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Further refinement of the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure using classical test theory and item response theory

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Abstract

Background Existing dermatology-specific Patient-Reported Outcome Measures (PROMs) do not fully capture the substantial physical, psychological and social impact of dermatological conditions on patients' lives and are not recommended for use according to the COSMIN criteria. Most were developed with insufficient patient involvement and relied on classical psychometric methods. We are developing the new Patient-Reported Impact of Dermatological Diseases (PRIDD) measure for use in research and clinical practice in partnership with patients.

Objectives To examine the factor structure of PRIDD, determine the definitive selection of items for each subscale, and establish structural validity and internal consistency through classical and modern psychometric methods.

Methods Two cross-sectional online surveys were conducted. Adults ($\geq$ 18 years) worldwide living with a dermatological condition were recruited through the membership network of the International Alliance of Dermatology Patient Organizations (GlobalSkin). They completed the PRIDD questionnaire and a demographics questionnaire via an online survey. We examined missing data and distribution of scores for each item. The factor structure was assessed using confirmatory and exploratory factor analysis (Survey 1). Internal consistency was examined using Cronbach's α. Rasch measurement theory analyses were conducted, including iterative assessment of rating scale function, fit to the Rasch model, unidimensionality, reliability, local dependence, targeting and differential item functioning (DIF) (Surveys 1 and 2).

Results Participants in Surveys 1 and 2 numbered 483 and 504 people, respectively. All items had $\leq$3% missing scores and all five response options were used. A four-factor model showed the best fit. PRIDD and all four subscales were internally consistent but showed some misfit to the Rasch measurement model. Adjustments were made to rectify disordered thresholds, remove misfitting items, local dependency and DIF, and improve targeting. The resulting 16-item version and subscales fit the Rasch model, showed no local dependency or DIF at the test level, and were well targeted.

Conclusions This field test study produced the final PRIDD measure, consisting of 16 items across four domains. The data triangulated and refined the conceptual framework of impact and provide evidence of PRIDD's structural validity and internal consistency. The final step in the development and validation of the PRIDD measure is to test the remaining measurement properties.

What is already known about this topic?

- No existing dermatology-specific patient-reported outcome measure (PROM) is recommended for use according to the COSMIN criteria.
- The conceptual framework of the impact of dermatological conditions on patients' lives depicts 'impact' as a multifaceted construct involving physical, daily life and responsibilities, psychological, social and financial impacts.
- The Patient-Reported Impact of Dermatological Diseases (PRIDD) instrument is in development with evidence of content validity, acceptability and feasibility.

What does this study add?

- This study produced the final PRIDD instrument, reduced to 16 items across four domains, for use in research and clinical practice.
- The data triangulated and refined the conceptual framework of impact from five to four domains: physical, life responsibilities, psychological and social impacts.
- The results provide evidence of PRIDD's structural validity and internal consistency and further support its content validity.

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What are the clinical implications of the work?

- This validated conceptual framework provides clinicians and researchers with a valuable framework for understanding and measuring the impact of dermatological conditions on patients' lives.
- Clinicians should select high-quality, evidence-based PROMs. The PRIDD has good evidence of content validity, acceptability, feasibility, structural validity and internal consistency.
- The remaining measurement properties (construct validity, test–retest reliability, measurement error and responsiveness) will be tested in the next and final step in the PRIDD's development.

Assessment of the full impact of dermatological conditions on patients' lives is crucial to effective management. Dermatology-specific (used across dermatological conditions) patient-reported outcome measures (PROMs) are ideally suited as they are more specific, sensitive and clinically sensible than generic PROMs while allowing for use and comparison across conditions.[1–3]

Recent systematic reviews reveal that no dermatology-specific PROMs meet the COSMIN standards[4] to be recommended for use according to their known measurement properties.[5–7] Many of the issues identified stem from insufficient patient involvement during development and the methodological limitations of classical test theory (CTT).[5]

We are developing the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure in partnership with patients and using both classic and modern psychometric methods. The PRIDD tool measures the impact of dermatological conditions on the patient's life and is for use in research and clinical practice with adults living with any dermatological condition worldwide.

Development and validation of the Patient-Reported Impact of Dermatological Diseases tool

PRIDD development and validation involves a content validity and subsequent psychometric testing phase (Figure S1; see Supporting Information).[4,8–11]

The content validity phase had three key stages: (1) concept elicitation,[12] (2) participatory item reduction[13] and (3) pilot testing.[14,15] The resultant 26-item English version of PRIDD, with each item rated on a 5-point scale ranging from 0 (never) to 5 (always), has strong evidence of content validity according to the COSMIN standards.[4] The conceptual framework of impact followed a reflective model[12] with five domains of impact – physical, daily life and responsibilities, psychological, social and financial (Figure S2; see Supporting Information)[13] – but is yet to be validated quantitatively.[16]

The current psychometric testing phase consists of two sequential stages: (4) field testing and (5) testing of the measurement properties. The field test aims to establish structural validity, an important measurement property that describes the 'degree to which the scores of an instrument are an adequate reflection of the dimensionality of the construct to be measured'.[17,18] Only once PRIDD is finalized through field testing can its measurement properties be fully established.

Factor analysis, an extension of CTT, and Rasch analysis, part of the item response theory (IRT) family, are the preferred statistical methods to assess structural validity.[19] Factor analysis is valuable for identifying the dimensions (or subscales) in a PROM, but cannot establish the psychometric quality of those dimensions. IRT, a modern psychometric method, is a powerful tool to assess PROM psychometrics as it overcomes many of the limitations of CTT. The Rasch model is a unidimensional measurement model that satisfies the fundamental assumptions of IRT,[20,21] meaning it provides a measurement template against which scales can be tested.[22]

This study (stage 4 of 5) aimed to examine the factor structure of the PRIDD measure, determine the definitive selection of items for each subscale, and establish structural validity and internal consistency through classical and modern psychometric methods. Based on the conceptual framework of impact we hypothesized that the PRIDD tool had five domains.

