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Measurement properties and interpretability of the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure

Rachael Pattinson[1], **Nirohshah Trialonis-Suthakharan**[2], **Tim Pickles**[3], **Jennifer Austin**[4], **Allison FitzGerald**[4], **Matthias Augustin**[2] and **Christine Bundy**[1]

[1]School of Healthcare Sciences, Cardiff University, Cardiff, UK
[2]Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, Hamburg, Germany
[3]Centre for Trials Research, Cardiff University, Cardiff, UK
[4]International Alliance of Dermatology Patient Organizations, Ottawa, Canada
Correspondence: Rachael Pattinson. Email: pattinsonr@cardiff.ac.uk

Abstract

Background Patient-reported outcome measures (PROMs) are crucial in assessing the impact of dermatological conditions on people's lives, but the existing dermatology-specific PROMs are not recommended for use, according to COSMIN. We developed the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure in partnership with patients. It has strong evidence of content validity, structural validity, internal consistency, acceptability and feasibility.

Objectives To test the remaining measurement properties of the PRIDD and establish the interpretability of scores against the COSMIN criteria, using classic and modern psychometric methods.

Methods A global longitudinal study consisting of two online surveys administered 2–4 weeks apart was carried out. Adults (≥ 18 years of age) living with a dermatological condition were recruited via the International Alliance of Dermatology Patient Organizations' (GlobalSkin) membership network. Participants completed PRIDD, a demographics questionnaire and other related measures, including the Dermatology Life Quality Index. We tested the criterion validity, construct validity and responsiveness (Spearman's ρ, independent-samples *t*-tests and ANOVA); test–retest reliability [interclass correlation coefficient (ICC)]; measurement error [smallest detectable change or limits of agreement (LoA), distribution-based minimally important change (MIC)]; floor and ceiling effects (number of minimum and maximum scores and person–item location distribution maps), score bandings (κ coefficient of agreement) and the anchor-based MIC of the PRIDD.

Results In total, 504 people with 35 dermatological conditions from 38 countries participated. Criterion validity (ρ=0.79), construct validity (76% hypotheses met), test–retest validity (ICC=0.93) and measurement error (LoA=1.3<MIC=4.14) were sufficient. Floor and ceiling effects were in the acceptable range (< 15%). Score bandings were determined (κ=0.47); however, the anchor-based MIC could not be calculated owing to an insufficient anchor.

Conclusions PRIDD is a valid and reliable tool to evaluate the impact of dermatological disease on people's lives in research and clinical practice. It is the first dermatology-specific PROM to meet the COSMIN criteria. These results support the value of developing and validating PROMs with a patient-centred approach and using classic and modern psychometric methods. Further testing of responsiveness and MIC, cross-cultural translation, linguistic validation and global data collection are planned.

Lay summary

Skin conditions are common and can affect a person's physical, psychological and social wellbeing. Assessing the impact of a skin condition is important, but the current tools do not meet scientific standards.

We are a team of dermatologists, health psychologists, researchers and patient leaders from Canada, Germany and the UK. We developed a new tool called the Patient-Reported Impact of Dermatological Diseases (or 'PRIDD') to use with adults. To see if a tool is scientifically valid, scientists check its 'measurement properties'. We already know PRIDD meets most of these.

We tested the remaining properties. This included whether PRIDD measures what it should, if its scores are consistent, how accurate it is and if it detects small changes. We also wanted to better understand what PRIDD scores mean. For example, does a score of 20 indicate no, mild, moderate, severe or a very severe impact of a disease? We also wanted to check whether PRIDD can detect very low

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or high scores ('floor' and 'ceiling' effects). We wanted to find out the smallest change in scores that patients consider important (known as the 'minimally important change').

Altogether, 504 people from 38 countries with 35 skin conditions completed PRIDD online. We found that PRIDD met the standards we tested for. We also provided cut-off scores for no, mild, moderate, severe and very severe impact. We could not establish the 'minimally important change'.

PRIDD is the only tool to meet scientific standards that can measure the impact of a skin condition on someone's life.

What is already known about this topic?

- Quantifying the impact of dermatological disease is fundamental to high-quality research and clinical practice.
- Existing dermatology-specific patient-reported outcome measures of impact cannot be recommended, as per COSMIN.
- Developed in partnership with patients, the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure, for use with adults in research and clinical practice, has strong evidence of content validity, structural validity, internal consistency, acceptability and feasibility.

What does this study add?

- This study concludes the development and validation of the 16-item PRIDD.
- The study establishes evidence of PRIDD's criterion validity, construct validity, test–retest reliability, measurement error and lack of floor and ceiling effects.
- The results indicate that PRIDD is the only dermatology-specific PROM to meet the COSMIN criteria to be recommended for use.
- We provide evidence-based score bandings for PRIDD total and subscale scores to aid interpretation in research and clinical practice.

What are the clinical implications of this work?

- PRIDD is a valid, reliable, acceptable and feasible tool to help clinicians evaluate the impact of dermatological disease on patients' lives.
- PRIDD is suitable for use in both research and clinical practice.
- PRIDD subscales can be combined or used individually to distinguish among domains of impact, making it a powerful and versatile tool for clinicians, supporting person-centred care and allowing for rapid referral to appropriate specialist care.

Dermatological diseases are highly prevalent and encompass a wide range of conditions that significantly affect people's physical, psychological and social wellbeing.[1–6] Their symptoms are often distressing and uncomfortable, ranging from pain, itch, redness, scaling and lesions, to death and disfigurement. The detrimental effects extend beyond the often-visible symptoms and can substantially reduce overall wellbeing. Patients may experience psychological distress;[7–12] stigmatization;[13–15] financial costs;[16–19] impairments to daily functioning and activities;[20] treatment-related problems;[21] cumulative life course impairment;[22–25] and comorbidities.[3,4,26–29] Psychological distress may persist even after symptoms have cleared.[3,30–33] The disease burden extends beyond the individual patient: families report emotional distress and caregiver burden;[34,35] healthcare systems see high utilization and costs; and society faces healthcare expenditure, productivity losses and diminished overall societal wellbeing.[36–41] Understanding the multifaceted impact of dermatological diseases is crucial for developing comprehensive strategies that address the needs of patients, their families, healthcare systems and society as a whole.

