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

Running head: Field testing of PRIDD

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

Corresponding author: Rachael Pattinson

Email: pattinsonr@cardiff.ac.uk

1 **Ethics statement:** Ethical approval was obtained from Cardiff University School of

2 Healthcare Sciences Ethics Committee (SREC:826). Informed consent was obtained from all

3 participants.

4

5

6 **What is already known about this topic?**

7 • No existing dermatology-specific patient-reported outcome measure (PROM) is

8 recommended for use according to the COSMIN criteria.

9 • The conceptual framework of the impact of dermatological conditions on patients'

10 lives depicts 'impact' as a multifaceted construct involving physical, daily life and

11 responsibilities, psychological, social, and financial impacts.

12 • The Patient-Reported Impact of Dermatological Diseases (PRIDD) instrument is in

13 development with evidence of content validity, acceptability, feasibility.

14 **What does this study add?**

15 • This study produced the final PRIDD, reduced to 16 items across four domains, for

16 use in research and clinical practice.

17 • The data triangulated and refined the conceptual framework of impact from five to

18 four domains: physical, life responsibilities, psychological and social impacts.

19 • The results provide evidence of PRIDD's structural validity and internal consistency

20 and further support its content validity.

21 **What are the clinical implications of this work?**

22 • This validated conceptual framework provides clinicians and researchers with a

23 valuable framework for understanding and measuring the impact of dermatological

24 conditions on patients' lives.

25 • Clinicians should select high-quality, evidence-based PROMs. PRIDD has good

26 evidence of content validity, acceptability, feasibility, structural validity, and internal

27 consistency. The remaining measurement properties (construct validity, test-retest

28 reliability, measurement error and responsiveness) will be tested in the next and

29 final step in PRIDD's development.

2

1

2 **Abstract**

3 **Background:** Existing dermatology-specific patient-reported outcome measures (PROMs) do
4 not fully capture the substantial physical, psychological, and social impact of dermatological
5 conditions on patients' lives and are not recommended for use according to the Consensus-
6 based Standards for the Selection of Health Measurement Instruments (COSMIN) criteria.
7 Most were developed with insufficient patient involvement and relied on classical
8 psychometric methods. We are developing the new Patient-Reported Impact of
9 Dermatological diseases (PRIDD) measure for use in research and clinical practice in
10 partnership with patients.

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

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

23 **Results:** 483 and 504 people participated in Survey 1 and 2, respectively. All items had ≤3%
24 missing scores and all five response options were used. A four-factor model showed best fit.
25 PRIDD and all four subscales were internally consistent but showed some misfit to the Rasch
26 measurement model. Adjustments were made to rectify disordered thresholds, remove
27 misfitting items, local dependency and DIF, and improve targeting. The resultant 16-item
28 version and subscales fit the Rasch model, showed no local dependency or DIF at the test
29 level, and were well-targeted.

1   **Conclusions:** This field test study produced the final PRIDD consisting of 16 items across four

2   domains. The data triangulated and refined the conceptual framework of impact and

3   provide evidence of PRIDD's structural validity and internal consistency. The final step in

4   PRIDD's development and validation is to test the remaining measurement properties.

5

6

Introduction

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 Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN)[4] to be recommended for use according to their known measurement properties.[5-7] Much 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. PRIDD 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 PRIDD

PRIDD development and validation involves a *content validity* and subsequent *psychometric testing* phase (Figure S1).[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)[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

1 of an instrument are an adequate reflection of the dimensionality of the construct to be

2 measured.'[17,18] Only once PRIDD is finalised through field testing can its measurement

3 properties be fully established.

4 Factor analysis, an extension of CTT, and Rasch analysis, part of the Item Response Theory

5 (IRT) family, are the preferred statistical methods to assess structural validity.[19] Factor

6 analysis is valuable for identifying the dimensions (or subscales) in a PROM, but cannot

7 establish the psychometric quality of those dimensions. IRT, a modern psychometric

8 method, is a powerful tool to assess PROM psychometrics as it overcomes many of the

9 limitations of CTT. The Rasch model is a unidimensional measurement model that satisfies

10 the fundamental assumptions of IRT,[20,21] meaning it provides a measurement template

11 against which scales can be tested.[22]

12 This study (stage 4 of 5) aimed to examine the factor structure of PRIDD, determine the

13 definitive selection of items for each subscale, and establish structural validity and internal

14 consistency through classical and modern psychometric methods. Based on the conceptual

15 framework of impact we hypothesised that PRIDD had five domains.

16

Patients and methods

Study design and setting

19 We conducted two cross-sectional online surveys. Ethical approval was obtained from

20 Cardiff University School of Healthcare Sciences Ethics Committee (SREC:826). Informed

21 consent was obtained from all participants.

Patients and recruitment

23 We employed convenience sampling to recruit eligible participants to both surveys through

24 the International Alliance of Dermatology Patient Organizations' (GlobalSkin) membership

25 network. GlobalSkin (https://globalskin.org/) is a not-for-profit alliance of over 245

26 dermatology patient organisations worldwide. The samples were independent of each

27 other. It is best practice to development and validate a PROM in one language with later

28 cross-cultural translation. PRIDD is initially being developed in English. Participants therefore

29 met the inclusion criteria if they were an adult (≥ 18 years), living with a dermatological

6

1 condition, and spoke English sufficient to complete the survey independently. We aimed to

2 recruit the recommended sample size of 250 – 500 for Rasch analysis to each survey.[23] Non-

3 participation was due to non-response.

Procedure and materials

5 Survey 1 was open from 1 November to 1 December 2021; Survey 2 from 29 June to 29 July

6 2022. Participants were directed to the online platform, which included the participant

7 information sheet (PIS), consent form, and survey consisting of demographic items and

8 PRIDD (Appendix S1) and given at least four weeks to respond.

Patient involvement

10 GlobalSkin conceived of the PRIDD measure, were involved in setting the research priorities

11 and defining research questions, and provided input into study design, conduct, and

12 dissemination. Our lead patient co-researchers JA and AF are named co-authors.