Patients and methods

Study design and setting

We conducted two cross-sectional online surveys. Ethical approval was obtained from Cardiff University School of Healthcare Sciences Ethics Committee (SREC:826). Informed consent was obtained from all participants.

Patients and recruitment

We employed convenience sampling to recruit eligible participants to both surveys through the membership network of the International Alliance of Dermatology Patient Organizations (GlobalSkin, https://globalskin.org/), which is a not-for-profit alliance of over 245 dermatology patient organizations worldwide. The samples were independent of each other. It is best practice to develop and validate a PROM in one language with later cross-cultural translation. PRIDD is being developed initially in English. Participants therefore met the inclusion criteria if they were an adult ($\geq$ 18 years), living with a dermatological condition, and understood English sufficiently to complete the survey independently. We aimed to recruit the recommended sample size of 250–500 for Rasch analysis to each survey.[23] Nonparticipation was due to nonresponse.

Procedure and materials

Survey 1 was open from 1 November to 1 December 2021, and Survey 2 from 29 June to 29 July 2022. Participants were directed to the online platform, which included the participant information sheet, consent form and survey

consisting of demographic items and PRIDD (Appendix S1; see Supporting Information), and given at least 4 weeks to respond.

Patient involvement

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

Data analysis strategy

We followed the order of data analysis for field testing set out by the COSMIN group and evaluated the results against their quality criteria for structural validity and internal consistency.[11,18] We completed all the steps outlined below on the Survey 1 data. This revealed that further amendments were required. After adjusting PRIDD, we conducted Survey 2, where we repeated many aspects of the analysis. We have noted below which parts of the data analysis used which dataset. We ran multiple iterations of the analysis on the different versions of PRIDD (Table S1; see Supporting Information): analysis of PRIDD V0.1 to V.04 used Survey 1 data and V.05 and V.1 used Survey 2 data. We used Little's test of Missing Completely at Random (MCAR) for missing values.[24]

Examination of individual items of the Patient-Reported Impact of Dermatological Diseases tool (Surveys 1 and 2)

The percentage of missing scores was examined for each item using SPSS 27 (IBM; Armonk, NY, USA). Items with $\leq 3\%$ missing scores were deemed 'acceptable' and $\geq 15\%$ 'not acceptable'.[18] Distributions of item scores were examined using item means ($\bar{x}$) and standard deviations.

Factor analysis (Survey 1)

Confirmatory factor analysis

Confirmatory factor analysis (CFA) is more appropriate than exploratory factor analysis (EFA) when a conceptual framework is available.[4,18,19,25] We performed a CFA with categorical factor indicators applying full information maximum likelihood to missing data using Mplus 8.2 (Muthén & Muthén, Los Angeles, CA, USA).[26,27] Mplus determines the number of categories for each factor indicator with a robust weighted least squares estimator (wlsmv).[28] Multicollinearity was assessed via bivariate correlations (Spearman's), with $r \leq 0.8$ deemed acceptable.[29] Table 1 outlines the goodness-of-fit criteria for CFA models.[30–33] Structural validity was sufficient if the comparative fit index (CFI) or Tucker–Lewis index (TLI) > 0.95, root mean square error of approximation (RMSEA) < 0.06 or standardized root mean square residual (SRMR) < 0.08.[11]

Exploratory factor analysis

As the CFA did not support our five-domain conceptual framework, we performed an EFA with listwise deletion on SPSS 27 using the principal factor method with oblique rotation (direct oblimin) to determine the number of dimensions.[18]

Table 1 Goodness-of-fit criteria for confirmatory factor analysis models

Fit	Criteria
Exact fit	χ^2, $P > 0.05$
Approximate fit	• RMSEA ≤ 0.06 (90% CI ≤ 0.06), CFI ≥ 0.95, TLI ≥ 0.95 and SRMR ≤ 0.08 (> 0.1 is poor fitting)[32,33] • χ^2/df ratio ≤ 3 rule[31] • χ^2 significant ($P \leq 0.05$), SRMR ≤ 0.08, and standardized residuals were small ($\lvert r_{res} \rvert < 0.1$)[30,31]
Poor fit	χ^2 significant ($P < 0.05$) and SRMR > 0.08

CFI, comparative fit index; CI, confidence interval; df, degrees of freedom; RMSEA, root mean square error of approximation; SRMR, standardized root mean square residual; TLI, Tucker–Lewis index.

The Kaiser–Meyer–Olkin (KMO) test (KMO > 0.5) and Bartlett's test of sphericity ($P < 0.05$) were used to confirm the adequacy of the sample and data, respectively.

Four criteria were used to determine the number of factors (see Table 2).[18,34–36] As uncertainty remained regarding the number of factors to extract, we followed Costello and Osborne's[37] recommendation to run multiple factor analyses, setting the number of factors to retain manually once at the projected number based on the a priori factor structure, then at the number of factors suggested by the scree test, and finally at numbers above and below those numbers. Item-loading tables were compared and the solution with the most factors and 'cleanest' factor structure (item loadings > 0.3, no or few cross-loadings, and no factors with fewer than three items) was deemed to have the best fit to the data. Residual correlations < 0.1 and factor loadings ≥ 0.5 were deemed acceptable.[30,31,38]

Internal consistency (Surveys 1 and 2)

We tested internal consistency for PRIDD and each factor separately with listwise deletion using SPSS 27. Items with inter-item correlations > 0.7 and item-total correlations < 0.3 were candidates for removal. Cronbach's $\alpha > 0.7$ was deemed acceptable and > 0.9 indicated item redundancy.[11]

Rasch analysis (Surveys 1 and 2)

Rasch analyses were performed iteratively on PRIDD and each subscale using RUMM2030 (RummLab Pty Ltd, Duncraig, Australia) according to the steps outlined in Table 3 (and Table S2; see Supporting Information).[39–44] We tested whether the subscales could be validly combined into an 'overall impact' total score using the subtest approach to obtain R (average latent correlation between the subscales) and A values (the amount of shared variance between the subscales).

