South East London Shared Care Prescribing Guideline for APO-go® (Apomorphine) for treatment of Parkinson's disease Date originally approved: November 2016 Last reviewed: November 2023 Next review date: November 2025 (or sooner if evidence or practice changes)



SHARED CARE PRESCRIBING GUIDELINE APO-go® for the treatment of Parkinson's in ADULTS

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SHARED CARE PROCESS FLOWCHART

Specialist clinician completes Shared Care Request Letter (Appendix 1) and sends to patient's GP via email.



GP considers shared care request, taking into account the following:

- Is the patient's condition predictable or stable?
- Whether they have the relevant knowledge, skills and access to equipment to allow them to monitor treatment as indicated in this shared care prescribing quideline?
- Whether they have been provided with relevant clinical details including monitoring data?





If YES to all the above, and after reading this shared care guideline then it is appropriate for GP to accept prescribing responsibility



If NO to any of these questions, GP should contact the requesting consultant or the local primary care Medicines Optimisation Team within 2 weeks of receipt to discuss



Complete Shared Care Agreement Letter (Appendix 2) and email back to the requesting clinician within 2 weeks of receipt

Complete Shared Care Refusal Letter (Appendix 3) and email back to the requesting clinician

NOTES

There may be implications for the patient where invitation to share care is declined. For example, the patient may need to be changed to an alternative treatment regimen. It would not normally be expected that shared care prescribing would be declined on the basis of cost.

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.

Prescribing should follow requirements in the <u>South East London Interface Prescribing Policy</u>. The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. The patient's best interests are always paramount.

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.

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1. AREAS OF RESPONSIBILITY

Consultant / Specialist team responsibilities

- Establish or confirm diagnosis and assess patient suitability for treatment.
- Baseline monitoring tests:
- ECG (for patient convenience GP may be request to carry out ECG and send the results to KCH), Apomorphine challenge, baseline bloods (Full blood count, renal function, coombes test and reticulocyte count) and assessments including measuring UPDRS (Unified Parkinson's Disease Rating Scale) part 3 to assess motor function, baseline lying and standing blood pressure and timed walk if possible.
- To initiate, stabilise and supply treatment over the first two weeks.
- To inform patients of practical issues related to the use of apomorphine, such as administration, storage and maximum dose, supported by written and audio information if required.
- At the time of initiating, notify GP in writing that apomorphine has been prescribed. The GP should be invited to share care once the patient is stable. Information provided to the GP should include:
 - o A copy of the shared care guidelines
 - o That a prescription for the first two weeks supply has been given
 - o Information on when the patient will next be reviewed and by whom
 - A request that the GP continue prescribing after two weeks
- Send a copy of the clinical management plan to the GP
- A repeat UPDRS part 3 (to monitor motor progression of Parkinson's) and assessment of effect of treatment on quality of life and non-motor assessments will be performed at each clinic appointment.
- To review patient every 12 months as a minimum. To additionally review patient (within two weeks) at the request of GP should any problems arise (side-effects / lack of efficacy).
- To communicate promptly (within two weeks) with the GP if treatment is changed.
- To report any suspected adverse effects to the MHRA: https://yellowcard.mhra.gov.uk/

General Practitioner responsibilities

- To consider shared care proposal within 2 weeks of receipt. If agree to request to continue prescribing as detailed in shared care guideline. Confirmation to the requesting consultant is required within 2 weeks of receipt of this guideline by completing and returning the agreement on page 10
- If do not agree to shared care discuss with requesting consultant or local primary care Medicines Optimisation
 Team within 2 weeks of receipt of shared care request
- To provide ongoing prescriptions for APO-go® (apomorphine) and associated items to allow home administration including neria lines and sharps bins after 2 weeks.
- To adjust the dose as advised by the specialist
- To agree monitoring requirements with specialist see page X of this document for GP monitoring requirements
- To report and seek advice regarding any concerns, for example: side-effects, co-morbidities, pregnancy, or lack of efficacy to the specialist team
- To advise the specialist if non-compliance is suspected
- To refer back to specialist if the patient's condition deteriorates
- To stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- To report any suspected adverse effects to the MHRA via the Yellow Card scheme: https://yellowcard.mhra.gov.uk/

