ascia
australasian society of clinical immunology and allergy

9 July 2024

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

Dear Professor Ward,

Re: PBS listing of Dupixent® (dupilumab) for treatment of severe atopic dermatitis

On behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA) I write to convey that ASCIA has serious concerns about the possible Pharmaceutical Benefits Scheme (PBS) delisting of Dupixent® (dupilumab) for treatment of chronic, severe atopic dermatitis.

A letter from ASCIA has also been sent to the supplier of Dupixent® (dupilumab), Sanofi, to request that they continue to work together with the PBAC to resolve the issues that have led to the possible PBS delisting of Dupixent® for chronic, severe atopic dermatitis.

ASCIA is very concerned about the potential effects for over 17,000 patients (12 years and over) who have been prescribed Dupixent® for chronic severe atopic dermatitis, for the following reasons:

- Since the PBS listing in 2021, Dupixent® has made a significant difference to the health and quality of life for people with chronic severe atopic dermatitis, and their families. PBS listing ensures equitable access for Australians with this condition, enabling them to lead productive, healthy lives.
- Dupixent® is a fully human monoclonal antibody and is not an immunosuppressant. Prior to its PBS listing, immunosuppressive treatments were the only option for patients who failed to respond to topical treatments, which have a weak evidence base, and considerable long term side effects.
- Clinical immunology/allergy specialists regularly manage patients with chronic severe atopic dermatitis and are experienced in appropriate selection and monitoring of patients being treated using immune modulating agents, including Dupixent®. It is important to have this treatment option, which would not be feasible without the PBS listing.

Please email jill@allergy.org.au if you require further information.

Yours sincerely,

Jill Smith
ASCIA CEO

Attachment: Summary of ASCIA support for PBS listing of Dupixent®

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- Dupixent® (dupilumab) was listed on the Pharmaceutical Benefits Scheme (PBS) in March 2021. for the treatment of patients, 12 years and above, with severe atopic dermatitis, who have failed to respond to optimally prescribed topical treatments. This was reported in an ASCIA website news item in 2021: https://www.allergy.org.au/about-ascia/info-updates/pbs-listing-of-dupixent-dupilumab-for-severe-atopic-dermatitis
- ASCIA had sent a letter of support for this PBS listing to the Pharmaceutical Benefits Advisory Committee (PBAC) in In March 2020. This letter is on the ASCIA website https://www.allergy.org.au/ascia-submissions/2020
- ASCIA also sent a letter of support in September 2020 for the PBS listing of Dupixent® (dupilumab) for uncontrolled severe asthma in adults and adolescents 12 years and older, in March 2021
- In May 2023 ASCIA sent a letter to the PBAC for consideration at the PBAC July 2023 meeting in response to a PBAC agenda item: To request the PBAC consider the previously estimated utilisation for chronic severe atopic dermatitis. The ASCIA letter is on the ASCIA website https://www.allergy.org.au/ascia-submissions/2023
- The outcomes from the PBAC July 2023 meeting on this agenda item are published on https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2023-07/pbac-web-outcomes-07-2023-v2.pdf The outcome states: The PBAC advised that it would be reasonable for the current **risk sharing arrangement (RSA) financial caps** for dupilumab (and upadacitinib), for the treatment of severe AD in patients aged 12 years and older, to be increased for the remaining years of the arrangement, to account for patients with severe AD of the hands and/or face.

  In providing this advice, the PBAC noted that such use was not accounted for in the original RSA caps, however, given the apparent quality of life impacts of disease affecting the hands and/or face appear similar to that for the whole body, considered that use in these patients is likely to be cost-effective.

  The PBAC considered the submission's other proposed changes to the financial estimates (increasing the proportion of patients inadequately controlled on topical corticosteroids and increasing the uptake rates) to be overestimated and highly uncertain.

  The PBAC considered that the submission did not provide sufficient justification in relation to changing these assumptions and therefore did not support these amendments.

  ASCIA does not have details about the **PBAC risk sharing arrangement (RSA) financial caps.**
- ASCIA understands that the PBS listing of Dupixent® (dupilumab) for uncontrolled severe asthma in adults and adolescents 12 years and older is not subject to **risk sharing arrangement (RSA) financial caps**.
- In July 2024 ASCIA has written to Sanofi and the PBAC to convey that ASCIA has serious concerns about the possible PBS delisting of Dupixent® (dupilumab) for treatment of chronic, severe atopic dermatitis. ASCIA requests that Sanofi and the PBAC work together to resolve to resolve the issues that have led to the possible PBS delisting of Dupixent® for chronic, severe atopic dermatitis.