Consensus adaptation

THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

Treatment goals for moderate-to-severe psoriasis in paediatric and adult Australian patients

Purpose: To provide recommendations on the treatment for moderate-to-severe psoriasis in both paediatric and adults in Australia.

Audience: Health professionals

Acknowledgements: This statement has been adapted by the Australasian College of Dermatologists (ACD) with permission from the authors from:

- Foley et al. A*ustralian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Considerations for paediatric patients.* AJD 2024 May 13. doi:10.1111/ajd.14303
- Foley et al. *Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Adult patients.* AJD 2023 Nov;64(4):467-487. doi:10.1111/ajd.14138

Endorsement: This consensus adaptation has been approved by the ACD Expert Advisory Committee.

Funding: ACD received an educational grant from Janssen Australia to undertake this adaptation.

Disclaimer: This consensus adaptation reflects the general views of the ACD at the date of release and may be subject to amendment to reflect emerging clinical and scientific evidence. This information provides educational information and is not intended as a substitute for individual patient assessment. Practitioners are advised to interpret and apply recommendations according to the needs and circumstances of each patient.

First endorsed by ACD: May 2024
Current: May 2024

ACD consensus adaptation – Treatment goals for moderate-to-severe psoriasis in paediatric and adult Australian patients

Purpose

The purpose of this consensus adaptation is to provide an overview of the recommendations – as outlined in Foley et al.'s (2023; 2024) papers – on the treatment and management of paediatric and adults with moderate-to-severe psoriasis in Australia.[1-2] A framework for the assessment, classification and management of adults with moderate-to-severe psoriasis in Australia, aligning with the international recommendations is available in ***Appendix A***. This framework also provides modifications for the paediatric setting.

Previous Australian guidance identified requirements for assessments and established treatment goals to facilitate decision-making, enhance appropriate use of available medications and increase patient satisfaction with care.[3] The updated guidance has focused on three key areas:[1-2]

1. widening the scope of the classification and definition of psoriasis to include the use of a wider range of metrics and encourage consideration of how best to evaluate disease at high impact sites;
2. revising overall treatment goals, now that more efficacious products are available, and consideration of strategies to help reduce treatment delays; and
3. expanding on the treatment goals to provide considerations for the management of paediatric patients.

While current Pharmaceutical Benefit Scheme (PBS) access criteria for biologics for high impact sites account only for face and palmoplantar psoriasis, high impact sites are not restricted to these areas. A key aspect of updated treatment goals has been to widen the definition of high impact sites (i.e., scalp, face, nails, genitalia, palmoplantar and intertriginous) and provide guidance on their assessment.

Background and context

Psoriasis is a chronic, inflammatory disorder with a wide range of systemic effects.[4] It affects nearly 3% of the population worldwide, with an estimated prevalence of 2-7% in Australia.[5-6] While only one-third of psoriasis cases begin during childhood, the clinical features and environmental triggers often differ from those in adult patients, contributing to misdiagnosis and undertreatment.[7-10] Paediatric patients commonly present with psoriasis affecting face, scalp and intertriginous skin.[8]

The visibility of the red scaly areas of the skin and physical impacts can lead to considerable psychological distress and disability (i.e., anxiety, stress and depression) for patients.[4, 11]Not only can this have an adverse effect on a patient's quality of life (QoL), it can also have an impact on their self-esteem, social stigma, relationships and school/work productivity.[8,12-13] To improve quality of life, early diagnosis, appropriate referral, and optimal treatment are critical.

A greater understanding of the psoriasis pathogenesis and advancements in treatment options available for moderate-to-severe psoriasis (i.e., new targeted therapies) have rapidly evolved how health professionals manage paediatric and adult patients with this condition. With the wider

availability of treatment options for psoriasis, the Australasian College of Dermatologists (ACD) sought to review and update the previous guidance and practical advice on the management of adults with moderate-to-severe psoriasis to improve treatment outcomes and patient satisfaction.[3] This guidance was expanded to accommodate the needs of paediatric patients with moderate-to-severe psoriasis as there was no established guidance in this cohort available.

Clinical statements for the treatment of moderate-to-severe psoriasis

A list of key clinical statements to assist either paediatric or adult patients, and their health professionals in making an informed decision on treatment and management of moderate-to-severe psoriasis has been developed and the statements are listed below. These statements are supported with the best available evidence and provide advice on the assessment, classification and management for both paediatric and adult patients with moderate-to-severe psoriasis in Australian clinical practice.