Since the 1990s, patient-reported outcome measures (PROMs) – most notably the Dermatology Life Quality Index (DQLI)[21] – have transformed our understanding and management of dermatological conditions, paving the way for patient-centred care and improved treatment outcomes. Systematic reviews have found that no dermatology-specific (can be used across conditions) PROM of life impact meets the COSMIN criteria to be recommended for use.[42–45] Most were developed before the publication of PROM development and validation guidelines, chiefly the COSMIN methodology and U.S. Food and Drug Administration (FDA) guidelines,[42,46–48] and the mainstream adoption of modern psychometric methods.[49,50]

We have developed the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure in partnership with patients using both classic and modern psychometric methods. PRIDD captures the multidimensional impact of dermatological diseases on adult patients (≥ 18 years old) using 16 items across 4 impact domains (physical, life responsibilities, psychological and social),[51] and is for use in research and clinical practice. It has been developed through a rigorous, multiyear mixed-methods process with 2218 patients from 74 countries representing 95 dermatological conditions.[3,29,43,51–54]

Before a PROM can be recommended for use in research and clinical practice, validation of its measurement properties is required.[55] PRIDD already has strong evidence of content validity, structural validity, internal consistency, acceptability and feasibility.[3,51–53] Its remaining measurement properties

– criterion validity, construct validity, test–retest reliability, measurement error and responsiveness – need to be evaluated.[56,57] Interpretability information – floor and ceiling effects, score banding (categorization of scores into clinically meaningful groups) and minimally important change (MIC; smallest difference in scores that patients perceive as clinically meaningful or worthwhile)[57] – is also needed to enhance practical utility and clinical relevance.

This final step in the development and validation of PRIDD aimed to (i) test criterion validity, construct validity, test–retest reliability, measurement error and responsiveness, and (ii) examine floor and ceiling effects and determine the score bands and MIC.

Patients and methods

Study design and setting

We conducted a quantitative longitudinal study consisting of two global online surveys administered 2–4 weeks apart.

Patients and recruitment

We used convenience sampling, recruiting participants via the International Alliance of Dermatology Patient Organizations' (GlobalSkin) network, a not-for-profit alliance of dermatology patient organizations worldwide (https://globalskin.org). Consistent with best practices, PRIDD is being validated in English initially with cross-cultural translation to follow. Participants met the inclusion criteria if they were an adult (aged $\geq$ 18 years), had a self-reported physician diagnosis of a dermatological condition and spoke English sufficiently to participate independently. Only those who participated in survey 1, provided the mandatory demographic information (age, sex and gender, and dermatological condition) and had $\leq$ 40% missing data, were eligible to participate in survey 2. COSMIN provides sample size requirements for each measurement property analysis.[58] Of those tested here, the minimum sample sizes range from 50 to 100. Nonresponse determined nonparticipation.

Procedure and materials

Survey 1 was open from 29 June to 29 July 2022 and survey 2 from 12 July to 9 September 2022. Participants were directed to the online platform, developed by information technologists, which included the information sheet, consent form and survey. Participants were given at least 4 weeks to respond, with an email reminder to participate 2 weeks after to complete survey 1 and/or 2 weeks after the survey 1 invitation was sent, if it had not been completed.

Both surveys consisted of a battery of PROMs. The characteristics of these can be found in Table 1; survey 1 included a brief demographics questionnaire (Appendix S1; see Supporting Information). Cronbach's α was calculated for each PROM.

Studies using the global perceived effect (GPE) scale have used different definitions of 'minimal importance'. The decision about MIC is often taken by researchers based on the category they define as minimally important (e.g. 'much improved').[59] As PRIDD emphasizes the patient perspective, the cutoff point was determined by patients using the following item in survey 2 (Appendix S2; see Supporting Information):

> *'Which phrase below captures the smallest amount of change you consider to be a meaningful reduction in the impact of your dermatological condition on your life?'*

- Completely improved
- Much improved
- Slightly improved

Patient involvement

GlobalSkin conceived of the PRIDD measure, was involved in setting the research priorities and defining research questions, and provided input into study design, conduct and dissemination. Our lead patient co-researchers are named co-authors (J.A. and A.F.).

Data analysis strategy

Data were analysed using SPSS version 27 (IBM, Armonk, NY, USA). Descriptive statistics (frequencies and percentages) were produced to summarize the sample and data. Continuous data were summarized using the mean and SD and range. Ordinal data were summarized using the median and interquartile range.

The percentage of missing scores was examined for each PRIDD item. Distributions of item scores were examined using item means ($\bar{x}$) and SDs. Little's χ^2 showed data were missing completely at random at survey 1 ($P > 0.99$) but not at survey 2 ($P < 0.001$).[60] Missing values in survey 2 were replaced following the expected maximization method. Listwise deletion was used.

