

## Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

### Application for change in traffic light colour classification

#### **GREEN - Non-specialist drugs**

Primary care prescribers may take full responsibility for initiation and continuation of prescribing. Local prescribing guidelines or NICE guidance may apply.

#### **BLUE - Specialist Input WITHOUT Formal Shared Care Agreement**

Prescribing initiated and stabilised by a specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement. Please note that in some circumstances a specialist may recommend that prescribing can be started in primary care.

Please note: the BLUE classification has been refined to either 'BLUE (with initiation)' or 'BLUE (on recommendation)'

#### **AMBER - Specialist Initiation WITH Shared Care Guidelines**

Prescribing initiated and stabilised by a specialist but has the potential to transfer to primary care under a formal shared care agreement.

#### **RED - Specialist ONLY drugs**

Treatment initiated and continued by specialist clinicians.

#### **Non-formulary**

Not recommended for use in any health setting across the Surrey Heartlands health economy.

### Medicine details

<b>Name, brand name</b>	Azithromycin
<b>Manufacturer</b>	Generic medicine
<b>Licensed indication (not relevant for this application)</b>	<p>Azithromycin is indicated for the following bacterial infections induced by microorganisms susceptible to azithromycin (see sections 4.4 and 5.1):</p> <ul style="list-style-type: none"> <li>• Acute bacterial sinusitis (adequately diagnosed)</li> <li>• Acute bacterial otitis media (adequately diagnosed)</li> <li>• Pharyngitis, tonsillitis</li> <li>• Acute exacerbation of chronic bronchitis (adequately diagnosed)</li> <li>• Mild to moderately severe community acquired pneumonia</li> <li>• Infections of the skin and soft tissues of mild to moderate severity e.g. folliculitis, cellulitis, erysipelas</li> <li>• Uncomplicated genital infections due to Chlamydia trachomatis and Neisseria gonorrhoeae.</li> </ul>
<b>Off-label indication (relevant for this indication)</b>	Long-term use for the prevention of exacerbation and infection in adults with severe respiratory disease (bronchiectasis, COPD and asthma).
<b>Formulation</b>	Tablets and capsules
<b>Usual dosage</b>	Usual dose 250mg to 500mg three times a week, or 250mg daily for a minimum of 6 months

	Current status	Proposed status
<b>Traffic Light Status</b>	None assigned for this indication	Blue with initiation. Transfer of care can be requested after one month, following second ECG and LFT monitoring, as per BTS recommendations.

### Reason for requested change

The British Thoracic Society (BTS) guidelines 2019 recommend long-term macrolide treatment to prevent exacerbations and infection with azithromycin in adult patients with COPD, bronchiectasis and some asthma patients. They recommend that long-term macrolide treatment is only initiated by a respiratory specialist following a shared decision-making consultation with the patient.

NICE guideline NG117 Bronchiectasis (non-cystic fibrosis), acute exacerbation: antimicrobial prescribing also recommends that prescribing of antibiotics for preventing acute exacerbations of bronchiectasis (non-cystic fibrosis) should be done following specialist advice.

BTS recommends that prior to initiation of long-term macrolides an ECG, LFTs and sputum culture are performed. LFTs and ECG are recommended at one month after initiation and LFTs again every 6 months. The BTS have produced a quick reference guide which describes the indications, tests required prior to initiation of treatment and ongoing monitoring required. See attached BTS recommendations and proposed responsibilities for monitoring.

BTS recommend 6 monthly monitoring of LFTs for patients on long-term macrolides. This is a good practice recommendation. BTS notes that a low rate (1%–5%) of asymptomatic elevation of serum aminotransaminase levels is known to occur with any of the four orally absorbed macrolide antibiotics. The elevation is generally mild to moderate in degree and rarely requires dose modification or discontinuation<sup>1</sup>. More seriously, a cholestatic picture can occur which carries a higher risk of permanent liver damage. The risk of serious liver injury is rare (estimates from 1:25,000 to 1:65,000) and usually arises within a few weeks of starting treatment<sup>3</sup>. CKS recommends 6 monthly LFTs are carried out in primary care for patients prescribed long-term macrolides for preventing exacerbations of bronchiectasis<sup>4</sup>.

Surrey Heartlands APC currently has no traffic light status assigned to azithromycin for long-term use for the prevention of respiratory infection in severe respiratory disease. This has caused confusion, as to whether the respiratory specialist team or the patient's GP is responsible for carrying out tests (ECG, LFTs) at initiation and monitoring during treatment.

