DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT
AMIODARONE

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.
- When transferred, the patient will be given a supply of amiodarone sufficient for 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

GP responsibilities	Consultant responsibilities
1. Prescribe amiodarone at the dose determined by the secondary care specialist and clearly document indication/ anticipated treatment duration in patient's notes. **2.** Refer to secondary care physician if the patient's condition deteriorates. **3.** Perform monitoring tests as outlined in section VI. Including annual ECG monitoring. **4.** Continue to perform 6 monthly TFT for up to 12 months after treatment completed. **5.** Check for drugs not recommended or should be avoided with amiodarone; or where concomitant use with amiodarone are cautioned. **6.** Stop treatment on the advice of the specialist or immediately if any urgent need to stop treatment arise. **7.** Report any adverse effects to the referring specialist and the MHRA yellow card scheme	**1.** To confirm the patient has no contra-indications to treatment and consider the relevance of any cautions. **2.** To discuss the benefits and possible side-effects of treatment with the patient. Counsel patient to report side effects from amiodarone treatment and to protect skin from sunlight. **3.** To initiate amiodarone (loading*) for the licensed indication in accordance with the manufacturer's Summary of Product Characteristics (SPC) and provide at least 4 weeks' supply. **4.** Perform monitoring tests as outlined in section VI. **5.** To discuss the possibility of sharing prescribing and monitoring of amiodarone with the patient's GP; to provide a copy of this shared care agreement for their consideration and not to transfer prescribing responsibility until the GP has formally agreed to share care in this way. **6.** Clearly communicate to GP the indication, dose and anticipated treatment duration. **7.** To advise on the clinical relevance of concomitant medication after initiation of amiodarone, as well as potential drug interactions (e.g. with anticoagulants, digoxin, beta-blockers etc). see section vii **8.** Annual reviews are unnecessary, however, consultants are asked to provide advice remotely when needed and review patients in cases of difficulty. **9.** To ensure that arrangements are in place for GPs to obtain advice and support where needed. **10.** To communicate promptly with the GP the results of any monitoring undertaken in secondary care and any changes to treatment made by the specialist.

Patient responsibilities

1. Report to the specialist or GP if he/she does not have a clear understanding of the treatment.

2. Share any concerns in relation to treatment with amiodarone.
- Seek urgent medical attention should their condition significantly worsen.

3. The patient must notify the GP or secondary care specialist straight away if they develop any of the following during treatment for in the period after stopping amiodarone:
- new or worsening breathlessness or non-productive cough
- symptoms of potential thyroid or liver injury (such as rapid weight loss or weight gain; sustained new-onset abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, itching, heat or cold intolerance, hair thinning, sweating, changes in menstrual periods, swelling of the neck (goitre), nervousness, irritability, restlessness, or decreased concentration.)
- Dizziness or fainting, palpitations/ chest pain
- New or worsening visual symptoms or loss of eyesight

4. Report any other adverse effects to the specialist or GP whilst taking amiodarone

3. COMMUNICATION AND SUPPORT

i. Hospital contact: **Derby Teaching Hospital Foundation Trust** Consultant/nurse via switchboard:01332 340131 **Chesterfield Royal Hospital Foundation Trust** Consultant via switchboard: 01246 277271	**ii. out of hours contact and procedures:** Pharmacy, DTHFT, ask for on-call pharmacist via switchboard: 01332 340131 Cardiology, DTHFT, ask for on-call Cardiology Consultant via switchboard: 01332 340131 Contact the CRH on-call Medic for the relevant speciality via switchboard: 01246 277271
Patient information https://www.bhf.org.uk/informationsupport/publications/heart-conditions/medicines-for-your-heart https://patient.info/medicine/amiodarone-for-irregular-heartbeats-cordarone-x http://www.heartrhythmalliance.org/files/files/afa/For%20Patients/Factsheet%20-%20Amiodarone%20Advice%20(160201).pdf	