The significance level was set at $\alpha = 0.05$ for all tests, unless stated otherwise. All Spearman's ρ correlations were interpreted according to Table S1 (see Supporting Information).[61]

Measurement properties

We followed the order of data analysis set out by COSMIN and evaluated the results against their quality criteria.[59,62] Criterion and construct validity, floor and ceiling effects, and score banding tests used survey 1 data. All other measurement properties and the MIC used survey 2 data. Structural validity and internal consistency results reported, including person-item location distribution maps, were derived from confirmatory factor analyses and Rasch measurement theory analyses conducted during a previous PRIDD development study.[51]

Criterion validity

There is no gold-standard PROM to measure the impact of dermatological disease;[57] however, given the ubiquity of the DLQI, we tested criterion validity against it. A Spearman's $\rho > 0.7$ between PRIDD and DQLI indicated sufficient criterion validity.[62]

Construct validity

Convergent validity consists of convergent (comparison with other outcome measurement instruments) and discriminative or known-groups validity (comparison between subgroups).[46] We assessed convergent validity by testing 14 a

Table 1 Summary of patient-reported outcome measures used

Measure	Construct of interest	Target population	Items (*n*)	Domains	Response options (item score)	Recall period	Score ranges	Score directions
PRIDD[51]	Impact of dermatological disease on patient's life	Adults with a dermatological condition	16	4 (Physical impact; Life responsibilities impact; Psychological impact; Social impact)	15 items – never (0), rarely (1), sometimes (2), often (3), always (4) 1 item – never (0), occasionally (1), often (2), always (3)	1 month	Total score: 0–63 (Physical impact: 0–16; Life responsibilities impact: 0–19; Psychological impact: 0–12; Social impact: 0–16)	Higher scores correspond to larger burden of disease
DLQI[21]	QoL	Adults with a dermatological condition	10	6 (Symptoms and feelings; Daily activity; Leisure; Work and school; Personal relationships; Treatment)	Very much (3), a lot (2), a little (1), not at all (0), not relevant (0)	1 week	Total score: 0–30 (Symptoms and feelings: 0–6; Daily activity: 0–6; Leisure: 0–6; Work and school: 0–3; Personal relationships: 0–6; Treatment: 0–3)	Higher scores correspond to larger impact on QoL and can be interpreted as no (0–1), mild (2–5), moderate (6–10), severe (11–20) or very severe impairment to QoL (21–30)[91]
HADS[92]	Anxiety and depression	Adults with physical health conditions	14	2 [Anxiety (HADS-A), Depression (HADS-D)]		1 week	HADS-A: 0–28;[93,94] HADS-D: 0–28	Higher scores indicate greater likelihood of the presence of anxiety or depression
PNQ[20]	Importance of treatment benefits	Adults with a dermatological condition	25	5 (Reducing social impairments; Reducing psychological impairments; Reducing impairments due to therapy; Reducing physical impairments; Having confidence in healing)[95]	Not a lot (0), somewhat (1), moderately (2), quite (3), very (4), does not apply to me (0)	1 day	Total score: 0–100 (Reducing social impairments: 0–24; Reducing psychological impairments: 0–20; Reducing impairments due to therapy: 0–16; Reducing physical impairments: 0–20; Having confidence in healing: 0–12)[96]	Higher scores indicate greater importance for treatment
PtGA-i[97]	Patient's global assessment of the impact of their disease	Adults with physical health conditions	1	–	None at all (0), only a little amount (1), a moderate amount (2), a large amount (3), a very large amount (4)	1 month	0– 4	Higher scores correspond to greater impact
PtGA-s[97]	Patient's global assessment of the severity of their disease	Adults with physical health conditions	1	–	Clear (0), mild (1), moderate (2), severe (3), very severe (4)	1 month	0–4	Higher scores correspond to greater severity
GPE	Condition improvement or deterioration	Adults with physical health conditions	1	–	Completely improved (3), much improved (2), slightly improved (1), no change (0), slightly worse (–1), much worse (–2)	Since survey 1 (approximately 2–4 weeks)		Higher positive scores correspond to greater improvement; lower negative scores correspond to greater deterioration

DLQI, Dermatology Life Quality Index; GPE, global perceived effect; HADS, Hospital Anxiety and Depression Scale; PNQ, Patient Needs Questionnaire; PRIDD, Patient-Reported Impact of Dermatological Diseases; PtGA-i, patient global assessment of impact; PtGA-s, patient global assessment of severity; QoL, quality of life.

priori hypotheses on the relationship between PRIDD and other PROMs using Spearman's ρ (Table S2; see Supporting Information). The statistical significance of correlations was not considered.[59] We tested three a priori hypotheses to evaluate discriminative validity (Table S3; see Supporting Information) using independent-samples *t*-tests. The significance level was determined using a Bonferroni-corrected α of 0.05/3 = 0.016. The number of hypotheses accepted and rejected was counted. Construct, convergent and discriminative validity were considered sufficient if ≥ 75% of the corresponding hypotheses were accepted, respectively.[46]

Test–retest reliability

An intraclass correlation coefficient (ICC), following the two-way random-effects model,[46,59] was calculated between PRIDD scores at survey 1 and survey 2. ICCs were interpreted according to Table S4 (see Supporting Information), with a coefficient of ≥ 0.70 indicating sufficient reliability. Only participants who responded 'no change' to the GPE were included.

Measurement error

We calculated the SEM, smallest detectable change (SDC), limits of agreement (LoA) and two distribution-based (effect size and half SD of PRIDD scores at survey 1) and anchor-based MIC values (Appendix S3; see Supporting Information). Measurement error was acceptable if the SDC or LoA was lower than the MIC.[46] Only participants who responded 'no change' to the GPE were included.

Responsiveness

We tested five a priori hypotheses to assess responsiveness (Table S5; see Supporting Information). A hypothesis was met if it reached the direction and magnitude hypothesized; statistical significance was not considered.[59] The number of hypothesises accepted and rejected was counted. Responsiveness was sufficient if ≥ 75% of the hypotheses were accepted.[46]

Interpretability

Floor and ceiling effects

Floor or ceiling effects were considered present when > 15% of the patients achieved the minimum or maximum possible score,[62,63] and through visual inspection of the person-item location distribution map, with respondents being below and above the range of measurement captured indicating floor and ceiling effects, respectively.

Score banding

Spearman's ρ correlations were used to examine the association between PRIDD scores with patient global assessment of impact (PtGA-i) scores, with ≥ 0.4 indicating that the PtGA-i was an acceptable patient-based anchor.[64,65] We used mean, mode and median PtGA-i scores to assign five impact categories to PRIDD scores: no, mild, moderate, severe and very severe impact. The weighted kappa coefficient of agreement (κ) was calculated for each set of potential bands and the banding option with the highest κ value was selected. κ coefficients were interpreted according to Table S6 (see Supporting Information).[66] The score banding sets identified were retested using the survey 2 data by calculating the κ coefficient.

