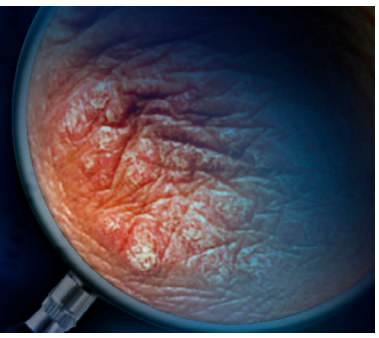
Dermatology Practice Review™



Making Education Easy

Issue 38 - 2025

In this issue:

Abbreviations used in this issue:

AD = atopic dermatitis; **AusPAR** = Australian Public Assessment Report; **CSU** = chronic spontaneous urticaria; **DEB** = dystrophic epidermolysis bullosa; **EADV** = European Academy of Dermatology and Venereology; **FDA** = US Food & Drug Administration; **GLP-1 RA** = glucagon-like peptide-1 receptor agonist; **IL** = interleukin; **JAK** = Janus kinase; **PBAC** = Pharmaceutical Benefits Advisory Committee; **PBS** = Pharmaceutical Benefits Scheme; **TGA** = Australian Therapeutic Goods Administration.

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Welcome to the 38th issue of Dermatology Practice Review.

This Review covers news and issues relevant to clinical practice in dermatology. It will bring you the latest updates, both locally and from around the globe, in relation to topics such as new and updated treatment guidelines, changes to medicines reimbursement and licensing, educational, professional body news and more. Finally, on the back cover you will a summary of upcoming local and international educational opportunities including workshops, webinars and conferences.

We hope you enjoy this Research Review publication and look forward to hearing your comments and feedback.

Kind Regards,

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Editor
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Clinical Practice

Systemic corticosteroid use in atopic dermatitis: A position paper to inform safer clinical practice and policy

In order to address the ongoing issue of persistent and widespread routine use of systemic corticosteroids to manage atopic dermatitis (AD), in direct opposition to clinical guideline recommendations, an expert group of US dermatology experts was convened to clearly define short-term use and develop consensus recommendations. A review of the literature revealed the extent of corticosteroid overuse in AD, with approximately 20% of US patients 12 years or older receiving systemic corticosteroid therapy - predominantly with orally administered agents - including more than one-quarter who received medium-to-long-term treatment exceeding thirty days. The expert panel highlighted the substantial and potentially irreversible harms associated with systemic corticosteroid treatment - even brief use with relatively low doses (< 20 mg/day prednisone equivalent) – with studies showing significantly increased risks of sepsis, venous thromboembolism, fractures and serious complications such as avascular necrosis and adrenal suppression, and emphasised that clinicians should not assume that short-term systemic corticosteroid use is safe. The discord between clinical guideline recommendations and clinical practice was attributed primarily to ambiguity in the definition of "short-term" that resulted in harmful prescribing practices with repeated systemic corticosteroid use and delayed access to advanced steroid-sparing therapeutics such as biologics or Janus kinase (JAK) inhibitors.

The fundamental practice standards proposed via a modified Delphi process were that:

- Systemic corticosteroid exposure should be minimised, with a strict maximum of 3-4 weeks
- Any exposure to systemic corticosteroids (even a single injection or short taper) should be considered a trial of systemic therapy and qualify for transition to advanced therapies

The biologically anchored classification of systemic corticosteroid duration in AD (short-term <3-4 weeks; long-term ≥ 3- 4 weeks) was set to align with the endocrine risk of hypothalamic–pituitary–adrenal axis suppression and reflects findings from the 2024 Endocrine Society guidance. The experts concluded that adoption of these standards in routine clinical practice for patients with moderate-to-severe AD would ensure safer and guideline-concordant care.

J Invest Dermatol. 2025; Sep 6. Online ahead of print

European Guideline (EuroGuiDerm) on atopic eczema: Living update

This publication details the second update to the 2022 living EuroGuiDerm Guideline for the systemic treatment of AD. Designed for use by physicians, the evidence- and consensus derived guidelines inform the optimal use of topical, antipruritic and systemic therapies plus phototherapy and photochemotherapy in a stepped-care fashion according to disease severity and advise considerations for specific populations such as pregnant women and children, as well as other aspects of care including dietary interventions and complementary medicine. Significant changes in the management paradigm in the three years since the original iteration, specifically in the realm of systemic therapeutics with regulatory approvals/extensions for three advanced biologic/targeted small molecules necessitated the modernisation.