Patient's / Carer's responsibilities

- To contact the specialist or GP if he or she does not have a clear understanding of any aspect of the treatment.
- To inform prescribing specialist, GP and other healthcare professionals of any other medication being taken, including over the counter products, alternative therapies or recreational drugs.
- To inform community pharmacists that they are using apomorphine before purchasing medication over-thecounter
- To attend all hospital and GP appointments
- To take medicines as agreed and take steps to ensure that no doses are missed and not to share medicines with others
- To read the patient information leaflet included with the medication.
- To report any adverse effects or warning symptoms to GP or hospital specialist
- To report to GP and maternity services team if pregnant or breastfeeding.
- To inform GP and hospital of any changes in addresses or telephone contact numbers.

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2. CLINICAL INFORMATION

NOTE: The information here is not exhaustive. Please also consult the current Summary of Product Characteristics (SPCs) for **Apo-Go** prior to prescribing for up to date prescribing information, including detailed information on adverse effects, drug interactions, cautions and contraindications (available via www.medicines.org.uk)

Background	Apomorphine is used in the management of disabling motor fluctuations ("on-off" phenomena) which persist despite efforts at individual optimisation of treatment with oral/transdermal Parkinson's medications. Apomorphine is a dopamine agonist which acts directly on D1 and D2 receptors. It is not an opiate or a controlled drug. Apomorphine is administered by intermittent subcutaneous injection or by continuous subcutaneous infusion.
Indications Note if indication is unlicensed or not	Licensed treatment of motor fluctuations ("on-off" phenomena) in patients with Parkinson's which are not sufficiently controlled by anti-Parkinson medication.
Place in Therapy Indicate what drugs should have been tried before this drug is considered	Apomorphine is indicated in patients with Parkinson's who display one or more of the following symptoms; predictable or unpredictable "on-off" motor fluctuations, disabling biphasic or peak dose dyskinesia (unresponsive to therapies such as levodopa, oral/transdermal dopamine agonists and enzyme inhibitors), and dystonia not controlled with oral therapy. See also NICE guidance for further information.
	For example: The intermittent injections (pre-filled pens) are used where patients have unpredictable "off" (sometimes described as freezing episodes) and need "rescue" therapy to get going quickly.
	The infusion (pre-filled syringes used to fill a Chrono Pump or APO-go POD) are used where patients have motor complications affecting their current therapy regime for example considerable time, or requiring rescue doses of apomorphine too frequently or suffering troublesome dyskinesias which are preventing titration of therapy.
Locally agreed off-label use Including supporting information	N/A
Initiation and ongoing dose regime	Initial stabilisation: (The loading period must be prescribed by the initiating specialist)
Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimized and with	Patient response to apomorphine is relatively quick, (within 30 minutes) and therefore assessment of response can be quickly made and then dosage can be adjusted to optimum response within hours. This allows transfer of care to be achieved quickly.
satisfactory investigation results for at least 4 weeks. • The duration of treatment & frequency of review will be	Maintenance dose (following initial stabilisation): (The initial maintenance dose must be prescribed by the initiating specialist)
determined by the specialist, based on clinical response and tolerability. • All dose or formulation	The apomorphine intermittent injection dose regimen is individually titrated according to the patient's symptom management. This may range from 1-5 intermittent subcutaneous injections daily.
 adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician. Termination of treatment will be the responsibility of the specialist. 	Continuous infusion dose may range from 50-120mg daily, usually during waking hours only (12-16 hours a day). Therefore the rate is usually between 2mg/hour and 8.5mg/hour. Using the 5mg/ml prefilled syringes the usual rate is between 0.4ml/hour and 1.7ml/hour. The dose starts at the lower end and is gradually titrated upwards to control symptoms. Refer to the NICE guidance on Parkinson's for further information on apomorphine regimens.