Minimally important change

The MIC of PROMs should be considered from the perspective of the patient.[59] We used the GPE as a patient-based anchor. Pearson correlations were used to establish the association between PRIDD change scores and the GPE, with ρ ≥ 0.3 indicating that the GPE was an acceptable anchor.[67] In line with the U.S. FDA,[68] we considered the interpretability of the change thresholds for both raw and transformed PRIDD scores, using two approaches – the mean change method and the visual anchor-based MIC distribution method[59,69] – and compared the MIC values against the SDC.

Results

In total, 874 people registered with the online survey platform (Figure 1). Of these, 504 were eligible for inclusion in survey 1 (57.7%) and 271 (53.8%) in survey 2. Demographic data are provided in Table 2. Mean (SD) participant age was 56.11 (15.00) years and most were female (*n* = 399/504; 79.2%) and White (*n* = 397/504; 79.1%). Thirty-five primary dermatological conditions and 38 countries were represented (Table 3). Cronbach's α for the scales was acceptable, ranging from 0.72 to 0.96 (Table S7; see Supporting Information).[70] The majority of participants (94.8%) completed surveys 1 and 2 within a 2–4-week interval; the remaining 17 (6.3%) completed them within a 4–10-week interval. The nonresponse analysis revealed significant differences in ethnicity, World Health Organization (WHO) region and Patient Needs Questionnaire (PNQ) scores (Appendix S4; see Supporting Information).

Descriptive statistics of the scores for each PROM are provided in Table 4. The percentage of missing values across the items was small, ranging from 0% to 3.3% (Table S8; see Supporting Information).

Measurement properties

Criterion validity

Criterion validity was sufficient as there was a moderate-to-high correlation between PRIDD and DLQI scores (ρ = 0.79).

Construct validity

Convergent validity was sufficient as 11 of 14 (79%) hypotheses were met (Appendix S5; see Supporting Information). Discriminative validity was insufficient as only two of three (67%) hypotheses were met. Overall, 13 of 17 (76%) hypotheses were met and therefore construct validity was achieved.

Test–retest reliability

In total, 161 (59.4%) participants responded 'no change' on the GPE. Test–retest reliability was sufficient for all scales as all ICCs ≥ 0.70 (Table S9; see Supporting Information). The ICC value of 0.93 indicates that PRIDD is appropriate for use with both individuals and groups.[70]

Measurement error

Measurement error was sufficient as the LoAs < MIC (Table S10; see Supporting Information).

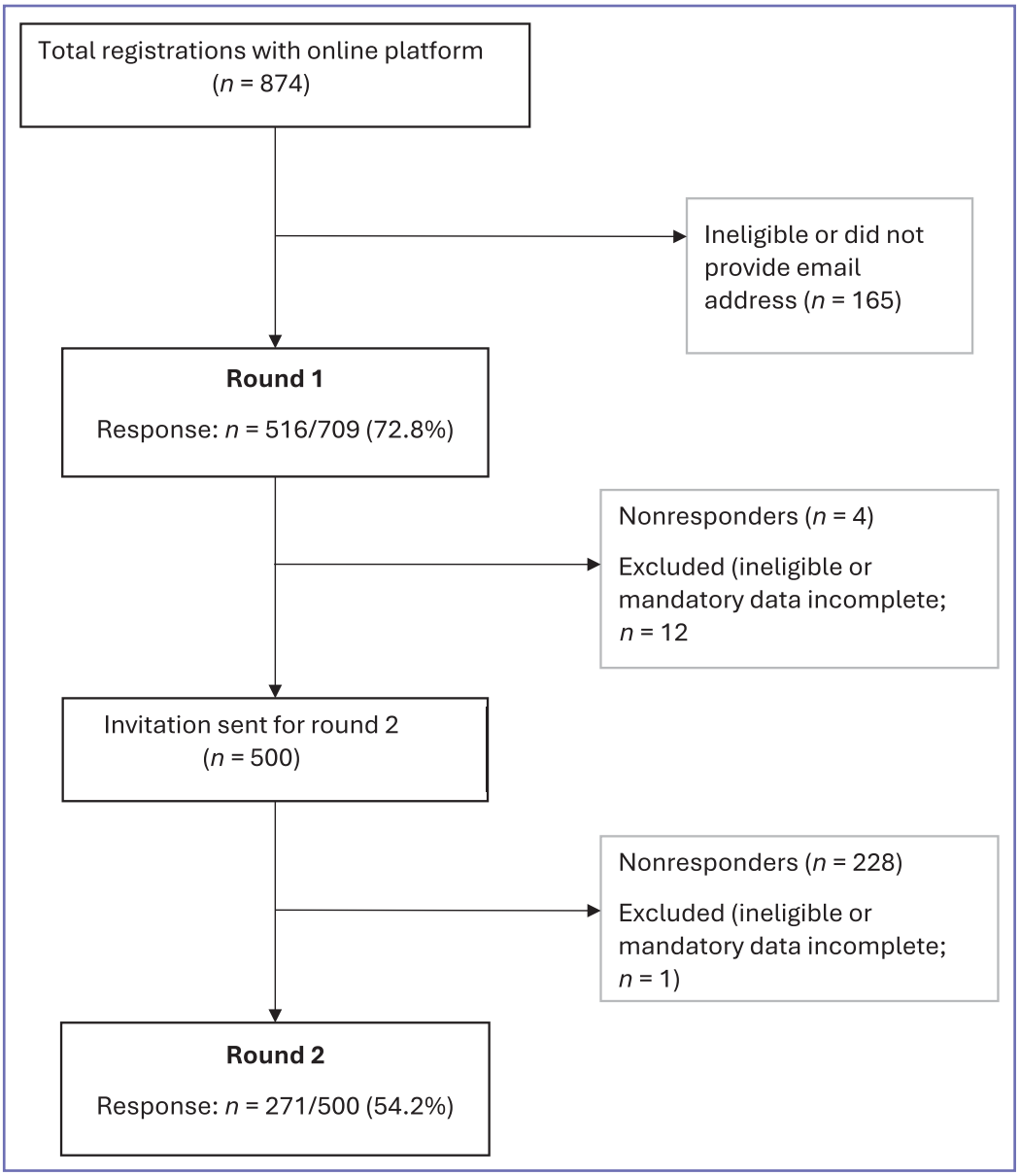

Figure 1 Study recruitment flowchart.