Data analysis strategy

14 We followed the order of data analysis for field testing set out by the COSMIN group and

15 evaluated the results against their quality criteria for structural validity and internal

16 consistency.[11,18] We completed all of the steps outlined below on the Survey 1 data. This

17 revealed that further amendments were required. After adjusting PRIDD, we conducted

18 Survey 2, where we repeated many aspects of the analysis. We have noted which parts of

19 the data analysis used which dataset below. We ran multiple iterations of the analysis on

20 the different versions of PRIDD (Table S1): analysis of PRIDD V0.1 to V.04 used Survey 1 data

21 and V.05 and V.1 used Survey 2 data. We used Little's test of Missing Completely at Random

22 (MCAR) for missing values.[24]

1. Examination of individual PRIDD items (Survey 1 and 2)

24 The percentage of missing scores was examined for each item using SPSS 27 (IBM, Armonk,

25 NY, USA). Items with ≤3% missing scores were deemed 'acceptable' and ≥15%' not

26 acceptable.'[18] Distributions of item scores were examined using item means ($\bar{x}$) and

27 standard deviations (SDs).

2. Factor analysis (Survey 1)

7

1   **a. Confirmatory factor analysis**

2 Confirmatory factor analysis (CFA) is more appropriate than exploratory factor analysis (EFA)

3 when a conceptual framework is available.[4,18,19,25] We performed a CFA with categorical

4 factor indicators applying full information maximum likelihood to missing data using Mplus

5 8.2 (Muthen & Muthen, Los Angeles, CA, USA).[26,27] Mplus determines the number of

6 categories for each factor indicator with a robust weighted least squares estimator

7 (wlsmv).[28] Multicollinearity was assessed via bivariate correlations (Spearman's Rho), with r

8 ≤ 0.8 deemed acceptable.[29] Goodness-of-fit of all the CFA models (Table 5) was examined

9 according to the criteria outlined in Table 1. Structural validity was sufficient if CFI or TLI >

10 0.95, RMSEA < 0.06, or SRMR < 0.08.[11]

11   **b. Exploratory factor analysis**

12 As the CFA did not support our 5-domain conceptual framework, we performed an EFA with

13 listwise deletion on SPSS 27 using the Principal Factor Method with oblique rotation (direct

14 oblimin) to determine the number of dimensions.[18] The Kaiser-Meyer-Olkin (KMO) test

15 (KMO > 0.5) and Bartlett's test of sphericity ($p < 0.05$) were used to confirm the adequacy of

16 the sample and data, respectively.

17 Four criteria were used to determine the number of factors (see Table 2). As uncertainty

18 remained regarding the number of factors to extract, we followed Costello and Osborne's[30]

19 recommendation to run multiple factor analyses, setting the number of factors to retain

20 manually once at the projected number based on the a priori factor structure, then at the

21 number of factors suggested by the scree test, and finally at numbers above and below

22 those numbers. Item loading tables were compared and the solution with the most factors

23 and 'cleanest' factor structure (item loadings > 0.3, no or few crossloadings, and no factors

24 with fewer than 3 items) was deemed to have best fit to the data. Residual correlations < 0.1

25 and factor loadings ≥ 0.5 were deemed acceptable.[31-33]

26 **3. Internal consistency (Survey 1 and 2)**

27 We tested internal consistency for PRIDD and each factor separately with listwise deletion

28 using SPSS 27. Items with inter-item correlations > 0.7 and item-total correlations < 0.3 were

8

1　candidates for removal. Cronbach's alpha (α) > 0.7 was deemed acceptable and > 0.9

2　indicated item redundancy.[11]

3　**4. Rasch analysis (Survey 1 and 2)**

4　Rasch analyses were performed iteratively on PRIDD and each subscale using RUMM2030

5　(RummLab Pty Ltd., Duncraig, Australia) according to the steps outlined in Table 3.[34] We

6　tested whether the subscales could be validly combined into an 'overall impact' total score

7　using the subtest approach to obtain R (average latent correlation between the subscales)

8　and A values (the amount of shared variance between the subscales).

9

10　**Results**

11　483 (Table 4) patients from 42 countries (Table S3) representing 49 dermatological

12　conditions (Table S4) participated in Survey 1; 504 from 38 countries with 34 dermatological

13　conditions in Survey 2. Of these, 703 (71%) were native English speakers (Table S5). PRIDD

14　missing data were MCAR, $p > 0.05$.

15　**Examination of PRIDD items**

16　All items had acceptable levels (≤3%) of missing scores (Table S6). All item means were close

17　to the centre of the range of possible scores, indicating that the response options detected

18　the full range of the construct, were well-worded, and had higher variances.[35]

19　**PRIDD V0.1**

20　Bivariate correlations for the CFA ranged from 0.2 to 0.76, indicating no multicollinearity.[29]

21　Approximate fit to the four-factor model was not achieved (Table 5), therefore we

22　conducted an EFA.

23　Three factors had eigenvalues > 1, six factors > 0.7 and the scree plot was slightly

24　ambiguous, showing inflexions that would justify retaining two or three factors (Appendix

25　S2). The parallel analysis diverged from these results, suggesting a 26-factor model (Table

26　S7). We consequently ran six EFAs setting the number of factors to retain manually at 5, 2,

27　3, 6, 4, and 1.

9

1 **PRIDD V0.2**

2 The 6-factor model was the 'cleanest' (Table S8) and item clustering suggested the following

3 underlying concepts:

4 • Factor 1: Negative Affect

5 • Factor 2: Physical Impact

6 • Factor 3: Appearance-Related Concerns

7 • Factor 4: Life Responsibilities Impact

8 • Factor 5: Interpersonal Relationships

9 • Factor 6: Identity

10 All factors were internally consistent (Appendix S3), however, Negative Affect demonstrated

11 item redundancy (α = 0.91). The item 'I have struggled to concentrate' had the highest 'α if

12 item deleted' value and was therefore removed, leaving 25 items (PRIDD V0.2).

