

Melanie Funk

MANAGING DIRECTOR
melanie.funk@eczemaSUPPORT.org.au
0400108153
www.eczemaSUPPORT.org.au



Pre-Budget 2020-21 Submission

Prepared by Eczema Support Australia Ltd

Atopic eczema is an under-recognised, under supported and misunderstood immune-related disease that requires significant investment by the Commonwealth.

Currently the treatments that are affordable to Australians with severe atopic eczema provide only limited control of the condition or have serious side-effects, including increasing the risk of cancer.¹ Consequently, many of our members report that life with severe atopic eczema is unbearable, and in some cases, say that it is not worth living.

This submission focuses on the immediate opportunity for the Federal Government to add the first biologic therapy for severe atopic eczema to the Pharmaceutical Benefits Scheme (PBS), delivering enormous benefit for patients living with this condition and realising sizeable savings to the Australian health system.

Budget Recommendations

Eczema Support Australia (ESA) is proposing that adequate funding is included in the forward estimates to accommodate the PBS listing of biologic therapy for the treatment of severe atopic eczema.

The Australian Government currently spends >\$1B annually to provide subsidised access to biologic therapies for a range of inflammatory conditions. This represents approximately 10% of total PBS expenditure.²

PBS-listed biologic therapies are considered cost-effective and have changed the lives of thousands of Australians, including those with dermatological conditions. The current level of PBS expenditure on biologic therapies for dermatological conditions is \$156M (chronic plaque psoriasis and chronic spontaneous urticaria).³

There is no biologic therapy listed on the PBS for severe atopic eczema. This is despite the Therapeutic Goods Administration approving a biologic medication, Dupixent (dupilumab) for the treatment of moderate-to-severe eczema in January 2018.⁴ This therapy has twice been rejected by the Pharmaceutical Benefits Advisory Committee (PBAC) and is now only available on private prescription at a cost of approximately \$19,200 per annum.

Eczema Support Australia hopes that the PBAC will review a third submission for Dupixent. The eczema community is hopeful of a favourable outcome, noting that the cost of the therapy is subsidised by governments in more than 20 countries overseas including France, Germany and the United Kingdom.

Our concern is that should Dupixent be deemed cost-effective and recommended for a Government subsidy, the Federal Health Minister may not be able to act on the recommendation without an increase in the PBS budget. We understand from last year's Federal Budget that the PBS budget is forecast to decrease in real terms by 18.6 per cent from

2019-20 to 2022-23⁴ and that future PBS listings are contingent on the Federal Government securing savings and/or providing additional funding.

ESA understands that only 17 new medicines were added to the PBS in 2019, a 40% reduction on the number listed in the previous year.⁵ A continuation of this trend, which may result in a failure to subsidise Dupixent, would be unacceptable to Australians living with severe and uncontrolled atopic eczema.

The PBAC has previously acknowledged the effectiveness of Dupixent in a therapeutic area of high clinical need, and noted the significant investment required to fund this medicine through the PBS.⁶ As such, we request that the 2020-21 Federal Budget include a provision that will allow Dupixent to be immediately added to the PBS (subject to positive PBAC recommendation), thus allowing the Federal Treasurer to announce a PBS listing on Budget night and reaffirm that the *“Morrison Government’s commitment to ensuring that Australians can access affordable medicines, when they need them, remains rock solid”*.⁷

Eczema Support Australia respects the independence of the PBAC and eagerly awaits the outcome of any future review of Dupixent, as well as other medicines for the treatment of atopic eczema. We request that the Department of Finance and Treasury work constructively with the Department of Health to ensure the PBS budget has the necessary headroom to list breakthrough treatment options that offer relief from the physical and psychological burden of atopic eczema.

On behalf of all Australians impacted by atopic eczema, we thank you for your consideration.

The following information is provided in support of the Budget Recommendations above.

About Eczema Support Australia

Eczema Support Australia Ltd is a national support network established and managed by volunteers with the aim of reducing social isolation, improving quality of life and overcoming social and other barriers created by atopic eczema.