Responsiveness

Participants were classified into six groups based on their responses to the GPE (Table S11; see Supporting Information). Owing to the small sample sizes of some GPE groups, we collapsed the GPE into three groups: worse ('much worse' and 'slightly worse'); no change ('no change'); and improved ('slightly improved', 'much improved' and 'completely improved'). There was no difference in the overall ANOVA results; therefore, the original responses were used. Responsiveness hypothesis 1 was not met as there were no statistically significant differences in PRIDD total change scores between the different GPE groups [$F(5, 219) = 0.57$, $P = 0.72$].

All correlation coefficients for responsiveness hypotheses 2–6 were negligible and therefore were not supported (Table S12; see Supporting Information). Overall, responsiveness was insufficient as no hypotheses were met.

Interpretability

Floor and ceiling effects

The person-item location distribution maps of PRIDD total and subscales showed that some respondents were above and below the range of measurement captured within the scale, indicating floor and ceiling effects (Figure S1; see Supporting Information).[51] However, fewer than 15% of participants achieved the minimum or maximum PRIDD scores at both survey 1 and survey 2 (Table S13; see Supporting Information), indicating that these were within acceptable levels.

Score banding

PRIDD total and subscales scores were moderately to very highly correlated with the PtGA-i at surveys 1 and 2 (Table S14; see Supporting Information). For each score of

Table 2 Sample characteristics

	Survey 1 ($n=504$)	Survey 2 ($n=271$)
Age (years), mean (SD)	56.11 (15.00)	56.74 (13.83)
Range	18–92	23–83
Years lived with condition, mean (SD)	14.44 (15.81)	16.19 (17.29)
Range	0–72	0–70
Sex/gender		
Male	100 (19.8)	43 (15.9)
Female	399 (79.2)	227 (83.8)
Other[a]	2 (0.4)	1 (0.4)
Ethnic background		
Black	11 (2.2)	6 (2.2)
East Asian	20 (4.0)	7 (2.6)
Latino	21 (4.2)	11 (4.1)
Middle Eastern	11 (2.2)	4 (1.5)
Mixed race	2 (0.4)	1 (0.4)
Oceania	2 (0.4)	1 (0.4)
South Asian	9 (1.8)	2 (0.7)
South East Asian	28 (5.6)	5 (1.9)
White	397 (79.1)	232 (85.9)
Other[b]	1 (0.2)	1 (0.4)
English as preferred language[c]	362 (73.9)[d]	204 (77.3)[d]
Highest qualification		
High-school qualifications	100 (19.9)	55 (20.3)
College or university diploma/degree	239 (47.5)	123 (45.4)
Higher degree/professional qualification (e.g. Doctorate or Master's-level degree)	160 (31.8)	93 (34.3)
None of these qualifications	4 (0.8)	0

Data are presented as *n* (%) unless otherwise stated. [a]Prefer to self-describe/prefer not to say. [b]Description not provided. [c]Other preferred languages identified by participants included Afrikaans, Arabic, Azerbaijani, Bulgarian, Cantonese, Cebuano, Chinese, Croatian, Czech, Danish, Dutch, Filipino, Finnish, French, German, Greek, Hindi, Italian, Japanese, Marathi, Norwegian, Portuguese, Romanian, Russian, Sinhalese, Spanish, Swedish, Tagalog, Telugu, Turkish, Urdu, Vietnamese. [d]Valid percentage.

PRIDD and the subscales, the number of patients with that score and their corresponding mode, mean and median PtGA-i score are provided in Table S15 (see Supporting Information). These, along with Figures S2–S6 (see Supporting Information), were used as the basis for grouping the PRIDD scores together into a set of five discrete bands. The bands with the highest coefficient for each scale are presented in Table S16 (see Supporting Information) and represent the final score bandings.

PRIDD total (0–63) and subscale scores are obtained in a two-step process by summing item scores and transforming these raw, ordinal level scores to interval-level data using a conversion table (Appendix S6; see Supporting Information).[51] We recommend using the transformed rather than the raw scores but recognize that the latter may be more feasible in routine practice. As PRIDD scores operate at the interval level, the score bandings provided in Table 5 and Table S16 cover the whole range of PRIDD scores as there are no scores between those provided (i.e. no scores between 14.01 and 15.04, for example). The bandings using the raw, ordinal scores are also provided.

Table S17 (see Supporting Information) shows that for all but 'Life responsibilities impact', the set of bands with the highest κ coefficient in survey 2 matched survey 1. Given the small sample size of survey 2 and minor difference between the highest κ values for 'Life responsibilities impact', we retained the survey 1 score banding.

Minimally important change

As the GPE was not an acceptable anchor ($\rho=0.1$), we could not calculate the anchor-based MIC.

Summary

A summary of the total measurement properties of the PRIDD and interpretability information evaluated against the COSMIN quality criteria is presented in Table 5. The subscales are summarized in Table S18 (see Supporting Information).

