

CONSENSUS ARTICLE

Treatment goals for moderate to severe psoriasis:
 An Australian consensus

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ABSTRACT

Background/Objectives: The high incidence of comorbidities in patients with psoriasis, significant impact on quality of life and patients’ dissatisfaction with treatment led a European group to develop a consensus position on psoriasis treatment goals. There is an evident need for similar treatment goals in Australia. The aim of this project was to develop Australian treatment goals that reflect the local environment.

Methods: A panel of 12 representatives was drawn from across Australia consisting of nine dermatologists and a rheumatologist, a dermatology nurse and a general practitioner (GP)/dermatology trainee. The group met on three occasions between September 2011 and March 2012. The panel undertook a literature review and critically examined available evidence-based treatment goals. A questionnaire relating to psoriasis assessment and specific treatment outcomes was developed. Following discussion and debate, recommended treatment goals for psoriasis patients in Australia were determined.

Results: The panel agreed by consensus on recommended psoriasis treatment goals in the Australian environment. There was recognition that in addition to psoriasis area severity index (PASI) assessment, a quality of life assessment was highly relevant in determining psoriasis severity and treatment outcome. Mild psoriasis was defined as PASI ≤ 10 and a dermatology life quality index (DLQI) ≤ 10, with moderate to severe psoriasis defined as PASI > 10

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Abbreviations:

BSA	body surface area
DLQI	dermatology life quality index
GP	general practitioner
HRQOL	health-related quality of life
PASI	psoriasis area severity index
PBS	Pharmaceutical Benefits Scheme
TNF	tumour necrosis factor

and/or DLQI > 10. The presence of certain defined-clinical features would elevate a patient's classification from mild to moderate/severe. The target for treatment was defined as a maintained change in PASI \geq 75% improvement and DLQI \leq 5. These largely concurred with the European treatment goals. A flow chart for psoriasis management in Australia based on outcome measures was developed.

Conclusions: There is a need to identify and articulate treatment goals for psoriasis. Assessment of psoriasis severity requires both physical scoring (PASI) and consideration of quality of life measures (DLQI). Identification of treatment goals will guide clinicians in treatment decision-making, enhance the availability and appropriate use of therapies and increase patient satisfaction with their care.

Key words: Australian, DLQI, PASI, psoriasis, quality of life, treatment goal.

INTRODUCTION

Once thought to be a benign dermatological disorder with few serious complications, psoriasis is now viewed as a systemic disease and there is growing evidence linking moderate to severe psoriasis with an increased risk of various comorbidities. These include inflammatory arthritis, inflammatory bowel disease, cardiovascular disease, the metabolic syndrome and lymphoma, which occur at higher rates among psoriasis patients than in the general population.¹ The risk of myocardial infarction in younger patients is particularly elevated.² This is in addition to the decrease in health-related quality of life (HRQOL) associated with the disease, which is comparable to that seen in medical conditions such as cancer and diabetes.³ Significant psychological difficulties – such as depression and anxiety, and a negative impact on interpersonal relationships – are also more prevalent among patients with severe psoriasis compared with controls and with patients who have mild psoriasis.⁴

Despite the complications associated with moderate to severe psoriasis, it has been shown that this condition is often less than optimally treated.⁵ This is reflected in high levels of patient dissatisfaction with therapy received^{6,7} and appears to be in part due to persistence with a given treatment in the absence of a significant clinical response, coupled with a relative reluctance of dermatologists to prescribe systemic therapies.⁶

In 2009 a European consensus programme was established to respond to this situation. The aim of the programme was to improve patient care by developing specific goals for the treatment of plaque psoriasis, which in turn necessitated a definition of disease severity.⁸ The results of this process were published online in September 2010 by Mrowietz and colleagues,⁸ essentially signalling a new European treatment paradigm for moderate to severe psoriasis.

It has become evident that there is a need for similar treatment goals in Australia. However, modifications of

those outlined in Mrowietz and colleagues⁸ are required to take into account the local medical environment and differences in prescribing patterns. Consequently, the Australian Psoriasis Treatment Goals Project was established in order to develop an Australian paradigm.