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	Conditions	iring doos selle	ustmont
	Conditions requiring dose adjustment		
	Adverse effects or symptom worsening.		
	<u>Duration of treatment</u>		
	Long term		
Pharmaceutical aspects	Route of administration	Subcutaneous	
	Formulation		r infusion, APO-go prefilled syringes for prefilled pens for intermittent injection
	Administration details	via continuo	a intermittent subcutaneous injection or ous subcutaneous infusion
	Other important information	N/A	
Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist	Baseline investigations: • Establish or confirm diagnosis of Parkinson's and suitability for treatment.		
	ECG (for patient convenience GP may be request to carry out ECG and send the results to KCH), Apomorphine challenge, baseline bloods (Full blood count, renal function, coombes test and reticulocyte count) and assessments including measuring UPDRS (Unified Parkinson's Disease Rating Scale) part 3 to assess motor function, baseline lying and standing blood pressure and timed walk if possible.		
	 Ongoing monitoring: A repeat UPDRS part 3 (to monitor motor progression of Parkinson's) and assessment of effect of treatment on quality of life and non-motor assessments will be performed at each clinic appointment. 		
Ongoing monitoring requirements to be undertaken	Monito	ring	Frequency
by primary care	Full blood	count	6 monthly
Adverse effects and management	Resu	ilt	Action for GP/Specialist Team
Any serious adverse reactions should be reported to the MHRA via the Yellow Care scheme	Haemolytic anaemia of thrombocytopenia	or	Immediate referral back to secondary care
www.mhra.gov.uk/yellowcard	Skin complaints aroun	nd injection site	Refer back to PDNS who will organise a nurse to visit and provide further advise (see information below)
	Nausea and vomiting		Domperidone 10mg three times daily to be started 72 hours prior to hospital admission. Treatment prescribed by consultant team, or by the GP depending on agreement and patient preference. To be continued until established on therapy; then gradually withdrawn over two weeks on advice of specialist team/consultant.

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	Dyskinesia	Treatment to be adjusted or discontinued by PDNS following discussion with consultant.
	Sedation	Usually transient at the start of therapy. Should resolve over the few first weeks. Treatment to be adjusted or discontinued by PDNS following discussion with consultant.
	Confusion and visual hallucinations	Usually mild and transient. More commonly reported in patients with a history of neuropsychiatric complications induced by L-dopa (as co-beneldopa/co careldopa) and/or dopamine agonists. If symptoms persist, attempts should be made to identify contributing factor under direct supervision of hospital team.
	Impulse control disorders including, but not limited to - Pathological gambling, increased libido, hypersexuality	Reversible on dose reduction or treatment discontinuation under supervision of consultant/PDNS.
	Injection site reactions (mild nodules to painful hard nodules)	Refer to PDNS for advice – see advice to patients and carers section for information on minimising skin reactions.
Advice to patients and carers	The specialist team in secondary care provides the patient with information and	

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

advice about apomorphine therapy, including how to administer therapy and the devices used. This information is supported by written and audio information if required. Only when the patient and their family are satisfied with the process will treatment proceed

The patient should be advised to report any of the following signs or symptoms to their GP without delay:

Skin complaints

It is important to minimise the development of nodules as it is thought that they may reduce absorption of apomorphine, thus reducing the efficacy of the treatment. A clean technique is essential to minimise local reactions. It is important that patients, and those who care for them, are taught the correct technique for managing the infusion prior to initiation of apomorphine therapy. This training will be completed by the PDNS in secondary care. Ongoing support and further training will be available as needed from the PDNS and the APO-go® (apomorphine) community nurse. Please note the following steps may help to reduce nodule formulation: (The patient and those who care for them will be trained in the following by the PDNS during in-patient initiation of therapy and training):