13 All six factors showed at least some misfit to the Rasch model (Table S9). Five factors

14 showed local dependency (Appendix S4). Correction involved removing three items and

15 grouping six other items into three testlets. This produced three factors with less than three

16 items, the minimum recommended number of items in a scale.[18,30] Given the conceptual

17 overlap of the remaining items, Appearance-Related Concerns was combined with Negative

18 Affect to create Psychological Impact, and Interpersonal Relationships and Identity to make

19 Social Impact. This resulted in a 22-item, four-factor model (PRIDD V0.3).

20 **PRIDD V0.3**

21 This four-factor model achieved approximate fit and met the COSMIN criteria for structural

22 validity (Table 5). All factors were internally consistent (Table S10) but showed some misfit

23 to the Rasch model (Table S11). This improved upon removal of two items: 'I have been

24 hiding, covering or concealing my condition' (Psychological Impact) and 'I have been

25 excluded, stigmatised or discriminated against by others' (Social Impact)

26 **PRIDD V0.4**

27 In this 20-item version, all factors were strictly unidimensional and had no evidence of DIF,

28 except for Life Responsibilities Impact, though this cancelled out at test level (Appendix S5).

29 That is, the effects from the item exhibiting DIF for those with an inflammatory condition

10

1   was cancelled out by the item exhibiting DIF for those with a non-inflammatory condition.

2   The Person-Item Threshold Distribution graphs indicated that the addition of an item

3   capturing more 'severe' impact to each factor would improve targeting (Figure S3). We

4   added four items based on patient prioritisation of items during the previous Delphi study

5   (Table S12).[13] Stigma ('I have been excluded, stigmatised or discriminated against by others')

6   emerged as an important impact during the content validity phase[15] but was not captured

7   by any of the included Social Impact items. While this item was not required for this

8   subscale to fit the Rasch model, we decided to retain this item for further testing alongside

9   the additional item above. This resulted in a 24-item, four-factor version (PRIDD V0.5).

10   **PRIDD V0.5**

11   The first three additional items plus the stigma item showed disordered thresholds.

12   Combining adject response categories improved fit to the model (Figure 1). All factors

13   demonstrated at least some misfit to the model (Table 4), with some also showing breaches

14   of unidimensionality, local dependency (Appendix S6) and DIF (Appendix S7).

15   **PRIDD V1**

16   Removal of nine items across the four factors (Table S13) resulted in a 16-item PRIDD

17   (PRIDD V1) with each dimension (Table 6) and item (Table 7) showing fit to the Rasch model,

18   strict unidimensionality, no local dependence (Appendix S8), no DIF at the test level

19   (Appendix S9), and was well-targeted (Figure 2).

20   The R (0.84) and A values (0.95) demonstrated high average pairwise correlation and very

21   high levels of common variance between the four subscales, indicating that summing the

22   four subscales to obtain an 'overall impact' total score was valid.

23   **PRIDD scoring**

24   PRIDD total (0 - 63) and subscale scores are obtained in a two-step process by summing item

25   scores and transforming these raw, ordinal level scores to interval level data using a

26   conversion table (full instructions in Appendix S10).

27

28   **Discussion**

11

1 This field test study represents the fourth of five steps in PRIDD's development and

2 validation. It examined PRIDD's factor structure and established the definitive selection of

3 items for each subscale. The findings and resultant adjustments produced the final 16-item

4 PRIDD within four domains.

5 This study further supported PRIDD's content validity, feasibility and refined the conceptual

6 framework of the impact of dermatological conditions.[12,14] While we found support for each

7 of the original five domains of impact; the data indicated a four-factor model (Figure 3)

8 consisting of Physical Impact, Life Responsibilities Impact (combining the previous daily life

9 and responsibilities and financial impacts domains), Psychological Impact and Social Impact

10 subscales. This validated conceptual framework provides clinicians and researchers with a

11 valuable, theoretically coherent framework for understanding and measuring the impact of

12 dermatological conditions. The multidimensionality demonstrates that holistic,

13 multidisciplinary approaches are fundamental to high-quality, personalised dermatological

14 care. PRIDD total and subscales scores can indicate targets for interventions and guide

15 shared decision-making and referral to appropriate specialists such as psychologists and

16 occupational therapists.

17 Structural validity is an important psychometric property and unidimensionality, the

18 assumption that a scale (or subscale) measures a single construct, is fundamental to this.

19 There is generally poor or mixed evidence for unidimensionality across many of the

20 commonly used dermatology-specific PROMs. This is often because unidimensionality has

21 been assumed but not tested or because of a reliance on CTT methods over IRT methods.

22 For example, the three subscales of the Skindex-29 – emotions, symptoms, and functioning -

23 were established using Cronbach's alpha and correlations.[36] However, a Rasch analysis

24 found evidence of unidimensionality for only two subscales: symptoms and combined

25 emotions and functioning.[37] It is also often erroneously assumed that PROM subscales can

26 automatically be summed to obtain a total score. This study provides empirical evidence

27 that PRIDD and all four subscales are unidimensional and can be validly combined into a

28 total score. This means that PRIDD can not only provide a single score of overall impact, but

29 the subscales can be used individually to distinguish among the domains of impact, making

30 it a powerful and versatile tool.

12

1 Existing dermatology-specific PROMs were development with a small number of patients in

2 one country and subsequently used globally, with limited revalidation. As PRIDD is intended

3 for use with adults with a dermatological condition worldwide, we recruited geographically

4 diverse samples throughout all stages of PRIDD's development to enhance transferability.

5 The final version of PRIDD, tested with this heterogenous study sample, showed no DIF,

6 indicating that it is well-worded and appropriate for use with the global dermatology patient

7 population. These results attest to the value of developing and validating PROMs with an

8 inclusive, patient-centered approach and following best practices, including a rigorous pilot

9 test, use of both CTT and modern psychometric methods, and combining participatory and

10 statistical methods of item reduction.

