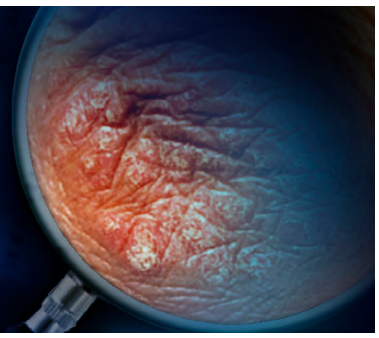
Dermatology Practice Review™



Making Education Easy

Issue 36 - 2025

In this issue:

Abbreviations used in this issue:

ACD = Australasian College of Dermatologists;
AusPAR = Australian Public Assessment Report; **ctDNA** = circulating tumour DNA;
EMA = European Medicines Agency; **FDA** = US Food & Drug Administration;
HS = hidradenitis suppurativa;
IHS4 = International Hidradenitis Suppurativa Severity Scoring System;
PBS = Pharmaceutical Benefits Scheme;
TGA = Australian Therapeutic Goods Administration.

Welcome to the 36th 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 find our COVID-19 resources for Dermatologists, and 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,

Dr Janette Tenne
Editor
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Clinical Practice

Australian Melanoma Clinical Guidelines being overhauled

The Cancer Council of Australia have published national clinical practice guidelines for the diagnosis and management of melanoma since 2016, with annual updates to incorporate novel treatments and diagnostic techniques. The evidence-based guidelines address the identification and management of high-risk individuals, diagnosis, biopsy technique, the treatment of primary disease and lentigo maligna, as well as considerations for treatment in special populations such as children and pregnant women. Briefly, the document advocates for early detection and accurate diagnosis of cutaneous malignancy and emphasises employment of appropriate wide local excision with/without sentinel node biopsy according to melanoma thickness.

Now, the guidelines are being overhauled in stages by a Guidelines Working Party comprised of experts from the Melanoma Institute of Australia in collaboration with Cancer Council Australia, with draft updates available in phases for public consultation prior to formulation of the final document. Feedback on the proposed modernised first six chapters is currently undergoing consideration. The next section of updated chapters is expected to be available on the 15th July.

The latest draft iteration of the first six chapters as well as information about how to submit feedback can be found on the Cancer Council Australia website

Earn CPD

Royal Australasian College of Physicians (RACP) MyCPD participants can claim the time spent reading and evaluating research reviews as CPD in the online MyCPD program. Please contact MyCPD@racp.edu.au for any assistance.

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 Activities'. More information is available at RACGP - Your myCPDhome member resources.

European S2k guidelines for hidradenitis suppurativa/acne inversa part 2: Treatment

Updates to the 2015 European S2K guidelines for hidradenitis suppurativa (HS) acne inversa have recently been published in two parts. The document discussed here details modernised treatment recommendations - necessitated by evidence for the efficacy of novel pharmacological agents - and provides supporting management algorithms for both inflammatory and non-inflammatory forms of the disease. Developed by a multidisciplinary panel of experts convened by the European Academy of Dermatology and Venereology (EADV) and the European Dermatology Forum (EDF) utilising a Delphi procedure, the updated advice aims to inform the selection of optimal therapy for patients with HS/acne inversa according to disease severity.

The pivotal changes to the guidelines include a novel classification system, whereby inflammatory disease is stratified as mild, moderate or severe using the International Hidradenitis Suppurativa Severity Scoring System (IHS4) and disease predominantly non-inflammatory is graded as stage 1 to 3 by Hurley staging. With regard to treatment, the main intervention for inflammatory disease is medical with removal of irreversible tissue damage, if necessary, whereas surgical procedures are the main focus for non-inflammatory cases. The document emphasises several other novel points such as the comparable effectiveness of systemic oral tetracyclines to combination clindamycin plus rifampicin. It further notes that most of the possible suggested therapeutic options – excepting antibiotic monotherapy and the biologics adalimumab, secukinumab and bimekizumab for moderate-to-severe active disease in patients who mount an inadequate response to conventional therapy - are not approved for the treatment of HS by most global regulatory bodies and are thus considered off label therapies.