METHODS

The Australian Psoriasis Treatment Goals Project was an initiative undertaken by the Skin and Cancer Foundation Inc. A panel of 12 participants was drawn from across Australia with representatives from each mainland state (Victoria four, New South Wales three, Queensland three, South Australia one and Western Australia one), and consisted of individuals involved in psoriasis and psoriatic arthritis management, some of whom had affiliations to tertiary care hospitals, major dermatology centres and universities. Among these were nine dermatologists, a rheumatologist, a dermatology nurse and a general practitioner (GP) and dermatology trainee.

The project involved three meetings of the panellists, which took place between September 2011 and January 2012. The first of these meetings focused on establishing a need for specific treatment goals in Australia, and the objectives for the group. These were to develop a clear definition of psoriasis severity (that is, what constituted mild versus moderate to severe psoriasis), and to establish treatment targets for moderate to severe psoriasis. Additionally, a treatment algorithm was to be produced, which would outline clear measures of response and assessment criteria, as well as provide guidance for monitoring response, and treatment modification or switching. All this was to be based on existing evidence-based treatment guidelines and standards of practice in Australia. It was decided that the current Australian Pharmaceutical Benefits Scheme (PBS) criteria for use of biologics or any other therapy would not form the major assessment or progression criteria used by the group.

Following the first meeting, a psoriasis treatment goals questionnaire was developed by the steering group and distributed to each member of the panel. The questions related to the content of the Mrowietz and colleagues' article⁸ and were aimed at assessing the extent of the panel's agreement with its proposals. The second and third meetings involved discussion of the results of this questionnaire. Specifically, areas where the views of the panel aligned with, differed from or were additional to those of the European consensus group were identified and discussed.

RESULTS

Definition of strength of agreement

The group agreed that if \geq 90 per cent of the panellists agreed with a questionnaire item, this would be regarded as strong consensus or 'agreement'.

Severity of plaque psoriasis

While the group agreed with the decision of Mrowietz and colleagues⁸ to use the PASI score for grading of psoriasis

symptoms, it was decided that the body surface area (BSA) should not be used as an assessment measure for the Australian treatment goals. The BSA was therefore omitted from the definition of psoriasis severity and all other categories where the BSA was listed by the European consensus group. There was unanimous agreement to include the dermatology life quality index (DLQI) as a measure of impact on HRQOL.

Definition of plaque psoriasis severity

There was unanimous consensus among the group with the following statement:

Psoriasis is defined in two main categories: mild versus moderate to severe.

Definition of mild plaque psoriasis

PASI ≤ 10 and DLQI ≤ 10 .

Excluding the BSA as a measure of severity, the group agreed with the definition of mild psoriasis proposed in Mrowietz and colleagues' article.⁸ According to current treatment guidelines, mild psoriasis should be treated with topical agents. There was unanimous agreement with the statement:

If PASI ≤ 10 indicates mild disease but DLQI > 10 indicates significant impact on quality of life, psoriasis can be considered moderate to severe and systemic therapy may be initiated when the patient's disease cannot be controlled by topical treatment.

It was recognised that the presence of one or more features may significantly impair quality of life in the setting of mild psoriasis and alter the classification of mild disease (PASI ≤ 10 and DLQI ≤ 10) to moderate to severe disease, thus indicating the possible need for phototherapy and/or systemic treatment. These include

- involvement of visible areas
- involvement of major parts of the scalp
- involvement of genitals
- involvement of palms and/or soles
- onycholysis or onychodystrophy of at least two fingernails
- pruritus leading to excoriation

Definition of moderate to severe plaque psoriasis

PASI > 10 and/or DLQI > 10 .

The group agreed with the above definition of moderate to severe plaque psoriasis. This concurred with Mrowietz and colleagues' definition,⁸ again with the exclusion of the BSA. According to current treatment guidelines, moderate to severe psoriasis warrants the use of phototherapy or systemic treatments.

There was consensus that a PASI > 10 indicates moderate to severe disease, irrespective of the DLQI, and also indicates the likely need for phototherapy or systemic therapy.

The group agreed that the following statement in the European treatment goals was not appropriate in the Australian setting:

If (BSA > 10 or) PASI > 10 indicates moderate to severe disease but DLQI ≤ 10 indicates no significant impact on quality of life psoriasis can be considered mild disease.

Consequently, it was decided that this statement would not be included in the Australian treatment goals and that a PASI > 10 would be considered moderate to severe disease regardless of the DLQI.

Treatment phases for systemic therapy of plaque psoriasis

There was unanimous agreement with the European definition of treatment phases.

