

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE SHARED CARE AGREEMENT AZITHROMYCIN FOR USE IN ADULT RESPIRATORY INFECTIONS

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 azithromycin sufficient for 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

GP responsibilities Consultant responsibilities 1. Prescribe 1. To confirm the patient has no contra-indications to azithromycin the dose treatment and consider the relevance of any cautions. determined by the secondary care 2. To discuss the benefits and possible side-effects of and specialist clearly document indication/anticipated treatment with patient. Counsel patient to report side duration in the patients notes. effects from azithromycin treatment. 2. Refer to secondary care if the patient's 3. Perform monitoring tests as outlined in section vii. condition deteriorates. 4. To discuss the possibility of sharing prescribing and 3. Perform monitoring tests as outlined in monitoring of azithromycin for their consideration and not to transfer prescribing until the GP has formally section vii. agreed to shared care in this way. **4.** Continue to perform six monthly LFTs. 5. Clearly communicate to GP the indication, dose and **5.** Check for drugs not recommended or should be avoided with azithromycin; or anticipated treatment duration. where concomitant use with azithromycin **6.** To advise on the clinical relevance of concomitant are cautioned. medication after initiation of azithromycin, as well as 6. Stop treatment on the advice of the potential drug interactions. specialist or immediately if any urgent need 7. Respiratory specialist will assess response after therapy to stop treatment arises. initiation and make recommendation to continue the 7. Report any adverse effects to the referring drug, after a period of 6 – 12 months. specialist and the MHRA yellow card **8.** Annual reviews are unnecessary; however, consultants scheme. 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. 11. Recognising antimicrobial stewardship is important and patients should be counselled about potential adverse effects before starting therapy, including gastrointestinal upset, hearing and balance disturbance, cardiac effects

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 azithromycin.
- 3. Seek urgent medical attention should their condition significantly worsen.
- 4. The patient must notify the GP or secondary care specialist if they develop any of the following:
 - chest pains or a faster or irregular heartbeat
 - yellow skin or the whites of eyes turn yellow, or pale stools with dark urine
 - tinnitus, temporary hearing loss, vertigo
 - severe pain in the stomach or back (pancreatitis)
 - diarrhoea that contains blood or mucus severe diarrhea without blood or mucus for more than 4 days should also reported to a doctor

and microbiological resistance.

5. Report any other adverse effects to the specialist or GP whilst taking azithromycin.

3. COMMUNICATION AND SUPPORT

i. Hospital contact:

University Hospitals of Derby & Burton

Respiratory consultant/nurse via switchboard:01332 340131

Specialist nurses:

Asthma Team:

01332 787221

Uhdb.adultasthmateam@nhs.net

IMPACT Team (COPD):

01332 788225

Dhft.impact-plus@nhs.net

Bronchiectasis/ Respiratory Infection Team: 01332787159

Dhft.derbyrespiratoryinfectionsteam@nhs.net

Chesterfield Royal Hospital Foundation

Trust

Respiratory consultant via switchboard:

01246 277271

ii. Out of hours contact and procedures:

Pharmacy, UHDB, ask for on-call pharmacist via switchboard: 01332 340131

Respiratory, UHDB, ask for on-call Respiratory Consultant via switchboard: 01332 340131

Contact the CRH on-call Medic for the relevant specialty via switchboard: 01246 277271

iii. Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change

As outlined in consultant responsibility.

