Enhancing current guidance for psoriatic arthritis and its comorbidities: recommendations from an expert consensus panel

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Abstract

Objectives: Existing guidelines for psoriatic arthritis (PsA) cover many aspects of management. Some gaps remain relating to routine practice application. An expert group aimed to enhance current guidance and develop recommendations for clinical practice that are complementary to existing guidelines.

Methods: A steering committee comprising experienced, research-active clinicians in rheumatology, dermatology and primary care agreed on themes and relevant questions. A targeted literature review of PubMed and Embase following a PICO framework was conducted. At a second meeting, recommendations were drafted and subsequently an extended faculty comprising rheumatologists, dermatologists, primary care clinicians, specialist nurses, allied health professionals, non-clinical academic participants and members of the Brit-PACT patient group, was recruited. Consensus was achieved via an online voting platform when 75% of respondents agreed in the range of 7–9 on a 9-point scale.

Results: The guidance comprised 34 statements covering four PsA themes. *Diagnosis* focussed on strategies to identify PsA early and refer appropriately, assessment of diagnostic indicators, use of screening tools and use of imaging. *Disease assessment* centred on holistic consideration of disease activity, physical functioning and impact from a patient perspective, and on how to implement shared decision-making. For *comorbidities*, recommendations included specific guidance for high-impact conditions such as depression and obesity. *Management* statements (which excluded extant guidance on pharmacological therapies) covered multidisciplinary team working, implementation of lifestyle modifications and treat-to-target strategies. Minimising corticosteroid use was recommended where feasible.

Conclusion: The consensus group have made evidence-based best practice recommendations for the management of PsA to enhance the existing guidelines.

Key words: Quality of care, Best practices, Psoriatic arthritis, Psoriasis, Care recommendations, Comorbidities

Key messages:

- This consensus programme aimed to complement existing psoriatic arthritis guidelines with practical, clinically relevant recommendations.
- Recommendations covered psoriatic arthritis diagnosis (screening, imaging) and assessment incorporating disease impact (including patient perspective).
- Management recommendations included a multidisciplinary approach for comorbidities, a treat-to-target strategy, and minimisation of corticosteroids.

Introduction

Psoriatic arthritis (PsA) is a chronic inflammatory joint disease occurring in approximately one quarter of individuals with psoriasis (PsO) (1). It is highly heterogeneous in its presentation, encompassing a range of musculoskeletal manifestations including peripheral arthritis, axial inflammation (spondylitis), dactylitis and enthesitis (1). In addition to progressive joint damage and pain, PsA is associated with extra-articular manifestations such as uveitis and inflammatory bowel disease (IBD), with comorbidities including metabolic syndrome and cardiovascular disease, and overall can adversely affect patients' quality of life (1–3).

Recent data emphasise the importance of timely diagnosis, as untreated PsA can lead to irreversible joint damage, experienced by approximately half of patients within two years of diagnosis (1). However, many patients experience significant diagnostic delay (4) owing in part to the challenges of differential diagnosis and lack of validated biomarkers (5,6). Following diagnosis, comprehensive assessment should consider arthritis, enthesitis, dactylitis, skin/nail disease and axial involvement, as well as the overall impact on individual patients. Comprehensive evaluation facilitates selection of appropriate treatments that target specific disease domains and associated comorbidities to reduce morbidity and mortality (2). To achieve optimal patient care, there is a need for clear and actionable guidance for clinicians on screening and referral (many patients with PsO are managed in primary care or dermatology settings), as well as optimal management of PsA and its comorbidities.

Existing guidelines such as those provided by the European Alliance of Associations for Rheumatology (EULAR), the British Society for Rheumatology (BSR), the American College of Rheumatology (ACR), the National Psoriasis Foundation (NPF) and the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), give comprehensive guidance on the diagnosis and pharmacological management of PsA (1,7). Owing to the complexity and heterogeneity of the disease, gaps have been identified relating to the application of guidance in

clinical practice, ongoing non-pharmacological management and quality of care benchmarking, often associated with a lack of evidence.

Consequently, an expert consensus group aimed to develop an evidence- and consensus-based set of recommendations for the management of PsA in clinical practice. A consensus programme was undertaken to define minimum and best quality standards for day-to-day PsA management, adding value to existing recommendations and guidelines, and provide practical strategies and tools to achieve these quality standards and support clinicians without replacing current guidance.

Methods

The consensus programme was based on a modified Delphi methodology (**Supplementary Figure S1, available at *Rheumatology* online**). A steering committee (SC) was formed of UK clinicians experienced in treating PsA (mean 20.1 years, range 1.5–30) and/or widely published in PsA: nine rheumatologists, one dermatologist, one primary care physician and one specialist nurse.

In an initial meeting held in September 2022, the SC discussed where gaps in current guidelines existed, or where clinicians would benefit from extra support in translating these into clinical practice. Four consensus themes were identified: PsA diagnosis; disease assessment; comorbidities; and management. Management of PsA in this context excluded guidance on pharmacological therapies, which is covered in detail by extant guidelines. Questions were drafted within each theme (15 in total) and a targeted literature review (TLR) was conducted to support and inform responses. Given the aim and context of this programme, certain questions relating to clinical practice and interpretation of the guidance were deemed appropriate to be addressed by the committee's clinical experience. The TLR was performed within Medline, through PubMed and Embase; 10,725 records were identified, with 174 studies selected for full-text review following application of exclusion criteria (**Supplementary Figure S2, available at *Rheumatology* online**).