Originally named Hands to Hold, Eczema Support Australia is registered as a Public Benevolent Institution and is an Australian registered charity and endorsed as a deductible gift recipient.

ESA was inspired by a family with twin boys who have severe allergies and eczema. Thanks to the initiative and drive of a friend, this family finally received wonderful community support, which is something that people with this distressing and isolating disease desperately need.

ESA provides support to eczema-affected individuals and families through social media platforms, the provision of practical resources and services, a national info-line, and community meetings. The organisation currently receives no formal funding but recognises the need for a national support network for people with severe eczema and is striving to provide this support.

ESA has recently launched a national initiative, *SOS – Save Us From Eczema*, to raise awareness of how severe eczema can be and call on the Federal Government to provide affordable access to new treatment options.

About Atopic Eczema

Atopic eczema is a chronic inflammatory skin condition characterised by skin that is red and itchy. But it is more than just a skin condition. It is an autoimmune disease caused by an overactive immune system, resulting in inflammation.

Eczema can vary in severity and symptoms may flare up or subside from day-to-day.⁸ Our members describe severe eczema itch as ‘being eaten alive by ants’, ‘a continual electric shock’ or ‘mosquito bites on top of sunburn’.

Atopic eczema can affect up to 25% of children and 7% of adults.⁹ In approximately 50% of cases of childhood eczema, the condition persists into adulthood and becomes a chronic, lifelong condition.¹⁰

Most patients with atopic dermatitis have mild-to-moderate disease that can be effectively managed. However, a significant proportion of patients develop severe symptoms, which include the presence of widespread skin lesions, an unbearable urge to itch, skin infections, agonising pain, and distress that significantly compromises quality of life.¹¹ This form of the disease is far more complex to treat.

Physical and Psychological Burden of Atopic Eczema

Atopic eczema is so much more than an irritating itch or rash. In its more severe forms, atopic eczema is often uncontrolled and responsible for significant physical and psychological distress.

In her evidence to the current House of Representatives Allergy and Anaphylaxis Inquiry on 19 November 2019, Professor Constance Katelaris, a Sydney based immunologist, said “This is a terrible disorder in its severe form, and any doctor knows that. These people are highly impacted by this condition. Their lives are miserable, their sleep is disturbed, and their family's life is bound up with treating these children and young adults day after day after day. It's a condition that is relentless, and it has a huge psychological impost.”¹²

Commonly, patients with severe atopic eczema are treated with corticosteroids or cyclosporin. Research indicates that many people with severe eczema report inadequate symptom control with itch severity remaining at 6.5 on a ten point scale, leaving 85% of patients suffering from frequent itch, 41.5% suffering from itch duration (up to or equal to 18 hours a day), more than half (55%) reporting sleep disturbances on five or more nights a week, and 21.8% experiencing clinically relevant anxiety or depression.¹³

Living with severe eczema impacts all aspects of life. Many of our members report feelings of social isolation, exhaustion and hopelessness. Sleep deprivation is common due to an unbearable and continual need to itch. Sleep disturbance can affect the whole family. This is a major risk factor for depression, anxiety and suicidal thoughts.

The continual need to itch makes it difficult to concentrate, negatively impacting education, work, social and family life. Our members report bullying at school, loss of work, being forced to change career, relationship breakdowns and loss of social connections. They also report hours spent moisturising, getting up in the middle of the night to bathe, being unable to swim with their children, and hours trying to recover from simple household chores that trigger an eczema attack.

Severe eczema can lead to repeat skin infections, repeated antibiotic use, and the need for immunosuppressant therapy which increases the risk of developing high blood pressure and cancer.¹

Australian research from 2018 found that 27,000 Australians are living with severe eczema. Many of these patients, who have been treated with corticosteroids and cyclosporin:¹⁴

- Reported that clinicians tell them “there is nothing we can do” (53% with severe eczema and 54% with very severe disease). *NB. This is no longer true with the advent of biologic therapy to treat severe eczema which is the focus of this submission.*
- Have significantly impacted quality of life in relation to self-esteem and confidence, leading to social isolation (46% with severe eczema and 40% with very severe disease).
- Experience significant impact on family relationships and intimacy with a partner (36% living with severe eczema and 45% with very severe disease).
- Experience physical symptoms causing regular sleep disturbance (85% with severe eczema and 95% with very severe disease).