11 Researchers, clinicians, and regulatory agencies should choose measurement instruments

12 based on their quality. The next and final step in PRIDD's development will be a study to test

13 the remaining measurement properties, interpretability information (e.g. Minimally

14 Important Change)[38] and comparison with other well used measures. Subsequently, PRIDD

15 will undergo cultural translation, linguistic validation, and be used to collect global data on

16 the life impact of dermatological conditions. It will also be beneficial to revalidate PRIDD's

17 measurement properties in a sample of patients not involved in the original development

18 and validation. The

19 **Strengths and limitations**

20 This study met the highest standards for tests of structural validity (Table S14) and internal

21 consistency outlined by COSMIN (Table S15).[39] We recruited a diverse sample enabling us to

22 test PRIDD's performance across a range of subgroups. However, as participants were

23 primarily recruited through patient organisations and the sample was predominantly White

24 and well-educated, these results may not be representative of the dermatology patient

25 population. As we used the same recruitment methods for both surveys, it is possible that

26 there was overlap between samples, but we were unable to verify this. We were also not

27 able to check that all participants were sufficiently proficient in English.

28 Using a combination of classical and modern psychometric methods enabled us to select the

29 best statistical methods for assessing structural validity and internal consistency. Data

30 triangulation from the multiple methods used – CFA, EFA, parallel and Rasch analysis –

31 provide strong support for the conceptual framework. The sample was relatively large for

13

1   factor and Rasch analyses, increasing the generalisability of the conclusions.[35] Existing

2   dermatology-specific PROMs use ordinal, Likert-type responses meaning that intervals

3   between successive points on the scales are not intrinsically equal.[40] This leads to challenges

4   in comparing intervention efficacy across patients with PROM scores on different portions

5   of the scale.[41] Using Rasch analysis allowed us to transform PRIDD's ordinal responses into

6   interval level scores. This optimises the level of quantitative information that can be

7   obtained, including the calculation of mean and change scores without the restrictions of

8   nonparametric, representational measurement,[37] and enables valid comparison of scores

9   across the scale.[34] We therefore recommend using the transformed rather than the raw

10   scores, though the latter may be more feasible in routine practice.

11   While we previously employed participatory methods to prioritise items for inclusion in

12   PRIDD, this study used purely statistical techniques of item reduction, which may reduce

13   item content coverage and consequently content validity. We recommend that PROM

14   developers consider involving patients during final item selection to ensure a good balance

15   between face validity and psychometric performance and ensure the final PROM is

16   acceptable to the target population.

17

of Copenhagen, Denmark), and Marc Yale (International Pemphigus Pemphigoid Foundation, US).

References

1   Chren MM, Lasek RJ, Quinn LM *et al.* Convergent and Discriminant Validity of a Generic and a Disease-Specific Instrument to Measure Quality of Life in Patients with Skin Disease. *Journal of Investigative Dermatology* 1997; **108**: 103.

2   Hilde B, Marie-Louise E-B, Jan B *et al.* Critical Review of Generic and Dermatology-Specific Health-Related Quality of Life Instruments. *Journal of Investigative Dermatology* 2007; **127**: 2726.

3   Bowling A. Health status and quality of life assessment. In: *Cambridge Handbook of psychology, health, and medicine* (Ayers S, Baum A, McManus C et al., eds), 2nd ed edn. Cambridge: Cambridge University Press. 2007.

4   Mokkink LB, de Vet HCW, Prinsen CAC *et al.* COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. *Qual Life Res* 2018; **27**: 1171-9.

5   Pattinson RL, Trialonis-Suthakharan N, Gupta S *et al.* Patient-reported Outcome Measures in Dermatology: A Systematic Review. *Acta Derm Venereol* 2021; **101**.

6   Gabes M, Tischer C, Apfelbacher C *et al.* Measurement properties of quality-of-life outcome measures for children and adults with eczema: An updated systematic review. *Pediatric allergy and immunology* 2020; **31**: 66-77.

7   Hopkins ZH, Thiboutot D, Homsi HA *et al.* Patient-Reported Outcome Measures for Health-Related Quality of Life in Patients With Acne Vulgaris: A Systematic Review of Measure Development and Measurement Properties. *JAMA Dermatol* 2022.

8   Apfelbacher CJ, Nelson PA. Patient-reported outcome measures and qualitative research in dermatology: the quest for authenticity. *British journal of dermatology (1951)* 2017; **176**: 285-7.

9   Mokkink LB, Prinsen CAC, Patrick DL *et al.* COSMIN Study Design checklist for Patient-reported outcome measurement instruments. In: COSMIN. 2019.

10   Mokkink LB, Terwee CB, Knol DL *et al.* The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: A clarification of its content. *BMC Medical Research Methodology* 2010; **10**: 22-.

11   Terwee CB, Bot SD, de Boer MR *et al.* Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007; **60**: 34-42.

12   Pattinson R, Hewitt RM, Trialonis-Suthakharan N *et al.* Development of a conceptual framework for a Patient-Reported Impact of Dermatological Diseases (PRIDD) measure: a qualitative concept elicitation study. *Acta Derm Venereol* 2022; **102**.

13   Trialonis-Suthakharan N, Pattinson R, Gandomkari NT *et al.* Patient prioritisation of items to develop the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure: A global Delphi study. *Manuscript submitted for publication*.

15

14 Pattinson R, Trialonis-Suthakharan N, Hewitt RM *et al.* Evidence of the content validity, acceptability, and feasibility of a new Patient-Reported Impact of Dermatological Diseases measure. *Frontiers in Medicine* 2023; **10**.

15 Trialonis-Suthakharan N, Pattinson R, Tahmasebi Gandomkari N *et al.* Patient prioritisation of impact items to develop the patient-reported impact of dermatological diseases (PRIDD) measure: European Delphi data. *J Eur Acad Dermatol Venereol* 2023; **37 Suppl 7**: 40-50.

