This policy statement is approved by Halton, Knowsley, Liverpool, Southport and Formby, South Sefton, St Helens, Warrington and

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PAN MERSEY APC

PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
REF: PS214 FINAL
APC BOARD DATE: 27 SEP 2017

NHS Pan Mersey Area Prescribing Committee

AZITHROMYCIN oral liquid and tablets – paediatric use

AMBER

The Pan Mersey Area Prescribing Committee recommends the prescribing of azithromycin following specialist initiation for certain chronic airway conditions in children

PATIENT RETAINED BY SPECIALIST

The Pan Mersey Area Prescribing Committee recommends azithromycin for the following indications on advice from the Paediatric Specialist Respiratory Team:

- Prophylaxis or treatment for respiratory infections in high risk children (e.g. cystic fibrosis (CF), neurodisability, immunodeficiency)
- Prophylaxis or treatment for respiratory infections in otherwise low risk children who appear prone to infections
- As an alternative therapy for poorly controlled asthma (particularly if neutrophilic)
- As an adjunctive therapy in infants with chronic lung disease of prematurity and interstitial lung disease
- Prophylaxis of or treatment for respiratory infection in children with bronchiectasis and or bronchiolitis obliterans.
- Prophylaxis of or treatment for respiratory infection in children with structural airways disease (bronchomalacia and/or bronchostenosis)

Azithromycin has anti-inflammatory, immunomodulatory and lung remodelling properties in chronic airways disease. Apart from its use in cystic fibrosis, use in the above indications is off label. Informed patient consent on its off label use should be sought before prescribing. The specialist should clearly communicate that this discussion has taken place and the recommended dose in the letter to the GP. Initiation of treatment should only be done under the instruction of the Paediatric Respiratory Specialist.

No routine monitoring is required whilst on treatment. The need for on-going therapy will be reviewed regularly by the Specialist.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

Version: 1.1
Review date: September 2019
(or earlier if there is significant new evidence relating to this recommendation)

AZITHROMYCIN oral liquid and tablets – paediatric use

EFFECTIVENESS[3-6]

Use of azithromycin in adults for COPD and bronchiectasis is well established and supported in the Pan Mersey statement on azithromycin for adults. Long-term azithromycin is also recommended in the Cystic Fibrosis (CF) Trust guideline on antibiotic treatment for children and young people, following evidence demonstrating clinical outcomes of lung function improvement, reduced pulmonary exacerbations, the need for other antibiotic treatment and reduced hospital admission. One small study in non-CF patients found a reduction in pulmonary exacerbation rates[6].The disease states mentioned in this document share common pathophysiological processes in adults with COPD / bronchiectasis as well as CF children. It is expected that the anti-inflammatory and immunomodulatory effects of azithromycin will result in the same clinical benefits in non-CF chronic lung airway conditions.

In specialists' experience, using azithromycin in this way reduces disease exacerbations thereby reducing the need for hospital admissions and further intravenous antimicrobial therapy.

SAFETY[1]

As with all antibacterial medications GI side effects are common with long term azithromycin use. Hepatotoxicity and rash occur less frequently. Hearing loss occurs commonly after long-term therapy with azithromycin, which is usually reversible. Other side effects can be found in the Summary of Product Characteristics (SPC).
Long term safety has not been established as published trial data does not extend to greater than 1 year.

Treatment is contraindicated in those patients with a hypersensitivity to azithromycin or other macrolides

Consensus of opinion of microbiologists locally is that azithromycin for prevention of exacerbation should not lead to bacterial resistance; however, consideration should be paid to the possibility of macrolide resistance.

COST[2]

Azithromycin oral liquid 200mg/5ml £210/year
Azithromycin 250mg tablets £52/year
Azithromycin 500mg tablets £52/year

This cost will be offset by a reduction in hospital admissions and reduced prescribing of antimicrobials

PATIENT FACTORS

Patients who receive 200mg/5ml liquid will require part of the supply to be provided as dry powder for reconstitution. It will be the responsibility of the community pharmacy to instruct the patient's carer on how this can be done.

PRESCRIBING INFORMATION

The following doses are used THREE times a WEEK on Monday/Wednesday/Friday as per specialist recommendation

- 10 mg/kg max 500mg for patients who cannot take tablets
- 250mg for 20-40kg patients who can take tablets
- 500mg for >40kg patients who can take tablets

All patients should be reviewed by a respiratory specialist after a 6 month trial to consider stopping therapy if no reduction in exacerbations is seen and establishing overall risk/benefit.
Please refer to the SPC for further information

IMPLEMENTATION NOTES

Azithromycin can be prescribed in primary care following recommendation by a respiratory specialist. The specialist should advise the GP of the dose and communicate that patient consent has been obtained.

REFERENCES

1. Summary of product characteristics (http://www.medicines.org.uk/emc/medicine/22608) accessed 17/5/17
2. BNFc – accessed 17/5/17
3. NICE Evidence Summary [ESUOM38] Non-cystic fibrosis bronchiectasis: long-term azithromycin 2014
4. NICE Evidence Summary [ESUOM37] Cystic fibrosis: long-term azithromycin 2014
5. Valery et al. Long-term azithromycin for Indigenous children with non-cystic-fibrosis bronchiectasis or chronic supurative lung disease (Bronchiectasis Intervention Study): a multicentre, double-blind, randomised controlled trial The Lancet 2013; 1(8): 610-620
6. Report of the UK Cystic Fibrosis Trust Antibiotic Working Group. Antibiotic treatment for cystic fibrosis – 3rd edition. 2009 (updated 2016)