4. CLINICAL INFORMATION

i. Prescribed indications	Treatment of severe heart rhythm disorder not responding to other therapies or when other treatments cannot be used. • Prior and post cardioversion • In patients who also have heart failure or left ventricular impairment **Licensed indications** • Tachyarrhythmias associated with Wolff-Parkinson-White syndrome. • Atrial flutter and fibrillation when other drugs cannot be used. • Tachyarrhythmias of paroxysmal nature including: supraventricular, nodal and ventricular tachycardias. Ventricular fibrillation; when other drugs cannot be used. Patients should NOT be on amiodarone for palpitation unless there is a clearly defined electrophysiological diagnosis.
ii. Therapeutic summary	Amiodarone is a class III antiarrhythmic drug (Vaughan-Williams classification) that reduces the incidence of arrhythmias by increasing the duration and refractory period of the cardiac action potential prolonging the QT interval. It also slows heart rate and cardiac action potential conduction through inhibition of beta receptors and ion channels in a similar manner to antiarrhythmic drugs from classes IA, II and IV
iii. Dose & Route of administration	Oral loading* (by consultant/ specialist) 200mg 3 times daily for 1 week, reduced to 200mg twice daily for a further week. Maintenance Usually 200mg daily or the minimum dose required to control the arrhythmia. The minimum effective maintenance dose should be given because undesirable effects are usually dose related. Do not take with grapefruit juice.
iv. Duration of treatment	For use after electrical cardioversion starting 4 weeks prior and continue for up to 12 months. Duration of treatment and review should be specified by cardiologist/specialist. For example 1. When PAF goes to permanent AF, amiodarone should be stopped and rate limiting medicines used instead. 2. Permanent AF/ Ventricular tachycardia- requires a 2 year prompt for consideration of stopping treatment 3. WPW- historic patients should be given opportunity to discuss treatment options Review regularly patients on long-term amiodarone treatment – some of these reactions may be life-threatening but onset can be delayed.
v. Adverse effects Refer to the SPC for a full list of adverse effects & further information	Amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin and peripheral nervous system. Patients on long term treatment should be carefully supervised because these reactions may be delayed. Lung problems may have slow onset but then

http://www.medicines.org.uk	progress rapidly and can happen at any time after starting treatment. Because of long half-life (around 50 days) of amiodarone, clinical problems may occur up to a year (e.g. photosensitivity) after stopping the drug (hyperthyroidism may occur up to several months after discontinuation). MHRA March 2022 • Arrhythmias/ bradycardia • Hyperthyroidism/ hypothyroidism (sometimes fatal) • Nausea & vomiting; constipation • Corneal microdeposits (reversible following discontinuation of treatment). • Isolated increase in serum transaminases (usually moderate (1.5 to 3 times normal range)), occurring at the beginning of therapy. • Photosensitivity -patients should be advised to shield the skin from light during treatment and for several months after discontinuing amiodarone; a wide-spectrum sunscreen to protect against both long-wave ultraviolet and visible light should be used. • extrapyramidal tremor (regression usually occurs after reduction of dose or withdrawal) • sleep disorders • pulmonary toxicity (sometimes fatal)- counsel patient to report unexplained dry cough or new/worsening shortness of breath • eczema
vi. Monitoring Requirements	**Consultant responsibility** **GP responsibility** **Every 6 months** • Assess compliance, ask patient about adverse effects (breathlessness, non-productive cough) and review possible interactions • TFTs (**and for up to 12 months after discontinuation**), U&Es, LFTs **Annually** • History & examination, Heart rate & ECG **Other monitoring if applicable** • Digoxin level- assess serum digoxin levels if dose increased or toxicity is suspected • INR- more frequent monitoring of INR both during and after amiodarone treatment (initially weekly for first 7 weeks) • Chest X-ray or CT scan if clinically indicated (suspected pulmonary toxicity) • Eye exam- Assess if new or worsening visual symptoms occur. • Check for drug interactions if new agents added to patient's usual prescription

	Baseline	*Loading
History & examination	♦	
adverse effects	♦	♦
Heart rate & 12 lead ECG	♦	♦
TFTs	♦	
U&Es	♦	
LFTs	♦	♦
Digoxin level (if applicable)	♦	♦
INR (if applicable)	♦	♦
CXR	♦	
PFTs inc DLCO	♦	