16 McKenna SP, Heaney A, Wilburn J *et al.* Measurement of patient-reported outcomes. 1: The search for the Holy Grail. *Journal of medical economics* 2019; **22**: 516-22.

17 Mokkink LB, Terwee CB, Patrick DL *et al.* The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol* 2010; **63**: 737-45.

18 de Vet HCW, Terwee CB, Mokkink LB *et al. Measurement in medicine : a practical guide*. Cambridge: Cambridge University Press. 2011.

19 Prinsen C, Mokkink L, Bouter L *et al.* COSMIN guideline for systematic reviews of patient-reported outcome measures. *Quality of Life Research* 2018; **27**: 1147-57.

20 Luce RD, Tukey JW. Simultaneous conjoint measurement: A new type of fundamental measurement. *Journal of Mathematical Psychology* 1964; **1**: 1-27.

21 Newby VA, Conner GR, Grant CP *et al.* The Rasch model and additive conjoint measurement. *J Appl Meas* 2009; **10**: 348-54.

22 Horton MC, Oyebode J, Clare L *et al.* Measuring Quality of Life in Carers of People With Dementia: Development and Psychometric Evaluation of Scales measuring the Impact of DEmentia on CARers (SIDECAR). *The Gerontologist* 2019.

23 Hagell P, Westergren A. Sample Size and Statistical Conclusions from Tests of Fit to the Rasch Model According to the Rasch Unidimensional Measurement Model (Rumm) Program in Health Outcome Measurement. *J Appl Meas* 2016; **17**: 416-31.

24 Little RJA. A Test of Missing Completely at Random for Multivariate Data with Missing Values. *Journal of the American Statistical Association* 1988; **83**: 1198-202.

25 Terwee C, Prinsen C, Chiarotto A *et al.* COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. *Quality of Life Research* 2018; **27**: 1159-70.

26 McKnight PE, McKnight KM, Sidani S *et al. Missing data: A gentle introduction*. New York, NY, US: Guilford Press. 2007.

27 Schafer JL, Graham JW. Missing data: Our view of the state of the art. *Psychological Methods* 2002; **7**: 147-77.

28 Muthén B. A general structural equation model with dichotomous, ordered categorical, and continuous latent variable indicators. *Psychometrika* 1984; **49**: 115-32.

29 Field A. *Discovering statistics using IBM SPSS statistics*: sage. 2013.

30 Costello AB, Osborne J. Best practices in exploratory factor analysis: Four recommendations for getting the most from your analysis. *Practical assessment, research, and evaluation* 2005; **10**: 7.

31 Asparouhov T, Muth´en B. SRMR in Mplus. In. 2018.

32 Kline RB. *Principles and practice of structural equation modeling, 4th ed*. New York, NY, US: Guilford Press. 2016.

33 Awang Z. *A Handbook on SEM*: MPWS Publisher. 2014.

1   34   Tennant A, Conaghan PG. The Rasch measurement model in rheumatology: what is it
2   and why use it? When should it be applied, and what should one look for in a Rasch
3   paper? *Arthritis Rheum* 2007; **57**: 1358-62.
4   35   DeVellis RF. *Scale development : theory and applications*, 4th edn. Los Angeles: SAGE.
5   2017.
6   36   Chren MM, Lasek RJ, Flocke SA *et al.* Improved discriminative and evaluative
7   capability of a refined version of Skindex, a quality-of-life instrument for patients
8   with skin diseases. *Arch Dermatol* 1997; **133**: 1433-40.
9   37   Nijsten TE, Sampogna F, Chren MM *et al.* Testing and reducing skindex-29 using
10   Rasch analysis: Skindex-17. *J Invest Dermatol* 2006; **126**: 1244-50.
11   38   Brod M, Tesler LE, Christensen TL. Qualitative research and content validity:
12   developing best practices based on science and experience. *Quality of life research*
13   2009; **18**: 1263-78.
14   39   Mokkink LB, Prinsen C, Patrick DL *et al.* COSMIN Study Design checklist for Patient-
15   reported outcome measurement instruments. *Amsterdam, The Netherlands* 2019: 1-
16   32.
17   40   Embretson S. The new rules of measurement. *Psychological Assessment* 1996; **8**:
18   341-9.
19   41   Zhao NW, Mason JM, Blum AM *et al.* Using Item-Response Theory to Improve
20   Interpretation of the Trans Woman Voice Questionnaire. *The Laryngoscope* 2022.
21   42   Hu Lt, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis:
22   Conventional criteria versus new alternatives. *Structural Equation Modeling: A*
23   *Multidisciplinary Journal* 1999; **6**: 1-55.
24   43   Brown TA. *Confirmatory factor analysis for applied research*: Guilford publications.
25   2015.
26   44   Kaiser HF. The Application of Electronic Computers to Factor Analysis. *Educational*
27   *and Psychological Measurement* 1960; **20**: 141-51.
28   45   Jolliffe IT. *Principal component analysis for special types of data*: Springer. 2002.
29   46   Andrich D, De Jong J, Sheridan BE. Diagnostic opportunities with the Rasch model for
30   ordered response categories. *Applications of latent trait and latent class models in*
31   *the social sciences* 1997; **59**: 70.
32   47   Andrich D. A rating formulation for ordered response categories. *Psychometrika*
33   1978; **43**: 561-73.
34   48   Khadka J, Gothwal V, McAlinden C *et al.* The importance of rating scales in measuring
35   patient-reported outcomes. *Health and quality of life outcomes* 2012; **10**: 80.
36   49   Christensen KB, Makransky G, Horton M. Critical Values for Yen's Q(3): Identification
37   of Local Dependence in the Rasch Model Using Residual Correlations. *Appl Psychol*
38   *Meas* 2017; **41**: 178-94.
39   50   Edelsbrunner PA, Dablander F. The Psychometric Modeling of Scientific Reasoning: a
40   Review and Recommendations for Future Avenues. *Educational Psychology Review*
41   2019; **31**: 1-34.