The latest iteration of the treatment algorithm for active inflammatory HS per the European S2k guidelines follows:

Line of therapy	Mild-to-moderate IHS4 1-10	Moderate-to-severe IHS4 4 - >11
First	• Three-month course of orally administered tetracycline antibiotic e.g., doxycycline or lymecycline* • Clindamycin monotherapy 2 x 300 mg/day orally for 12 weeks	
	• Clindamycin 1% gel/lotion/cream • Resorcinol 15% peel 2x/day • Intralesional triamcinolone acetonide 10-40 mg/mL injection/lesion^ (± systemic therapy)	• Clindamycin + rifampicin – both 2 x 300 mg/day for 10-12 weeks • Intravenous clindamycin monotherapy 3 x 600 mg/day for 5 days
Second	• Zinc gluconate 90 mg/day orally as long-term maintenance**	• Adalimumab 40 mg/week or 80 mg every 2 weeks*** • Secukinumab 300 mg every 2 or 4 weeks • Bimekizumab 320 mg every 2 weeks for 16 weeks then every 4 weeks
Third	• Acitretin 0.25-0.50 mg/kg/day • Hormonal antiandrogens e.g., cyproterone acetate and oestrogens& • Metformin	
	• Dapsone 25-200 mg/day for at least three months • Photodynamic therapy	• Infliximab 5 mg/kg every 8 weeks • Adalimumab biosimilars • Brodalumab 210 mg every 2 weeks • Povorcitinib 15-180 mg/day • Upadacitinib 15 mg/day • Spesolimab 1,200 mg every 2 weeks • Ustekinumab 45 mg at weeks 0,4, 16 & 28 • Anakinra 100 mg/day • Ciclosporine 2-6 mg/kg/day • Ertapenem 1 g/day intravenously as a six-week course#
Later-line		• Ciclosporine 2–6 mg/kg/day for 6 weeks–7 months (for recalcitrant disease)

* Should not be administered to pregnant women or children younger than 9 years

** Dose may be lowered according to results and to mitigate gastrointestinal tract side effects

*** Adult and paediatric patients > 12 years

Only for severe disease and for down-staging prior to surgery

^ As monotherapy or in combination with systemic treatments

& As an adjust treatment for female patients with polycystic ovary syndrome (PCOS), menstrual abnormalities, signs of hyperandrogenism or upper normal or high serum levels of dehydroepiandrosterone, androstenedione and/or sexual hormone-binding proteins

The treatment algorithm for inactive (non-inflammatory) HS can be found in the guidelines.

J Eur Acad Dermatol Venereol. 2025;39(5):899-941

Earn CPD

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Regulatory News

TGA registrations

New registrations

The Australian Therapeutic Goods Administration (TGA) have recently approved several novel medications and expanded the indications for previously approved drugs relevant to clinicians treating patients with dermatological conditions including:

Several generic brands of **apremilast** (Otezla®; Amgen Australia Pty Ltd) from Cipla Australia:

- Cipla apremilast (30 mg tablet blister pack; ARTG ID 460187)
- Cipla apremilast titration pack (4 x 10 mg plus 4 x 20 mg plus 19 x 30 mg tablets; ARTG ID 444611)
- Ozeprem apremilast (30 mg tablet blister pack; ARTG ID 444612)
- Ozeprem apremilast titration pack (4 x 10 mg plus 4 x 20 mg plus 19 x 30 mg tablets; ARTG ID 444613)

All novel apremilast products are approved for the same indications as the brand-name Otezla®, namely, the treatment of signs and symptoms of active psoriatic arthritis in adult patients, the treatment of plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy and the treatment of oral ulcers associated with Behçet's Disease in patients who are candidates for systemic therapy. These generic brands have not yet been listed on the Pharmaceutical Benefits Scheme (PBS).

The approved indications for the interleukin (IL)-17A/17F inhibitor **bimekizumab** (Bimzelx®; 320 mg/2 mL solution for injection; UCB Australia Pty Ltd) has been expanded to include the treatment of moderate-to-severe HS in patients who have an inadequate response to conventional systemic therapy. Other indications include plaque psoriasis, psoriatic arthritis, non-radiographic axial spondyloarthritis and non-radiographic axial spondyloarthritis. The PBAC recommended the PBS subsidy of **bimekizumab** for this new indication at their May intracycle meeting.

A number of new sunscreen products have been recently added to the ARTG including:

- Advent Calendar (Naked Sundays)
- Neutrogena Ultra Sheer Fluid Sunscreen Age Shield (Johnson & Johnson Pacific Pty Ltd)
- 3 lin 1 Sunscreen setting spray & Hydration mist (The Quick Flick Pty Ltd)
- Nifty Fifty Sunstick (Go-To Skincare Pty Ltd)
- SPF50+ Face Mist (Outside Beauty & Skincare Pty Ltd)
- SPF50+ Mineral Sunscreen (Clinical Aesthetics Pty Ltd)
- Sun Zapper Pure Zinc Anti-Mozzie Sunscreen SPF50 (Veganic SKN)
- Sun Zapper Pure Zinc Sunscreen SPF50
- Sun Motion SPF50+ Sports Sunscreen (Sun Motion)
- Sun Buster Gel Sunscreen (The Weringa Group Pty Ltd)
- Natural sunscreen SPF50+ (Netura Pty Ltd)
- ZINC SPF50+ Green, White & Yellow (Sunlife Products Pty Ltd)