Actions to be taken

Parameter	Action
Symptoms of pulmonary toxicity (new/worsened cough or shortness of breath)	Perform prompt ECG and CXR to exclude alternative diagnoses. If pulmonary toxicity remains a possibility, contact cardiologist/specialist or a respiratory physician urgently for confirmation of diagnosis and consideration of alternative anti-arrhythmics. Acute admission may be required. Early investigation with HRCT chest scan is important.
ECG	If there are signs of the following discuss with the oncall cardiology specialist: • QTc interval ≥ 500 milliseconds • QRS duration>120 milliseconds • prolonged PR interval (>240 milliseconds) if previously normal • Morbitz Type II or complete heart block GPs can also contact cardiologist for advice on • Interpretation of ECG • Consideration for stopping treatment e.g. if patient develop permanent AF/ ventricular tachycardia.
Thyroid function tests (see appendix 1)	An increase of up to 40% above the baseline T4 is a normal effect of amiodarone. This occurs approximately 2 months after initiation and does not require discontinuation if there is no clinical or further biological evidence (TSH) of thyroid disease. If TFTs are borderline repeat test in 6 weeks. In the event of thyrotoxosis seek the urgent advice of an endocrinologist.
Liver function tests (See appendix 2)	Normal results - continue treatment and reassess in 6 months If ALT increase within three times the normal range and patient is not jaundiced, continue amiodarone and repeat LFTs in 2 weeks. If still raised, refer to initiating hospital specialist urgently. If ALT increase exceeds three times the normal range or jaundiced- Stop amiodarone & refer to initiating specialist urgently.
U&E's / potassium	In cases of hypokalaemia, corrective action should be taken and QT interval monitored. (SPC)
Visual disturbances or loss of sight (new onset/ worsening)	Perform eye examination, make urgent ophthalmology referral to exclude optic neuropathy and discuss alternative anti-arrhythmics with initiating cardiologist/ specialist
Proarrhythmia	Stop amiodarone and arrange urgent specialist appointment. Acute admission may be required.
Bradycardia (HR <50bpm or symptoms present)	Check for symptoms and arrange an ECG urgently If the patient has syncope or second or third degree heart block, admission is advised. Mild sinus bradycardia is common but if the patient has symptoms such as increased breathlessness or presyncope which you feel may be due to this- discuss with the specialist or arrange review.

	Neurological symptoms (e.g. tremor, ataxia)	A reduced dosage may be required
	Blue skin discolouration	A reduced dosage may be required

vii. Clinically relevant drug interactions

Refer to the SPC for more detailed information on drug interactions http://www.medicines.org.uk.