42

Figure Legends

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

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 the patient's life

1 **Table 1 Goodness-of-fit criteria for confirmatory factor analysis (CFA) models**

Fit	Criteria
Exact fit	Chi-square (χ^2), $p > .05$
Approximate fit	- Root mean square error of approximation (RMSEA) ≤ 0.06 (90% CI ≤ 0.06); standardised root mean square residual (SRMR) ≤ 0.08 (> 0.1 is poor fitting); comparative fit index (CFI) ≥ 0.95; and Tucker–Lewis index (TLI) ≥ 0.95[42,43] - Chi-square/df ratio ≤ 3 rule[32] - Chi-square significant ($p ≤ .05$), SRMR ≤ 0.08, and standardised residuals were small ($\lvert r_{res} \rvert < 0.1$)[31,32]
Poor fit	Chi-square significant ($p < 0.05$) and SRMR > 0.08

2

3

19

1 **Table 2: Criteria to determine number of factors extracted in the exploratory factor**
2 **analysis (EFA)**

	Criteria
1	Kaiser's criterion of eigenvalues > 1[44]
2	Joliffe's criteria of eigenvalues > 0.7[45]
3	Visual inspection of the scree plot to identify the number of eigenvalues before the slope flattens out[18]
4	Parallel analysis[35]

3

4

1 **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.[46,47] This indicates that respondents are able to discriminate between response options.[47,48] 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 chi-square, was non-significant ($p > .05$) and the item and person residuals had $\bar{x} \approx 0$ and $SD \approx 1$. Individual items and persons were regarded as misfitting if their residuals fell outside of the range of ±2.5. Individual items were also tested by chi-square 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% CI < 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.[49]
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 (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 non-inflammatory). Inflammatory type was chosen over discrete diseases as DIF analysis can handle no more than four categories. For categorisation 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.[50]

2

1 **Table 4 Participant characteristics**

	Survey 1, *n* (%)	Survey 2, *n* (%)
Total	483	504
Age	M = 48.97 (SD = 15.24; range = 18-90)	M = 56.11 (SD = 15; range = 18-92)
Years lived with condition	M = 20.211 (SD = 17.1279; range = 0-86)	M = 14.44 (SD = 15.81; range = 0-72)
Gender		
Male	129 (26.7)	100 (19.8)
Female	535 (73.1)	399 (79.2)
Other	1 (0.2)	2 (0.4)
Ethnicity		
Black	20 (4.2)	11 (2.2)
East Asian	15 (3.2)	20 (4)
Latino	5 (1.1)	21 (4.2)
Middle Eastern	2 (0.4)	11 (2.2)
Mixed Race	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 (79.1)
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 masters level degree)	122 (25.4)	160 (31.8)
None of these qualifications	12 (2.5)	4 (0.8)

22

1 **Table 5 Fit indices of the CFA models for PRIDD V0.1, V0.3 and V1**

Model fit indices	Tests of model fit				RMSEA				
	X^2	df	p	Ratio	Estimate	90% CI	CFI	TLI	SRMR
PRIDD V0.1									
Model 1a: 4 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: 4 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: 4 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: 4 factors, second-order* (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: 4 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: 4 factors, second order (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: 4 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: 4 factors, second order (Physical Impact + Life Responsibilities Impact + Psychological Impact +	467.429	100	0.00	4.67	0.09	0.08-0.09	0.98	0.97	0.04

23

Social Impact)			p > .05	≤ 3	≤ 0.06		≥ 0.95	≥ 0.95	≤ 0.08
Target values			*p > .05*	*≤ 3*	*≤ 0.06*		*≥ 0.95*	*≥ 0.95*	*≤ 0.08*

*Higher order models tested the factors with 'overall impact' as the second-factor order.

CFI = comparative fit index; df = degrees of freedom; PRIDD = Patient-Reported Impact of Dermatological Diseases; RMSEA = root mean square error of approximation; SRMR = standardised root mean square residual; TLI = Tucker–Lewis index; V = version

1

24

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

	Analysis	No. items	Valid *n* (no. of extremes)	Item fit residual		Person fit residual		Overall chi-squared interaction			PSI	α	Unidimensionality t tests (CI)	
				x̄	SD	x̄	SD	Value	df	*p*			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
Physical Impact	Q6 rescored	7	485 (19)	0.24	1.45	-0.36	1.20	42.94	49	0.72	0.86		0.08	0.06
Physical Impact	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 Responsibilities Impact	Initial	6	474 (30)	0.04	2.15	-0.37	1.13	68.60	42	0.01	0.85		0.04	0.02
Life Responsibilities Impact	Q12 rescored	6	474 (30)	-0.02	2.08	-0.38	1.14	55.64	42	0.08	0.85		0.04	0.02
Life Responsibilities 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 Impact	Initial	6	480 (24)	-0.29	2.72	-0.39	1.02	92.60	42	0.00	0.90		0.08	0.06
Psychological 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

		Items												
	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
Social Impact	Q25 rescored	6	444 (60)	-0.04	1.95	-0.33	1.09	65.73	42	0.01	0.84		0.06	0.04
Social Impact	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	Non-significant (p > 0.05)		>0.7	> 0.7	Lower CI ≤ .05			