Table 2 Criteria to determine number of factors extracted in the exploratory factor analysis

	Criteria
1	Kaiser's criterion of eigenvalues > 1[35]
2	Joliffe's criteria of eigenvalues > 0.7[36]
3	Visual inspection of the scree plot to identify the number of eigenvalues before the slope flattens out[18]
4	Parallel analysis[34]

Table 3 Steps in the iterative Rasch analysis

1	Threshold ordering	Rating scales function optimally when thresholds are ordered. Thresholds correspond with the threshold points between two different scores on the rating scale, in this case 'never' to 'always'. At the threshold point, it is equally likely to obtain either score (i.e. the probability of scoring 2 or 3 on the item is 50/50). This is demonstrated by category probability curves where each curve shows a distinct peak which illustrates the position along the continuum where the categories are most likely to be selected.[40,41] This indicates that respondents are able to discriminate between response options.[41,42] Disordered thresholds indicate that an item is not working properly as the response categories are not progressing in a logical order. In this case, even when the probability of selecting a particular response option is at its highest, it is still more likely that another option will be selected. We examined threshold ordering visually using the threshold map. The category probability curves of disordered thresholds were visually inspected to determine whether the item response options were functioning optimally and whether rescoring was indicated.
2	Tests of fit	Model fit was acceptable if the item–trait interaction, reported as χ^2, was nonsignificant ($P > 0.05$) and the item and person residuals had $\bar{x} \approx 0$ and SD ≈ 1. Individual items and persons were regarded as misfitting if their residuals fell outside the range of ± 2.5. Individual items were also tested by χ^2 and F-tests.
3	Unidimensionality	Strict unidimensionality was confirmed with a series of *t*-tests reporting significantly different person estimates in $< 5\%$ of cases (or the lower bound of the 95% confidence interval $< 5\%$).
4	Local independence	Local dependency among the items was assessed via the residual correlations using a cut-point of the average plus 0.2.[43]
5	Differential item functioning (DIF)	DIF occurs when members from different groups who have the same level of the latent trait (i.e. impact) have a different probability of giving a certain response to an item. DIF was tested by: • gender (male or female) • age group (years; four equal groups: Survey 1: 18–36, 37–55, 56–74, 75–90; Survey 2: 18–37, 38–57, 58–77, 78+) • inflammatory type (inflammatory and noninflammatory). Inflammatory type was chosen over discrete diseases as DIF analysis can handle no more than four categories. For categorization of diseases see Table S2 • highest qualification • English as a first language (yes or no) A statistically significant Bonferroni-adjusted *P*-value indicated DIF.
6	Targeting	We visually inspected the Person–Item Threshold Distribution graphs and reported the $\bar{x}$ person location value. Mean person locations within $+0.5$ logits of the mean item location (i.e. 0 logits) suggested acceptable targeting.[44]

Results

Survey 1 included 483 patients (Table 4) from 42 countries (Table S3; see Supporting Information) representing 50 dermatological conditions (Table S4; see Supporting Information); Survey 2 included 504 patients from 38 countries with 34 dermatological conditions. Of these, 703 (71%) were native English speakers (Table S5; see Supporting Information). PRIDD missing data were MCAR, $P > 0.05$.

Examination of PRIDD items

All items had acceptable levels ($\leq 3\%$) of missing scores (Table S6; see Supporting Information). All item means were close to the centre of the range of possible scores, indicating that the response options detected the full range of the construct, were well worded and had higher variances.[34]

PRIDD V0.1

Bivariate correlations for the CFA ranged from 0.2 to 0.76, indicating no multicollinearity.[29] Approximate fit to the four-factor model was not achieved (Table 5); therefore, we conducted an EFA.

Three factors had eigenvalues > 1, six factors > 0.7 and the scree plot was slightly ambiguous, showing inflexions that would justify retaining two or three factors (Appendix S2; see Supporting Information). The parallel analysis diverged from these results, suggesting a 26-factor model (Table S7; see Supporting Information). We consequently ran six EFAs, setting the number of factors to retain manually at 5, 2, 3, 6, 4 and 1.

PRIDD V0.2

The six-factor model was the 'cleanest' (Table S8; see Supporting Information) and item clustering suggested the following underlying concepts:

- Factor 1: Negative Affect
- Factor 2: Physical Impact
- Factor 3: Appearance-related Concerns
- Factor 4: Life Responsibilities Impact
- Factor 5: Interpersonal Relationships
- Factor 6: Identity

All factors were internally consistent (Appendix S3; see Supporting Information); however, Negative Affect demonstrated item redundancy ($\alpha = 0.91$). The item 'I have struggled to concentrate' had the highest 'α if item deleted' value and was therefore removed, leaving 25 items (PRIDD V0.2).

All six factors showed at least some misfit to the Rasch model (Table S9; see Supporting Information). Five factors showed local dependency (Appendix S4; see Supporting Information). Correction involved removing three items and grouping six other items into three testlets. This produced three factors with fewer than three items, the minimum recommended number of items in a scale.[18,37] Given the conceptual overlap of the remaining items, Appearance-related Concerns was combined with Negative Affect to create Psychological Impact, and Interpersonal Relationships and Identity were combined to make Social Impact. This resulted in a 22-item, four-factor model (PRIDD V0.3).