Patient information

https://patient.info/medicine/azithromycin-for-infection-zithromax

4. CLINICAL INFORMATION

i. Prescribed indications	Off Label Use
muications	Chronic Obstructive Pulmonary Disorder (COPD) – patients with COPD, in line with NICE NG115, i.e., if they: • do not smoke and
	 have optimised, non-pharmacological management and inhaled therapies, relevant vaccinations and (if appropriate) have been referred for pulmonary rehabilitation and
	 continue to have 1 or more of the following, particularly if they have significant daily sputum production: frequent (typically 4 or more per year) exacerbations with sputum
	production o prolonged exacerbations with sputum production o exacerbations resulting in hospitalisation
	Bronchiectasis – For adults who have high exacerbation rates (3 or more per year) (BTS) (CKS)
	Asthma – For adults (>18yrs) who have ongoing symptoms despite use of high- dose inhaled steroids and at least one exacerbation requiring oral corticosteroids in the past year (BTS) (CKS)
ii. Therapeutic summary	Azithromycin is a macrolide-type antibiotic that can be applied for the treatment of infections, when caused by microorganisms sensitive to azithromycin.
iii. Dose & Route of administration	COPD Usually, 250mg three times weekly (NICE NG115). BTS recommends 250mg - 500mg three times a week
	Bronchiectasis A starting dose of azithromycin 250 mg three times a week. Titrate up to 500mg three times a week according to clinical response. (BTS)

Asthma A starting dose of azithromycin 250 mg three times a week. Titrate up to 500mg three times a week according to clinical response. (BTS) **Pregnancy:** The safety of azithromycin has not been confirmed with regard to the use of the active substance during pregnancy. Therefore, azithromycin should only be used during pregnancy if the benefit outweighs the risk. Breastfeeding: Azithromycin is excreted in breast milk. Because of the long halflife, accumulation in the milk is possible. Information available from published iv. Pregnancy, paternal literature indicates that, in short-term use, this does not lead to clinically relevant exposure and quantities in the milk. No serious side effects have been observed by breastfeeding azithromycin in breast-fed children. A decision should be taken whether breastfeeding is discontinued or that treatment with azithromycin is discontinued/initiated or not, considering the benefit of breastfeeding for the child and the benefit of treatment for the woman. v. Duration of A specialist will assess its effectiveness over 6 – 12 months, and if it reduces the treatment exacerbation frequency, azithromycin will be recommended to continue by the GP until specialists instruct to stop. Total duration of treatment will vary, but if beneficial, it may be recommended lifelong. **COPD** Subsequent follow-up at 6 and 12 months should determine whether benefit is being derived from therapy using objective measures, such as the exacerbation rate, CAT score or quality of life as measured by a validated assessment tool, such as SGRQ. If there is no benefit, treatment should be stopped. **Bronchiectasis** Subsequent follow-up at 6 and 12 months should determine whether benefit is being derived from therapy using objective measures, such as the exacerbation rate, quality of life as measured by a validated assessment tool, such as SGRQ. Even if benefit is seen, consideration should be given to stopping treatment for a period each year, for example over the summer. Such a drug holiday may help with reducing the development of resistance whilst maintaining efficacy. **Asthma** If macrolide therapy is considered for symptom reduction, this should be for a defined period (6-12months) and stopped if no symptomatic improvement is seen. vi. Adverse effects Very Common Nausea Refer to the SPC for a full Diarrhea Abdominal pain list of adverse effects & Flatulence further information http://www.medicines.org.uk Common Anorexia Headaches Dizziness Paraesthesia Fatigue Dysgeusia Visual impairment Deafness Vomitina Dyspepsia Rash/pruritis Arthralgia

Serious side effects

- Chest pain or palpitations
- Hepatitis,
- Hepatic function abnormal,
- Jaundice cholestatic
- Tinnitus, temporary hearing loss, vertigo
- Pancreatitis
- Diarrhea that contains blood or mucus, severe diarrhea without blood or mucus for more than 4 days

vii. Monitoring Requirements

Consultant responsibility

Baseline tests:

- sputum culture and sensitivity (including tuberculosis culture), to identify
 other potential causes of persistent or recurrent infection that may need
 specific treatment (for example, antibiotic-resistant organisms, atypical
 mycobacteria or Pseudomonas aeruginosa)
- training in airway clearance techniques to optimise sputum clearance
- a CT scan of the thorax to rule out bronchiectasis and other lung pathologies
- an ECG to rule out prolonged QT interval
- Liver function test / Renal function test
- LFT/ECG at 1 month (including interpreting ECG)
- Advise patients there is a small risk of hearing loss and tinnitus and to contact a healthcare professional if this occurs
- Respiratory specialist will review prophylactic azithromycin after the first 3 months, and subsequently assess response and make recommendation to continue the drug, after a period of 6 – 12 months. (NICE)