α = Cronbach's alpha; CI = confidence interval; df = degrees of freedom; PSI = Person Separation Index. Extremes = people scoring either maximally or minimally across the complete item set.
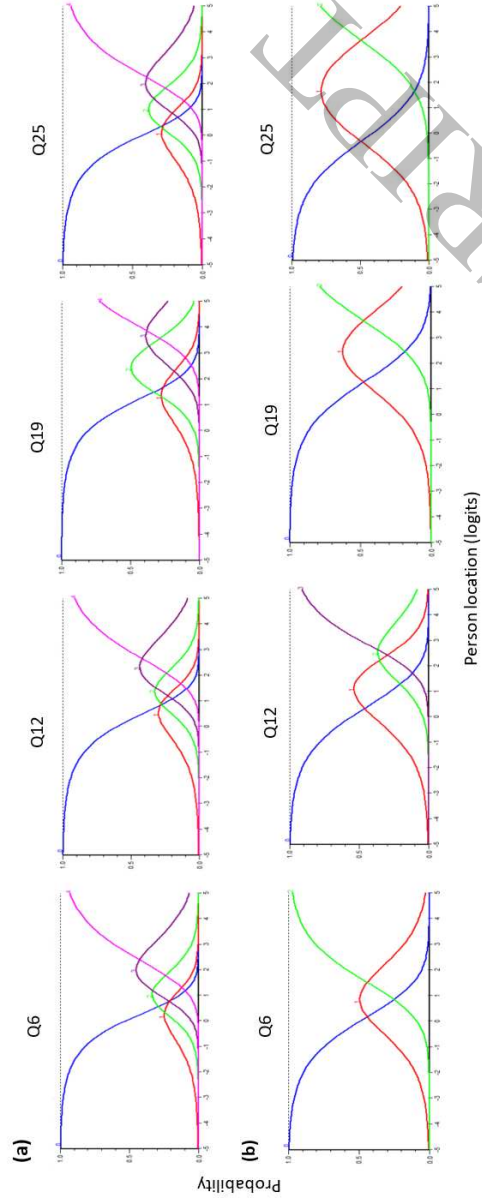
1   **Table 7: Individual item fit of PRIDD V1**

Item	Location parameter	SE	Fit statistics		
			Fit residual	Chi-square	Chi-square probability*
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

* Bonferroni-adjusted probability value

2

3

Figure 1
372x150 mm (x DPI)

Figure 2
204x174 mm (x DPI)

Figure 3
122x108 mm (x DPI)

1
2
3

Bimzelx®▼
(bimekizumab)

THIS ADVERT CONTAINS PROMOTIONAL CONTENT FROM UCB AND IS INTENDED FOR HCPS IN GREAT BRITAIN ONLY
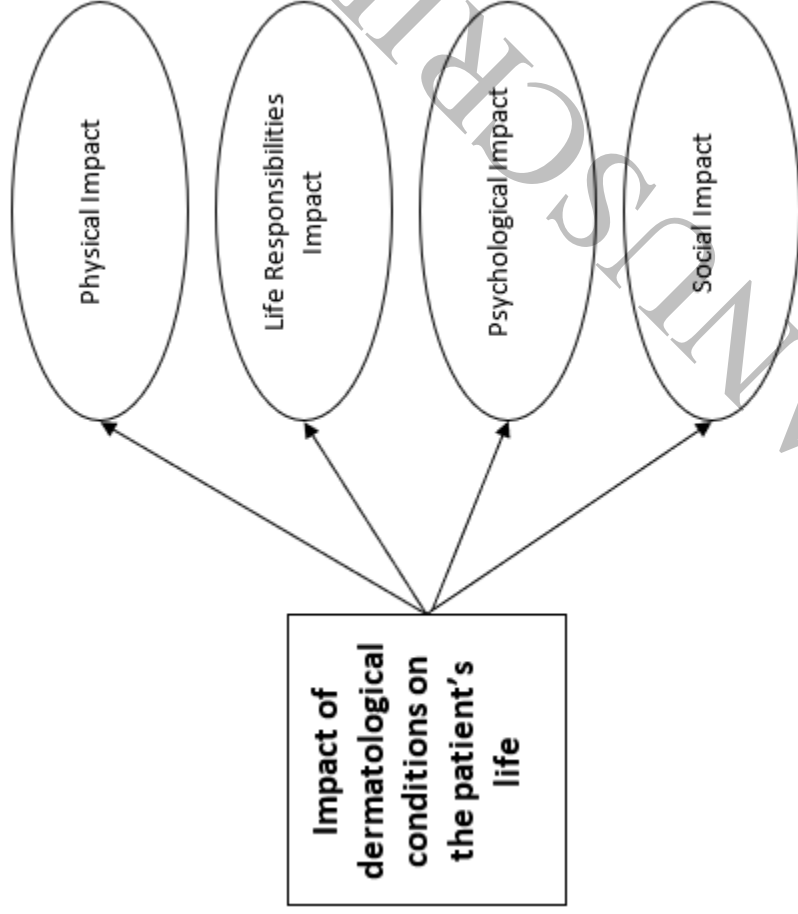
THE OPPORTUNITY FOR COMPLETE, FAST AND LASTING SKIN CLEARANCE [1,2]

68.2% achieved PASI 100 at Week 16[¥1]

75.9% of patients achieved PASI 75 at Week 4[¥1]

82% of week 16 PASI 100 responders maintained this response up to 3 years[2]

BIMZELX was well tolerated, the most frequently reported adverse reactions were: upper respiratory tract infections (14.5%, 14.6%, in plaque psoriasis (Pso), and psoriatic arthritis (PsA) respectively) and oral candidiasis (7.3%, 2.3% in Pso, and PsA respectively). Other common reported adverse reactions include Tinea infections, Ear infections, Herpes simplex infections, Oropharyngeal candidiasis, Gastroenteritis, Folliculitis, Headache, Rash, Dermatitis, Eczema, Acne, Injection site reactions, and Fatigue. Please refer to the SmPC for further information.[1]

Challenge expectations in plaque psoriasis[1,2]

Visit **Bimzelx.co.uk** to discover more.

This site contains promotional information on UCB products.

Stay connected with UCB by scanning the QR code and set your digital preferences.

Use this QR code to access Bimzelx.co.uk

This is a promotional UCB website

Footnotes: [¥]co-primary endpoints PASI 90 and IGA 0/1 at Week 16

Pso - Plaque Psoriais; PsA - Psoriatic Athritis

BIMZELX® (Bimekizumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Bimzelx, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). Please refer to the SmPC for further information.[1]

PRESCRIBING INFORMATION FOR HCP'S IN GREAT BRITAIN

BIMZELX® ▼ (Bimekizumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; and for active psoriasis arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs), alone or in combination with methotrexate.[1] (Please consult the Summary of Product Characteristics (SmPC) before prescribing).

