

Based upon the NHSE national shared care protocol and amended for local use within NHS BSW:

Amiodarone for patients within adult services

Review date – June 2028

The content of this shared care protocol was correct as of June 2025. As well these protocols, please ensure that [summaries of product characteristics](#) (SPCs), [British national formulary](#) (BNF) or the [Medicines and Healthcare products Regulatory Agency](#) (MHRA) or [NICE](#) websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol ([section 2](#)) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see [section 11](#)) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see [section 4](#)) and interactions (see [section 7](#)).
- Conduct required baseline investigations and initial monitoring (see [section 8](#)).
- Initiate treatment as outlined in [section 5](#). Provide at least 4 weeks of medication to the patient.
- Send the shared care agreement (or link to it) to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information ([section 13](#)).
- Conduct the required reviews and monitoring in [section 8](#) and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#) remains appropriate.
- Reassume prescribing responsibilities if a patient becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Reply to the request for shared care as soon as practicable using the forms linked [here](#) (in writing or via secure email). It is asked that this be undertaken within 14 days of the request being made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per [section 5](#), taking into account potential drug interactions in [section 7](#).
- Adjust the dose of amiodarone prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in [section 9](#). Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in [section 10](#) and discuss with specialist team when required.
- Stop amiodarone and make an urgent referral to the specialist if hyperthyroidism, thyrotoxicosis, new or worsening arrhythmia or heart block, ophthalmological effects, hepatotoxicity, pulmonary toxicity or bullous skin reactions are suspected.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take amiodarone as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in [section 11](#).
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of amiodarone with their pharmacist before purchasing any OTC medicines.
- Avoid grapefruit juice while taking amiodarone and for several months after discontinuation.
- Moderate their alcohol intake to no more than 14 units per week to reduce the risk of hepatotoxicity.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Amiodarone is used in the treatment of arrhythmias, as detailed in [section 2](#). It has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. Amiodarone has potentially serious adverse effects and its use requires regular monitoring.

Due to the significant safety concerns, NHS England (NHSE) and NHS Clinical Commissioners' (NHSCC) [guidance](#) advises that prescribers should not initiate amiodarone in primary care for any new patients unless they have written specialist advice to do so. In exceptional circumstances, if there is a clinical need for amiodarone to be prescribed, this is usually initiated by a specialist and only continued long-term under a shared care arrangement in line with NICE clinical guidance [Atrial fibrillation: NG 196](#). NICE defines the place in therapy of amiodarone in NG196 and has made a "Do not do" recommendation: "**Do not offer amiodarone for long-term rate control**". Amiodarone may also be suitable in patients prior and post cardioversion or in specific patients who have heart failure or left ventricular impairment.

Where there is an existing cohort of patients taking amiodarone who are not currently under shared care, it is recommended that these patients be reviewed to ensure that prescribing remains safe and appropriate and a shared care arrangement is introduced.

Historic patients on amiodarone

There will be a cohort of patients already on amiodarone who will have been initiated on the medication under different arrangements to those now accepted on this shared care protocol. Previously, there was no shared care agreement used locally so the arrangements were not robust and did not clarify any requirement for long-term follow-up and monitoring in secondary care.

Accordingly, it is likely that there are patients taking amiodarone in whom arrangements for continuing monitoring have not been clarified.

Primary care: In patients who are taking amiodarone and have not been seen in secondary care cardiology within the last year, please do the monitoring as per section 9 and refer back to cardiology for review if advice is needed because tests are abnormal or indication for use is uncertain via Cinapsis with full details of test results.

Primary care should review historic patients as and when they come up for annual review so as not to overwhelm cardiology services.

Please continue 6 monthly blood tests as described below (section 9, p13) whilst review awaited.

Secondary care: Such referrals should be accepted and ongoing review initiated as described.

2. Indications

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Licensed indications:

- Tachyarrhythmias associated with Wolff-Parkinson-White Syndrome.