Specifically, pertinent changes to the guideline include:

- Incorporation of the interleukin (IL)-13 inhibitor lebrikizumab into the treatment algorithm for both adult and adolescent/paediatric patients with severe disease uncontrolled by topical therapies
- The addition of the JAK inhibitors baricitinib and abrocitinib as therapeutic options for severe disease

A summary of the stepped-care treatment algorithm for adult and paediatric patients per the most recent EuroGuiDerm guidelines can be found in the table below. Strong recommendations support the use of each intervention with the exception of off-label azathioprine and methotrexate, glucocorticosteroids, as well as wet wraps, which all have weak recommendations. Systemic glucocorticosteroids are not included in the treatment algorithm for paediatric/adolescent patients.

Severity

	Stepped-care treatment algorithm for patients with AD		
Mild	Emollients	Avoidance of allergens	Educational programs
	Continue measures recommended above and select from (if appropriate):		
	Topical corticosteroids	Topical calcineurin inhibitors	Wet wraps
	Continue measures recommended above and select from (if appropriate):		
	Topical corticosteroids	Topical calcineurin inhibitors	NB-UVB and median dose UVA1 Psychosomatic counselling
Severe	Continue measures recommended above and select from (if appropriate):		
	Biologics: Dupilumab@ Lebrikizumab^ Tralokinumab^	JAK inhibitors: Abrocitinib^ Baricitinib# Upadacitinib^	Conventional drugs: Azathioprine Ciclosporin* Methotrexate Systemic glucocorticosteroids**

** Weak recommendation supports use in adult patients only. ^ Licensed for ≥ 12 years of age.

Licensed for ≥ 2 years of age. @ Licensed for ≥ 6 months of age. * Licensed for ≥ 16 years of age.

NB-UVB = narrow-band ultraviolet B; **UVA1** = ultraviolet A1

In addition to refurbishment of the overall treatment recommendations, the document provides tables detailing the appropriate dosing, monitoring, time to response and relapse, and suitability for special populations for each systemic therapy.

The full guideline can be downloaded from the European Dermatology Forum website

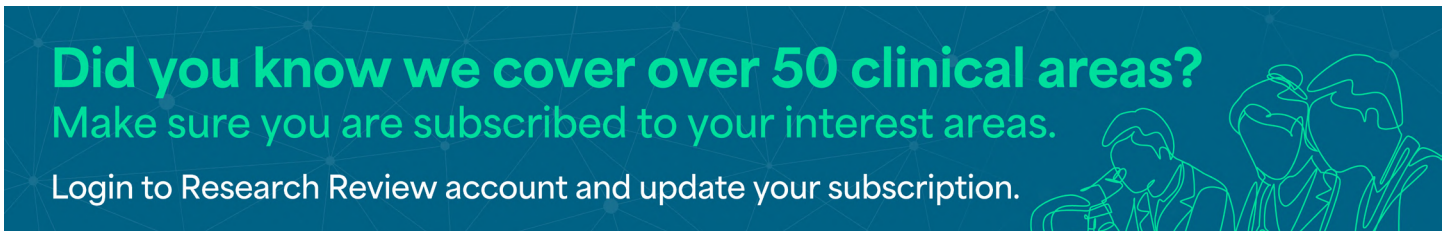
J Eur Acad Dermatol Venereol. 2025;39(9):1537-66

Earn CPD

The Australasian College of Dermatologists (ACD) has approved all Dermatology Research Reviews for accreditation as a Category 1 Education Activities - Professional Reading and Study. Activity should be logged in hours. For further information please click here.

Australian College of Rural and Remote Medicine (ACRRM) Professional Development Program (PDP) participants can claim Educational Activity hours in the self-directed learning category for reading Research Reviews. More info.

The Royal Australian College of General Practitioners (RACGP) members can **Quick Log** (self-record) a CPD activity such as reading a Research Review publication or watching a video under the CPD activity type 'Educational Activites'. More information is available at RACGP - Your myCPDhome member resources



Regulatory News

TGA registrations

New registrations

The Australian Therapeutic Goods Administration (TGA) recently approved a novel prescription-only cream - **delgocitinib** (Anzupgo®; 20 mg/g cream tube; LEO Pharma Pty Ltd) - for the treatment of moderate-to-severe chronic hand eczema in adults for whom topical corticosteroids are inadequate or inappropriate. Anzupgo® is available in 15 g and 60 g tubes and should be stored below 25 degrees Celsius.

Product and Consumer Medical Information can be downloaded here.

Delgocitinib cream has been approved by several global regulatory bodies for recalcitrant moderate to severe chronic hand eczema including in the European Union, the United Kingdom and most recently, the US.

Dermatology medicines under evaluation

The TGA are currently evaluating an application from Novartis Pharmaceuticals Australia that seeks approval of the oral Bruton's tyrosine kinase (BTK) inhibitor remibrutinib for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite antihistamine treatment.