During further meetings in October and November 2022, the results of the TLR were reviewed and consensus recommendations drafted to address each question. In addition to the recommendations, the SC proposed 'implications for clinical practice' statements, practical guidance to further support actionability in day-to-day practice. An extended faculty (EF) of UK PsA-interested clinicians and patients was recruited, comprising rheumatologists, dermatologists, primary care representatives, specialist nurses, allied health professionals, non-clinical academic participants and members of the Brit-PACT patient group. Via an online voting platform, each member of the SC and EF indicated an agreement score for each recommendation on a scale from 1 (strongly disagree) to 9 (strongly agree). For scores lower than 7, voters were requested to provide written rationale. Patients voted

on a selection of recommendations, and lay language was applied to facilitate understanding. Consensus was achieved when 75% of respondents gave scores in the range 7–9. If consensus was not achieved, a re-vote on the updated recommendation was required. In the early stages of development, the main concept of each 'implication for clinical practice' was validated with the EF via their voting responses of 'Yes', 'No', or 'Not sure' to each point; this feedback was used to refine the wording and ensure maximum clinical applicability.

At a final meeting in May 2023, the SC discussed the results of the voting and the implications for clinical practice were refined to improve relevance and maximise their use from a clinical perspective.

Results

Overview

A total of 34 recommendations were drafted by the SC and put to vote. The invited EF comprised 40 rheumatologists, 11 dermatologists, two primary care professionals, 11 specialist nurses, nine academic professionals and the Brit-PACT patient advocacy group. Of the invited group, three nurses, one dermatologist, six rheumatologists and six patients from the Brit-PACT group, in addition to the 12 SC members, voted on the recommendations (N=27 in total), for an overall participation rate of 29.7%.

Consensus was achieved for all suggested recommendations, eliminating the need for a second round of voting, with 29 recommendations achieving consensus in the range of 90–100%, four in the range of 80–89% and one in the range of 75–79% (**Tables 1–4**). The questions and recommendations for each theme, and their strength of recommendation and level of consensus are provided below (**Tables 1–4**), along with the implications for clinical practice (**Table 5**). A graphical summary of the recommendations and implications for clinical practice is shown in **Figure 1**.

Diagnosis

Within the 'Diagnosis' theme (**Table 1**), the TLR was used to investigate risk factors associated with the development of PsA. Age (8), body mass index (BMI) (9,10), severity of PsO (10–12) and duration of PsO (13) emerged as strong predictive indicators (in a Danish registry study of 10,011 patients with PsO, mean duration of PsO at PsA onset was 3.5 years (13)). Despite anecdotal observation of joint stiffness as a predictive indicator in clinical practice, published evidence remains inconclusive. The SC felt it important to distinguish between true 'risk factors', and co-occurring symptoms and features of the underlying disease returned by the TLR such as arthralgia (10) and spondylitis (12); however, the importance of ensuring that patients with peripheral/axial disease are not 'missed' was

emphasised. The importance of suspecting PsA in patients with PsO and ≥1 extra-articular manifestation was also highlighted. Similarly, there was overlap between risk of developing PsA and some key comorbidities. The SC agreed that obesity or high BMI should be treated as an independent comorbidity; the same applies to depression (3,14), with guidance provided for these. Low-quality evidence pertaining to the presence of genetic risk factors was noted, but beyond this programme's scope given its practical focus for clinical use.

Given the heterogeneity of PsA, it is of paramount importance to screen patients with PsO, who represent the main at-risk group (15). Screening tools available in a primary care setting were investigated, including the German Psoriasis Arthritis Diagnostic (GEPARD) patient questionnaire (16), the Toronto Psoriatic Arthritis Screen II (ToPAS II), the Psoriatic Arthritis Screening and Evaluation (PASE), the Psoriasis Epidemiology Screening Tool (PEST) and the Early Arthritis for Psoriatic Patients (EARP) (17). PEST was selected as the most practical, user-friendly tool for those managing patients with musculoskeletal conditions in primary care, in alignment with UK National Institute for Health and Care Excellence (NICE) guidelines (18). While sensitivity of screening tools is generally adequate, their specificity is relatively poor (19); assessment by a rheumatologist is the gold standard for making a diagnosis of PsA, and the key purpose of screening tools is to prompt consideration of referral to rheumatology services.

Adequate timing for referral from primary to specialist care was also agreed upon, aligning to the recommendations of the National Early Inflammatory Arthritis Audit (NEIAA), which advises three weeks (20). The association between diagnostic delay and poorer outcomes in PsA is well documented (21), with longer time to diagnosis/specialist care linked to a more severe disease course and worse outcomes (22).

Disease assessment

The recommendations within the 'Disease Assessment' theme (**Table 2**) aim to achieve two key objectives: To highlight the need for individualised assessments addressing factors affecting the individual most significantly, and to provide practical guidance for assessing PsA in the clinic.

PsA has a notably broad impact on quality of life (greater than PsO alone (23)), due to associated symptoms of pain and fatigue, among others, leading to impairments in functional ability and ability to work (3). This impact may not only be linked to PsA symptoms but also to comorbid conditions, including mental health conditions, which need to be identified and managed as early as possible. Extra-articular manifestations, as previously mentioned, can provide important diagnostic indicators,

but are also important to assess on an ongoing basis due to their impact on the burden of disease and as a factor in driving therapy selection (24).

Evidence from the TLR suggested that sex is closely linked with disease course in PsA, resulting in distinct clinical presentations in men and women. Women reported worse quality of life associated with higher levels of disability, fatigue, pain and overall disease severity, as well as a lower likelihood of achieving remission (25). Men with PsA experienced less overall functional impairment, but a higher impact on their self-esteem (26).