Read more here

Dermatology medicines under evaluation

The TGA are currently reviewing a new medication application from LEO Pharma for **delgocitinib** (Anzupgo®) cream for the treatment of chronic hand eczema in adults. The topical pan-Janus kinase (JAK) inhibitor cream is also being evaluated by the US Food & Drug Administration (FDA) and has been approved for the treatment of moderate to severe chronic hand eczema in adults for whom topical corticosteroids are inadequate or inappropriate in the European Union, United Kingdom, Switzerland and the United Arab Emirates.

The Prescription medicine under evaluation summary can be found here

AusPARs for ritlecitinib & garadacimab

The Australian Public Assessment Reports (AusPARs) for the following medications are now available:

- **Ritlecitinib** (Litfulo®; Pfizer Australia Pty Ltd). The approved therapeutic use for ritlecitinib is the treatment of severe alopecia areata in adults and adolescents at least 12 years of age
- **Garadacimab** (Andembry®; CSL Behring). Andembry is indicated for routine prevention of recurrent hereditary angioedema attacks in patients aged 12 years and older with C1-esterase inhibitor deficiency or dysfunction.

All AusPARs can be downloaded from the TGA website here

PBS listings

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

- Several new strengths of an **adalimumab** biosimilar (Hyrimoz®; 40 mg/0.4 mL syringe and pen device for injection and 80 mg/0.8 ml pen device for injection) for severe chronic plaque psoriasis and moderate to severe HS, as well as several rheumatological indications
- **Risankizumab** (Skyrizi®; 150 mg/ml pen device for injection) for the treatment of severe psoriatic arthritis
- **Clobetasol propionate** (Xobet®; 0.05% cream and ointment) for the treatment of corticosteroid-responsive dermatoses

From the 1st June, **secukinumab** (Cosentyx®) no longer has a PBS listing for Grandfather arrangements for patients with moderate-to-severe HS.

Full PBS subsidy conditions can be found on the PBS website. Most initial and continuing treatment Authority applications can be made either in real-time using the Online PBS Authorities system.

Earn CPD

Nursing and Midwifery Board of Australia (NMBA) Journal reading and watching videos (including Research Reviews) may be considered a self-directed activity set out in the NMBA Registration Standard: Continuing Professional Development. One hour of active learning will equal one hour of CPD. Details at NMBA CPD page.

PBAC recommendations

At its March 2025 meeting the Pharmaceutical Benefits Advisory Committee (PBAC) recommended the PBS listing of the following:

- A new 50 mg strength of **dapsone** (Dapsomed®) under the same conditions as the currently listed strengths for the treatment of dermatitis herpetiformis, leprosy and actinomycotic mycetoma
- Two new doses of **dupilumab single dose pre-filled syringes** (Dupixent®; Sanofi-Aventis; 200 mg in 1.14 mL and 300 mg in 2 mL) for the treatment of severe atopic dermatitis in paediatric patients (< 12 years)
- A new strength and form of **omalizumab** (300 mg/2 mL pre-filled pen; Xolair®; Novartis Pharmaceuticals Australia) under the same conditions as the current PBS listings of the pre-filled syringe form for the treatment of severe chronic spontaneous urticaria, as well as uncontrolled severe and severe allergic asthma
- Several new biosimilars including:
  - A new **infliximab biosimilar** (Ixifi®) for the same indications as existing PBS-listed biosimilar brands of infliximab (Inflectra® and Renflexis®), including severe chronic plaque psoriasis
  - A new biosimilar brand of **omalizumab** (Omlyclo®; 75 mg in 0.5 mL and 150 mg in 1 mL pre-filled syringe; Celltron Healthcare Australia) for the same indications as the PBS-listed reference biologic, Xolair®, including severe chronic spontaneous urticaria
  - A new biosimilar brand of **ustekinumab** (Epyztek®; 45 mg in 0.5 mL and 90 mg in 1 mL prefilled syringes and 130 mg in 26 mL solution for intravenous infusion; Samsung Bioepis Au) under the same circumstances as the PBS-listed reference biologic, Stelara®, for the same indications including severe chronic plaque psoriasis and severe psoriatic arthritis

The PBAC also supported changing the authority level of **subcutaneous infliximab** (Remsima® SC) from Authority Required (Written or Telephone/ Online) to Authority Required (Streamlined) for the continuing treatment listings of all the requested indications, including severe chronic plaque psoriasis. In addition, the 2021 recommendation for PBS listing of **secukinumab** (Cosentyx®; pre-filled syringes and pens) for paediatric psoriasis was rescinded following the failure of Novartis Pharmaceuticals to accept the positive recommendation. Another positive recommendation for the PBS listing of **secukinumab** pre-filled pens and syringes for multiple indications including severe chronic plaque psoriasis will be reviewed at the July PBAC meeting for the same reason.