Table 4 Participant characteristics

	Survey 1, *n* (%)	Survey 2, *n* (%)
Total	483	504
Age (male), years (SD; range)	48.97 (15.24; 18–90)	56.11 (15; 18–92)
Lived with condition (male), years (SD; range)	20.211 (17.1279; 0–86)	14.44 (15.81; 0–72)
Gender		
Male	129 (26.7)	100 (19.8)
Female	353 (73.1)	402 (79.8)
Other	1 (0.2)	2 (0.4)
Ethnicity		
Black	20 (4.2)	11 (2.2)
East Asian	15 (3.2)	20 (4.0)
Latino	5 (1.1)	21 (4.2)
Middle Eastern	2 (0.4)	11 (2.2)
Mixed race	0	2 (0.4)
Oceania	0	2 (0.4)
South Asian	4 (0.8)	9 (1.8)
Southeast Asian	12 (2.5)	28 (5.6)
White	415 (87.7)	397 (79.2)
Highest educational qualification		
High school qualifications	122 (25.4)	100 (19.9)
A college or university diploma or degree	225 (46.8)	239 (47.5)
A higher degree or professional qualification (e.g. doctorate or master's level degree)	122 (25.4)	160 (31.8)
None of these qualifications	12 (2.5)	4 (0.8)

PRIDD V0.3

This four-factor model achieved approximate fit and met the COSMIN criteria for structural validity (Table 5). All factors were internally consistent (Table S10; see Supporting Information) but showed some misfit to the Rasch model (Table S11; see Supporting Information). This improved on removal of two items: 'I have been hiding, covering or concealing my condition' (Psychological Impact) and 'I have

Table 5 Fit indices of the confirmatory factor analysis models for PRIDD V0.1, V0.3 and V1

	Tests of model fit				RMSEA				
Model fit indices	χ^2	df	*P*	Ratio	Estimate	90% CI	CFI	TLI	SRMR
PRIDD V0.1									
Model 1a: Four factors (Physical Impact + Life Responsibilities Impact + Psychological Impact + Social Impact)	1459.95	269	0.00	5.42	0.1	0.93–0.1	0.94	0.94	0.05
Model 1b: Four factors [Physical Impact + Life Responsibilities Impact (including Financial Impact) + Psychological Impact + Social Impact]	1491.982	293	0.00	5.09	0.09	0.09–0.1	0.94	0.94	0.05
Model 1c: Four factors [Physical Impact + Life Responsibilities Impact + Psychological Impact + Social Impact (including Financial Impact)]	1605.811	293	0.00	5.48	0.1	0.09–0.1	0.94	0.93	0.05
Model 3: Four factors, second order[a] (Physical Impact + Life Responsibilities Impact + Psychological Impact + Social Impact)	1338.161	269	0.00	4.97	0.09	0.09–0.1	0.95	0.943	0.05
PRIDD V0.3									
Model 2a: Four factors (Physical Impact + Life Responsibilities Impact + Psychological Impact + Social Impact)	944.229	203	0.00	4.65	0.09	0.08–0.09	0.96	0.95	0.04
Model 2b: Four factors, second order[a] (Physical Impact + Life Responsibilities Impact + Psychological Impact + Social Impact)	1005.067	205	0.00	4.9	0.09	0.08–0.1	0.95	0.95	0.05
PRIDD V1									
Model 3a: Four factors (Physical Impact + Life Responsibilities Impact + Psychological Impact + Social Impact)	454.394	98	0.00	4.64	0.09	0.08–0.09	0.98	0.97	0.03
Model 3b: Four factors, second order[a] (Physical Impact + Life Responsibilities Impact + Psychological Impact + Social Impact)	467.429	100	0.00	4.67	0.09	0.08–0.09	0.98	0.97	0.04
Target values			$P > 0.05$	≤ 3	≤ 0.06		≥ 0.95	≥ 0.95	≤ 0.08

[a]Higher-order models tested the factors with 'overall impact' as the second-factor order. CFI, comparative fit index; CI, confidence interval; df, degrees of freedom; PRIDD, Patient-Reported Impact of Dermatological Diseases; RMSEA, root mean square error of approximation; SRMR, standardized root mean square residual; TLI, Tucker–Lewis index; V, version.

been excluded, stigmatized or discriminated against by others' (Social Impact).

PRIDD V0.4

In this 20-item version, all factors were strictly unidimensional and had no evidence of differential item functioning (DIF), except for Life Responsibilities Impact, although this cancelled out at test level (Appendix S5; see Supporting Information). That is, the effects from the item exhibiting DIF for those with an inflammatory condition was cancelled out by the item exhibiting DIF for those with a noninflammatory condition. The Person–Item Threshold Distribution graphs indicated that the addition of an item capturing more 'severe' impact to each factor would improve targeting (Figure S3; see Supporting Information). We added four items based on patient prioritization of items during the previous Delphi study (Table S12; see Supporting Information).[13] Stigma ('I have been excluded, stigmatized or discriminated against by others') emerged as an important impact during the content validity phase[15] but was not captured by any of the included Social Impact items. While this item was not required for this subscale to fit the Rasch model, we decided to retain this item for further testing alongside the additional item above. This resulted in a 24-item, four-factor version (PRIDD V0.5).

PRIDD V0.5

The first three additional items plus the stigma item showed disordered thresholds. Combining adjacent response categories improved fit to the model (Figure 1). All factors demonstrated at least some misfit to the model (Table 6), with some also showing breaches of unidimensionality, local dependency (Appendix S6; see Supporting Information) and DIF (Appendix S7; see Supporting Information).