Remibrutinib (Rhapsido®) was recently granted US Food and Drug Administration (FDA) approval for this indication, based on demonstration of superior relief from itch and alleviation of urticaria activity versus placebo in the phase 3 REMIX-1 and REMIX-2 trials (FDA Novel Drug Approvals for 2025), offering an effective alternative to the currently available injectable therapies. It is also under consideration from multiple other regulatory bodies across the globe including in the European Union, Japan, and China for this indication and is in clinical development for two other dermatologic conditions (chronic inducible urticaria and hidradenitis suppurativa), as well as food allergy.

The TGA Prescription medicine under evaluation summary can be found here

AusPAR for omalizumab biosimilar

The Australian Public Assessment Report (AusPAR) for the omalizumab biosimilar Omlyclo® is now available. The approved therapeutic use for Omlyclo® in dermatology is the treatment of CSU in adults and adolescents (≥ 12 years of age) who remain symptomatic despite H1 antihistamine treatment and one of H2 receptor antagonists, montelukast or doxepin.

All AusPARs can be downloaded from the TGA website here

PBS listings

There have been several expanded Pharmaceutical Benefits Scheme (PBS) listings recently, providing access to government subsidised medication for more patients with dermatological conditions including:

- **Dupilumab** (Dupixent®; 1.14 mL & 2 mL injection and pen devices) for the treatment of chronic severe AD (and uncontrolled severe asthma)
- **Secukinumab** (Cosentyx®; 2 mL injection & pen device) for severe chronic plaque psoriasis and moderate-to-severe hidradenitis suppurativa (plus several rheumatological indications including severe psoriatic arthritis and ankylosing spondylitis)
- **Adalimumab** (multiple brands; all strengths and formulations) for paediatric patients with severe chronic plaque psoriasis

Novel PBS listings include both the **omalizumab** originator Xolair® and the biosimilar Omlyclo® for the treatment of patients with severe CSU (as well as uncontrolled severe and severe allergic asthma). Several strengths of Xolair® are available in a pen device (75mg/0.5 mL, 150 mg/mL & 300 mg/2mL) - the 150 mg/mL injection in 1 mL syringe has been delisted. Two strengths of Omlyclo® are available in pre-filled syringes (75 mg/0.5 mL and 150 mg/mL).

An **ustekinumab** biosimilar (Steqeyma®) is now PBS listed for the treatment of severe chronic plaque psoriasis (as well as other rheumatological and gastroenterological indications).

Restrictions to PBS subsidy of **nivolumab** (Opdivo®) and **ipilimumab** (Yervoy®) for Stage 3 or 4 malignant melanoma have changed. Authority applications for initial and continuing treatment with nivolumab can be made either in real-time using the Online PBS Authorities system or by telephone. Prescriptions for ipilimumab induction treatment are Authority required.

Full PBS subsidy conditions can be found on the PBS website. Most initial and continuing treatment Authority applications can be made in real-time using the Online PBS Authorities system (more information can be found at Services Australia).

Pricing dispute precludes PBS listing of two eczema drugs

Despite positive Pharmaceutical Benefits Advisory Committee (PBAC) recommendations for PBS listing of two eczema drugs in 2024, neither lebrikizumab (Ebglyss®) or abrocitinib (Cibinqo®) will be publicly funded for Australian patients with severe disease. In recognition of the need for more systemic therapeutic agents for patients with severe AD – plus a similar efficacy of both agents versus dupilumab - the PBAC supported the PBS listing of the IL-13 inhibitor lebrikizumab for adolescents and adults and the JAK1 inhibitor abrocitinib for adults last year, with the caveat that they be cost-minimised to the lowest cost alternative of dupilumab or upadacitinib. Subsequent failed pricing negotiations have resulted in Eli Lilly and Pfizer withdrawing their applications to list lebrikizumab and abrocitinib, respectively.

More information is available on the PBS medicine Status Website here and here

Lebrikizumab has approval from multiple regulatory bodies globally for the treatment of moderate-to-severe AD that is not well controlled with topical therapies in patients at least 12 years of age, including in the European Union, the United Kingdom, the US, Japan and Canada and is publicly subsidised in some places (e.g., Italy and the UK).