Discussion

This study has established evidence of the construct validity, test–retest reliability and measurement error of PRIDD, and provides evidence-based score bandings to aid clinical interpretation. Despite the need for the best evidence-based measures, those that fall short of the scientific standards remain in widespread use.[43,71] To date, PRIDD is the only dermatology-specific PROM that can be recommended for use, according to the COSMIN criteria (Table 5).[42–45]

PRIDD is the first theory-led dermatology-specific PROM to be tested across all seven COSMIN measurement properties.[43] This study met the highest COSMIN standards for tests of construct validity, test–retest reliability and measurement error (Table S19; see Supporting Information).[58]

We recruited a diverse, international sample; however, as participants were primarily recruited through patient organizations, they may not be representative of the broader dermatology patient population. Despite a 46% attrition rate, the sample size remained sufficient for validation studies.[72] A small number of participants ($n=17/271$; 6.3%) completed survey 2 more than 4 weeks after survey 1, constraining

Table 3 Table 3 Dermatological conditions and countries represented according to World Health Organization (WHO) region

Dermatological condition	Survey 1 ($n=504$)	Survey 2 ($n=271$)
Albinism	3 (0.6)	1 (0.4)
Atopic dermatitis	33 (6.5)	16 (5.9)
Autoimmune skin diseases	5 (1.0)	4 (1.5)
Bullous pemphigoid	49 (9.7)	26 (9.6)
Cutaneous lymphomas	10 (2.0)	7 (2.6)
Cutis laxa	3 (0.6)	3 (1.1)
Dyshidrotic eczema	2 (0.4)	2 (0.7)
Epidermolysis bullosa	3 (0.6)	2 (0.7)
Hidradenitis suppurativa	14 (2.8)	10 (3.7)
Ichthyoses	6 (1.2)	4 (1.5)
Lichen sclerosus	80 (15.9)	52 (19.2)
Lupus erythematosus	4 (0.8)	3 (1.1)
Mucous membrane pemphigoid (cicatricial pemphigoid)	31 (6.2)	16 (5.9)
Mycosis fungoides	3 (0.6)	2 (0.7)
Pachyonychia congenita	12 (2.4)	7 (2.6)
Pemphigoid	19 (3.8)	10 (3.7)
Pemphigus foliaceus	15 (3.0)	8 (3.0)
Pemphigus superficial	2 (0.4)	1 (0.4)
Pemphigus vulgaris	91 (18.1)	44 (16.2)
Psoriasis	75 (14.9)	29 (10.7)
Psoriasis arthritis	10 (2.0)	5 (1.8)
Psoriatic spondylitis	2 (0.4)	0
Topical steroid withdrawal syndrome	21 (4.2)	13 (4.8)
Other[a]	11 (1.9)[b]	6 (2.2)
Inflammatory condition	438 (86.9)	229 (84.5)
WHO region		
African region[c]	5 (1.0)	4 (1.5)
Americas region[d]	269 (55.5)	148 (56.5)
South-East Asian region[e]	21 (4.3)	4 (1.5)
European region[f]	119 (24.6)	76 (29.0)
Eastern Mediterranean region[g]	2 (0.4)	1 (0.4)
Western Pacific region[h]	68 (14.0)	29 (11.1)

Data are presented as *n* (%) (valid percentage). [a]Actinic keratosis (solar keratosis), burning mouth syndrome, corticosteroid addiction skin, dermatitis herpetiformis, dermatitis seborrhoeic, Hailey-Hailey disease, IgA pemphigus, lichen planus, ocular cicatricial pemphigoid, rosacea, sarcoidosis, Vitiligo (all $n=1$). [b]Valid percentage. [c]Algeria, South Africa. [d]Argentina, Brazil, Canada, Colombia, Cuba, Mexico, USA. [e]India, Philippines, Sri Lanka. [f]Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Ireland, Israel, Italy, Netherlands, Norway, Russia, Spain, Sweden, Switzerland, UK. [g]Lebanon, Pakistan. [h]Australia, China, Hong Kong, Japan, New Zealand, Papua New Guinea, Vietnam.

Table 4 Patient-reported outcome measure descriptive statistics

	Survey 1		Survey 2	
Measure	**Mean (SD)**	**Range**	**Mean (SD)**	**Range**
PRIDD	29.38 (8.7)	0–63	27.42 (7.81)	0–47.59
Physical impact	8.38 (3.43)	0–16	7.61 (3.09)	0–16
Life responsibilities impact	9.36 (3.95)	0–19	8.79 (3.77)	0–19
Psychological impact	5.89 (2.99)	0–12	5.39 (2.87)	0–12
Social impact	6.47 (3.77)	0–16	5.81 (3.75)	0–16
DLQI	9.31 (7.78)	0–30	8.85 (7.67)	0–30
Symptoms and feelings	2.45 (1.76)	0–6	2.32 (1.7)	0–6
Daily activities	2.02 (1.96)	0–6	2 (1.98)	0–6
Leisure	1.87 (2.05)	0–6	1.81 (2.05)	0–6
Work and school	0.63 (1.05)	0–3	0.17 (0.41)	0–2
Personal relationships	1.35 (1.76)	0–6	1.24 (1.7)	0–6
Treatment	0.97 (0.97)	0–3	0.96 (0.99)	0–3
PtGA-i	1.83 (1.13)	0–4	1.57 (1.1)	0–4
PtGA-s	1.78 (1.09)	0–4	1.64 (0.98)	0–4
HADS-A	7.5 (4.72)	0–21	–	–
HADS-D	5.66 (4.35)	0–21	–	–
PNQ	67.27 (23.24)	2–100	–	–
Social impairments	16.60 (6.51)	0–24	–	–
Psychological impairments	15.46 (4.81)	0–20	–	–
Impairments due to therapy	11.47 (4.39)	0–16	–	–
Physical impairments	16.55 (3.82)	1–20	–	–
Confidence in healing	9.92 (2.79)	0–12	–	–
GPE	–	–	3.24 (0.92)	1–6

DLQI, Dermatology Life Quality Index; GPE, Global Perceived Effect; HADS-A; Hospital Anxiety and Depression – anxiety subscale; HADS-D, Hospital Anxiety and Depression – depression subscale; PNQ: Patient Needs Questionnaire; PRIDD, Patient-Reported Impact of Dermatological Diseases; PtGA-I, patient global assessment of impact; PtGA-s, patient global assessment of severity.

