatment. Patients should specifically report if they experience a racing heartbeat, palpitations, dizziness, fainting, or black outs.
- Ensure that they have a clear understanding of their treatment and they attend for monitoring requirements as per shared care guideline.
- Take prescriptions to the pharmacy / dispensing surgery as soon as possible so they have adequate time to obtain supplies of the medicine.

2.10.10. **BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE PARKINSON'S TEAM AND RELEVANT APO-go®/Dacepton® SUPPORT ROUTES**

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice).
Lead	Head of Prescribing Support Unit.
Tool	Audit and review tool using patient documentation.
Frequency	As required according to clinical incident reports.
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee.
Acting on recommendations and Lead(s)	Relevant Clinical Staff.
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Apomorphine for Treatment of Parkinson's Disease Shared Care Guideline V5.0
This document replaces (exact title of previous version):	Shared care guideline for treatment of Parkinson's Disease with apomorphine V4.1
Date Issued/Approved:	November 2023
Date Valid From:	November 2023
Date Valid To:	November 2026
Directorate / Department responsible (author/owner):	Parkinson's Disease Team / Pharmacy - Head of Prescribing Support Unit.
Contact details:	01872 253548
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists.
Suggested Keywords:	Apomorphine, Parkinson's disease
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee
Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming consultation and ratification:	Kevin Wright
Links to key external standards:	None required
Related Documents:	Summaries of Product Characteristics. APO-go® information for both patients and healthcare professionals. https://www.apo-go.com/

Information Category	Detailed Information
	24/7 Helpline manned by APO-go® advisers: 0844 8801327. Dacepton® information for both patients and healthcare professionals. https://www.d-minecare.com/ 24/7 Helpline manned by D-mine® advisers: 0800 254 0175.
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
21 Nov' 2012	V1.0	Initial Issue.	M Wilcock, Head of Prescribing Support Unit
Sept 2014	V2.0	Update warning for domperidone.	M Wilcock, Head of Prescribing Support Unit
May 2016	V2.1	ECG monitoring advice included.	M Wilcock, Head of Prescribing Support Unit
Mar 2019	V3.0	New format and minor changes 2.3 and 2.10.3.	M Wilcock, Head of Prescribing Support Unit
July 2020	V4.0	Updated to include Dacepton® brand of Apomorphine.	L Osborne, Nurse Consultant Parkinson's Service M Wilcock, Head of Prescribing Support Unit

Date	Version Number	Summary of Changes	Changes Made by
August 2021	V4.1	Replacement of shared care agreement letter with suggested wording template instead (Appendix 4). Addition of key words.	M Wilcock, Head of Prescribing Support Unit
November 2023	V5.0	Inclusion of Apo-go POD and relevant text.	L Osborne, Nurse Consultant Parkinson's Service M Wilcock, Head of Prescribing Support Unit

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Apomorphine for Treatment of Parkinson's Disease Shared Care Guideline V5.0
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow
Contact details:	01872 253548

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide information on prescribing of apomorphine to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area).
3. Policy Intended Outcomes	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. How will you measure each outcome?	Six monthly review.
5. Who is intended to benefit from the policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Cornwall Area Prescribing Committee.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Apomorphine challenge

Before therapy can be initiated an apomorphine challenge is necessary in order to: determine whether a patient has a positive response to the medication; establish the optimum dose for the individual patient and observe the patient for side effects such as nausea, vomiting, postural hypotension, hallucinations and sleepiness. Two - three days prior to and throughout the challenge, domperidone 10mg** orally TDS is commenced (usually at home) to avert the significant emetic effects of apomorphine. Exceptionally a higher dose of domperidone 20mg TDS may be used). The challenge is usually performed as a day case in a safe clinical environment with medical support. On an occasional basis if the patient is homebound and a risk assessment has taken place, apomorphine could be commenced through the pump at 0.5mgs and gradually titrated up over a period of time to ascertain effect.

1. Obtain a starter pack of 5 APO-go®/ D-mine® Pens. APO-go® Pens are available free of charge from Britannia Pharmaceuticals for the challenge procedure. EVER Pharma can also supply starter packs of D-mine® Pens to Healthcare Professionals by contacting the local representative. Pre-treat with domperidone 10mg TDS** for 72 hours prior to and ongoing following a positive outcome of the challenge. The dosage may then be titrated downwards as tolerance develops.

2. Patients should obtain a prescription from the specialist team. The patient should not receive any oral anti-Parkinson medication for a minimum of eight hours prior to the challenge, unless necessary in order to provoke an “off” state. The patient’s mobility should be considered if the challenge is to be performed as a day case. If necessary for mobility a dose of medication such as co-beneldopa dispersible 62.5mg may be required.

3. Motor function is assessed at baseline using the Unified Parkinson’s Disease Rating Scale (UPDRS) section III Motor Function, together with a timed a 12 (if practicable) metre walk (the time it takes the patient to rise from a chair with arms folded then walk 6m, turn, return 6m, then sit down). Lying and standing blood pressure is also recorded due to the possible hypotensive effects of dopamine agonists. These assessments are repeated after sequential doses of apomorphine.

4. Administer 1mg apomorphine subcutaneously as a test dose and repeat above motor assessment and blood pressure 20-30 minutes following dose, monitor for side effects and observe for a positive response.

5. If there is no or a poor response, give a subsequent dose of 2-3 mg apomorphine. Continue to assess as above and observe.

6. Increase the dose in incremental steps every 45-60 minutes (eg. 2mg, 3mg, 5mg, 7mg) Stop when a positive response is seen. If at 7 mg there is no response, then the patient is termed a non-responder. If a mild response is noted at 7mg, discuss with the patient’s neurologist as to whether then the maximum dose of 10mg should be administered.

A challenge is positive if either the following are seen, for example:

- A decrease in UPDRS motor score by at least 20%.
- A minimum of 20% improvement in timed walking.

The apomorphine (APO-go®/Dacepton®) syringes are supplied by both Britannia and EVER Pharma free of charge for the challenge tests. It is good practice to record the batch no of the syringes used together with the expiry dates against the patient name preferably on the prescription chart. Pharmacy will also have a note of receipt and will store the syringes until needed.

** Note recent MHRA safety warnings with domperidone. See ‘Specialist Team Responsibilities’ section.

Appendix 4. Suggested wording for Specialist communication re commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you are in agreement, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment.).

Baseline tests: (insert information).

Next review with this department: (insert date).

You will be sent a written summary within (XX) days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.