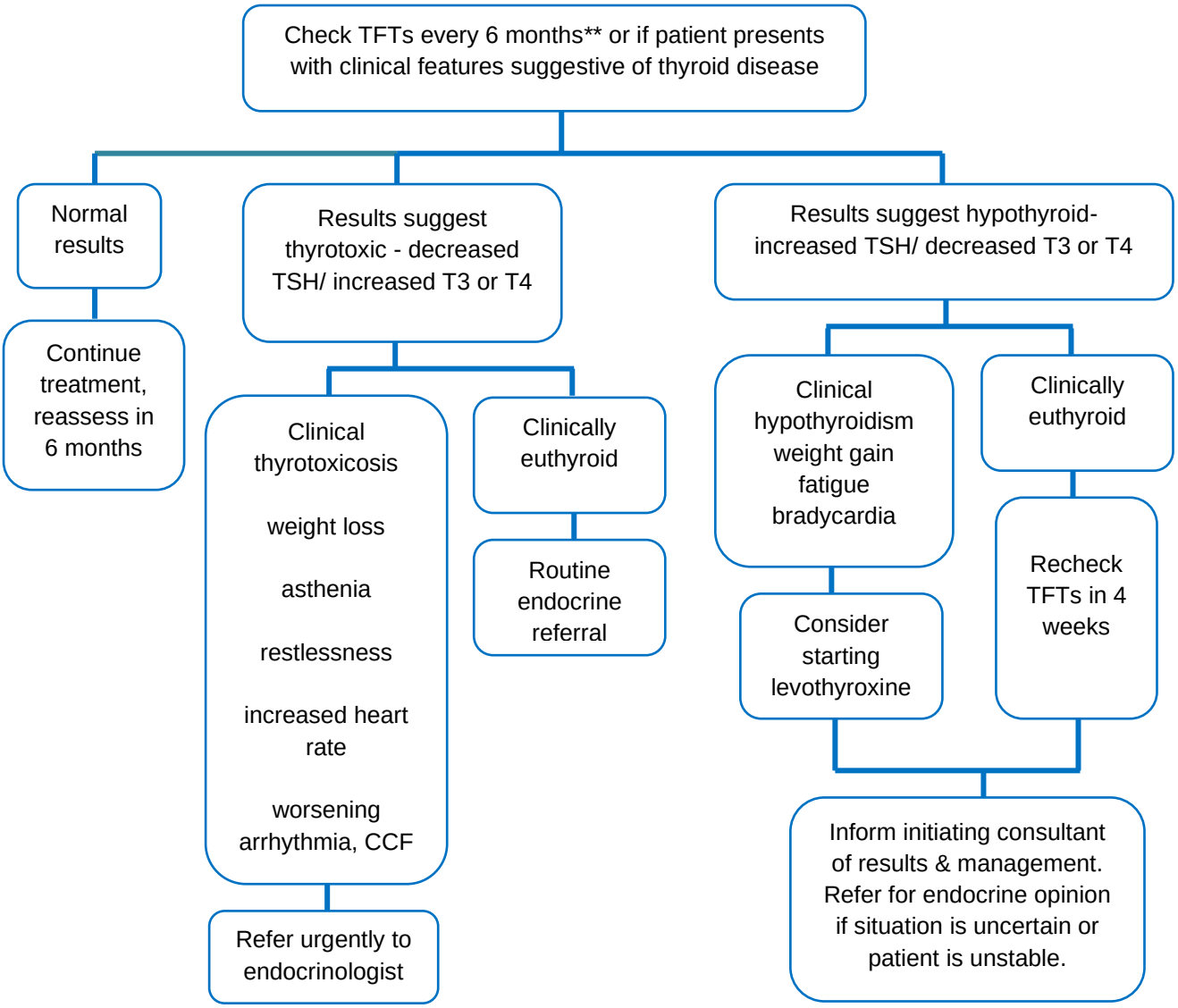
Amiodarone inhibits metabolism through several cytochrome P450 pathways, causing interactions with many commonly used drugs. Due to the long half-life of amiodarone, the onset of drug interactions may be slow after initiating amiodarone, and interactions may be observed for several months after discontinuation of amiodarone.

Concomitant use with amiodarone *contraindicated*	
Anti-arrhythmics	Class Ia anti-arrhythmic drugs eg.**, Disopyramide** and Class III anti-arrhythmic drugs eg. **Sotalol,** prolong the QT interval therefore increase the risk of torsades de pointes.
Antibacterial drugs	**Parental erythromycin, moxifloxacin, co-trimoxazole** and **pentamidine** injection prolong the QT interval.
Antidepressants	**Lithium** and tricyclics eg. **Doxepin, amitriptyline** prolong the QT interval. Manufacturer of **citalopram** and **escitalopram** states concomitant use of class III antiarrhythmics (amiodarone) that prolong the QT interval is contraindicated.
Anti-psychotics	**Chlorpromazine, fluphenazine, pimozide, haloperidol, amisulpiride** and prolong the QT interval.
Antihistamines	and **mizolastine** prolong the QT interval
Anti-malarias	**Quinine, mefloquine, chloroquine,** prolong the QT interval
Concomitant use with amiodarone *not recommended* or should be *avoided*	
Antivirals	*Avoid* combination therapy containing simeprevir and sofosbuvir due to risk of severe bradycardia and heart block; unless other antiarrhythmics cannot be given MHRA, 2015
Beta-blocker	Potentiation of negative chronotropic properties and conduction slowing effects may occur. Concomitant administration is *not recommended*
Calcium channel inhibitors	Rate lowering calcium channel inhibitors eg. **Diltiazem, verapamil** potentiate negative chronotropic properties and conduction slowing effects may occur. Concomitant administration is *not recommended*
Fluoroquinolone	eg. **levofloxacin,** may prolong QT interval. Concomitant use of amiodarone should be *avoided.*
Grapefruit & grapefruit juice	Inhibit cytochrome P450 3A4 and may increase the plasma concentration of amiodarone therefore should be *avoided*.
Laxatives (stimulant)	Stimulant laxatives eg. **Bisacodyl, senna** may cause hypokalaemia and increase the risk of torsades de pointes. Concomitant administration is *not recommended*
Concomitant use with amiodarone are *cautioned*	
Anticoagulants	**Warfarin** clearance is reduced. This can lead to sudden and pronounced increase in INR. Interaction reaches its peak in 6-7 weeks. Reduce warfarin dose and monitor weekly, tailoring the warfarin dose to the INR target.