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

Read more here

Upcoming PBAC agenda items

On the agenda for consideration at the upcoming July PBAC meeting are the following requests for new PBS listings:

- **Calcipotriol with betamethasone dipropionate cream** (Wynzora®) for the treatment of chronic plaque type psoriasis vulgaris in patients who have not adequately responded to potent topical corticosteroid monotherapy
- A new **etanercept biosimilar** (Nepexto®) and a new **infliximab biosimilar** (Remsima®), both for the same indications as other approved biosimilar brands, including severe chronic plaque psoriasis
- **Nemolizumab** (Nemluvio®; pre-filled dual-chamber pen) for the treatment of patients with severe atopic dermatitis affecting the whole body, face, and/or hands
- **Tacrolimus ointment** (Zematop®; Arrotex Pharmaceuticals) for the treatment of moderate to severe atopic dermatitis

In addition, the utilisation of PBS listed **cemiplimab** (Libtayo®; Medison Pharma Australia; 350 mg in 7 mL solution concentrate for intravenous infusion) for metastatic or locally advanced cutaneous squamous cell carcinoma will be assessed by a sub-committee Drug Utilisation Sub Committee (DUSC) analysis.

Read more here

Recent dermatology drug approvals in the EU

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) have recently made recommendations for several novel medications relevant to patients with a dermatological condition.

Positive recommendation was given for the approval of two **ustekinumab biosimilars** (Qoyvolma® & Usymro®) for the treatment of plaque psoriasis in paediatric and adult patients, as well as the treatment of psoriatic arthritis, Crohn's disease and ulcerative colitis in adults

Marketing authorisation for the following novel medications were not supported:

- **Clascoterone** (Winlevi®) for the topical treatment of acne vulgaris. In Australia, clascoterone 1% w/w cream tube was approved by the TGA for the topical treatment of acne vulgaris in patients at least 12 years of age in March 2024 (Australian Prescription Medicine Decision Summary)
- Resminostat (Kinselby®) for the treatment of advanced stage mycosis fungoides and Sezary syndrome

More information can be found on the EMA's website

News in Brief

BRAF inhibitor gel promising for acneiform rash

Results from a phase 2 trial of an investigational topical BRAF inhibitor gel - LUT014 gel - indicate that it is efficacious for alleviation of acneiform rash associated with epidermal growth factor receptor (EGFR)-targeted drug treatment in patients with colorectal cancer, and may improve cancer treatment compliance and oncological outcomes. The placebo-controlled trial evaluated two doses of LUT014 gel (0.1% and 0.03%) in 118 patients with colorectal cancer who developed a moderate to severe rash while undergoing treatment with cetuximab or panitumumab. After 28 days of treatment both doses of the gel demonstrated efficacy versus placebo by a composite outcome measure (comprised of a ≥ one-grade reduction in rash severity and/or improvement in at least five skin-specific, health-related quality-of-life criteria), boosting the treatment success rate from 33% to 56% with the 0.03% and 74% with the 0.03% and 0.1% formulations, respectively.

Results were presented at the recent 2025 American Association for Cancer Research (AACR) Annual Meeting (Abstract CT018) and are published in a supplement to *Cancer Research*.

ctDNA analysis predicts resected melanoma recurrence

A biomarker analysis of the COMBI-AD trial of adjuvant dabrafenib plus trametinib versus placebo for resected *BRAF*^{V600}-mutant stage 3 melanoma finds that monitoring of circulating tumour DNA (ctDNA) analysis may aid in the prediction of melanoma recurrence and enable personalised risk-informed post-operative therapy. Results showed a strong correlation between ctDNA positivity prior to initiation of adjuvant therapy and disease recurrence, as well as associations between the magnitude of detectable ctDNA and the timing of recurrence. Post-resection ctDNA positivity and adverse ctDNA kinetics also portended inferior outcomes, including worse overall survival.

Lancet Oncol. 2025;26(5):641-53

2026 ACD Annual Scientific Meeting

The Australasian College of Dermatologists (ACD) 57th Annual Scientific Meeting will be held at the Melbourne Convention & Exhibition Centre 16-18 May 2026.

More information is available here

COVID-19 Resources for Dermatologists

American Academy of Dermatology

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

Psoriatic Arthritis Research Review with Associate Professor Andrew Östör

Skin Cancer Research Review with Dr David Simpson

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