PRIDD V1

Removal of nine items across the four factors (Table S13; see Supporting Information) resulted in a 16-item PRIDD (PRIDD V1) with each dimension (Table 6) and item (Table 7) showing fit to the Rasch model, strict unidimensionality, no local dependence (Appendix S8; see Supporting Information), no DIF at the test level (Appendix S9; see Supporting Information), and was well targeted (Figure 2).

The R (0.84) and A values (0.95) demonstrated high average pairwise correlation and very high levels of common variance between the four subscales, indicating that summing the four subscales to obtain an 'overall impact' total score was valid.

PRIDD scoring

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 (full instructions in Appendix S10; see Supporting Information).

Discussion

This field test study represents the fourth of five steps in PRIDD's development and validation. It examined PRIDD's factor structure and established the definitive selection of items for each subscale. The findings and resultant adjustments produced the final 16-item PRIDD within four domains.

This study further supported PRIDD's content validity, feasibility and refined the conceptual framework of the impact of dermatological conditions.[12,14] While we found support for each of the original five domains of impact; the data indicated a four-factor model (Figure 3) consisting of Physical Impact, Life Responsibilities Impact (combining the previous daily life and responsibilities and financial impacts domains), Psychological Impact and Social Impact subscales. This validated conceptual framework provides clinicians and researchers with a valuable, theoretically coherent framework for understanding and measuring the impact of dermatological conditions. The multidimensionality demonstrates that holistic, multidisciplinary approaches are fundamental to high-quality, personalized dermatological care. PRIDD total and subscales scores can indicate targets for interventions and guide shared decision-making and referral to appropriate specialists such as psychologists and occupational therapists.

Structural validity is an important psychometric property and unidimensionality, the assumption that a scale

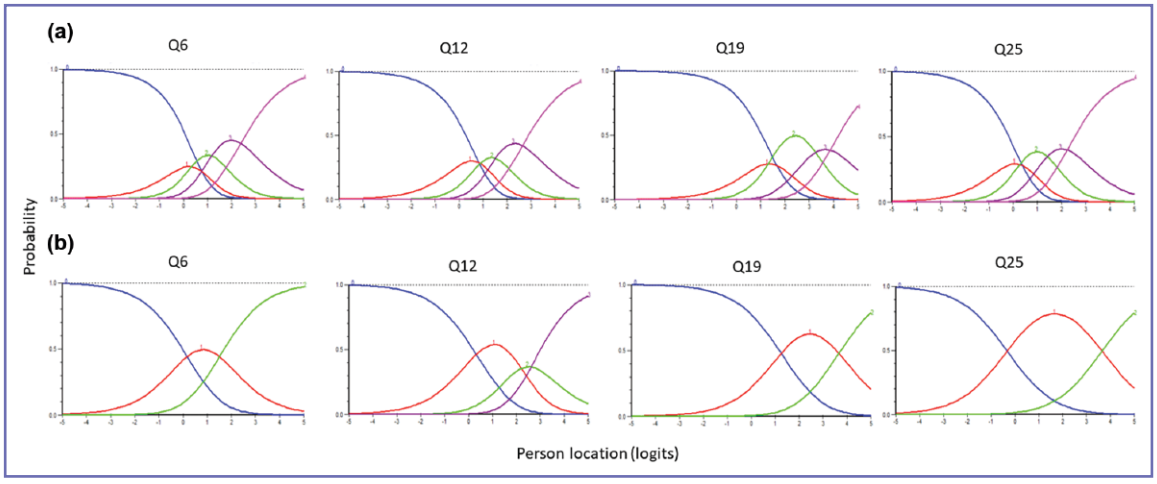

Figure 1 Category characteristic curves for PRIDD V1 items 6, 12, 19 and 25 (a) prior to rescoring and (b) after rescoring.

Table 6 Rasch summary statistics of PRIDD V0.5 and PRIDD V1

				Item fit residual		Person fit residual		Overall χ^2 interaction					Unidimensionality *t*-tests (CI)	
	Analysis	No. of items	Valid *n* (no. of extremes)[a]	$\bar{x}$	SD	$\bar{x}$	SD	Value	df	*P*	PSI	α	Proportion significance	Lower bound, 95% CI
All items	Initial	25	55 (4)	0.10	2.62	–0.25	1.54	393.45	175	0.00	0.96		0.21	0.19
Physical Impact	Initial	7	489 (15)	0.39	1.73	–0.35	1.23	64.88	49	0.06	0.87		0.07	0.05
	Q6 rescored	7	485 (19)	0.24	1.45	–0.36	1.20	42.94	49	0.72	0.86		0.08	0.06
	Final	4 (Q1, Q3 and Q6 removed)	473 (31)	0.17	1.02	–0.46	1.19	26.58	28	0.54	0.81	0.85	0.04	0.02
Life	Initial	6	474 (30)	0.04	2.15	–0.37	1.13	68.60	42	0.01	0.85		0.04	0.02
Responsibilities	Q12 rescored	6	474 (30)	–0.02	2.08	–0.38	1.14	55.64	42	0.08	0.85		0.04	0.02
Impact	Final	5 (Q9 removed)	470 (34)	0.03	1.37	–0.34	0.99	41.11	35	0.22	0.81	0.81	0.04	0.02
Psychological	Initial	6	480 (24)	–0.29	2.72	–0.39	1.02	92.60	42	0.00	0.90		0.08	0.06
Impact	Q19 rescored	6	478 (26)	–0.42	2.85	–0.43	1.09	74.43	42	0.00	0.90		0.06	0.04
	Final	3 (Q17, Q18 & Q19 removed)	449 (55)	0.12	0.20	–0.44	0.87	31.40	21	0.07	0.86	0.9	0.03	0.01
Social Impact	Initial	6	444 (60)	–0.03	1.99	–0.32	1.09	89.95	42	0.00	0.83		0.05	0.03
	Q25 rescored	6	444 (60)	–0.04	1.95	–0.33	1.09	65.73	42	0.01	0.84		0.06	0.04
	Final	4 (Q23 and Q25 removed)	432 (72)	0.3	1.1	–0.43	1.15	33.52	28	0.22	0.77	0.86	0.04	0.02
PRIDD V1		16 (4 subscales)	496 (7)	0.25	0.8	–0.41	1.04	37.26	28	0.11	0.89	0.95	0.06	0.05
Target values				0	1	0	1	Nonsignificant ($P > 0.05$)			> 0.7	> 0.7	Lower CI ≤ 0.05	