Definition of induction phase

Induction phase is generally defined as the treatment period until week 16; however, depending on the type of drug and dose regimen used, induction phase can be extended until week 24 according to the decision of the treating dermatologist.

Definition of maintenance phase

Maintenance phase is defined for all drugs as the treatment period after the induction phase; therapeutic success should be assessed in intervals according to recommendations in the available guidelines.

Treatment goals

There was unanimous consensus with all the remaining aspects of the treatment goals proposed in Mrowietz and colleagues' article.⁸ These were as follows:

Definition of treatment success after induction phase

If at the end of the induction phase a reduction in PASI of $\geq 75\%$ (Δ PASI $\geq 75\%$) as compared to disease severity at the time of treatment initiation has been achieved, continuing with the treatment regimen is recommended.

Definition of treatment failure after induction phase

If at the end of the induction phase an improvement of PASI of $\geq 50\%$ (Δ PASI $\geq 50\%$) as compared to disease severity at the time of treatment initiation has not been achieved, modification of the treatment regimen is recommended.

In situations where a reduction in PASI of ≥ 50 per cent but < 75 per cent was achieved, the group agreed that the

DLQI and patient preference should be used in deciding whether to continue or modify the treatment regimen.

Definition of intermediate response to treatment after induction phase

If at the end of the induction phase an improvement of PASI of $\geq 50\%$ but $< 75\%$ ($\Delta\text{PASI} \geq 50 < 75\%$) as compared to disease severity at the time of treatment initiation has been achieved, but $\text{DLQI} \leq 5$ has not been achieved, modification of the treatment regimen is recommended.

If at the end of the induction phase a reduction in PASI of $\geq 50\%$ but $< 75\%$ ($\Delta\text{PASI} \geq 50\% < 75\%$) as compared to disease severity at the time of treatment initiation and $\text{DLQI} \leq 5$ has been achieved, continuing with the treatment regimen is recommended.

Definition of treatment success during maintenance phase

If during maintenance therapy an improvement of PASI of $\geq 75\%$ ($\Delta\text{PASI} \geq 75\%$) as compared to disease severity at the time of treatment initiation has been achieved, continuing with the treatment regimen is recommended.

Definition of treatment failure during maintenance treatment

If during maintenance therapy an improvement of PASI of $\geq 50\%$ ($\Delta\text{PASI} \geq 50\%$) as compared to disease severity at the time of treatment initiation has not been achieved, modification of the treatment regimen is recommended.

Definition of intermediate response to treatment during maintenance phase

If during maintenance therapy an improvement of PASI of $\geq 50\%$ but $< 75\%$ ($\Delta\text{PASI} \geq 50\% < 75\%$) as compared to disease severity at the time of treatment initiation can be maintained, but $\text{DLQI} \leq 5$ has not been achieved, modification of the treatment regimen is recommended.

If during maintenance therapy an improvement of PASI of $\geq 50\%$ but $< 75\%$ ($\Delta\text{PASI} \geq 50\% < 75\%$) as compared to disease severity at the time of treatment initiation can be maintained and $\text{DLQI} \leq 5$ has been achieved, continuing with the treatment regimen is recommended.

Finally, based on the consensus agreements, the algorithm in Figure 1 was developed as a schematic representation of the results. It should also be noted that this is in agreement with figure 2 in the Mrowietz and colleagues' article.⁸

DISCUSSION

The positive treatment outcomes of treating to a target have been established in diabetes, cholesterol and blood pressure management.⁹⁻¹¹ There has been significant interest in the setting of treatment goals by consensus in rheumatoid

arthritis¹² and a demonstration of the enhanced therapeutic outcomes of using goals in routine clinical care.¹⁵ It appears that many patients with moderate to severe plaque psoriasis may not be receiving adequate treatment. This has been attributed partly to the underuse of systemic therapies, as well as the failure to modify treatment in the absence of a significant clinical response. As a consequence, a considerable proportion of these patients are dissatisfied with the therapy they have received.^{6,7}

This European treatment goal consensus was used as a basis for developing a set of Australia-specific treatment goals, which would take into account differences in the local medical environment and prescribing patterns. The process involved three meetings between a panel of 12 representatives, during which the results of the European group and current literature was discussed and debated. A questionnaire was completed by all panellists to assess the extent of agreement with the proposals.