Research from Europe reveals that among people living with atopic eczema:¹⁵

- 10.1% also have diagnosed depression;
- 17.6% also have diagnosed clinical anxiety; and
- 15% report thoughts of suicide.

A recent systematic review and meta-analysis found that patients with eczema are 44% more likely to exhibit suicidal ideation and 36% more likely to attempt suicide compared with patients without the condition.¹⁶

The psychological distress associated with atopic eczema is also reported by our members.

Financial Burden of Atopic Eczema

Many people with severe atopic eczema are restricted in their ability to work and fully contribute to society; incur significant out-of-pocket costs associated with specialist care and treatment; and are regular users of the health system through doctor consultations and hospitalisation.

- Out-of-pocket costs associated with atopic eczema have recently been calculated at €927 (approximately \$1,500) per patient per year in Europe.¹⁷
- Australian analysis found that out-of-pocket costs to patients with atopic eczema can be as high as \$2,000 per year.¹⁸
- Out-of-pocket costs in Australia are increasing as a growing number of people with atopic eczema elect to pay for prescription medication that is not subsidised through the PBS.
- Further indirect costs associated with atopic eczema include loss of income, time away from work, travel and cessation of employment.¹⁹
- Australian research revealed that the personal financial cost of managing eczema in children is greater than the cost for asthma, which is national health priority. This research revealed that those with severe atopic eczema require on average: 23.3 visits to doctors and are hospitalised for 6.5 days per year.²⁰

New biologic therapy needs to be subsidised through the PBS as soon as possible

The advent of a new biologic therapy called Dupixent to treat severe atopic eczema means that the suffering described above is no longer necessary.

In her evidence to the Parliamentary Inquiry on Allergy and Anaphylaxis, Professor Katelaris said, “We now have available and registered in this country a brand-new form of medication, a monoclonal antibody called dupilumab [Dupixent]. The trial data with this is nothing less than astounding and it has an incredibly good safety profile. While we have immunosuppressant agents that I and my colleagues have been dishing out for decades to these patients at this severe end, they come at a huge cost of side effects and potential toxicities. Dupilumab appears to be devoid of that.”¹²

Professor Katelaris told the inquiry that she has treated a dozen Australians with severe atopic eczema with Dupixent through an early access program provided by the manufacturer, saying, “It’s one of the happiest things I’ve ever done. These people walk in and say, ‘This is life changing.’ Two or three months down the track, you would never believe the photos that we took at the beginning. I am overwhelmed. I’ve seen the difference it has made.”¹²

Some of our members, who have received this medicine through an early access program, report to us that they are anxious about losing access to the therapy if it is not subsidised through the PBS. One of our members, who was actively planning suicide before he gained access to Dupixent, said that the treatment has been “life-changing” for him. He says that if his access to the therapy was withdrawn, he would effectively go back to being tortured and it would be very easy for him to again become suicidal.

While Dupixent is a high cost medicine, Professor Katelaris told the inquiry that “I understand they are high cost. But against that you have the side effects of long-term corticosteroids. These people who qualify for this have been on drugs like cyclosporin, Imuran, methotrexate or

mycophenolate. All these immunosuppressant drugs can work but they come at a huge cost – a possibility of cancers down the track, particularly skin cancers.