[a]Extremes: people scoring either maximally or minimally across the complete item set. α, Cronbach's α; CI, confidence interval; df, degrees of freedom; PRIDD, Patient-Reported Impact of Dermatological Diseases; PSI, Person Separation Index

Table 7 Individual item fit of PRIDD V1

Item	Location parameter	SE	Fit statistics		
			Fit residual	χ^2	χ^2 probability[a]
1	–0.89	0.07	1.67	6.18	0.52
2	0.53	0.06	–0.42	6.50	0.48
3	0.07	0.06	–0.51	5.98	0.54
4	0.29	0.06	–0.08	7.92	0.34
5	–0.25	0.06	1.60	1.90	0.97
6	–0.25	0.05	–1.63	12.30	0.09
7	–0.53	0.05	–1.00	10.00	0.19
8	1.59	0.07	0.08	11.45	0.12
9	–0.56	0.05	1.12	5.47	0.60
10	–0.61	0.08	–0.11	13.60	0.06
11	–0.20	0.08	0.18	7.55	0.37
12	0.81	0.08	0.26	10.26	0.17
13	0.32	0.06	–0.09	13.79	0.06
14	–0.20	0.06	–1.02	16.01	0.03
15	–0.44	0.05	0.81	2.22	0.95
16	0.32	0.06	1.50	1.51	0.98

[a]Bonferroni-adjusted probability value. PRIDD, Patient-Reported Impact of Dermatological Diseases.

(or subscale) measures a single construct, is fundamental to this. There is generally poor or mixed evidence for unidimensionality across many of the commonly used dermatology-specific PROMs. This is often because unidimensionality has been assumed but not tested or because of a reliance on CTT methods over IRT methods. For example, the three subscales of the Skindex-29 – emotions, symptoms and functioning – were established using Cronbach's α and correlations.[45] However, a Rasch analysis found evidence of unidimensionality for only two subscales: symptoms and combined emotions and functioning.[46] It is also often erroneously assumed that PROM subscales can automatically be summed to obtain a total score. This study provides empirical evidence that PRIDD and all four subscales are unidimensional and can be validly combined into a total score. This means that PRIDD can not only provide a single score of overall impact, but the subscales can be used individually to distinguish among the domains of impact, making it a powerful and versatile tool.