Overall, the responses to the questionnaire reflected general agreement with the proposals put forth in the Mrowietz and colleagues' article.⁸ However, there were a number of areas which the Australian consensus group felt required modification in order to render the article suitable for application in Australia.

With respect to assessment measures for defining disease severity, the group agreed with the European consensus to use the PASI and DLQI scores. However, the group felt that the BSA score should be omitted as a measure of disease severity, on the basis that it is not routinely used in Australian clinical practice and adds little clinical value to the PASI score. The BSA score was therefore deleted from the definition of psoriasis severity for the Australian Treatment Goals.

Although the group broadly agreed with Mrowietz and colleagues' definition of mild psoriasis,⁸ modifications were made to the list of disease manifestations which may lead to a significantly impaired quality of life in the setting of mild psoriasis. This included, firstly, the decision to replace 'pruritus leading to scratching' with 'pruritus leading to excoriation'. Pruritus is a common symptom in psoriasis¹⁴ that does not necessarily indicate severe disease. It was the opinion of the group that pruritus leading to scratching alone did not necessarily reflect a significant impact on quality of life, and thus should not be sufficient to alter the classification of mild disease to moderate to severe disease. However, it was felt that pruritus and scratching leading to excoriation suggested severe pruritus and thus a considerable impact on quality of life, potentially warranting reclassification to moderate to severe psoriasis. Secondly, the group decided to delete altogether the statement 'the presence of a single recalcitrant plaque', as it was felt that circumstances where a single recalcitrant plaque might impair quality of life – such as sited on the face or genitalia – were covered by other items.

While the group were also in broad consensus with Mrowietz and colleagues' definition of moderate to severe psoriasis,⁸ there was disagreement with the European consensus that a PASI > 10 in the presence of a $\text{DLQI} \leq 10$ should be classified as mild disease. Instead, there was a consensus among the Australian group that a PASI > 10