Given the variability in patients' experience of PsA, it is recommended that the Psoriatic Arthritis Impact of Disease (PsAID-12) questionnaire be used at every consultation. PsAID-12 covers all key domains, and can be administered digitally (27); it was endorsed at OMERACT2018 as a core outcome measure to asses PsA-specific health-related quality of life (15). While recognising that a complete skin examination at every visit may be challenging in practice, it is an aspirational goal. Special attention should be paid to challenging body areas like the natal cleft, genitals, palmoplantar sites, nails, and scalp, as well as sites prone to enthesitis; tools such as the Leeds Enthesitis Index are easy to administer and provide a comprehensive assessment as a minimum (28). Evaluation of the patient experience should also be conducted, using a tool such as the Patient Reported Experience Measures tool provided by Commissioning for Quality in Rheumatoid Arthritis (29). Other assessments advised as part of routine PsA care include cardiovascular risk evaluation, recommended every five years based on EULAR cardiovascular guidelines (30).

Overall, it was clear that while there are minimum quality standards for assessments that form part of day-to-day PsA care, the heterogeneity of the condition requires that the patient perspective be at the centre of the assessment, goal setting and decision-making process; the utility of any outcome measurement tool is dependent on clear communication between the healthcare professional and the patient.

Comorbidities

Recommendations (**Table 3**) and implications for clinical practice (**Table 5**) were made for assessment and management of comorbidities, with specific guidance for high-impact conditions, such as depression and obesity.

The SC distinguished between comorbidities that affect a patient's health overall (such as cardiovascular disease), those that directly impact PsA outcomes including depression (14), obesity (31) and fibromyalgia (32), and those with implications for the treatment of PsA due to contraindications with pharmacological therapies, such as fatty liver disease (33). Obesity should be

addressed for optimal PsA outcomes, using lifestyle and/or treatment interventions. Both NICE obesity guidelines and EULAR cardiovascular guidelines provide useful direction for clinicians (30,34). Published literature indicates a positive impact on treatment outcomes in patients with obesity who lose at least 5–10% of their body weight (35). GRAPPA and EULAR guidelines are other useful resources for clinicians for the management of patients with PsA and depression or obesity (33,36,37), while EULAR and the European Society of Cardiology have provided guidance on the management of cardiovascular risk (30,38). In addition, comorbidity guidance for PsO may have clinical utility in PsA (39).

The TLR indicated insufficient literature regarding the outcomes of coordinated management of comorbidities in patients with PsA; more evidence is needed. However, extensive experience working within multidisciplinary teams demonstrates that any successful comorbidity management approach requires collaboration with and support from primary care and relevant specialists. It is paramount that clinicians do not consider PsA as a disease existing in a vacuum, and instead address the patient's health in totality, proactively engaging with them to monitor risk factors and assess potential and existing comorbidities.

Management

Recommendations (**Table 4**) and implications for clinical practice (**Table 5**) within management cover the benefits of early intervention, lifestyle modifications, treating to target and the risks associated with the use of corticosteroids. Guidance on pharmacological therapies is given in extant guidelines and is outside the scope of this work.

Regarding therapy initiation and goal setting, early intervention was agreed to be of paramount importance (4), which may include management in early arthritis clinics (40) and assessment for subclinical enthesitis (41,42). Patients with PsA are presenting later and receiving less therapy than patients with rheumatoid arthritis, and delay in presentation has been associated with poorer outcomes (21,43). A thorough early assessment is advised since in early PsA, the extent and severity of disease can be underestimated, particularly in polyarticular disease. It has been observed that the disease phenotype can worsen over time (44); thus, early therapy may alter the disease course (45) (though data are lacking). Preliminary evidence indicates early biologic treatment of PsO may delay PsA onset (41), although findings on this are conflicting (46), highlighting the need for additional population-based research.

Lifestyle factors can play a key role in PsA management. Smoking cessation is strongly recommended, in alignment with guidance provided by BSR (1). There is evidence that exercise is

linked to a reduced risk of PsA (31), and that patients with PsA can tolerate high-intensity training without worsening of disease activity (47), despite persisting concerns around mechanical stress triggering inflammatory response or enthesitis. However, there is a lack of evidence to support the recommendation of specific types of exercise, and given that patients may be unsure what is safe for them, exercise regimens should be tailored to the individual, their current fitness level and degree of disease activity (48).

For disease activity and therapy monitoring, patient-reported outcome measures (PROMs) were regarded by the SC as useful to include alongside standard clinical assessments. These can be collected digitally, but must reflect the individual and local need in terms of usability, language and health literacy. A treat-to-target model incorporating PROMs of significance to the individual forms the backbone of recommendations in this theme (**Table 4**).

Use of corticosteroids in PsA management was discussed. In alignment with national and international guidelines, the SC agreed that while steroids serve a notable role, their use should be minimised in PsA (1,36,49,50). Treatment with systemic disease-modifying anti-rheumatic drugs prior to introducing steroids may minimise risk of psoriasis skin flares, although supporting data are limited. The committee agreed that oral steroids should not be included in routine PsA management, particularly at high doses (≥10 mg prednisolone daily) or over the long term, though intramuscular or local joint injections may be considered in carefully selected cases (alongside other treatments such as disease-modifying anti-rheumatic drugs or biologics) with proper consideration given to the risk of rebound psoriasis skin flares. The need to communicate these nuances to patients was highlighted; it is important that patients appropriately understand the risk of increased skin disease or erythrodermic reaction. The risk may be higher in patients with unstable skin disease or a previous erythrodermic reaction. The importance of an effective dermatology and rheumatology multidisciplinary approach was highlighted for optimal management; the SC noted that there is room for improvement on this front, and that there is a pressing need to find balance between treatment of the joints and the skin to maximise patient quality of life.

Patient votes

Two recommendations did not reach consensus among the patient voters. The first recommendation, within the 'Comorbidities' theme, was: 'In PsA patients who are overweight/obese, a proactive approach to weight loss should be considered following national guidelines and local services' – for which only 60% consensus was achieved. Patient feedback highlighted that this advice is relevant for the whole population and should not serve as a specific feature in PsA recommendations. Moreover, patients felt that currently, patient–healthcare

professional discussions around weight are not approached in a positive or constructive manner, and thus improvements should be made by clinicians to achieve less negative, more realistic conversations on weight loss.