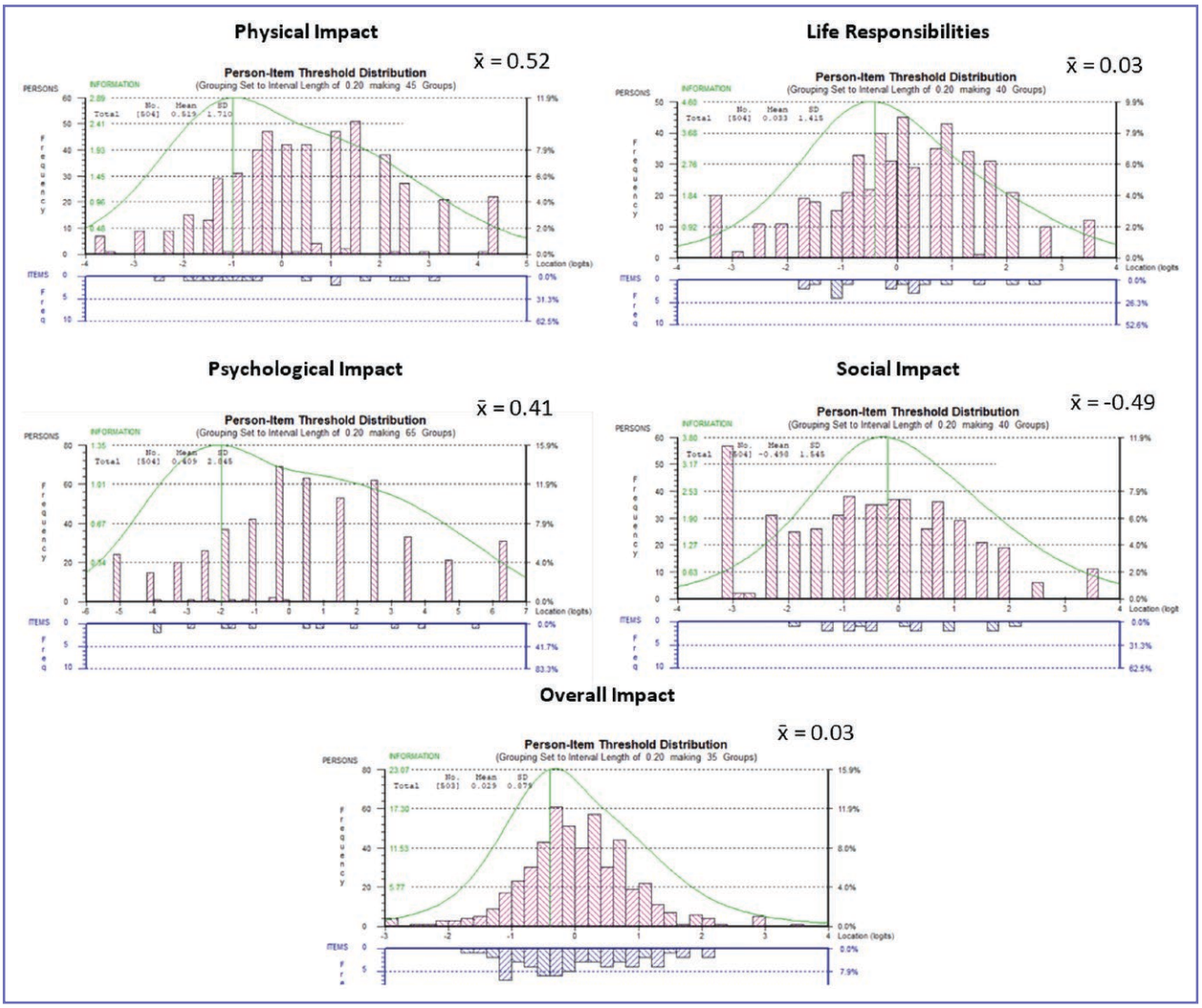

Figure 2 Person–Item Threshold Distribution graphs for PRIDD V1 'Overall Impact' and the Physical Impact, Life Responsibilities Impact, Psychological Impact and Social Impact subscales.

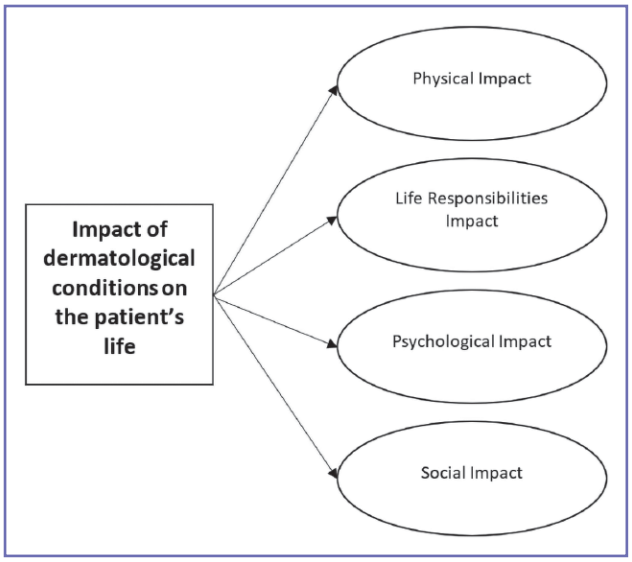

Figure 3 Conceptual framework of the impact of dermatological conditions on a patient's life.

Existing dermatology-specific PROMs were developed with a small number of patients in one country and subsequently used globally, with limited revalidation. As PRIDD is intended for worldwide use with adults with a dermatological condition, we recruited geographically diverse samples throughout all stages of PRIDD's development to enhance transferability. The final version of PRIDD, tested with this heterogenous study sample, showed no DIF, indicating that it is well worded and appropriate for use with the global dermatology patient population. These results attest to the value of developing and validating PROMs with an inclusive, patient-centred approach and following best practices, including a rigorous pilot test, use of both CTT and modern psychometric methods, and combining participatory and statistical methods of item reduction.

Researchers, clinicians and regulatory agencies should choose measurement instruments based on their quality. The next and final step in PRIDD's development will be a study to test the remaining measurement properties, interpretability information (e.g. minimally important change)[47] and comparison with other well-used measures. Subsequently, PRIDD will undergo cultural translation and linguistic validation, and be used to collect global data on the life impact of dermatological conditions. It will also be beneficial to revalidate PRIDD's measurement properties in a sample of patients not involved in the original development and validation.

This study met the highest standards for tests of structural validity (Table S14; see Supporting Information) and internal consistency outlined by COSMIN (Table S15; see Supporting Information).[9] We recruited a diverse sample enabling us to test PRIDD's performance across a range of subgroups. However, as participants were primarily recruited through patient organizations and the sample was predominantly White and well educated, these results may not be representative of the dermatology patient population. As we used the same recruitment methods for both surveys, it is possible that there was overlap between samples, but we were unable to verify this. We were also not able to check that all participants were sufficiently proficient in English.

Using a combination of classical and modern psychometric methods enabled us to select the best statistical methods for assessing structural validity and internal consistency. Data triangulation from the multiple methods used – CFA, EFA, parallel and Rasch analysis – provide strong support for the conceptual framework. The sample was relatively large for factor and Rasch analyses, increasing the generalizability of the conclusions.[34] Existing dermatology-specific PROMs use ordinal, Likert-type responses, meaning that intervals between successive points on the scales are not intrinsically equal.[48] This leads to challenges in comparing intervention efficacy across patients with PROM scores on different portions of the scale.[49] Using Rasch analysis allowed us to transform PRIDD's ordinal responses into interval level scores. This optimizes the level of quantitative information that can be obtained, including the calculation of mean and change scores without the restrictions of nonparametric, representational measurement,[46] and enables valid comparison of scores across the scale.[39] We therefore recommend using the transformed rather than the raw scores, although the latter may be more feasible in routine practice.

While we previously employed participatory methods to prioritize items for inclusion in PRIDD, this study used purely statistical techniques of item reduction, which may reduce item content coverage and consequently content validity. We recommend that PROM developers consider involving patients during final item selection to ensure a good balance between face validity and psychometric performance and ensure the final PROM is acceptable to the target population.