It was recognised that the transitional period from child to adolescent presents its own unique set of challenges for the health professional.[14] There was consensus that selecting an age-appropriate Health-Related QoL (HR-QoL) assessment tool is important to navigate this transition.

Paediatric patients

<u>Definition and classification</u>

- Paediatric patients with psoriasis should be classified either as candidates for topical therapy, or for phototherapy or systemic therapy. Candidates for systemic therapy are patients who meet at least one of the following criteria:
    - Body Surface Area (BSA) >10%
    - Psoriasis Area and Severity Index (PASI) >10
    - Physician's Global Assessment (PGA) >2 (scale of 0-4)
    - Disease involving specific high impact areas
    - Severe pruritus leading to excoriation
    - Dermatology Life Quality Index (DLQI) >10
    - Failure of topical therapy
- Psoriasis should be classified as: (1) ***Mild or mild-to-moderate*** which can be adequately controlled with topical therapy alone; or (2) ***Moderate-to-severe or severe*** which requires phototherapy or systemic therapy (including targeted therapies, such as biological agents and newer targeted synthetic agents).
- Psoriasis can be classified quantitatively using a combination of the following metrics: BSA, PASI, DLQI, PGA and specific high impact areas.
- When assessing paediatric patients, use an age-appropriate validated scale to determine psoriasis severity.
- The definition of treatment success (a 75% reduction in PASI [ΔPASI ≥75%] or a 50% reduction in PASI [DPASI ≥50%] and a DLQI ≤5) is now outdated.

Treatment goals and response definitions

- Higher treatment outcomes are now attainable. Treatment targets should be patient-centric and based on a composite of outcomes that take the individual's needs into account.
- When assessing response to treatment in paediatric patients, targets should include age-appropriate validated scales to determine disease impact and account for the burden of treatment on the family/carers.
- A HRQoL metric should be included in disease management targets.
- A DLQI score of 0 or 1 indicates the absence of any impact of psoriasis on the patient's quality of life.
- When there is a partial response (based on PASI or PGA), DLQI (or alternative HRQOL measure) should be considered when making treatment decisions.
- PGA is a validated objective score, which is an alternative to PASI for assessing psoriasis severity.
- PGA is a validated objective score, which is useful measuring response to treatment.
- PGA clear/almost clear is an appropriate alternative absolute treatment end point.
- Absolute PASI is easier to calculate than PASI 75, is independent of variations in baseline severity and better reflects the clear or almost clear status (or a physician global assessment [PGA] score of 0-1] of the patient.
- PASI 90 response better reflects a "clear"/"almost clear" status than PASI 75.
- Absolute PASI ≤ 3 and PGA clear/almost clear represent relevant disease end points to inform treat-to-target management strategies in psoriasis.
- Absolute PASI ≤ 2 and PGA clear/almost clear represent relevant disease end points to inform treat-to-target management strategies in psoriasis.
- Treatment response should consider disease severity (PASI or PGA) and psychosocial impact on the patient and their family/carer.
- Treatment should be continued in patients who achieve an adequate response. An adequate response to treatment is defined as either absolute PASI ≤, PGA = 0/1 or PGA 2 with and/or minimal impact on age appropriate QoL measure. Age-appropriate QoL measures include:
    - Age <4 years: IDQoL <5
    - Age ≥4 years to <12 years: CDLQI <7
    - Age ≥ 12 to <20 year: T-QoL <5

- Where available, validated site-specific assessment scales should be used to monitor treatment response at high impact sites.
- An adequate response rate at high impact sites is defined as site specific PGA 0/1.
- Treatment should be modified in patients with an inadequate response. An inadequate response to treatment is defined as any one of the following:
    - Absolute PASI >3
    - PGA ≥2
    - Moderate impact on age-appropriate QoL measure (as defined above).
- Complete skin clearance (PGA = 0) is a clinically significant treatment goal from the patient perspective.
- Time to onset of action varies between treatment options.
- During the induction treatment phase, initial response should be assessment up to 16 weeks after therapy initiation or up to 24 weeks for therapies with closer onset of action.

<u>Therapeutic strategies</u>

- Patient-reported outcome measures can provide additional, relevant information to facilitate individualised treatment.
- Control of comorbidities is an important consideration in the assessment of disease control/therapy.
- A multidisciplinary approach is recommended to manage patients with comorbidities.
- Use a validated tool to assess the impact of family quality of life.
- Targeted therapies should be initiated where there is an inadequate response to conventional systemic agents, they are contraindicated, or they are not tolerated.
- In cases of severe, active disease, the initiation of targeted therapy is the preferred first-line choice.
- Combination treatment may be of benefit in some patients.