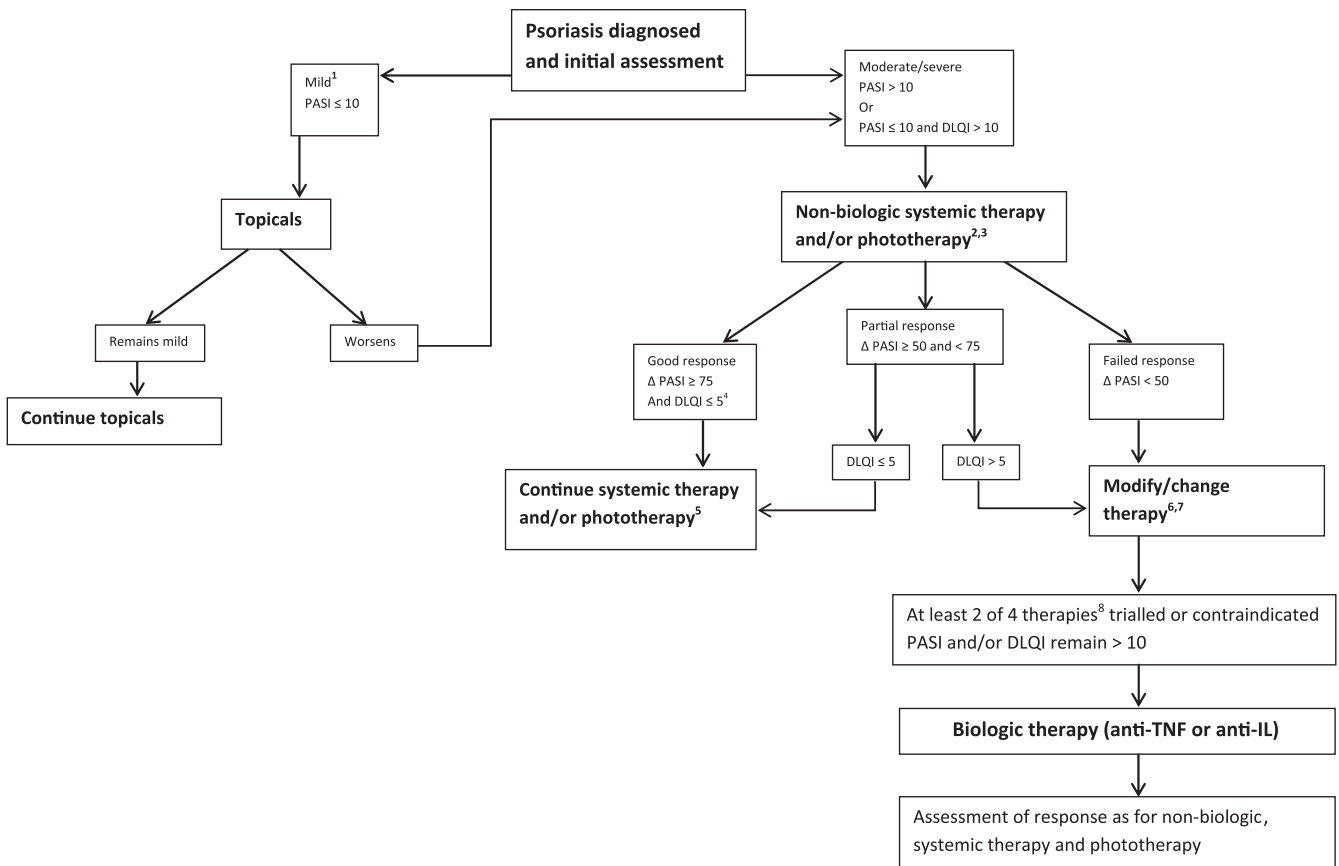


Figure 1 Treatment goals algorithm for patients with psoriasis in Australia.

Notes:

1. In absence of modifying features such as visible site, genital, palmoplantar, nails involvement, pruritus with excoriation (see text).
2. Appropriate time to review varies with each treatment and the range is 6–24 weeks.
3. Non-biologic therapies include methotrexate, cyclosporin and acitretin.
4. Psoriasis area severity index (Δ PASI) ≥ 75 but dermatological quality of life index (DLQI) ≥ 5 may occur if modifying features such as the visible site, genital, palmoplantar, nail involvement or pruritus are present or the response is discordant with patient's expectations. Physician assessment whether to continue, modify or change therapy.
5. Continuation/discontinuation is modulated by toxicity and contraindication.
6. Treatment change to take into account patient wishes.
7. In addition to change of treatment, modify may include adding topicals, adding other systemic treatment, increasing dose or frequency or hospital admission.
8. The Australian consensus group propose that two of four therapies as reasonable and best practice. The current requirement of the Australian reimbursement body, the Pharmaceutical Benefits Scheme, is three of four therapies.

indicates moderate to severe disease, regardless of the DLQI, and that this also indicates a likely need for systemic therapy or phototherapy. It was felt that some patients may not recognise the severity of their psoriasis or that the DLQI may not always reflect the true impact of the disease on HRQOL due to the nature of the questions asked. Furthermore, although definitive evidence relating the severity of psoriasis to the severity of comorbidities is lacking, it was the experience of the panel that increasing severity of psoriasis has an adverse impact on comorbidities. In light of this, the group supported all PASI > 10 being classified as moderate to severe disease and warranting more aggressive treatment.

Despite these modifications to the Mrowietz and colleagues' definitions of disease severity, the Australian con-

sensus group was in unanimous agreement with the specific treatment goals outlined in the article, making no modification to the targets agreed upon by the European group. While not a major focus of the Australian group, there was also consensus with the article's definitions of induction and maintenance phases. In particular, there was strong agreement that the induction phase may be extended for treatments with a known slow onset of action. It was felt that this element of flexibility was important, given the considerable variation in onset of action between different psoriasis treatments, and that this should be kept in mind when determining appropriate review periods.

In the process of discussing and debating the Mrowietz and colleagues' article, there were some additional points raised by the panellists that are worthy of consideration

here. At present the PBS does not take into account DLQI in determining treatment success or failure. Other countries – including the UK, Scotland, Spain and Germany – currently use DLQI in criteria for determining the eligibility of biologics, recognising the contribution of an elevated DLQI score to disease burden. This is consistent with strong evidence supporting the use of HRQOL measures in assessing disease burden.¹⁵ Although dermatologists utilise a number of different HRQOL measures, the DLQI is the most commonly used worldwide, with studies having demonstrated that it is a valid and easy to use tool for assessing response to therapy.^{16–18} It is therefore the opinion of the Australian consensus group that the DLQI should be taken into account as patients progress through systemic, including biologic, therapy in Australia. This is on the basis that DLQI identifies a more significant impact on HRQOL in a group that might otherwise be considered to have mild disease, while also giving some indication of patient satisfaction with treatment.