The second recommendation that did not achieve patient consensus was: 'Treat to target in PsA recommendations have stated that the target should be remission or inactive disease'. Patient voters expressed that remission or minimal disease activity is not a realistic goal, and that a more individualised approach is needed. This aligned with SC discussions around the need for a personalised treat-to-target approach, implementing individualised goals; however, overall remission or minimal disease activity is likely to remain the gold standard from a clinical and population guideline perspective.

Discussion

In this programme, an SC of 12 healthcare professionals in the fields of rheumatology, dermatology and primary care convened with the aim of developing an evidence- and consensus-based set of recommendations for the management of PsA in clinical practice to enhance existing guidance. The objective was to define minimum and best quality standards for day-to-day PsA management, complementing and adding value to existing recommendations and guidelines, and provide a set of practical strategies and tools to achieve these quality standard goals to support clinicians. The majority of recommendations (29/34) achieved 90–100% consensus among the faculty.

Unsurprisingly, the topics generating the most challenging discussions were those pertaining to the coordinated management of comorbidities, and use of steroids in the treatment of PsA and PROMs to measure its impact in routine clinical practice. Though it was unanimously agreed that a well-coordinated, multidisciplinary approach is required, it was also acknowledged that establishing a multidisciplinary approach is challenging in clinical practice; practical strategies such as raising awareness of screening tools in primary care, and rheumatologists spending some time working in an MDT clinic to gain skills in other areas, are proposed. Concerning corticosteroids, although this programme did not aim to make pharmacological therapy recommendations, the SC agreed that their use should be strictly minimised. Regarding use of PROMs, much consideration was given to how these could be best applied in clinical practice. In the digital age, it is easier than ever to collect PROMs, and thus the SC agreed these can and should be used in routine practice. However, it was suggested that in order to be useful, the specific PROMs and collection platform employed must be appropriate and individualised to the patient's disease state and degree of digital and health literacy, as well as to the local need. The SC also discussed the possibility of linking PROMs to an individualised treat-to-target approach, reflecting an overall theme – PsA is a heterogeneous and

multifaceted condition that does not exist in a vacuum, and each patient needs to be considered individually and holistically.

Both the SC and EF were UK based; this may limit the ease of generalising some of the recommendations to all healthcare settings. The limited sample size of the EF, especially among patients, is another limitation; owing to the low number of patients recruited for voting, the results could be easily skewed. Moreover, there was a low degree of engagement from the EF; of the 79 members invited, only 16 voted on the recommendations. Other limitations pertained to the programme's remit. Pharmacoeconomic and treatment access considerations, and further guidance on identifying and managing extra-articular manifestations, were outside the scope of this work although the SC acknowledge their significance in holistic patient care. Reproductive health is a key concern for patients with PsA not covered here; BSR guidelines provide comprehensive guidance on pregnancy and breastfeeding (51) but further work is needed.

The two recommendations that did not achieve consensus among patient voters pertained to management of obesity and using remission or minimal disease activity as a treatment target. However, the patient board provided rationale for rating recommendations 6 or less, and in both cases the SC agreed a more targeted and individualised approach is essential to successfully manage comorbidities such as obesity, and implement a treat-to-target approach.

This consensus programme identified critical areas beyond pharmacological therapy where existing guidance on PsA management could be enhanced. Recommendations and implications for clinical practice aim to provide relevance to healthcare professionals and a clinical resource to support the care of patients with PsA. Owing to the practical and specific nature of the recommendations, it is hoped that the guidance can be easily and rapidly implemented into practice for use in conjunction with current guidelines.

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Conflicts of interest

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Data availability

The data underlying this article is available upon reasonable request to the corresponding author.

References

1. Tucker L, Allen A, Chandler D, Ciurtin C, Dick A, Foulkes A, et al. The 2022 British Society for Rheumatology guideline for the treatment of psoriatic arthritis with biologic and targeted synthetic DMARDs. *Rheumatol Oxf Engl* 2022;61(9):e255–66.

2. Coates LC, Helliwell PS. Psoriatic arthritis: State of the art review. *Clin Med Lond Engl* 2017;17(1):65–70.

3. Tillett W, Merola JF, Thaçi D, Holdsworth E, Booth N, Lobosco LS, et al. Disease characteristics and the burden of joint and skin involvement amongst people with psoriatic arthritis: a population survey. *Rheumatol Ther* 2020;7(3):617–37.

4. Cooksey R, Rahman MA, Kennedy J, Brophy S, Choy E. Biologic use in psoriatic arthritis and ankylosing spondylitis patients: A descriptive epidemiological study using linked, routine data in Wales, UK. *Rheumatol Adv Pract* 2021;5(2):rkab042.

5. Wirth T, Balandraud N, Boyer L, Lafforgue P, Pham T. Biomarkers in psoriatic arthritis: A meta-analysis and systematic review. *Front Immunol* 2022;13.

6. Van den Bosch F, Coates L. Clinical management of psoriatic arthritis. *Lancet Lond Engl* 2018;391(10136):2285–94.

7. Ogdie A, Coates LC, Gladman DD. Treatment guidelines in psoriatic arthritis. *Rheumatol Oxf Engl* 2020;59(Suppl 1):i37–46.

8. Deike M, Brinks R, Meller S, Schneider M, Sewerin P. Risk of psoriatic arthritis depending on age: Analysis of data from 65 million people on statutory insurance in Germany. *RMD Open* 2021;7(3).

9. Green A, Shaddick G, Charlton R, Snowball J, Nightingale A, Smith C, et al. Modifiable risk factors and the development of psoriatic arthritis in people with psoriasis. *Br J Dermatol* 2020;182(3):714–20.