Adult patients

Definition and classification

- Adult patients with psoriasis should be classified either as candidates for topical therapy or for phototherapy or systemic therapy. Candidates for systemic therapy are patients who meet at least one of the following criteria:

  - BSA >10%
  - PASI >10
  - PGA >2 (scale of 0-4)
  - Disease involving specific high impact areas
  - Severe pruritus leading to excoriation
  - DLQI >10
  - Failure of topical therapy

- Psoriasis should be classified as: (1) ***Mild or mild-to-moderate*** which can be adequately controlled with topical therapy alone; or (2) ***Moderate-to-severe or severe*** which requires phototherapy or systemic therapy (including targeted therapies, such as biological agents and newer targeted synthetic agents).

- Psoriasis can be classified quantitatively using a combination of the following metrics: BSA, PASI, DLQI, PGA and specific high impact areas.

- High impact psoriasis sites include face, palmoplantar (hands/feet), scalp, nails, genitalia, backs of hands, flexures/intertriginous areas.

- PASI is not a reliable measure of the severity of high impact psoriasis sites.

  - Site-specific (modified) PASI should only be used to assess severity of high impact sites if it has been validated for that site.

  - PGA-F (fingernail psoriasis), sPGA-G (genital psoriasis), ScPGA (scalp psoriasis) and Hf-PGA (hand/foot psoriasis) are validated global assessment scores that can be used as objective scores to assess psoriasis severity in these identified specific high impact sites.

  - In patients whose psoriasis affects specific high impact sites, quality of life (QoL) is an important component in the assessment of disease severity.

- The definition of treatment success (a 75% reduction in PASI [DPASI ≥75%] or a 50% reduction in PASI [DPASI ≥50%] and a DLQI ≤5) is now outdated.

Treatment goals and response definitions

- Higher treatment outcomes are now attainable. Treat-to-target is an approach to the management of healthcare conditions in which the goal is to accomplish a set of therapeutic targets within a pre-selected timeframe.
- There is a need for options in a treat-to-target approach, including PASI, PGA, BSA to accommodate the specialist's choice of criteria.
- A HRQoL metric should be included in disease management targets.
- A DLQI score of 0 or 1 indicates the absence of any impact of psoriasis on the patient's quality of life.
- PGA is a validated objective score, which is useful for measuring response to treatment. PGA clear/almost clear is an appropriate alternative absolute treatment end point. Complete skin clearance (PGA = 0) is a clinically significant treatment goal from the patient perspective.
- Absolute PASI is easier to calculate than ΔPASI because it is independent of variations in baseline severity and better reflects the clear or almost clear status (or a PGA score of 0–1) of the patient.
- Time to onset of action varies between treatment options. During the induction treatment phase, initial response should be assessed up to 16 weeks after therapy initiation, or up to 24 weeks for therapies with slower onset of action.
- When there is a partial response (based on PASI or PGA), DLQI (or alternative HRQOL measure) should be considered when making treatment decisions.
- New biological and targeted therapies have improved treatment outcomes to the extent that, in the clinical trial setting, a PASI 90 response better reflects a "clear"/"almost clear" status than the traditional gold standard of PASI 75.
- Absolute PASI ≤ 3 and PGA clear/almost clear represent relevant disease end points to inform treat-to-target management strategies in psoriasis.
- Treatment should be continued in patients who achieve an adequate response. An adequate response to treatment is defined as either absolute PASI ≤3 or PGA = 0/1.

    - If DLQI is considered, an adequate response to treatment is defined as either >3 absolute PASI ≤6 with DLQI <5 or PGA = 2 with DLQI <5.

    - If ΔPASI is being used as the metric, an adequate response to treatment is defined as either: ΔPASI ≥90, ≥75 ΔPASI <90 and absolute PASI ≤3 or ≥75 ΔPASI <90 and absolute PASI >3 with DLQI <5.

- Treatment should be modified in patients with an inadequate response. An inadequate response to treatment is defined as any one of the following:

    - Absolute PASI >3
    - PGA ≥2
      If neither of these criteria are met DLQI should also be considered
    - >3 absolute PASI ≤6 with DLQI ≥5
    - PGA = 2 with DLQI ≥5
      If ΔPASI is being used as the metric:
    - ΔPASI <90
    - ≥75 ΔPASI <90 and absolute PASI >3
    - ≥75 ΔPASI <90 and absolute PASI >3 with DLQI ≥5

- Where available, validated site-specific assessment scales should be used to monitor treatment response at high impact sites.