The individual trusts in Surrey Heartlands have differences in their recommendations for long term prophylaxis of azithromycin in their antimicrobial guidelines. ASPH and SASH have no entry or recommendation for the long-term use of azithromycin for prophylaxis in bronchiectasis or respiratory disease. RSCH antimicrobial guidelines recommend long-term use of antibiotics (azithromycin, doxycycline or clarithromycin) on recommendation of respiratory consultant only, with review every 3 to 6 months. The RSCH recommendation is in line with this proposal to change traffic light status.

The BTS recommendations for long-term macrolide therapy would fit with APC criteria for a blue traffic light status with initiation by the respiratory specialist team with potential to transfer to primary care.

Sussex APC have currently designated azithromycin as "Purple for prophylaxis CF and bronchiectasis (Purple is - specialist recommendation or initiation where noted)". It is green for all other indications. The proposal in this paper would align our recommended traffic light status with Sussex APC.

### Key Considerations

**Cost implications to the local health economy****Cost of product:**

Drug Tariff prices January 2026 (all category M products)

Azithromycin 250mg tablets	18p/tablet
Azithromycin 500mg tablets	26p/tablet
Azithromycin 250mg capsules	20p/capsule

**Annual cost per patient:**

Depending on dose between £28.08 to £73.00 per year

**Availability of PAS and details (if appropriate):** NA

**Is this product included in the Medicines Procurement and Supply Chain (MPSC) Framework Agreements and Products?** NA

**Availability of homecare service (if appropriate):** NA

**Impact to current prescriber or medication initiator**

- The current lack of clarity about which prescriber is responsible for pretreatment ECG, LFTs and subsequent monitoring may represent a risk to patient safety.
- Some local GPs are unwilling to initiate prescribing of azithromycin on recommendation from secondary care, as they have expressed the view that it should be initiated in secondary care.
- Local GP practices are not remunerated for carrying out pre-initiation and one month monitoring ECG, LFT and sputum tests for long-term azithromycin initiated by respiratory specialist teams.

**Impact to proposed prescriber or medication initiator**

- Potential increase in work for some respiratory teams in secondary care carrying out pre-treatment ECG and LFTs, and one month monitoring, who are not currently carrying out this monitoring.
- Clarify responsibility in primary care to do 6 monthly LFTs on patients on long-term azithromycin to ensure patient safety, as per CKS recommendation.

**Impact to patients**

- Reduced risk to patient safety by ensuring required pre-treatment and one month monitoring tests are carried out by the specialist team.
- Less confusing for patients, when there is clarity about responsibility for pre-treatment and monitoring tests for long-term azithromycin therapy.

**Additional comments**

- Proposed information sheet from the British Thoracic Society on long-term use of macrolides in adults with respiratory disease, with specialist and GP responsibilities added.
- Optimise Rx messages to be updated to reflect change in traffic light status

**Identified lead for development of necessary documents e.g., shared care agreement**

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**Designation:** Lead Respiratory Specialist Pharmacist

**Organisation:** Surrey Heartlands ICB

**Estimated date of preparation:** March 2026

## Equality Impact Assessment:

Protected characteristics <a href="#">Protected Characteristics - Information</a>	Describe any considerations or concerns for each group.	Describe suggested mitigations to reduce inequalities.
Age	None	
Disability	None	
Gender reassignment	None	
Marriage and civil partnership	None	
Pregnancy & maternity	None	
Race	None	
Religion and belief	None	
Sex	None	
Sexual orientation	None	
Impact on any other vulnerable groups?	None	

## References:

1. Smith D et al. [British Thoracic Society guideline for the use of long-term macrolides in adults with respiratory disease](#). Thorax 2020; **0** :1-35
2. [NICE NG117 Bronchiectasis \(non-cystic fibrosis\), acute exacerbation: antimicrobial prescribing](#). 2018
3. LiverTox: Clinical and Research Information on Drug Induced Liver Injury [Internet]. Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases; 2012-. Azithromycin. [Updated 2025 Jul 1]. [Azithromycin - LiverTox - NCBI Bookshelf](#)
4. Clinical Knowledge Summaries. Bronchiectasis. March 2025. [Bronchiectasis | Health topics A to Z | CKS | NICE](#)

## Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
<b>Prepared by</b>	Helen Marlow	Lead Respiratory Specialist Pharmacist	5/01/26	None
<b>Reviewed by</b>	Sarah Watkin	Head of Medicines Resource Unit	23/02/26	None

Explanation of declaration of interest:

None.