GP responsibility

For patients where the drug is continued after 1 month:

- Perform six monthly LFTs
- Medication reviews for potential drug interactions/QTc prolongation
- ECG yearly if on another QTc prolonging drug.
- Perform an ECG if new drugs that could prolong QTc are prescribed

Actions to be taken

Parameter	Action
	Stop azithromycin if QTc >450msec (men) or QTc>470msec (women)
ECG	GPs can also contact cardiologist for advice on interpretation of ECG, and/or respiratory physician for recommendation of action (e.g. via advice and guidance or directly to responsible physician) if ECG changes are considered attributable to azithromycin or there is is uncertainty.

viii. Clinically relevant drug interactions

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

Antacids	Peak serum concentrations are reduced. Recommend 2
	hours between dose and taking antacids.
Atorvastatin	Post-marketing cases of rhabdomyolysis in patients receiving azithromycin with statins have been reported. Report unexplained muscle ache.
Digoxin	Concomitant administration with digoxin, has been reported to result in increased serum levels of digoxin. Monitor digoxin levels, if showing signs of toxicity.
Dabigatran	Azithromycin is predicted to increase the exposure to dabigatran.
Edoxaban	Azithromycin is predicted to increase the exposure to edoxaban.

		Ticagrelor	Azithromycin is predicted to increase the exposure to ticagrelor. Manufacturer advises use with caution or avoid.
		Colchicine	Azithromycin is predicted to increase the exposure to colchicine. Manufacturer advises avoid P-glycoprotein inhibitors or adjust colchicine dose.
		Medicinal products known to prolong the QT interval	Azithromycin should be used with caution if co- administered with other medicinal products known to prolong the QT interval
ix.	Contra-indications Refer to the SPC for more detailed information	antibiotic, soya lecit Hepatotoxicity – the use of azithromycin hepatic disease.	he active substance, erythromycin, any macrolide or ketolide hin or to any of the excipients liver is the principal route of elimination for azithromycin, the should be undertaken with caution in patients with significant
x.	Additional information	another, a new shall	is transferred from one specialist service or GP practice to red care agreement must be completed. ary to stop prophylactic azithromycin during an acute of the DPD unless another antibiotic with potential to affect the QT en prescribed
xi.	Supply of ancillary equipment	N/A	·
xii.	Supply, storage, and reconstitution instructions	N/A	
xiii.	To be read in conjunction with the following documents	NHSE policy- F Secondary/Tertiary	Responsibility for prescribing between Primary & Care
xiv.	Prepared by	Derbyshire shared	care and guideline group
		General Medicine	: hesterfield Royal Hospital, Consultant, Respiratory & niversity Hospitals of Derby & Burton, Respiratory

This does not replace the SPC, which should be read in conjunction with it.

Date Prepared: August 2022 Reviewed: June 2025 Next review: May 2028

References:

British Thoracic Society guideline for the use of long-term macrolides in adults with respiratory disease

AZITHROMYCIN | Drug | BNF content published by NICE Accessed online 05/05/22

Azithromycin 500mg Tablets (SPC) Accessed online 05/05/22

NICE ESUOM38: Non-cystic fibrosis bronchiectasis: long-term azithromycin (November 2014)

NICE NG115: Chronic obstructive pulmonary disease in over 16s: diagnosis and management (July 2019)

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 a	pplicable):	

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	Yes / No

been explained and agreed	
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 $\underline{\textbf{NOT}}$ 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)

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 applies
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 patient's 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	

6.	 medication that you have recommended. Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you. 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}

Please send a copy of this response to the specialist/consultant requesting shared care