- An adequate response rate at high impact sites is defined as site specific PGA 0/1 or site-specific PGA =2 with DLQI <5.

    - PGA-F, sPGA-G, ScPGA and Hf-PGA are validated global assessment scores that can be used as objective scores to measure response to treatment in these identified specific high impact sites.

- In patients who psoriasis affects specific high impact sites, QoL is an important component for measuring response to treatment.

<u>Therapeutic strategies</u>

- Targeted therapies should be initiated where there is an inadequate response to conventional systemic agents, they are contraindicated, or they are not tolerated.

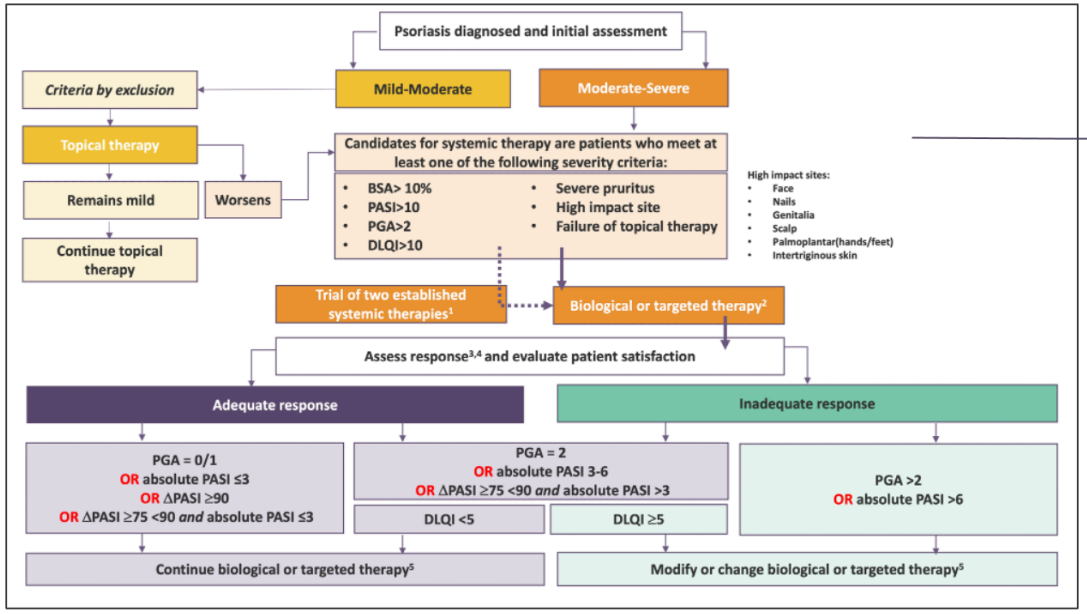
- In cases of severe, active disease, the initiation of targeted therapy is the preferred first-line choice.

- Combination treatment may be of benefit in some patients.

ACD consensus adaptation – Treatment goals for moderate-to-severe psoriasis in paediatric and adult Australian patients

Appendix A

Treatment goals algorithm for adult patients with psoriasis in Australia



1 To be eligible for access to biological or targeted therapies, the Australian reimbursement body, the Pharmaceutical Benefits Scheme, requires that a patient has failed to achieve an adequate response following a minimum of 6 weeks treatment to at least 2 of the following 5 treatments: phototherapy, methotrexate, cyclosporin, acitretin, apremilast. **The Australian consensus group failed to reach consensus with the requirement to use established systemic agents before moving onto targeted therapy and propose that in cases of severe, active disease the initiation of targeted therapy was reasonable and best practice.**

2. Targeted therapies available via the Australian reimbursement body, the Pharmaceutical Benefits Scheme, are: adalimumab, apremilast, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, ustekinumab.

3 Appropriate time for review varies with each treatment and the range is 16-24 weeks.

4 For high impact sites use validated, site-specific assessment tools where available.

5 Continuation/discontinuation is modulated by: toxicity, contraindications, patient preferences and may also include adding topical therapies, adding other systemic treatment, increasing dose and/or frequency of a treatment, or admission to hospital.

Modifications for the paediatric setting

Treatment outcomes mutually agreed with the family as part of an individualised care plan.