- Atrial flutter fibrillation / atrial fibrillation when other drugs cannot be used or are ineffectual. In patients undergoing cardiothoracic surgery, amiodarone can be considered as an option to treat postoperative atrial fibrillation.
- All types of tachyarrhythmias of paroxysmal nature including: supraventricular, nodal and ventricular tachycardias and ventricular fibrillation when other drugs cannot be used.

3. **Locally agreed off-label use** [Back to top](#)

National scoping did not identify any additional appropriate off-label indications

4. **Contraindications and cautions**

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This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see [BNF](#) & [SPC](#) for comprehensive information.

Contraindications:

- Sinus bradycardia and sino-atrial heart block/severe conduction disturbances (high grade AV block, bifascicular or trifascicular block) or sinus node disease (unless pacemaker fitted)
- History of thyroid dysfunction. Use of amiodarone may be considered in patients who are euthyroid, after case-by-case assessment of the risks and benefits and with appropriate monitoring.
- Known hypersensitivity to iodine or amiodarone, or any of the excipients (including patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption)
- Concurrent use with medicines that may prolong the QT interval or increase the risk of Torsades de Pointes
- Pregnancy - except in exceptional circumstances (see [section 12](#))
- Breastfeeding

Cautions:

- Amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin and peripheral nervous system; it is subject to a number of cautions. Because these reactions may be delayed, patients on long-term treatment should be carefully supervised. As undesirable effects are usually dose-related, the minimum effective maintenance dose should be given.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after at least 4 weeks, with satisfactory investigation results.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation 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 on advice from the specialist.

Initial stabilisation:

200mg three times per day for one week, then reduce to 200mg twice per day for one week.

Amiodarone is initiated with a loading dose in order to achieve adequate tissue levels rapidly.

Rarely, the specialist team may use an alternative loading regimen.

Maintenance dose (following initial stabilisation):

200mg per day, or less if appropriate. The minimum dose required to control the arrhythmia should be used.

Rarely, a higher maintenance dose may be required. The maintenance dose should be reviewed regularly, particularly if it exceeds 200mg per day.

Conditions requiring dose adjustment:

Although there is no evidence that dose requirements for elderly patients are lower, they may be more susceptible to bradycardia and conduction defects if too high a dose is prescribed. The minimum effective dose should be used. Particular attention should be paid to monitoring thyroid function.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	<ul style="list-style-type: none">• Tablets; 100mg and 200mg

Administration details:	<p>For oral administration.</p> <p>Maintenance dose can be given once daily, however doses >200 mg daily (including loading period) may be given as split doses to minimise nausea.</p> <p>If necessary, tablets may be crushed and dispersed in water, but have a bitter taste (unlicensed). Different brands of may disperse in water at notably different rates. The solution for injection is irritant and should not be given orally.</p>
Other important information:	<p>The half-life of amiodarone is very long, with an average of 50 days (range 20-100 days). Side effects slowly disappear as tissue levels fall. Following drug withdrawal, residual tissue bound amiodarone may protect the patient for up to a month. However, the likelihood of recurrence of arrhythmia during this period should be considered.</p> <p>Grapefruit juice should be avoided during treatment with oral amiodarone and for several months after discontinuation (see section 7).</p>

7. Significant medicine interactions

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The following list is not exhaustive. Please see [BNF](#) or [SPC](#) for comprehensive information and recommended management.

Amiodarone is associated with a large number of interactions, some of which are significant enough to contraindicate concurrent use, require dose adjustment and/or additional monitoring (see [section 4](#)).

Amiodarone is an enzyme inhibitor and can increase exposure to a number of medicines including:

- P-glycoprotein (PgP) substrates (e.g. digoxin, dabigatran)
- CYP2C9 substrates (e.g. warfarin, phenytoin)
- CYP3A4 substrates (e.g. ciclosporin, statins, fentanyl, sildenafil, colchicine)
- CYP2D6 substrates (e.g. flecainide)

Amiodarone interacts with other medicines that:

- induce Torsade de Points or prolong QT (e.g. other anti-arrhythmics, antipsychotics, antidepressants, clarithromycin, erythromycin)
- lower heart rate (e.g. beta-blockers, calcium channel blockers)
- induce hypokalaemia (e.g. diuretics, stimulant laxatives)
- induce hypomagnesaemia (e.g. diuretics, systemic corticosteroids)