10. Eder L, Polachek A, Rosen CF, Chandran V, Cook R, Gladman DD. The development of psoriatic arthritis in patients with psoriasis is preceded by a period of nonspecific musculoskeletal symptoms: A prospective cohort study. *Arthritis Rheumatol Hoboken NJ* 2017;69(3):622–9.

11. Merola JF, Tian H, Patil D, Richardson C, Scott A, Chen YH, et al. Incidence and prevalence of psoriatic arthritis in patients with psoriasis stratified by psoriasis disease severity: retrospective analysis of an electronic health records database in the United States. *J Am Acad Dermatol* 2022;86(4):748–57.

12. Feld J, Ye JY, Chandran V, Inman RD, Haroon N, Cook R, et al. Axial disease in psoriatic arthritis: The presence and progression of unilateral grade 2 sacroiliitis in a psoriatic arthritis cohort. *Semin Arthritis Rheum* 2021;51(2):464–8.

13. Egeberg A, Skov L, Zachariae C, Gislason GH, Thyssen JP, Mallbris L. Duration of psoriatic skin disease as risk factor for subsequent onset of psoriatic arthritis. *Acta Derm Venereol* 2018;98(6):546–50.

14. Lewinson RT, Vallerand IA, Lowerison MW, Parsons LM, Frolkis AD, Kaplan GG, et al. Depression is associated with an increased risk of psoriatic arthritis among patients with psoriasis: a population-based study. *J Invest Dermatol* 2017;137(4):828–35.

15. Perez-Chada LM, Gottlieb AB, Cohen J, Mease P, Duffin KC, Garg A, et al. Measuring psoriatic arthritis symptoms: A core domain in psoriasis clinical trials. *J Am Acad Dermatol* 2020;82(1):54–61.

16. Härle P, Letschert K, Wittig B, Mrowietz U. Sensitivity of the GEPARD patient questionnaire to identify psoriatic arthritis in patients with psoriasis in daily practice: The GEPARD-life study. *Dermatol Basel Switz* 2016;232(5):597–605.

17. Mishra S, Kancharla H, Dogra S, Sharma A. Comparison of four validated psoriatic arthritis screening tools in diagnosing psoriatic arthritis in patients with psoriasis (COMPAQ Study). *Br J Dermatol* 2017;176(3):765–70.

18. National Institute for Health and Care Excellence [Internet]. CG153. Psoriasis: assessment and management [cited 2023 Aug 4]. Available from: https://www.nice.org.uk/guidance/cg153.

19. Iragorri N, Hazlewood G, Manns B, Danthurebandara V, Spackman E. Psoriatic arthritis screening: A systematic review and meta-analysis. *Rheumatol Oxf Engl* 2019;58(4):692–707.

20. HQIP.org [Internet]. Ref.-342-NEIAA-Fourth-Annual-Report_FINAL.pdf [cited 2023 Aug 4]. Available from: https://www.hqip.org.uk/wp-content/uploads/2022/10/Ref.-342-NEIAA-Fourth-Annual-Report_FINAL.pdf.

21. Karmacharya P, Wright K, Achenbach SJ, Bekele D, Crowson CS, Ogdie A, et al. Diagnostic delay in psoriatic arthritis: A population-based study. *J Rheumatol* 2021;48(9):1410.

22. Haroon M, Gallagher P, FitzGerald O. Diagnostic delay of more than 6 months contributes to poor radiographic and functional outcome in psoriatic arthritis. *Ann Rheum Dis* 2015;74(6):1045.

23. Duvetorp A, Østergaard M, Skov L, Seifert O, Tveit KS, Danielsen K, et al. Quality of life and contact with healthcare systems among patients with psoriasis and psoriatic arthritis: Results from the NORdic PAtient survey of Psoriasis and Psoriatic arthritis (NORPAPP). *Arch Dermatol Res* 2019;311(5):351–60.

24. Novelli L, Lubrano E, Venerito V, Perrotta FM, Marando F, Curradi G, et al. Extra-articular manifestations and comorbidities in psoriatic disease: A journey into the immunologic crosstalk. *Front Med* 2021;8.

25. Gossec L, Walsh JA, Michaud K, Peterson S, Holdsworth EA, Karyekar CS, et al. Women with psoriatic arthritis experience higher disease burden than men: Findings From a real-world survey in the United States and Europe. *J Rheumatol* 2023;50(2):192–6.

26. Brihan I, Ianoși SL, Boda D, Hălmăjan A, Zdrîncă M, Fekete LG. Implications of self-esteem in the quality of life in patients with psoriasis. *Exp Ther Med* 2020;20(6):202.

27. Salaffi F, Di Carlo M, Carotti M, Farah S, Gutierrez M. The Psoriatic Arthritis Impact of Disease 12-item questionnaire: Equivalence, reliability, validity, and feasibility of the touch-screen administration versus the paper-and-pencil version. *Ther Clin Risk Manag* 2016;12:631–42.

28. Healy PJ, Helliwell PS. Measuring clinical enthesitis in psoriatic arthritis: Assessment of existing measures and development of an instrument specific to psoriatic arthritis. *Arthritis Rheum* 2008;59(5):686–91.

29. Bosworth A, Cox M, O'Brien A, Jones P, Sargeant I, Elliott A, et al. Development and validation of a Patient Reported Experience Measure (PREM) for patients with rheumatoid arthritis (ra) and other rheumatic conditions. *Curr Rheumatol Rev* 2015;11.

30. Agca R, Heslinga SC, Rollefstad S, Heslinga M, McInnes IB, Peters MJL, et al. EULAR recommendations for cardiovascular disease risk management in patients with rheumatoid arthritis

and other forms of inflammatory joint disorders: 2015/2016 update. *Ann Rheum Dis* 2017;76(1):17–28.

