



australasian society of clinical immunology and allergy

20 September 2022

Professor Andrew Wilson,
Chair, Pharmaceutical Benefits Advisory Committee (PBAC)
Department of Health and Ageing
GPO Box 9848 Canberra ACT 2601
Email: pbac@health.gov.au

Dear Professor Wilson,

Re: Nucala® (mepolizumab) for treatment of nasal polyps in chronic rhinosinusitis

On behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA) we are writing this submission in support of an application from GSK for Nucala® (mepolizumab) to be listed on the Pharmaceutical Benefits Scheme (PBS) for treatment of in nasal polyps in chronic rhinosinusitis (CRS).

ASCIA has developed a **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Position Paper** www.allergy.org.au/hp/papers/crswnp which provides detailed information about Nucala® (mepolizumab) on pages 28-29 and a treatment algorithm.

Nucala® (mepolizumab) has been approved for use and listed on the PBS since 2017 for patients with severe eosinophilic asthma following demonstrable benefit in phase II (Dream) and phase III (Mensa) studies published in 2014.

Analyses of the severe asthma studies indicated that Nucala® (mepolizumab) could be of benefit in treatment of CRSwNP. Efficacy versus placebo in the treatment of CRSwNP has since been demonstrated in two phase II clinical trials, with a statistically significant reduction in nasal polyps for at least one month after dosing in most patients, and a decreased number of patients requiring surgery.

ASCIA strongly supports this application for the following reasons:

- The advent of effective, targeted biologic therapies such as Nucala® (mepolizumab), for the management on nasal polyps in CRS, with very acceptable safety profiles, is a welcome addition to current management options. The PBS listing of Nucala® (mepolizumab) will ensure equitable access to Australians with nasal polyps in CRS.
- Studies have shown statistically significant reduction in nasal polyps after treatment with Nucala® (mepolizumab) dosing in most patients, and a decreased number of patients requiring surgery. Therefore, the PBS listing of Nucala® (mepolizumab) for treatment of patients with nasal polyps in CRS should make a significant difference to the health outcomes for patients and health-economic benefits for the health system, by decreasing the need for surgery and reducing the use of steroids.
- CRSwNP has a significant impact on quality of life, especially when atopic diseases, asthma or other comorbidities are present. Therefore, the PBS listing of Nucala® (mepolizumab) for nasal Polyps in CRS should also have indirect health-economic benefits by improving the health related quality of life for patients, reducing absenteeism and increasing productivity.

Clinical immunology/allergy specialists regularly manage patients who have CRSwNP, and recognise the need for responsible and considered use of treatments such as Nucala® (mepolizumab) in appropriate patients who are likely to benefit, with ongoing monitoring.

We hope that this submission provides sufficient information for the PBS listing of Nucala® (mepolizumab) for nasal polyps in CRS.

Yours sincerely,

Prof Connie Katelaris AM
Chair, ASCIA CRSwNP Working Party
ASCIA Past President

A/Prof Theresa Cole
ASCIA President

Jill Smith
ASCIA CEO