Although the group felt strongly that specific disease severity definitions and treatment goals were needed in Australia, it was acknowledged that there may be circumstances where strict adherence to these may not be in the best interests of the patient. Therefore, it was decided that there should be some flexibility in the treatment protocol to cater for these circumstances. A number of potential circumstances were discussed.

For example, although the group agreed that a high DLQI > 10 in the presence of a low PASI ≤ 10 can be considered moderate to severe disease, the point was raised that the high DLQI may be influenced by factors other than the psoriasis itself. Such factors may include other comorbid conditions or psychiatric issues. Alternatively, some patients may have unrealistic expectations of treatment, resulting in a persistently high DLQI despite a significant reduction in their PASI score. Thus, the group felt that it was important to consider the potential of these factors to affect the DLQI when making treatment decisions.

Furthermore, there are certain factors which may temporarily worsen a patient's PASI or DLQI or delay a response to treatment, such as a significant life event or serious illness. The group felt that changes in severity scores in these situations do not necessarily require a modification of treatment, as they are likely to be temporary and may not reflect true treatment failure.

Additionally, the group identified the importance of incorporating patients' wishes in treatment decisions. It was felt that patient preferences regarding the type of treatment and their views relating to treatment success or failure should be taken into consideration when making treatment decisions. For instance, it was recognised that a patient with a satisfactory response to treatment may have reasons to wish to modify the treatment regimen despite the treatment goal recommendation. Alternatively, a patient who has had only a minor improvement and who has a DLQI above 5 may wish to continue with the current treatment regime for a further period, again contrary to the treatment goal recommendation. The general consensus was that there should be some flexibility in the application of the Australian treat-

ment goals, and that patient's wishes may therefore override protocol where appropriate. This was not considered in the article of Mrowietz and colleagues.⁸

Another area not explored in the Mrowietz and colleagues' article was the applicability of the psoriasis treatment goals to the paediatric population. This was discussed by the Australian group, and the consensus of the panel was that the treatment goals should be used in paediatrics. It was decided that, although a PASI score could be obtained, it was appropriate to use a HRQOL tool specific for the paediatric group and paediatric DLQI was adequate for this purpose.¹⁹

The European consensus did not specifically address severity and response of involvement of the hands, feet or face. In Australia, a patient is classified as severe if at any one site they have involvement of >30 per cent of surface area or >2 sub-scores (erythema, scale or induration) graded 3 or 4. Satisfactory response in a hand, foot or face site, is defined as a greater than 75 per cent improvement in surface area or sub-scores returning to 0 or 1 for all indices. The Australian group considered that the definitions for severity and response of these areas were appropriate and could be combined with the proposed DLQI assessment for inclusion in the Australian treatment goal framework.

The possibility of including reference to particular morphological types of psoriasis in treatment goals was also considered. This suggestion was made on the basis that certain morphological types of psoriasis may significantly impair quality of life in the setting of otherwise mild psoriasis, and are at present not covered by other headings. During the consensus process, morphologies such as 'pustular' and 'unstable patch or plaque' were two suggested morphological types that could significantly impair quality of life independent of site and extent. This may be considered in future guidelines and recommendations for treatment.

The Australian health-care model is structured so that most of the population access health care primarily through their GP. Family doctors therefore play a major role in managing the chronic medical conditions of their patients, such as cardiovascular disease and diabetes. In light of this, and the increased risk of cardiovascular disease and other comorbidities associated with psoriasis, it is imperative that GP as well as dermatologists are familiarised with psoriasis comorbidities and treatment guidelines.

CONCLUSION

Many patients with moderate to severe plaque psoriasis receive less than optimal treatment. In 2009 a European consensus programme sought to overcome this problem by developing a set of specific psoriasis treatment goals. It has since become evident that there is a need for similar treatment goals in Australia, and consequently the Australian Treatment Goals Project was established. Using the European guidelines as a reference point, the Australian group made some modifications to produce treatment guidelines that took into account the local health-care setting. The major objective of the project was to improve therapeutic

outcomes for psoriasis patients and to propose an appropriate treatment framework. The next step will be to educate dermatologists and GPs on the findings of this consensus group to help confer the greatest benefits to patients. Finally, the ongoing evaluation of patient outcomes is imperative to assess the effectiveness of these guidelines.

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