Table 5 Summary of the total measurement properties and interpretability information of the Patient-Reported Impact of Dermatological Diseases (PRIDD) against the COSMIN quality criteria[62]

		Requirement	Rating	Results
Structural validity	Unidimensionality	No violation of unidimensionality No violation of local independence Adequate model fit: $\chi^2 > 0.01$	+	PRIDD and all subscales unidimensional with no local dependency; $\chi^2 = 0.1151$
	Structural validity	CFI or TLI or comparable measure > 0.95 or RMSEA < 0.06 or SRMR < 0.08	+	CFI = 0.96; TLI = 0.97; RMSEA = 0.09; SRMR = 0.0351
Internal consistency		Person separation index ≥ 0.7 Cronbach's $\alpha \geq 0.7$	+	Person separation index = 0.8951; $\alpha = 0.95$
Hypothesis testing for construct validity		75% of hypotheses met	+	76% of hypotheses met
Test–retest reliability		ICC or weighted $\kappa \geq 0.70$	+	ICC = 0.93
Measurement error		SDC or LoA < MIC	+	LoA (1.3) < MIC (4.14); unable to determine anchor-based MIC
Responsiveness		The result is in accordance with the hypothesis or AUC ≥ 0.70	–	0 hypotheses met
Floor and ceiling effects		Considered present when > 15% of the patients achieved the minimum or maximum possible score	+	< 0.9% with minimum or maximum score
MIC		NA		4.14 (pending patient-perspective MIC)
Score banding		NA		No impact: 0–14.01 (raw score 0–5); mild impact: 15.04–25.73 (raw score 6– 26); moderate impact: 26.14–34.26 (raw score 27–44); severe impact: 34.86–39.69 (raw score 45–52); very severe impact: 40.53–63.00 (raw score 53–63)

(+), sufficient; (–), insufficient, AUC, area under the curve; CFI, Comparative Fit Index; ICC, intraclass correlation coefficient; LoA, limits of agreement; MIC, minimally important change; NA, not applicable; RMSEA, root mean square error of approximation; SDC, smallest detectable change; SRMR, standardized root mean square; TLI, Tucker–Lewis Index.

the validity of the test–retest reliability, measurement error and responsiveness results. Nonresponder analysis found a significant difference in the ethnicity, WHO region and PNQ scores of participants who did and did not respond to survey 2, potentially affecting the generalizability of the results. Although the GPE and PtGA-i are widely used, they have not been validated for use with dermatology patients.

We were unable to determine the MIC and responsiveness of PRIDD. The distribution-based MIC could not serve as a substitute as it does not incorporate the patient perspective.[59,73] That said, while work to establish the anchor-based MIC is ongoing, we tentatively propose a MIC value of 4.14. As we followed COSMIN's recommendation to use a standardized, patient-based anchor, we assumed that the issues encountered did not arise from the GPE anchor, but from the study design. We initially chose a 2–4-week interval, in line with PROM evaluation guidance.[46,74] In hindsight, a 1-month interval would have been more appropriate given PRIDD's 1-month recall period; a shorter follow-up would not adequately capture the experiences and changes respondents had over the past month, potentially leading to incomplete or inaccurate assessments. Therefore, we recognize that recall bias may have affected participants' responses. Insufficient cases across some GPE responses may have affected the precision of the results. Finally, PRIDD may not be responsive. Our ongoing study with a larger sample and a 1-month interval aims to address these concerns and determine the responsiveness and MIC of PRIDD.

National Institute for Health and Care Excellence (NICE) guidelines recommend a biopsychosocial approach to the management of dermatological conditions – measuring disease severity and the wider impact on the person's life, including physical, psychological and social wellbeing.[27,75–77] PRIDD's subscales directly measure each of these impact domains. By providing clinicians with a more comprehensive understanding of people's experiences, needs and concerns, PRIDD can support patient-centred care, improve communication between patients and their clinical team, inform shared decision-making, guide patient self-management, and reveal high levels of psychological distress or physical symptoms that may require an immediate response (known as a patient-reported outcome alert), allowing for rapid referral to appropriate specialist care.[78,79]

Through the stepped model of care, PROMs significantly affect treatment decision-making,[80] influencing both the medications prescribed and the psychological support offered. For example, NICE guidelines specify a Psoriasis Area and Severity Index score of ≥ 10 and DLQI > 10 before recommending apremilast to adult patients.[75] This gatekeeping approach, where treatment access is contingent on meeting predetermined score thresholds, erroneously assumes the validity and reliability of dermatology PROMs.[42–45] Even with patient involvement in PROM development, the final version may prioritize items that are more important to the developers than to patients as they are rarely consulted during the item-reduction process.[43] This bias raises ethical concerns as powerful entities are shaping tools that affect less powerful individuals. To ensure the ethical use of PROMs in treatment decisions, there is a pressing need for them to genuinely capture what matters most to patients. Patients directly contributed to the prioritization of PRIDD items.[29,81] Therefore, we have produced a valid, reliable, acceptable and feasible tool that demonstrates what patients identify as important to consider within the stepped model of care.[53] We provide score bandings but emphasize that these should be used to aid clinical interpretation and support and initiate rather than replace holistic discussions.

Core outcome sets (COS) can advance dermatology by allowing us to systematically collate and compare findings from clinical trials and reduce selection bias.[82–84] The CHORD COUSIN Collaboration (C3) focuses on COS for trials and clinical practice in dermatology.[85] Quality of life has been identified as a core outcome domain in COS across several disease areas, but no existing PROMs can be recommended for use;[86–88] PRIDD represents a promising candidate measure.

Dermatology-specific measures are often recommended or required by regulators as they can be used across the dermatology patient population and resultant data can be compared and collated.[89,90] As with any dermatology-specific PROM, we recommend that PRIDD is used alongside, rather than instead of, disease-specific PROMs and intend to develop disease-specific additions to PRIDD.