PBAC recommendations

At its July 2025 meeting the PBAC recommended novel PBS listings for the following medications:

- **Calcipotriol with betamethasone cream** (Wynzora®; Actor Pharmaceuticals) for the treatment of chronic stable plaque type psoriasis vulgaris in patients who have not adequately responded to potent topical corticosteroid monotherapy. The PBAC concluded that the cream formulation was another topical alternative with a comparable efficacy to the foam and ointment formulations already PBS listed for this patient population
- **A new etanercept biosimilar** (Nepexto®; Maxx Pharma; 50 mg single use pre-filled syringe) for the same indications and under the same circumstances as the reference biologic Enbrel®, including the treatment of severe chronic plaque psoriasis. An administrative note on the proposed listing encourages use of a biosimilar brand for treatment naïve patients
- **Tacrolimus ointment** (aZematop®; 0.1% ointment; Arrotex Pharmaceuticals) for the treatment of moderate-to-severe AD. This recommendation was based on recognition of the multiple issues with currently available tacrolimus compounded products as well as a need for a therapeutic option for patients unable to use topical corticosteroid therapies

A request from Galderma Australia for a General Schedule Authority Required PBS listing of **nemolizumab** (Nemluvio®) for the treatment of patients with severe AD affecting the whole body, face, and/or hands was not supported by the PBAC. While they acknowledged a need for treatments with different mechanisms of action, data suggesting comparable efficacy to dupilumab was based on a dosing schedule not TGA approved.

PBAC recommendations will be provided to the Federal Government for a final decision on public funding.

Read more here

Upcoming PBAC agenda items

At the next three-day meeting, scheduled for November 2025, the PBAC will consider the following requests for new PBS listings:

- A new strength of **bimekizumab** (Bimzelx®; 320 mg in 2 mL single-use pre-filled pen) for severe chronic plaque psoriasis
- A new gel form of **calcipotriol with betamethasone** for the treatment of chronic stable plaque type psoriasis vulgaris (Actobet®)
- **Glycopyrronium cream** (Axhidrox®) for the treatment of adult patients with severe primary axillary hyperhidrosis
- **Spesolimab** (Spevigo®) for the prevention of generalised pustular psoriasis flares in patients aged ≥ 12 years who have a high risk of generalised pustular psoriasis flares due to their background flare history

The public agenda for this meeting is available online here.

News in Brief

Updated label for DEB topical gene therapy in the US

The topical gene therapy beremagene geperpavec-svdt (Vyjuvek®) is now approved for US patients of all ages with wounds from dystrophic epidermolysis bullosa (DEB), with the FDA recently expanding the approved indication from patients at least six months of age to from birth. The revised label also makes the treatment more convenient, with the requirement for application

A relevant press release from Krystal Biotech can be read here

Morpheus-Melanoma neoadjuvant immunotherapy trial results

Results from the international phase 1b/2 Morpheus-Melanoma trial may lead to a novel standard of care for resectable melanoma, demonstrating a comparable efficacy but improved safety profile for neoadjuvant tobemstomig versus nivolumab plus ipilimumab in patients with Stage 3 disease. The trial also evaluated the combination of tobemstomig plus tiragolumab, and atezolizumab plus tiragolumab.

Nat Med. 2025; Sep 24. Online ahead of print

GLP-1 RAs linked to hair loss

As the prescribing of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) such as semaglutide and tirzepatide continues to expand beyond type 2 diabetes with indications for weight management and demonstrated benefits in cardiovascular and kidney disease, more evidence regarding the side effect profile also accumulates. Recently, a retrospective analysis of real-world data from almost half a million US patients prescribed a GLP-1 RA in the ten-year period spanning 2014 to 2024 found a substantially increased incidence of androgenic alopecia and nonscarring hair loss compared to individuals not prescribed a GLP-1 RA. This observation may be attributed to rapid weight loss as opposed to a direct drug toxicity.

This data was presented at the European Academy of Dermatology and Venereology (EADV) 2025 Congress (EADV 2025 Congress website).

Investigational IL-23 inhibitor bests deucravacitinib for psoriasis

Promising data for icotrokinra - a novel oral peptide that inhibits the IL-23 receptor – has been reported from the phase 3 ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2 trials in patients with moderate-to-severe plaque psoriasis. Pooled data from the active comparator trials - presented at the EADV 2025 Congress - revealed that icotrokinra elicited superior skin responses than both placebo and deucravacitinib, with significantly higher rates of investigator global assessment (IGA) 0/1 and Psoriasis Area and Severity Index score of 90% (PASI 90) after 16 weeks of treatment. In addition, icotrokinra exhibited a very tolerable safety profile with particularly low rates of infections and infestations.

More information about the trials can be found on the clinicaltrials.gov website (NCT06143878 & NCT06220604).

Conferences, Workshops, and CPD

The Australasian College of Dermatologists
DermNet New Zealand
Australian Dermatology Nurses' Association
COMS - Conferences and Meetings on Dermatology

Research Review Publications

Dermatology Research Review with Dr Warren Weightman

Hidradenitis Suppurativa Research Review with Associate Professors John Frew and Erin McMeniman

Melanoma Research Review with Professors Michael Henderson and Peter Hersey

Psoriasis Research Review with Dr Rebecca Nguyen and Associate Professor John Frew

Skin Cancer Research Review with Dr David Simpson

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