31. Thomsen RS, Nilsen TIL, Haugeberg G, Gulati AM, Kavanaugh A, Hoff M. Adiposity and physical activity as risk factors for developing psoriatic arthritis: Longitudinal data from a population-based study in Norway. *Arthritis Care Res* 2021;73(3):432–41.

32. Elsawy NA, Helal AMH, Abd ElHamid HA, Abdel-Fattah YH. Fibromyalgia in patients with psoriatic arthritis: Impact on disease activity indices, fatigue and health-related quality of life. *Int J Rheum Dis* 2021;24(2):189–96.

33. Campanholo CB, Maharaj AB, Corp N, Bell S, Costa L, de Vlam K, et al. Management of psoriatic arthritis in patients with comorbidities: An updated literature review informing the 2021 GRAPPA Treatment Recommendations. *J Rheumatol* 2023;50(3):426–32.

34. National Institute for Health and Care Excellence [Internet]. CG189. Obesity: identification, assessment and management. Available from: https://www.nice.org.uk/guidance/cg189.

35. Di Minno MND, Peluso R, Iervolino S, Russolillo A, Lupoli R, Scarpa R. Weight loss and achievement of minimal disease activity in patients with psoriatic arthritis starting treatment with tumour necrosis factor α blockers. *Ann Rheum Dis* 2014;73(6):1157–62.

36. Coates LC, Soriano ER, Corp N, Bertheussen H, Callis Duffin K, Campanholo CB, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): Updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol* 2022;18(8):465–79.

37. Gwinnutt JM, Wieczorek M, Balanescu A, Bischoff-Ferrari HA, Boonen A, Cavalli G, et al. 2021 EULAR recommendations regarding lifestyle behaviours and work participation to prevent progression of rheumatic and musculoskeletal diseases. *Ann Rheum Dis* 2023;82(1):48.

38. Visseren FLJ, Mach F, Smulders YM, Carballo D, Koskinas KC, Bäck M, et al. 2021 ESC Guidelines on cardiovascular disease prevention in clinical practice: Developed by the Task Force for cardiovascular disease prevention in clinical practice with representatives of the European Society of Cardiology and 12 medical societies with the special contribution of the European Association of Preventive Cardiology (EAPC). *Eur J Prev Cardiol* 2022;29(1):5–115.

39. Daudén E, Castañeda S, Suárez C, García-Campayo J, Blasco AJ, Aguilar MD, et al. Clinical practice guideline for an integrated approach to comorbidity in patients with psoriasis. *J Eur Acad Dermatol Venereol* 2013;27(11):1387–404.

40. Nisar MK. Early arthritis clinic is effective for rheumatoid and psoriatic arthritides. *Rheumatol Int* 2019;39(4):657–62.

41. Acosta Felquer ML, LoGiudice L, Galimberti ML, Rosa J, Mazzuoccolo L, Soriano ER. Treating the skin with biologics in patients with psoriasis decreases the incidence of psoriatic arthritis. *Ann Rheum Dis* 2022;81(1):74.

42. Acquacalda E, Albert C, Montaudie H, Fontas E, Danre A, Roux CH, et al. Ultrasound study of entheses in psoriasis patients with or without musculoskeletal symptoms: A prospective study. *Joint Bone Spine* 2015;82(4):267–71.

43. Charlton R, Coates L, Galloway J, McHugh N, McGrogan A, Hackett S, et al. Diagnostic delay and less intensive therapy for people with psoriatic arthritis compared with rheumatoid arthritis: A nested matched cohort study from within the UK National Early Inflammatory Arthritis Audit. *Arthritis Rheumatol* 2022;74(Suppl 9).

44. McHugh NJ. Progression of peripheral joint disease in psoriatic arthritis: A 5-yr prospective study. *Rheumatology* 2003;42(6):778–83.

45. 16-Week Results from FOREMOST, a Placebo-Controlled Study Involving Oligoarticular Psoriatic Arthritis Treated with Apremilast [Internet]. ACR Meeting Abstracts. [cited 2024 Feb 6]. Available from: https://acrabstracts.org/abstract/16-week-results-from-foremost-a-placebo-controlled-study-involving-oligoarticular-psoriatic-arthritis-treated-with-apremilast/.

46. Lindberg I, Lilja M, Geale K, Tian H, Richardson C, Scott A, et al. Incidence of psoriatic arthritis in patients with skin psoriasis and associated risk factors: A retrospective population-based cohort study in Swedish routine clinical care. *Acta Derm Venereol* 2020;100(18):5929.

47. Thomsen RS, Nilsen TIL, Haugeberg G, Bye A, Kavanaugh A, Hoff M. Impact of high-intensity interval training on disease activity and disease in patients with psoriatic arthritis: A randomized controlled trial. *Arthritis Care Res* 2019;71(4):530–7.