Other interactions include:

- CYP3A4 and CYP2C8 inhibitors: may increase exposure to amiodarone (e.g. cimetidine, letermovir, ritonavir, darunavir, grapefruit juice)
- Sofosbuvir with daclatasvir; sofosbuvir and ledipasvir; simeprevir with sofosbuvir: risk of severe bradycardia and heart block (mechanism unknown) see [MHRA advice](#)
- **Due to the long half-life of amiodarone, there is potential for drug interactions to occur for several weeks/months after treatment has been discontinued.** See [SPC](#) for information on managing interactions.

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline is the responsibility of the specialist; prescribing and monitoring will then be transferred to primary care and the patient supplied with 4 weeks of medication.

Baseline investigations (if not already provided in primary care):

- Thyroid function tests (free T4, free T3 and TSH)
- Liver function tests (LFTs, particularly transaminases)
- Urea and electrolytes (U&Es, including magnesium and potassium)
- Electrocardiogram (ECG)
- Assessment of normal lung capacity if appropriate, which may be done by one of the following: Chest X-ray (CXR)/ chest CT within last year OR forced expiratory volume in 1 second (FEV1) and forced vital capacity(FVC) OR chest examination - checking for crackles.
- Caution should be exercised in patients co-prescribed direct oral anticoagulants (DOACs) as there is potential for decreased clearance and therefore increased risk of bleeding reported with edoxaban and dabigatran.
- For patients taking warfarin: reduce dose by at least 25% and ensure arrangements are in place for the international normalised ratio (INR) to be checked at least weekly during the first 7 weeks of treatment.
- For patients taking digoxin: clinical monitoring is recommended and the digoxin dose should be halved. Digoxin levels should be monitored appropriately.
- Inform the patient of the risks of potential adverse effects, the need for ongoing monitoring, and the need to use regular sunscreen.

Secondary care will review patients when deemed necessary. Not all patients will require regular review by secondary care.

After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.

9. Ongoing monitoring requirements to be undertaken by primary care

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See [section 10](#) for further guidance on management of adverse effects/responding to monitoring results.

Annual review:

- Current symptoms, examination as required clinically.
- Confirm indication for amiodarone to continue.
- ECG
- Take bloods for annual monitoring. (U&E or C&E, LFT, full TFTs including TSH, T3, T4, state in request that patient on amiodarone to ensure full tests done)
- Assess lungs and arrange imaging and pulmonary function tests, if concerns of respiratory symptoms or toxicity suspected, but not required routinely.
- Assess visual symptoms and arrange eye examination if suspicion of eye complications

If there are abnormal test results or the GP is unsure of the continued need for treatment or the indication for use, seek advice via cinapsis.

If the patient has persistent AF and the indication was rhythm control, seek specialist advice to stop.

ECG interpretation: escalate if QTc \geq 500 ms or conduction changes; automated QTc may be unreliable with BBB.

Monitoring and advice	Frequency
<ul style="list-style-type: none"> • Thyroid function tests (free T4, free T3 and TSH) • LFTs (particularly transaminases) • U&Es (including magnesium and potassium) 	<p>Perform all tests every 6 months during treatment, and 6 months after discontinuation. Thyroid function should continue to be monitored for up to 12 months after discontinuation, with frequency determined clinically.</p>
<ul style="list-style-type: none"> • ECG 	<p>At least annually</p>

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.

The most serious toxicity with amiodarone is seen with long-term use and patients may therefore present first to primary care. Due to the long half-life of amiodarone there is potential for adverse effects to occur for several weeks/months after treatment has been discontinued.

The prevalence of adverse effects from amiodarone therapy is as high as 15% within the first year of use and up to 50% for long-term use.

