Pharmac officer
PHARMAC
Simpl House
Level 9/40 Mercer Street
Wellington 6011

16th January 2020

Dear Sir/madam

Re: Pharmac consultation on funding Mepolizumab for severe asthma patients in New Zealand

I am writing as the NZ branch president of the Thoracic Society Australia & New Zealand (TSANZ) on behalf of the NZ members, and as a respiratory physician with a special interest in asthma at Middlemore Hospital in response to the consultation on funding of Mepolizumab.

Firstly, we would like to thank Pharmac for funding this important medication which will greatly benefit the severe asthma patients in New Zealand. Even though this group makes up only 4-10% of the entire asthma population, they are known to have a high burden of disease with frequent asthma exacerbations resulting in excessive utilisation of health care resources including hospitalisations. We strongly support the proposal to fund Mepolizumab for this population as international studies have demonstrated significant reduction in exacerbations, reduction in corticosteroid use, improved asthma control and quality of life with this treatment.

In response to the criteria published by Pharmac, we have the following points to make:

1. The blood eosinophil count should be altered to reflect evidence based studies.
Blood eosinophil ≥300 cells/ml in the last 12 months should be used instead of ≥ 500 cells/ml

International studies on Mepolizumab demonstrated clinically relevant reduction in exacerbations and reduction in oral glucocorticoid dose in patients with blood eosinophil ≥ 300cells/ml (MENSA study by Ortega et al NEJM 2014 and SIRIUS study by Bel et al NEJM 2014).

This is in line with reimbursement agencies in other countries such as Australia where blood eosinophil criteria of ≥ 300cells/ml in the previous 12 months or ≥ 150 cells/µl at initiation of Mepolizumab is required for funding.

In the event that Pharmac is unable to fund mepolizumab at a ≥ 300cells/ml cut-off at this time, it is important that the proposed cut-off of "greater than 500 cells/ml" is amended to ≥ 500 cells/ml as this matches the analysis from Ortega et al which provided the rationale for a ≥ 500 cells/ml cut-off (https://www.nejm.org/doi/full/10.1056/NEJMoa1403290). There is evidence base to support a "greater than 500 cells/ml" cut-off and as eosinophil counts are routinely measured to one decimal place would enforce a de facto cut off of 0.6, which does not appear to be Pharmac's intent.

2. A lower blood eosinophil count should apply to patients who are on oral corticosteroid.
Patients receiving treatment with oral corticosteroid (≥ 10mg/day) must have blood eosinophil count ≥ 0.15 cells/ml in the last 12 months

A subset of patients with severe asthma require oral corticosteroid in addition to optimised inhaled therapy to control their asthma (GINA step 5 recommendation). A small number of these patients will remain uncontrolled on this regime despite a reduction in their blood eosinophil count, and continue to exacerbate. A blood eosinophil criteria of ≥ 500 cells/ml or ≥ 300 cells/ml will

disadvantage this small but significant group of severe asthma patients. We propose a lower blood eosinophil criteria of ≥ 150 cells/ml for this group.

3. **Remove asthma control test (ACT) requirement from renewal criteria.**

The use of asthma control test score as a criterion for renewal of Mepolizumab does not fit with the evidence base for this medication. The primary benefits of Mepolizumab demonstrated in the clinical trial programme were reductions in exacerbations and oral corticosteroid use. These are clinically important outcomes in their own right and are poorly correlated with change in asthma control in response to treatment. If a patient had a >50% reduction in exacerbations and a >50% reduction in oral steroid use but did not see an ACT improvement >5 they may lose access to a medication that was providing substantial clinical benefit. Furthermore, some patients with severe asthma may have fixed airflow obstruction from airway remodelling. In this group, we might see a significant improvement in exacerbation rates and corticosteroid use but continue to have daily symptoms. It would be appropriate to remove the ACT requirement from the renewal criteria.

We thank you for taking these points into consideration.

Kind regards

Dr Elaine Yap
NZ branch president
Thoracic Society Australia & New Zealand