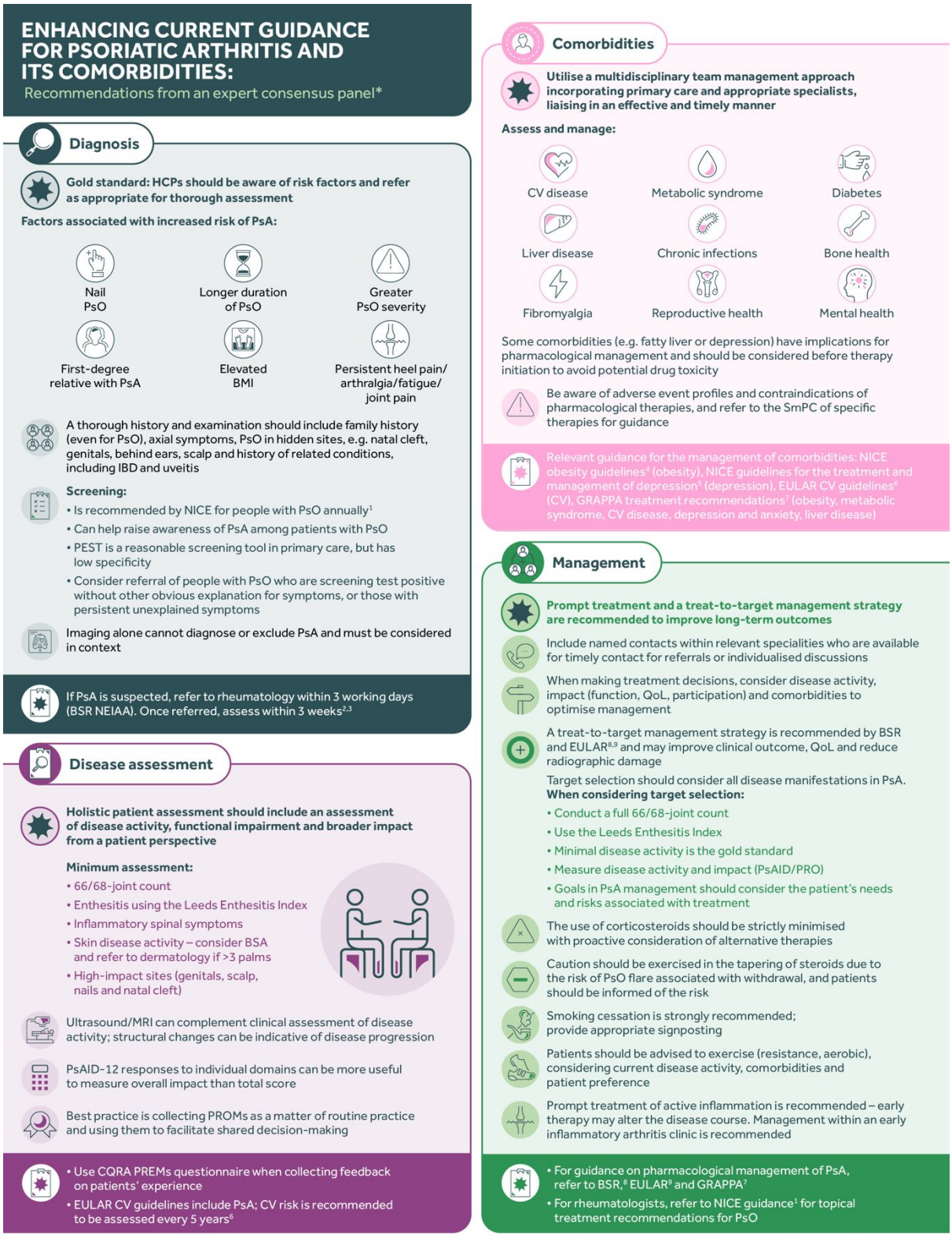
48. Koduri GM, Gullick NJ, Hayes F, Dubey S, Mukhtyar C. Patient perceptions of co-morbidities in inflammatory arthritis. *Rheumatol Adv Pract* 2021;5(1):rkaa076.

49. Gossec L, Baraliakos X, Kerschbaumer A, De Wit M, McInnes I, Dougados M, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis* 2020;79(6):700–12.

50. Coates LC, Kavanaugh A, Mease PJ, Soriano ER, Acosta-Felquer ML, Armstrong AW, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. *Arthritis Rheumatol* 2016;68(5):1060–71.

51. Russell MD, Dey M, Flint J, Davie P, Allen A, Crossley A, et al. British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: Immunomodulatory anti-rheumatic drugs and corticosteroids. *Rheumatology* 2023;62(4):e48–88.

Figure 1: Graphical summary of consensus recommendations



*Wording amended for conciseness; please refer to the full list of recommendations within the manuscript. **BMI**, body mass index; **BSA**, body surface area; **BSR**, British Society for Rheumatology; **CV**, cardiovascular; **CQRA PREM**, Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure; **EULAR**, European Alliance of Associations for Rheumatology; **GRAPPA**, Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; **HCP**, healthcare professional; **IBD**, inflammatory bowel disease; **MRI**, magnetic resonance imaging; **NEIAA**, National Early Inflammatory Arthritis Audit; **NICE**, UK National Institute for Health and Care Excellence; **PEST**, Psoriasis Epidemiology Screening Tool; **PRO**, patient-reported outcome; **PROM**, patient-reported outcome measure; **PsA**, psoriatic arthritis; **PsAID**, Psoriatic Arthritis Impact of Disease questionnaire; **PsO**, psoriasis; **QoL**, quality of life; **SmPC**, Summary of Product Characteristics. **References: 1.** NICE (2023) Psoriasis; **2.** BSR NEIAA. Year 4 Annual Report. Available at: https://www.hqip.org.uk/wp-content/uploads/2022/10/Ref.-342-NEIAA-Fourth-Annual-Report_FINAL.pdf Accessed 04 August 2023; **3.** NICE. Diagnosis and referral of inflammatory arthritis; **4.** NICE (2023) Obesity: Identification, assessment and management. NICE guideline (CG189); **5.** NICE (2022) Depression in adults: Treatment and management. NICE guideline (NG222); **6.** Agca R, et al. Ann Rheum Dis. 2017;76(1):17–28; **7.** Coates LC, et al. Nat Rev Rheumatol. 2022;18(8):465–79; **8.** Tucker L, et al. Rheumatology (Oxford). 2022;61(9):e255–e266; **9.** Gossec L, et al. Ann Rheum Dis. 2020;79(6):700–12.

