

AZITHROMYCIN PROPHYLAXIS IN ADULTS WITH RESPIRATORY DISEASE V1.0

Guidance on azithromycin prophylaxis for reducing exacerbations in adults with severe COPD, bronchiectasis and asthma. The use of azithromycin in people with cystic fibrosis or post lung transplantation is not covered in this guidance

Target Audience: Healthcare professionals involved in the prescribing, dispensing or administering of azithromycin prophylaxis for patients with severe COPD, bronchiectasis and asthma. Audiologists reviewing patients on azithromycin.

This guideline has been developed with the clinical expertise input from the National Clinical Lead in Respiratory Medicine in collaboration with the Respiratory Antimicrobial Guideline Expert Advisory Group and AMRIC Clinical Lead

- Azithromycin prophylaxis may be beneficial for a small subgroup of patients who have repeated exacerbations of COPD, bronchiectasis or asthma. As well as antimicrobial effects, macrolides possess immunomodulatory properties and hence have a role in the management of patients with certain inflammatory respiratory conditions.
- Azithromycin prophylaxis has been shown to decrease the number of exacerbations in patients with COPD, asthma and bronchiectasis. Consideration must be given to the risk of adverse effects (gastrointestinal upset, hearing and balance disturbance, liver and cardiac effects) and the development of antimicrobial resistance with long term use of azithromycin. The use of azithromycin in this manner represents an off-label use of this medicine but is recommended in many guidelines.
- Long-term azithromycin should not be used to manage patients with unexplained chronic cough.
- It is not necessary to stop azithromycin prophylaxis during an acute infective exacerbation unless another antibiotic with potential to affect the QT interval (e.g. quinolone, macrolide, azole antifungal or co-trimoxazole) has also been prescribed.
- An [audit tool](#) is available to support healthcare professionals reviewing patients on azithromycin.

INITIATING AZITHROMYCIN PROPHYLAXIS

- **Azithromycin prophylaxis should be initiated by a consultant in respiratory medicine or a consultant with a special interest in respiratory medicine.**
- **At initiation, a written plan should be documented and communicated to both the patient and GP, regarding the ongoing review of azithromycin prophylaxis every 6-12 months.**
- **Table 1: Criteria for considering azithromycin prophylaxis, all must be met.**

| Severe COPD | Bronchiectasis | Asthma |
|--|---|--|
| <ul style="list-style-type: none">• 2 or more treated exacerbations in previous 12 months• Non-smoker• Optimisation of inhaler choice, technique and adherence• Optimisation of airways clearance techniques• Pulmonary rehabilitation completed | <ul style="list-style-type: none">• 3 or more exacerbations in previous 12 months• Optimisation of airway clearance• Pulmonary rehabilitation | <ul style="list-style-type: none">• Symptomatic despite >800mcg / day high dose inhaled steroids• 1 or more exacerbation in previous 12 months• Optimisation of inhaler choice, technique and adherence• Note: azithromycin should not be offered as a way to reduce oral steroid dose |

HSE Antimicrobial Resistance and Infection Control Programme

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The following baseline assessment should be completed prior to initiating azithromycin prophylaxis:

- Perform ECG to assess QTc interval. If QTc is >450 ms for men or >470 ms for women, this is considered a contraindication to initiating azithromycin therapy.
- Check if patient has ongoing pro-arrhythmic conditions or on other medication that prolong QTc interval.
- Perform a clinical check for evidence of liver impairment and measure LFTs where feasible. Azithromycin should be used with caution in liver impairment and can itself cause liver dysfunction.
- Check for history of hearing or balance difficulties. Such patients should be made aware of the potential for a further deterioration in hearing or balance with azithromycin therapy.
- Microbiological assessment of sputum should be considered before therapy where feasible.
- Azithromycin monotherapy should be avoided if a non-tuberculous mycobacteria (NTM) is identified.
- Patients should be informed that the goal of azithromycin prophylaxis is to reduce the number/ frequency of exacerbations and its benefit will be reviewed every 6-12 months.
- Patients should be counselled on potential adverse effects before starting therapy including gastrointestinal upset, hearing and balance disturbance, cardiac and liver effects and microbiological resistance. [A patient information leaflet is available to support this.](#)

REVIEWING AZITHROMYCIN PROPHYLAXIS

- **Azithromycin prophylaxis should be reviewed every 6-12 months. If there is no evidence of clinical benefit or there is evidence of adverse effects, it should be discontinued, with discussion with the original prescriber.**
- **This review should include an assessment of: ECG, hearing, LFTs, current medication, any relevant results of microbiological sampling, adverse effects and frequency of exacerbations.**
- **This review can occur at an outpatient appointment, opportunistically if the patient has an inpatient stay or at a routine GP review.**
- **Clear communication between the original prescriber and GP should include details of the intended plan for review and de-prescribing as appropriate.**

Good practice points for regular review with a view to de-prescribing, if any of the following criteria are met:

- No objective evidence of improvement: i.e. no reduction in exacerbation number/ frequency, or no improvement in symptoms
- ECG changes
- Change in patient perception of hearing/ balance from baseline
- Jaundice, abdominal pain, nausea, and/ or pruritus
- Deranged LFTs (twice the upper limit of normal)
- Other significant side effects, including gastrointestinal/ *C. difficile* associated diarrhoea
- On other essential medication with significant drug interactions
- Change in sputum microbiology

If azithromycin is de-prescribed this should be communicated to patient, acute care consultant, GP and community pharmacist including the reason for this decision.

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Treatment table

| AZITHROMYCIN PROPHYLAXIS FOR REDUCTION OF EXACERBATIONS OF RESPIRATORY CONDITIONS Azithromycin prophylaxis should be initiated by a consultant in respiratory medicine or a consultant with a special interest in respiratory medicine. See information above for reviewing therapy. | | | |
|--|---|---|---|
| Drug | Initial Dose | Duration | Notes |
| Azithromycin | 500mg three times a week (e.g. Mon, Wed, Fri) OR 250mg every 24 hours | Review every 6-12 months for benefit/risks. | See monitoring requirements above If gastrointestinal side effects occur at the higher dose of azithromycin (500 mg thrice weekly), a dose reduction to azithromycin 250 mg thrice weekly could be considered if macrolide therapy has been of clinical benefit. |

Patient Information

[Azithromycin prophylaxis patient information leaflet](#)