“Cyclosporin, in particular, can cause hypertension and renal disease. These drugs have to be used carefully, they have to be monitored very regularly, and they're not the answer. Drugs like dupilumab – I should say medications because it's not a drug; it's an antibody – target specific molecules that drive this Th2, this allergic response. And because they are such clean drugs – they target the right molecule – we don't see the fallout in side effects like you get with, for instance, corticosteroids.”¹²

In summary, there is a strong case for subsidising Dupixent through the PBS, as it will vastly improve the lives of Australians with severe atopic eczema, while also realising sizeable savings to the Australian health system in terms of eliminating the direct and indirect healthcare costs associated with current treatment practices.

References

1. Cyclosporin Australian Product Information. Available from the Therapeutic Goods Administration <http://bit.ly/384NMOR>
2. Australian Government Department of Human Services. *Pharmaceutical Benefits Schedule Item Reports*.
3. Australian Government Department of Health. Australian Register of Therapeutic Goods. *Dupilumab Product Information*.
4. Commonwealth of Australia. *Health Budget 2019–20*. Available at: https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/BudgetReview201920/Health
5. Pharma in Focus. *PBS Listing Drop in 2019*. 3 December 2019. Available at: [https://www.pharmainfocus.com.au/news.asp?newsid=15768&u=am1vcnRvbkbldGhpY2Fsc3RyYXRIZ2llcy5jb20uYXU=](https://www.pharmainfocus.com.au/news.asp?newsid=15768&u=am1vcnRvbkbldGhpY2FsY2Fsc3RyYXRIZ2llcy5jb20uYXU=)
6. Australian Government Department of Health. *Public Summary Document (PSD) July 2019 PBAC Meeting*. Available at: <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2019-07/dupilumab-injection-300-mg-in-2-ml-single-use-pre-filled>
7. Hon. Greg Hunt MP, Minister for Health PBS Media Releases. Available at: <https://www.greghunt.com.au/media/media-releases/>
8. The Australasian College of Dermatologists. *Atopic Dermatitis*. Available at: <https://www.dermcoll.edu.au/atoz/atopic-dermatitis/>
9. Harris VR, Cooper AJ. *Atopic Dermatitis: The New Frontier*. Medical Journal of Australia. 2017; 207: 351-6
10. Margolis JS, et al. *Persistence of mild to moderate atopic dermatitis*. JAMA Dermatol. 2014; 150:593-600.

11. Spergel JM, Lio PA. *Management of severe atopic dermatitis (eczema) in children*. 2019. Available at: <https://www.uptodate.com/contents/management-of-severe-atopic-dermatitis-eczema-in-children>
12. House of Representatives Standing Committee on Health, Aged Care and Sport, Allergies and anaphylaxis, Tuesday 19 November 2019.
13. Simpson EL, et al. Patient burden of moderate to severe atopic dermatitis (AD): insights from a phase 2b clinical trial of dupilumab in adults. *J Am Acad Dermatol* 2016;74:491-8
14. ICCDR. 2018. *Atopic Dermatitis Australian Study*. PEEK. 1:4. Available at: https://www.cc-dr.org/wp-content/uploads/2018/05/2018AUADE_FULL-REPORT.pdf
15. Dalgard FJ, et al. *The psychological burden of skin diseases: a cross-sectional multicentre study among dermatological out-patients in 13 European countries*. *J Invest Dermatol*. 2015;135: 984-91
16. Sandhu JK et al. Association Between Atopic Dermatitis and Suicidality: A Systematic Review and Meta-analysis. *JAMA Dermatol*. 2019 Feb 1;155(2):178-187
17. Zink AGS, et al. *Out-of-pocket costs for individuals with atopic eczema: a cross-sectional study in nine European countries*. *Acta Derm Venereol*. 2019; 99: 263-7.
18. Jenner N, et al. *Morbidity and cost of atopic eczema in Australia*. *Australas J Dermatol*. 2004.
19. International Alliance of Dermatology Patient Organisation. *Atopic Dermatitis: A collective global voice for improving care*. 2018. Available from: <https://globalskin.org/images/Publications/AtopicDermatitis.pdf>
20. Su JC. et al, *Atopic eczema: its impact on the family and financial cost*. *Archives of Disease in Childhood*. 1997; 76:159-162