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(GRIDD) project. GlobalSkin is a not-for-profit alliance of dermatology patient organizations worldwide. Participants were recruited through GlobalSkin's network of patient organizations.

Conflicts of interest

The authors report no conflicts of interest in this work.

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). 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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Cosentyx® secukinumab

Cosentyx® (secukinumab) is available for eligible patients with moderate to severe hidradenitis suppurativa (HS)*[1,2]

Cosentyx can help to provide **fast relief and lasting control** for your eligible patients with HS[3]

FAST: Improved outcomes in HiSCR50 vs placebo by Week 16[1,2]

LASTING: Improved outcomes lasted through Week 52 (observed data with no statistical testing)[3–5]

HiSCR50 (primary endpoint)

>40%

of patients achieved **HiSCR50 at Week 16 in both trials**†[1,2]

Pain (observational, pooled data)

>65%

of patients who started with moderate or severe pain had only **mild or no pain at Week 52**‡[4]

Flares (observational, pooled data)

>70%

of patients **were flare free at Week 52**§[3]

Draining tunnels (observational, pooled data)

>80%

of patients **had no increase in draining tunnels at Week 52**¶[5]

The primary endpoint was met for Cosentyx 300 mg Q2W in both SUNRISE and SUNSHINE (p=0.015 and p=0.007, respectively) and was met for Cosentyx 300 mg Q4W in SUNRISE (p=0.002), but not in SUNSHINE.[4]

The most frequently reported adverse reactions are upper respiratory tract infections (17.1%) (most frequently nasopharyngitis, rhinitis).[1,2]

No new safety signals observed in HS trials[3]

The most frequently reported adverse events in SUNSHINE and SUNRISE were headache, nasopharyngitis and worsening of hidradenitis up to Week 16.[3]

Please consult the SmPC before prescribing.

Cosentyx is recommended by NICE as an option for the treatment of moderate to severe HS in adults who have not responded to conventional systemic treatment (subject to eligibility criteria)[6]

Cosentyx is approved for use in eligible patients with HS[1,2]

Click here to find out more

Cosentyx licensed indications in dermatology: Cosentyx is indicated for the 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 moderate to severe **HS** (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. For full indications, please see the SmPC.[1,2]

SUNSHINE AND SUNRISE: Two randomised, double-blind, multicentre, Phase III trials: SUNSHINE and SUNRISE (Cosentyx 300 mg Q4W, n=360 or Cosentyx 300 mg Q2W, n=361). The primary endpoint for both SUNSHINE and SUNRISE studies in adult patients with moderate to severe HS was the clinical response (as measured by HiSCR), defined as a decrease in abscess and inflammatory nodule count by 50% or more with no increase in the number of abscesses or draining fistulae compared with baseline, of Cosentyx versus placebo at Week 16, assessed in the overall population. Clinical response was sustained to Week 52 in both trials.[4]

*Cosentyx is indicated in adult patients with moderate to severe HS (acne inversa) with an inadequate response to conventional HS therapy.[1,2] Please see above for the licensed dermatology indications.

†HiSCR50: ≥50% decrease in abscesses and inflammatory nodules count with no increase in the number of abscesses and/or in the number of draining fistulae relative to baseline at Week 16. In HS study 1 HiSCR50 was 41.8% and 45.0% in the Q4W arm (n=180) and Q2W arm (n=181), respectively. In HS study 2 HiSCR50 was 46.1% and 42.3% in the Q4W arm (n=180) and Q2W arm (n=180), respectively.[1,2]

‡The percentage of patients who started with moderate or severe pain and had mild or no pain was 65.3% in the Cosentyx group and 80.9% in the placebo group for the Q2W dosing regimen. The percentage of patients who started with moderate or severe pain and had mild or no pain at Week 52 was 70.1% in the Cosentyx group and 64.8% in the placebo group for the Q4W dosing regimen.[3]

§Flare, a prespecified exploratory endpoint, is defined as at least a 25% increase in AN count with a minimum increase of 2 in absolute AN count relative to baseline. In the Q4W arm, 360 patients were evaluable at Week 16 and 278 patients were evaluable at Week 52, 27.3% of patients experienced flares at Week 52. In the Q2W arm, 361 and 289 were evaluable at Week 16 and Week 52, respectively with 20.4% of patients experiencing flares at Week 52.[4]

¶Observed data from full analysis set. Number of patients with no increase from baseline from Week 16 to Week 52 in patients with at least one draining fistulae at baseline. 82.6% in Q4W arm (n=218), 80.7% in Q2W arm (n=239).[5]

Abbreviations: AN, abscess and inflammatory nodule; HiSCR, hidradenitis suppurativa clinical response; HS, hidradenitis suppurativa; Q2W, every 2 weeks; Q4W, every 4 weeks; SmPC, summary of product characteristics.

References: 1. Cosentyx® (secukinumab) GB Summary of Product Characteristics; **2.** Cosentyx® (secukinumab) NI Summary of Product Characteristics; **3.** Kimball AB, et al. *Lancet* 2023;401(10378):747–761 and supplementary appendix; **4.** Novartis Data on File. SUNNY clinical programme post-hoc analysis of skin pain severity. March 2023; **5.** Novartis Data on File. Draining fistulas; **6.** National Institute for Health and Care Excellence. Secukinumab for treating moderate to severe hidradenitis suppurativa. Available at: https://www.nice.org.uk/guidance/ta935 [Accessed April 2024].

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

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NOVARTIS

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.

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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. 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:** PLGB 00101/1205 – 75 mg pre-filled syringe x 1 - £304.70; PLGB 00101/1029 - 150 mg pre-filled pen x2 £1,218.78; PLGB 00101/1030 - 150 mg pre-filled syringe x2 £1,218.78; PLGB 00101/1198 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** June 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.

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