		Amiodarone increases the exposure to **dabigatran** thus increase the risk of bleeding. Adjust the dosage of dabigatran according to manufacturers' advice (note dose may be different for different clinical indications).
	Cardiac Glycosides	Plasma level of **Digoxin** approximately doubles over weeks after commencement of amiodarone. Reduce digoxin dose and monitor digoxin level if applicable.
	Ciclosporin	Plasma level of ciclosporin increased when used with amiodarone. . Manufacturer advises monitor concentration and adjust dose.
	Drugs may cause hypokalaemia/ hypomagnesaemia	Caution should be exercised over combined therapy with the following drugs which may also cause hypokalaemia: and/or hypomagnesaemia e.g. **diuretics**, **systemic corticosteroids**, **tetracosactrin**, **IV amphotericin, aminophylline, theophylline**
	Lipid-regulating	Increased incidence of myopathy with **Simvastatin** (do not exceed 20mg per day.)
	Phenytoin	Plasma level of phenytoin increased with amiodarone. Phenytoin dosage should be reduced in signs of overdosage and plasma levels may be measured.
	Ticagrelor	Manufacturer advises use with caution or avoid.
viii. Contra-indications Refer to the SPC for more detailed information	Sinus bradycardia and sino-atrial heart block: In patients with severe conduction disturbances (high grade AV block, bifascicular or trifascicular block) or sinus node disease, amiodarone should be used only in conjunction with a pacemaker. Evidence of history of thyroid dysfunction: Thyroid function tests should be performed prior to therapy in all patients. Known hypersensitivity to iodine or to amiodarone The combination of amiodarone with drugs which may induce Torsades de Pointes (see vii interaction)Pregnancy - except in exceptional circumstances Lactation	
ix. Supply of ancillary equipment	Not applicable	
x. Supply, storage and reconstitution instructions	Not applicable	
xi. Prepared by	Derbyshire shared care and guideline group In consultation with: Dr. Julia Baron consultant cardiologist UHDB Dr. J Cooke consultant cardiologist CRHFT	