- Daily rotation of injection sites.
- Thumb tack needles, such as neria, should be sited slowly and gently into un-pinched skin at a 90-degree angle. When using this type of needle, it is important to hold on to the infusion line tube just above the head (tack) of the needle, to ensure full depth of insertion.
- Gentle massaging of the injection sites on a daily basis, by hand or with a hand held massage device, could help to reduce nodule formation. Massage promotes healthy skin by encouraging good circulation to the adipose tissue whilst desloughing dead skin cells. Silicone gel patches* are rarely required however can help to reduce nodule formation and relieve itchiness. The patches are placed over the nodules and left in place overnight. The patches can be used many times if they are rinsed in warm water and dried carefully. Each packet contains instructions for use. It is not fully understood how these patches work to reduce nodule formation, although silica is known to exert a beneficial effect on scar tissue.

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	*Silicone gel patches should only be prescribed in exceptional circumstances on the advice of the supporting specialist. Any prescribeable silicone gel patch would
	be acceptable. For example: BAP Scarcare T, Cica Care, Ciltech or Dermatix (clear or fabric)
Criteria for stopping treatment e.g. poor response, adverse effects requiring cessation	Significant side effects, lack of response at adequate doses, as determined by the consultant, Parkinson's Disease Nurse Specialist (PDNS), and the patient.
Follow up arrangements e.g. frequency of specialist clinic attendance	Patients will be reviewed by the specialist team at KCH initially 3 monthly and then 6 monthly thereafter. Continuing appropriateness of therapy will be reviewed at each appointment.
Pregnancy, paternal exposure	Pregnancy:
and breast feeding It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the	APO-go should not be used during pregnancy unless clearly necessary – patients planning pregnancy should be referred to the specialist team (note it is extremely unlikely a woman of childbearing age will be started on apomorphine). Breastfeeding: An individual decision on whether the benefits of breastfeeding outweigh the risk for an individual posterior will be made in appropriate with the appointment to the product of
GP and the specialist.	for an individual patients will be made in conjunction with the specialist team (again note it is extremely unlikely a woman of childbearing age will be started on apomorphine).
Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.
Evidence base for treatment and key references Include hyperlinks to original sources and access dates To be read in conjunction with	1. National Institute for Health and Clinical Excellence (2017) Parkinson's Disease: Diagnosis and management in primary and secondary care. Department of Health, London. Overview Parkinson's disease in adults Guidance NICE 2. Claudia Trenkwalder, K.Ray Chaudhuri, Pedro J. García Ruiz, Peter LeWitt, Regina Katzenschlager, Friederike Sixel-Döring, Tove Henriksen, Ángel Sesar, Werner Poewe, Mary Bakerk, [], Stuart Isaacsonr, Teus van Laars, Andrew Leest, Simon Lewisu, Juan Carlos Martínez Castrillov, Pablo Martinezmartinw, Per Odinx, John Osullivany, Georgios Tagarisz, Karoline. Expert Consensus Group Report on the use of apomorphine in the treatment of Parkinson's disease – clinical practice recommendations Parkinsonism & Related Disorders 06/2015; DOI:10.1016/j.parkreldis.2015.06.012 3. Bhidayasiri R, Chaudhuri KR, LeWitt P, Martin A, Boonpang K, van Laar T. Effective delivery of apomorphine in the management of Parkinson disease: practical considerations for clinicians and Parkinson nurses. Clin Neuropharmacol. 2015 May-Jun;38(3):89-103. doi: 10.1097/WNF.000000000000000000000000000000000000
the following documents	Solution for Infusion in Pre-filled Syringe - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk), APO-go Pen 10mg/ml Solution for Injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

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	NICE Guideline Overview Parkinson's disease in adults Guidance NICE
Local arrangements for referral	The hospital will make contact with the primary care prescriber via letter – including this shared care document.
Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.	For referral back should the patient's condition change, the consultant secretary or specialist nurse can be contacted. For more urgent advice normal escalation channels including ERS can be used.