Result	Action for primary care
Electrolyte deficiency: hypokalaemia / hypomagnesaemia	Continue amiodarone. Correct deficiency as per local guidelines. Review other medicines that may be contributing to a deficiency
Cardiovascular effects:	
<ul style="list-style-type: none"> Heart rate 50 - 60bpm without symptoms 	Normal range pulse. Continue amiodarone. Repeat monitoring. No action required unless symptoms develop or heart rate decreases further.
<ul style="list-style-type: none"> Heart rate \leq 50bpm, or \leq 60bpm with symptoms 	Discuss with specialist team; dose reduction may be required
Worsening of arrhythmia, new arrhythmia	Urgent referral to initiating specialist. Urgent advice request to discuss stopping amiodarone.
Second or third degree heart block	Urgent hospital referral for consideration of pacemaker, hospital admission probably required.
Thyroid dysfunction:	
Borderline results according to local reference range	Continue amiodarone. Repeat test after 6 weeks.
<u>Hyper</u> thyroidism / thyrotoxicity: high T4, normal/high T3, low TSH	Urgent referral to initiating specialist and endocrinologist. Anyone with hyperthyroidism should be discussed via cinapsis (if available).

<p>Hypothyroidism: low/normal T4, low/normal T3, high TSH</p>	<p>Continue amiodarone. Inform initiating specialist. Consider starting levothyroxine based on initiating specialist's advice. Monitor levothyroxine according to local pathways.</p>
<p>Subclinical hypothyroidism normal T4, raised TSH; clinical features not overtly manifest</p>	<p>Contact specialist team for advice, which may include input from endocrinology services. Relative hypothyroidism such as this is common and does not need treatment if asymptomatic. Anticipate the need for additional monitoring, investigations and potentially thyroid hormone replacement based on specialist recommendations.</p>
<p>For further information about the management of amiodarone-associated thyroid dysfunction, see: Bartalena L, Bogazzi F, Chiovato L, Hubalewska-Dydejczyk A, Links TP, Vanderpump M. 2018 European Thyroid Association (ETA) Guidelines for the Management of Amiodarone-Associated Thyroid Dysfunction. Eur Thyroid J. 2018 Mar;7(2):55-66. doi: 10.1159/000486957. Epub 2018 Feb 14.</p>	
<p>Ophthalmological effects:</p>	
<p>Optic neuropathy/neuritis; blurred or decreased vision</p>	<p>Stop amiodarone. Urgent referral to initiating specialist and ophthalmology.</p>
<p>Corneal micro-deposits: blueish halos when looking at bright lights, with no blurred or decreased vision</p>	<p>Continue amiodarone; reversible on discontinuation. The deposits are considered essentially benign and do not require discontinuation of amiodarone. Discuss with initiating specialist if concern.</p>
<p>GI disturbance: nausea, anorexia, vomiting, taste disturbance</p>	<p>Continue amiodarone. May require dose reduction; discuss with specialist if persistent.</p>
<p>Hepatotoxicity: abnormal LFTs +/- symptoms of hepatic injury (e.g. hepatomegaly, weakness, ascites, jaundice)</p>	<p>If serum transaminases elevated >3xULN but no symptoms of hepatic injury continue amiodarone and – repeat LFTs in 2 weeks. If still elevated may require dose reduction; discuss with specialist. If serum transaminases >5xULN or any symptoms of hepatic injury- stop amiodarone. Urgent referral to initiating specialist and hepatologist.</p>
<p>Neurological symptoms: Extrapyramidal tremor, ataxia, peripheral neuropathy, myopathy</p>	<p>Continue amiodarone. May require dose reduction; discuss with specialist.</p>

<p>Pulmonary toxicity: including pneumonitis or fibrosis new/worsening cough, shortness of breath or deterioration in general health (e.g. fatigue, weight loss, fever)</p>	<p>Stop amiodarone. Urgent referral to initiating specialist and respiratory specialist. Admission may be required.</p>
<p>Bullous skin reactions: life threatening or even fatal cutaneous reactions Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN)</p>	<p>Stop amiodarone. Urgent referral to dermatology, inform initiating specialist.</p>
<p>Photosensitivity</p>	<p>Continue amiodarone. Reinforce appropriate self-care e.g. sun avoidance and purchasing of a broad spectrum sunscreen (at least SPF30).</p>
<p>Skin discolouration (blue/grey): occurs in unprotected, light exposed skin</p>	<p>Continue amiodarone. May require dose reduction; discuss with specialist. Reinforce self-care measures (as for photosensitivity above). Pigmentation slowly disappears following treatment discontinuation</p>

11. Advice to patients and carers

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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.