Substitute DLQI with an age-appropriate disease impact score:

- Age <4 years: Infants' Dermatitis Quality of Life Index
- Age 4-12 years: Infants' Dermatitis Quality of Life Index
- Age 12-17 years: Adolescent Psoriasis Quality of Life instrument

Use validated tools to quantity impact on the family, particularly for young children.

Be sensitive to the changing needs of adolescent patients.

References

1. Foley et al. Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Considerations for paediatric patients. AJD 2024 May 13.doi:10.1111/ajd.14303
2. Foley et al. Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Adult patients. AJD 2023 Nov;64(4): 467-487.doi:10.1111/ajd.14138
3. Baker C, Mack A, Cooper A, Fischer G, Shumack S, Sidhu S, et al. Treatment goals for moderate to severe psoriasis: an Australian consensus. *Australas J Dermatol*. May 2013;54(2):148-54. doi:10.1111/ajd.12014
4. Armstrong AW, Read C. Pathophysiology, Clinical Presentation, and Treatment of Psoriasis: A Review. *Jama*. May 19 2020;323(19):1945-1960. doi:10.1001/jama.2020.4006
5. Parisi R, Iskandar IYK, Kontopantelis E, Augustin M, Griffiths CEM, Ashcroft DM. National, regional, and worldwide epidemiology of psoriasis: systematic analysis and modelling study. *Bmj*. May 28 2020;369:m1590. doi:10.1136/bmj.m1590
6. https://www.mja.com.au/journal/2020/psoriasis-comorbidities-make-it-more-skin-disease
7. Seyger MMB, Augustin M, Sticherling M, Bachhuber T, Fang J, Hetherington J, et al. Physician-reported Clinical Unmet Needs, Burden and Treatment Patterns of Paediatric Psoriasis Patients: A US and EU Real-world Evidence Study. *Acta Derm Venereol*. Feb 28 2022;102:adv00660. doi:10.2340/actadv.v101.981
8. Bronckers IM, Paller AS, van Geel MJ, van de Kerkhof PC, Seyger MM. Psoriasis in Children and Adolescents: Diagnosis, Management and Comorbidities. *Paediatr Drugs*. Oct 2015;17(5):373-84. doi:10.1007/s40272-015-0137-1
9. Diotallevi F, Simonetti O, Rizzetto G, Molinelli E, Radi G, Offidani A. Biological Treatments for Pediatric Psoriasis: State of the Art and Future Perspectives. *Int J Mol Sci*. Sep 22 2022;23(19)doi:10.3390/ijms231911128
10. Hamm H, Höger PH. [Psoriasis in children and adolescents : Short update and guideline-based treatment]. *Dermatologie (Heidelb)*. Mar 28 2023:1-8. Psoriasis im Kindes- und Jugendalter : Kurzes Update und leitliniengerechte Therapie. doi:10.1007/s00105-023-05132-7
11. Kovitwanichkanont T, Chong AH, Foley P. Beyond skin deep: addressing comorbidities in psoriasis. *Med J Aust*. Jun 2020;212(11):528-534. doi:10.5694/mja2.50591
12. De Jager MEA, De Jong E, Evers AWM, Van De Kerkhof PCM, Seyger MMB. The burden of childhood psoriasis. *Pediatr Dermatol*. Nov-Dec 2011;28(6):736-737. doi:10.1111/j.1525-1470.2011.01489.x
13. Kelly KA, Balogh EA, Kaplan SG, Feldman SR. Skin Disease in Children: Effects on Quality of Life, Stigmatization, Bullying, and Suicide Risk in Pediatric Acne, Atopic Dermatitis, and Psoriasis Patients. *Children (Basel)*. Nov 16 2021;8(11)doi:10.3390/children8111057

14. Mahé E. Optimal Management of Plaque Psoriasis in Adolescents: Current Perspectives. *Psoriasis: Targets and Therapy*. 2020/12/31 2020;10:45-56. doi:10.2147/PTT.S222729

This consensus adaptation is also available online. For more topics, visit dermoll.edu.au or scan the QR code.

About us

The Australasian College of Dermatologists (ACD) is Australia's accredited training body and peak professional and membership organisation for medical specialists in dermatology. We are the Australian authority in skin, hair and nail health, education, information and advocacy.

THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS
Cammeraygal Country
Level 6, 33 Chandos Street, St Leonards NSW 2065 Australia
T: +61 2 8765 0242 | E: admin@dermcoll.edu.au | W: www.dermcoll.edu.au