3. COMMUNICATION AND SUPPORT

King's College and Princess Royal Hospitals switchboard: 0203 299 9000			
Consultant/specialist team			
Professor Kay Ray Chaudhuri (Professor of Movement Disorders and Neuroscience)	Email: Ray.chaudhuri@nhs.net		
Miriam Parry (Parkinson's Disease Nurse Specialist)	Alternative contact: e.g. for clinic/specialist nurse miriamparry@nhs.net Tel: 02032996508		
Medication – Prescribing advice, interactions, availability of medicines			
Neuro-medicines helpline for South London	Email: kch-tr.neuropharmacy@nhs.net Tel: 02032994162		
KCH Pharmacy Helpline	Email: kch-tr.pharmacyhelpline@nhs.net Tel: 02032990588 Note: open Monday to Friday, 9.30am to 4.30pm		
Guy's and St. Thomas' Hospital			
Consultant/specialist team			
Dr Tomasin Andrews, Consultant Neurologist Parkinson's nurse team	Tel:02071885832 Email: gst-tr.parkinsonsnurse@nhs.net Note: working hours Monday to Thursday 9-5pm and Fridays 9am-12.30.		
Medication – Prescribing advice, interactions, availability of medicines			
Sarah Swabey – Lead pharmacist Ageing and Health	Tel: 02071887188 ext 85051 Email: sarah.swabey@gstt.nhs.uk / sarah.swabey@nhs.net		
GSTT Medicine Information Department	Tel: 02071888748 Email: gst-tr.mymedicines@nhs.net		

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear [insert Primary Care Prescriber's name]

Patient name: [insert patient's name]
Date of birth: [insert date of birth]
NHS Number: [insert NHS Number]
Diagnosis: [insert diagnosis]

As per the agreed South East London shared care prescribing guideline for APO-go (apomorphine) for the treatment of Parkinson's, this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

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

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	Yes / No
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	Yes / No
The risks and benefits of treatment have been explained to the patient	Yes / No
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	Yes / No
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	Yes / No
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	Yes / No
I have included with the letter copies of the information the patient has received	Yes / No
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timeframe e.g. within 3 months / 6 months (please specify)	

Treatment was started on [insert date started] and the current dose is [insert dose and frequency].

If you are in agreement, please undertake monitoring and treatment from [insert date] NB: date must be at least 2 weeks from initiation of treatment.

The next blood monitoring is due on [insert date] and should be continued in line with the shared care guideline. Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

Primary Care Prescriber Response

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Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Dear [insert Doctor's name]				
Patient	[insert Patient's name]			
NHS Number	[insert NHS Number]			
Identifier	[insert patient's date	of birth and/oraddress]		
Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment				
N	/ledicine	Route	Dose & frequency	
I can confirm that I am willing to take on this responsibility from [insert date] and will complete the monitoring as set out in the shared care protocol for this medicine/condition.				
Primary Care P	rescriber signature:		Date:	
Primary Care Prescriber address/practice stamp:				

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Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient [insert Patient's name]

NHS Number [insert NHS Number]

Identifier [insert patient's date of birth and/oraddress]

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety, the local NHS in South East London have classified [insert medicine name] as a Shared Care medicine, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which
		apply
1.	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	
	As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because [insert reason]. 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.	
	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.	
2.	The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement	
	As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC (Regional Medicines Optimisation Committees) or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.	
	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	
3.	A minimum duration of supply by the initiating clinician	
	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.	
	Until the patient has had the appropriate length of supply the responsibility for providing the	
	patient with their medication remains with you.	
4.	Initiation and optimisation by the initiating specialist	
	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.	

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	Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.	
5.	Shared Care Protocol not received	
	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.	
	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.	
	Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.	
6.	Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted. NB: Capacity issues to be discussed with local primary care Medicines Optimisation Team prior to returning this form)	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs." In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

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	
Primary Care Prescriber signature:	Date:
Primary Care Prescriber address/practice stamp:	