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

- **Breathlessness, non-productive cough or deterioration in general health (e.g. fatigue, weight loss, fever)**
- **New or worsening visual disturbances**
- **Progressive skin rash +/- blisters or mucosal lesions**
- **Signs and symptoms of bradycardia or heart block, e.g. dizziness, fatigue, fainting, shortness of breath, chest pain or palpitations, confusion or trouble concentrating**

The patient should be advised:

- To use appropriate self-care against the possibility of phototoxic reactions: e.g. sun avoidance, protective clothing, avoiding tanning (including tanning beds) and to purchase

and use a broad spectrum sunscreen (at least SPF30). These measures to be continued for the duration of therapy and for several months after discontinuation.

- If taking a statin and amiodarone, to report any signs of unexplained muscle pain, tenderness, weakness or dark coloured urine.
- Avoid grapefruit and grapefruit juice while taking amiodarone and for several months after discontinuation.
- Although there have been no case reports on enhanced hepatotoxicity with alcohol, patients should be advised to moderate their alcohol intake to no more than 14 units per week while taking amiodarone.

Patient information:

British Heart Foundation – anti-arrhythmics:

<https://www.bhf.org.uk/information-support/heart-matters-magazine/medical/drug-cabinet/anti-arrhythmics>

12. Pregnancy, paternal exposure and breast feeding

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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 primary care prescriber and the specialist.

Pregnancy:

Due to the risk of neonatal goitre, amiodarone should only be prescribed in pregnancy if there is no alternative. Under these circumstances prescribing and monitoring will be the responsibility of the initiating specialist.

Breastfeeding:

Amiodarone is excreted into the breast milk in significant quantities; breast feeding is considered contraindicated due to the potential risk of iodine-associated adverse effects in the infant.

- Information for healthcare professionals: <https://www.sps.nhs.uk/medicines/amiodarone/>

13. Specialist contact information

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Via Cinapsis

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

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- eBNF accessed via [BNF \(British National Formulary\) | NICE](#) on 15/01/2021
- Amiodarone hydrochloride 100 milligram tablets (Cordarone X 100®). Zentiva. Date of revision of the text: 14/10/2020. Accessed via [Home - electronic medicines compendium \(emc\)](#) on 24/06/2025.
- Amiodarone hydrochloride 200 milligram tablets (Cordarone X 200®). Zentiva. Date of revision of the text: 15/10/2020. Accessed via [Home - electronic medicines compendium \(emc\)](#) on 24/06/2025.
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- Specialist Pharmacy Service. Lactation Safety Information: Amiodarone. Last reviewed 17/09/2018. Accessed via <https://www.sps.nhs.uk/medicines/amiodarone/> on 15/01/2021.
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- LiverTox. Amiodarone. Last updated 01/03/2016. Accessed via <https://www.ncbi.nlm.nih.gov/books/NBK548109/> 15/01/2021.

- NEWT Guidelines: amiodarone. Last updated February 2019. Accessed via [NEWT Guidelines](#) on 15/01/2021

This document has also been developed with material from Buckinghamshire, Oxfordshire & Berkshire west ICS shared care protocol for amiodarone, with their permission.

16. Other relevant national guidance

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- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/>
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/>
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care>
- NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>

APC board date: 22/01/2026

Last updated:

Appendix 1: Shared Care Agreement Letter (Primary Care Prescriber to Specialist) A template agreement letter is available [here](#)

Appendix 2: Shared Care Refusal Letter (Primary Care Prescriber to Specialist) A template refusal letter is available [here](#)

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Date Last Updated:	11/11/2025
Date Approved by BSW:	22/1/2026
Review Date:	Jan 2028
Document Version:	V1.7