Active Ingredient: Bimekizumab – solution for injection in pre-filled syringe or pre-filled pen: *160 mg of bimekizumab in 1 mL of solution (160mg/mL).* **Indications:** Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Alone or in combination with methotrexate, for active psoriatic arthritis in adults who have had an inadequate response or are intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). Adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy. **Dosage and Administration:** Should be initiated and supervised by a physician experienced in the diagnosis and treatment of conditions for which Bimzelx is indicated. **Recommended dose:** Plaque Psoriasis: 320 mg (given as two subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. Psoriatic arthritis: 160 mg (given as 1 subcutaneous injection of 160 mg) every 4 weeks. For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, the recommended dose is the same as for plaque psoriasis. After 16 weeks, regular assessment of efficacy is recommended and if a sufficient clinical response in joints cannot be maintained, a switch to 160 mg every 4 weeks can be considered. Axial spondyloarthritis (nr-axSpA and AS): 160 mg (given as 1 subcutaneous injection) every 4 weeks. For patients with plaque psoriasis (including psoriatic arthritis with coexistent moderate to severe psoriasis) and a body weight ≥ 120 kg who did not achieve complete skin clearance at week 16, 320 mg every 4 weeks after week 16 may further improve treatment response. Consider discontinuing if no improvement by 16 weeks of treatment. Renal or hepatic impairment: No dose adjustment needed. Elderly:

No dose adjustment needed. Administer by subcutaneous injection to thigh, abdomen or upper arm. Rotate injection sites and do not inject into psoriatic plaques or skin that is tender, bruised, erythematous or indurated. Do not shake pre-filled syringe or pre-filled pen. Patients may be trained to self-inject. **Contraindications:** Hypersensitivity to bimekizumab or any excipient; Clinically important active infections (e.g. active tuberculosis). **Warnings and Precautions:** Record name and batch number of administered product. *Infection:* Bimekizumab may increase the risk of infections e.g. upper respiratory tract infections, oral candidiasis. Caution when considering use in patients with a chronic infection or a history of recurrent infection. Must not be initiated if any clinically important active infection until infection resolves or is adequately treated. Advise patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection, the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy do not administer bimekizumab until infection resolves. *TB:* Evaluate for TB infection prior to initiating bimekizumab – do not give if active TB. While on bimekizumab, monitor for signs and symptoms of active TB. Consider anti-TB therapy prior to bimekizumab initiation if past history of latent or active TB in whom adequate treatment course cannot be confirmed. *Inflammatory bowel disease:* Bimekizumab is not recommended in patients with inflammatory bowel disease. Cases of new or exacerbations of inflammatory bowel disease have been reported. If inflammatory bowel disease signs/symptoms develop or patient experiences exacerbation of pre-existing inflammatory bowel disease, discontinue bimekizumab and initiate medical management. *Hypersensitivity:* Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, discontinue immediately and treat. *Vaccinations:* Complete all age appropriate immunisations prior to bimekizumab initiation. Do not give live vaccines to bimekizumab patients. Patients may receive inactivated or non-live vaccinations. **Interactions:** A clinically relevant effect on CYP450 substrates with a narrow therapeutic index in which the dose is individually adjusted e.g. warfarin, cannot be excluded. Therapeutic monitoring should be considered. **Fertility, pregnancy and lactation:** Women of child-bearing potential should use an effective method of contraception during treatment and for at

least 17 weeks after treatment. Avoid use of bimekizumab during pregnancy. It is unknown whether bimekizumab is excreted in human milk, hence a risk to the newborn/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Bimzelx therapy. No data available on human fertility. **Driving and use of machines:** No or negligible influence on ability to drive and use machines. **Adverse Effects:** Refer to SmPC for full information. Very Common *(≥ 1/10):* upper respiratory tract infection; Common *(≥ 1/100 to < 1/10):* oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis; headache, rash, dermatitis and eczema, acne, injection site reactions, fatigue; Uncommon *(≥ 1/1,000 to < 1/100):* mucosal and cutaneous candidiasis (including oesophageal candidiasis), conjunctivitis, neutropenia, inflammatory bowel disease. Storage precautions: Store in a refrigerator (2°C – 8°C), do not freeze. Keep in outer carton to protect from light. Bimzelx can be kept at up to 25°C for a single period of maximum 25 days with protection from light. Product should be discarded after this period or by the expiry date, whichever occurs first.

Legal Category: POM

Marketing Authorisation Numbers: PLGB 00039/0802 (Pre-filled Syringe), PLGB 00039/0803 (Pre-filled Pen).

UK NHS Costs: £2,443 per pack of 2 pre-filled syringes or pens of 160 mg each.

Marketing Authorisation Holder: UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom.

Further information is available from: UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE. Tel: 0800 2793177 Email: ucbcares.uk@ucb.com

Date of Revision: August 2023 (GB-P-BK-AS-2300047) Bimzelx is a registered trademark.

> **Adverse events should be reported. Reporting forms and information can be found at http://www.mhra.gov.uk/yellowcard. Adverse events should also be reported to UCB Pharma Ltd at ucbcares.uk@ucb.com or 0800 2793177.**

References: 1. BIMZELX (bimekizumab) SmPC. Available at: https://www.medicines.org.uk/emc/product/12834/smpc. Accessed September 2023 **2.** Strober et al. [BE BRIGHT open label extension] Br J Dermatol. 2023. 188(6): 749-759.

GB-BK-2300081 Date of preparation: September 2023.

© UCB Biopharma SRL, 2023. All rights reserved.

BIMZELX® is a registered trademark of the UCB Group of Companies.

Inspired by **patients.** Driven by **science.**

Design code 0001