This study validated the original English-language version of PRIDD. It has since been translated into 16 other languages using best practice forward- and back-translation methods with linguistic validation underway. Further studies are required to test PRIDD in different dermatology populations and settings. It will also be beneficial to revalidate the measurement properties of PRIDD in a sample of patients who were not involved in the original development and validation.

PRIDD is a valid and reliable tool to help clinicians provide better care and stakeholders to better understand the burden of dermatological disease. It is the first theory-led dermatology-specific PROM tested across all seven COSMIN measurement properties and the only one that can be recommended for use according to the COSMIN criteria. The results confirm the value of developing and validating PROMs with a patient-centred approach and using modern psychometric methods. The next steps include further testing of measurement error and responsiveness, linguistic validation and collecting global data on the burden of dermatological conditions.

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Conflicts of interest

The authors declare no conflicts of interest.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Ethics statement

Ethical approval was obtained from Cardiff University School of Healthcare Sciences Ethics Committee (SREC: 826).

Patient consent

Informed consent was obtained from all participants.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website.

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Consistent safety profile with over 8 years of real-world evidence, across licensed indications[1–3]

Cosentyx® secukinumab

1,000,000 patients treated globally, and counting across indications[4]

150+ clinical trials across indications[5]

8+ years of real-world evidence, worldwide across indications[1–3]

8 indications[1–3]

Click here to visit our HCP portal and learn more

Real-world evidence shows a consistent safety profile with long-term use of Cosentyx over 6 years[6,7]

No trend toward increased AE rates over time (pooled PsA, AS, PsO):*[6]

AEs of select interest (EAIR per 100 PY)	1 year	2 years	3 years	4 years	5 years	6 years	Cumulative rate
Serious infections Cases	2.0 n=149	1.7 n=475	0.7 n=649	1.3 n=1,841	1.3 n=2,285	1.1 n=2,226	1.3 n=8,719
Malignant or unspecified tumours Cases	0.2 n=15	0.2 n=50	0.2 n=225	0.3 n=422	0.3 n=520	0.3 n=573	0.3 n=1,896
MACE Cases	0.2 n=15	0.1 n=39	0.2 n=151	0.2 n=238	0.2 n=264	0.1 n=287	0.2 n=1,031
Total IBD Cases	0.2 n=12	0.2 n=46	0.2 n=185	0.3 n=340	0.2 n=312	0.1 n=261	0.2 n=1,291
Exposure (PY)	7450	28,549	93,744	137,325	182,024	212,636	680,470

No trend towards increased rates of malignancy, MACE or IBD over time[6]

The most frequently reported adverse reactions are upper respiratory tract infections (17.1%) (most frequently nasopharyngitis, rhinitis).[1,2] Refer to the prescribing information for a summary of adverse events.

Adapted from Novartis Data on File. 2021.[6]

Refer to the Cosentyx Summary of Product Characteristics for full details, dosing and administration, including special populations.

Cosentyx is indicated for the treatment of moderate to severe **PsO** in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active **PsA** in adult patients (alone or in combination with methotrexate) when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate; active **AS** in adults who have responded inadequately to conventional therapy; active **nr-axSpA** with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active moderate to severe **HS** (acne inversa) in adults with an inadequate response to conventional systemic HS therapy; active **ERA** in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active **JPsA** in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.[1,2]

Prescribing information, adverse event reporting and full indication can be found on the next page.

*Successive time periods of PSUR shown with cumulative rate: 26 Dec 2014 to 25 Dec 2015; 26 Dec 2015 to 25 Dec 2016; 26 Dec 2016 to 25 Dec 2017; 26 Dec 2017 to 25 Dec 2018: 26 Dec 2018 to 25 Dec 2019; 26 Dec 2019 to 25 Dec 2020.[6]

Abbreviations: AE, adverse event; AS, ankylosing spondylitis; EIAR, exposure-adjusted incidence rate; ERA, enthesitis-related arthritis; HCP, healthcare professional; HS, hidradenitis suppurativa; IBD, inflammatory bowel disease; JPsA, juvenile psoriatic arthritis; MACE, major adverse cardiac event; nr-axSpA, non-radiographic axial spondyloarthritis; PsA, psoriatic arthritis; PsO, plaque psoriasis; PY, patient year.

References: 1. Cosentyx® (secukinumab) GB Summary of Product Characteristics; **2.** Cosentyx® (secukinumab) NI Summary of Product Characteristics; **3.** European Medicines Agency. European public assessment report. Available at: https://www.ema.europa.eu/en/documents/overview/cosentyx-epar-medicine-overview_en.pdf [Accessed August 2024]; **4.** Novartis Data on File. Secukinumab – Sec008. 2023; **5.** ClinicalTrials.gov. Search results for 'secukinumab', completed, terminated and active, not recruiting trials. Available at: https://clinicaltrials.gov/search?term=Secukinumab,&aggFilters=status:com [Accessed August 2024]; **6.** Novartis data on file. Cosentyx Periodic Safety Update Report (PSUR); 26 December 2019 – 25 December 2020. 22 February 2021; **7.** Deodhar A, et al. Arthritis Res Ther 2019;21(1):111.

NOVARTIS

UK | August 2024 | FA-11239622

Cosentyx® (secukinumab) Northern Ireland Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg monthly. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab than placebo in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. *Fertility:* Effect on human fertility not evaluated. **Adverse Reactions**: *Very Common* (≥1/10): Upper respiratory tract infection. *Common* (≥1/100 to <1/10): Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reactions, exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. *Not known:* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). *Infections:* Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). *Neutropenia:* Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions:* Urticaria and rare cases of anaphylactic reactions were seen. *Immunogenicity*: Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** EU/1/14/980/005 - 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/010 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** May 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

UK | 284832 | May 2023

Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com

Cosentyx® (secukinumab) Great Britain Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 75 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 75 mg dose is given as one injection of 75 mg. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 75mg and 150 mg pre-filled syringe and 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. 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UK | 290802 | June 2023

Adverse Event Reporting:

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If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com