



australasian society of clinical immunology and allergy

24 January 2024

Professor Andrew Wilson  
Chair, Pharmaceutical Benefits Advisory Committee (PBAC)  
MDP 952, GPO Box 9848  
Canberra, ACT 2601  
Email: [pbac@health.gov.au](mailto:pbac@health.gov.au)

Dear Professor Wilson,

**Re: PBS listing of dupilumab (Dupixent®) for uncontrolled severe asthma in 6 to 11 year olds**

On behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA) we write in support of a submission from Sanofi-Aventis to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) Pharmaceutical Benefits Scheme (PBS) listing of dupilumab (Dupixent®) for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years.

We note that dupilumab (Dupixent®) has been approved for use and listed on the PBS for patients with uncontrolled severe asthma aged 12 years or older.

ASCIA supports this submission for the following reasons:

- It is important to have biologicals such as dupilumab, with a very strong evidence base, as a treatment option to help manage severe, uncontrolled asthma, which can greatly impact health and quality of life, particularly in patients with other atopic diseases and/or comorbidities.
- Whilst dupilumab does not replace the need for oral corticosteroids (OCS), it can potentially bring the use of OCS into more acceptable risk-benefit doses for patients with severe asthma. This is important regarding growth and development in patients aged from 6 to 11 years.

The efficacy and safety of dupilumab in the treatment of severe asthma has been reviewed and published in the European Academy of Allergy and Clinical Immunology (EAACI) *Allergy Journal* in May 2020:

- *Efficacy and safety of treatment with biologicals (benralizumab, dupilumab, mepolizumab, omalizumab and reslizumab) for severe eosinophilic asthma. A systematic review for the EAACI Guidelines - recommendations on the use of biologicals in severe asthma.*
- *The authors of this systematic review concluded that all biologicals reduce exacerbation rates with high certainty of evidence. In addition, benralizumab, dupilumab and mepolizumab reduce the daily dose of oral corticosteroids (OCS) with high certainty of evidence.*

Clinical immunology/allergy specialists regularly manage patients of all ages who have uncontrolled severe asthma and recognise the need for responsible and considered use of treatments such as dupilumab in appropriate patients who are likely to benefit, with ongoing monitoring.

We hope that this letter provides sufficient information for the proposed PBS listing of Dupixent® for uncontrolled severe asthma in patients aged from 6 to 11 years.

Yours sincerely,

A/Professor Theresa Cole  
ASCIA President

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