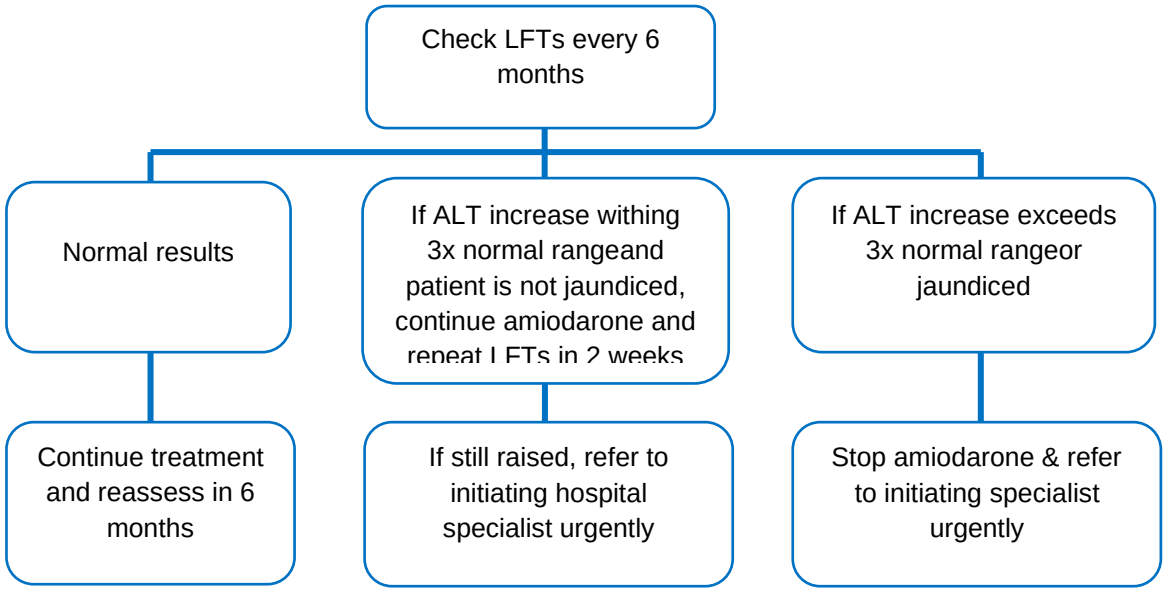
This does not replace the SPC, which should be read in conjunction with it.
Date Prepared: November 2019 **Review Date**: October 2022 (Extended to April 2023)

Appendix 1 Thyroid function test algorithm



** and for up to 12months after discontinuation of amiodarone as hyperthyroidism may occur up to several month after discontinuation.

Appendix 2 Liver function test algorithm



Appendix 3. Amiodarone Patient Advice

Many people take Amiodarone for a long period to maintain a regular heart rhythm without experiencing any problems.

However, unwanted effects can occur as a result of taking Amiodarone including:

- unexplained dry cough and/or shortness of breath
- yellowing of skin or eyes (jaundice), fatigue, loss of appetite, stomach pain or fever
- rapid weight loss or weight gain, heat or cold intolerance, hair thinning, sweating, changes in menstrual periods, swelling of the neck (goitre), nervousness, irritability, restlessness, or decreased concentration
- dizziness or fainting, or heartbeat becomes even more uneven or erratic, or becomes very slow
- new or worsening visual symptoms or loss of eyesight

If you experience any of the above symptoms while taking Amiodarone please see your GP.

You will require regular (every six months) blood tests to check your thyroid and liver function during treatment with amiodarone and for up to 12 months after, due to potential adverse effects.

Protect your skin from sunlight
Keep out of direct sunlight while taking this medicine and for a few months after you have finished taking it. This is because your skin may become more sensitive to the sun. Use high factor, wide-spectrum sunscreen to protect against both long-wave ultraviolet and visible light, and/or wear a hat and clothes which cover your arms and legs.

Amiodarone can also affect the action of other medications taken for other medical conditions including:

Warfarin: Amiodarone increases the blood thinning effect of Warfarin. If you notice increased bruising, nose bleeds or difficulty stopping bleeding from cuts please make an appointment to see your GP immediately to adjust your dose of Warfarin.

Digoxin: Amiodarone increases the effect of Digoxin. Your GP will halve your dose of Digoxin when you start taking Amiodarone. If you notice any unexplained dizziness, nausea or vomiting, loss of appetite or visual disturbances see your GP immediately, as the level of Digoxin in your blood could be too high.

Antidepressants: Certain medications such as Lithium and Amitriptyline can increase the risk of irregular electrical activity in the heart if taken together with Amiodarone.

Please inform your GP about any other medications you take when you first see them after starting Amiodarone.

{Insert Hospital Logo here}

Sample transfer letter

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_ADDRESS_4»
«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):		

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 timescale	

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*)

* For completeness please record medication on GP clinical system as per guidance- 'Recording medicines prescribed and issued by other Healthcare Providers'

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.	**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 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. ***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)**	

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}