NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: February 2022

Intervention: nebulised liposomal amikacin

Indication: non-tuberculous mycobacterial pulmonary disease caused by mycobacterium avium complex without cystic fibrosis that is refractory to current treatment options (adults and post pubescent children)

URN: 2111

Gateway: 2, Round 1

Programme: Internal Medicine

CRG: Specialised Respiratory

Information provided to the Panel

Evidence Review completed by Solutions for Public Health

Policy Proposition

Blueteq™ Form

Evidence to Decision Making Summary

Patient Impact Report

Equality and Health Inequalities Assessment (EHIA) Report

Clinical Priorities Advisory Group (CPAG) Summary report

Policy Working Group Appendix

This Policy Proposition recommends the routine commissioning use of nebulised liposomal amikacin in addition to the current oral guidance based treatment (GBT) in cases of non-tuberculous mycobacteria (NTM) pulmonary disease caused by mycobacterium avium complex (MAC) in patients without cystic fibrosis that are refractory to the current GBT. Approximately 40% of those patients requiring treatment fail to respond to the GBT. NTM MAC pulmonary disease has a 5 year all-cause mortality of 25% or more.

Clinical Panel members were presented with the evidence base supporting this proposition which consisted of four studies. Two randomised controlled trials and two open-label follow-up studies which followed up patients from the CONVERT trial. The four studies identified for this review provided very low to high certainly evidence suggesting that adding liposomal amikacin to GBT in individuals with NTM PD caused by MAC with limited treatment options increases the proportion of patients who achieve culture conversion up to six months and the effect is sustained for up to 12 months and endures three months after discontinuing full (at least 12 months) of treatment. No significant improvement in Quality of Life was identified or reported in the 6 minute walk test. No evidence was identified for mortality which was identified as a critical outcome.

No cost effectiveness evidence was found.

Clinical Panel considered the public health implications of this condition and the intended impact of the treatment in reducing the spread of the disease, which is important to address.

The Panel members discussed why cystic fibrosis was excluded as this is not clear in the documentation. The NHS England drugs list states this is not for routine commissioning in those with cystic fibrosis.

EHIA – needs a redraft as it is not considered to be sufficiently describing the impact on those with protected characteristics or groups facing health inequalities.

Patient Impact Report – no additional comments received.

Recommendation

Clinical Panel recommends that this proposition progresses as proposed, with the amendments requested.

Why the panel made these recommendations

Clinical Panel members considered that the proposition was written reflective of the evidence base, although uncertain using GRADE methodology, and acknowledged it addresses an important public health issue.

Documentation amendments required

Evidence Review:

- Page 5 short summary - comparison – amikacin to GBT vs GBT alone – needs to be reviewed, check the language for accuracy.

Policy Proposition:

- The title and the text it state 'without cystic fibrosis'. Stating this exclusion criteria in the title makes it lengthy and clumsy. This should be revised.
- Plain language summary page 3 – misspelled aminoglycosides (an antibiotic class). Needs correcting
- The flow diagram page 6 - helpful and made clear this is in addition to standard of care however this is not clear in text and needs addressing.
- The proposition states this treatment be given for a maximum duration of 18 months. This needs to be more specifically stated in the Blueteq form Q7.

Declarations of Interest of Panel Members: None

Panel Chair: James Palmer, National Director, Specialised Services

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Post -panel note

Short summary reviewed and checked for accuracy. Tilte amended as suggested. Mis-spelling of aminoglycosides corrected. Text amended on page 6 as suggested. Bluteq form amended to refer specifically to Summary of Product Characteristics.