Tables

Table 1: Recommendations, Theme 1: Diagnosis

Q1: What factors are associated with a diagnosis of PsA?		
Consensus recommendation	**Strength of recommendation[a]**	**Level of consensus[b]**
CR1: Be aware that anyone with PsO or with a family history of PsO may develop PsA.	9 (8.4)	96.3% n/N=26/27
CR2: Be aware that axial disease may be present in a high proportion of PsA patients.	8 (7.5)	85.7% n/N=18/21
CR3: When considering a potential diagnosis of PsA, the following factors are associated with increased risk: • Nail PsO • Longer duration of PsO • Greater PsO severity • First-degree relative with PsA • Elevated BMI	8 (8.1)	95.0% n/N=19/20
CR4: Although presentation of PsA may be variable, in people with PsO the following persistent symptoms may warrant consideration of PsA: • Heel pain • Arthralgia • Fatigue • Joint pain in a patient with recent onset PsO • Enthesitis	8 (8.4)	100% n/N=21/21
Q2. What is the value of PsA screening tools for use in patients with known psoriasis?		
CR5: Questionnaire-based screening tools have moderate accuracy for screening for PsA, but the cost-effectiveness and number needed to screen has yet to be established.	8 (7.4)	81.0% n/N=17/21
Q3. What screening tools should be used/are available in primary care and dermatology?		

CR6: Patient-completed screening tools may be useful in detecting PsA in patients with PsO, although they have limited specificity.	8 (7.9)	95% n/N=19/20
CR7: Be aware that screening tools are not diagnostic tools, and cannot prove or exclude a diagnosis of PsA but may be useful in determining the need for referral to rheumatology.	8 (8.2)	95.2% n/N=20/21
CR8: Consider referral of people with PsO who are screening test positive without other obvious explanation for symptoms, or those with persistent unexplained symptoms.	8 (7.9)	95.2% n/N=20/21
Q4. What diagnostic challenges exist in the identification of PsA? Why are diagnostic delays for PsA so much longer than RA?		
CR9: There is a diagnostic delay in patients with PsA compared to RA.	9 (8.2)	89.5% n/N=17/19
Q5. Where and how should imaging be used for PsA diagnosis? • **What features should be assessed in imaging?** • **How should non-specialists interpret imaging?**		
CR10: Imaging alone cannot diagnose or exclude PsA and must be considered in context.	9 (8.6)	100% n/N=19/19
Q6. What are appropriate/acceptable timings for referral from primary care to the patient being seen by a specialist?		
CR11: Aligned with wording used by BSR NEIAA audit: To ensure an accurate and timely diagnosis, adults with suspected persistent joint inflammation (synovitis) in more than one joint, or the small joints of the hands and feet, should be referred to rheumatology services within three working days of presenting in primary care. Once referred, people with suspected persistent joint inflammation should be assessed in a rheumatology service within three weeks.	9 (7.9)	85.7% n/N=18/21

[a]Median score on a 1–9 scale (mean score in brackets); [b]Percentage of scores of 7–9 on a 9-point scale.

BMI, body mass index; BSR, British Society for Rheumatology; CR, clinical recommendation; NEIAA, National Early Inflammatory Arthritis Audit; PsA, psoriatic arthritis; PsO, psoriasis; RA, rheumatoid arthritis.

Table 2: Recommendations, Theme 2: Disease assessment

Q7: What assessments are most relevant to measure, from the patient perspective?		
Consensus recommendation	**Strength of recommendation[a]**	**Level of consensus[b]**
CR12: Best practice for PsA management should involve shared decision-making with alignment of patient and HCP goals.	9 (8.6)	96.3% n/N=26/27
CR13: Holistic patient assessment should include an assessment of disease activity, functional impairment and broader impact from a patient perspective.	9 (8.7)	96.3% n/N=26/27
CR14: Routine and regular use of patient-reported outcome measures is recommended.	8.5 (8.1)	92.3% n/N=24/26
CR15: If auditing quality of care, consider including patient-reported experience measures.	9 (8.3)	100% n/N=24/24
Q8. What are the minimum and best quality standards for day-to-day PsA management in terms of disease assessment?		
CR16: As a minimum, HCPs caring for someone with PsA should include assessment of joints, enthesitis, spine, skin and comorbidities.	9 (8.6)	100% n/N=21/21
Q9. How should existing imaging be used for ongoing disease assessment and assessing treatment efficacy?		
CR17: Imaging may be used as an adjunct to support clinical decision-making in terms of whether to change/escalate therapy.	8 (8.3)	100% n/N=19/19

[a]Median score on a 1–9 scale (mean score in brackets); [b]Percentage of scores of 7–9 on a 9-point scale.

CR, clinical recommendation; HCP, healthcare professional; PsA, psoriatic arthritis.

Table 3: Recommendations, Theme 3: Comorbidities

Q10: Does coordinated management of comorbidities in patients with PsA improve the likelihood of successful patient outcomes?		
Consensus recommendation	**Strength of recommendation[a]**	**Level of consensus[b]**
CR18: Given the limited data on the management of many common comorbidities in the PsA population, we recommend using appropriate condition-specific recommendations to guide management of problems such as hyperlipidaemia, hypertension, diabetes, etc.	9 (8.4)	100% n/N=21/21
CR19: Treatment of comorbidities in patients with PsA should utilise a multidisciplinary team management approach incorporating primary care and appropriate specialists in secondary care.	9 (8.4)	96.3% n/N=26/27
CR20: In PsA patients who are overweight/obese, a proactive approach to weight loss should be considered following national guidelines and local services.	9 (8.4)	100% n/N=20/20
CR21: In PsA patients who are depressed, proactive management should be considered following national guidelines and local services.	8.5 (8.2)	96.2% n/N=25/26
CR22: Be aware that some comorbidities (depression, fatty liver disease) have implications for pharmacological management of PsA and should be considered before therapy initiation.	9 (8.6)	95.2 n/N=20/21

[a]Median score on a 1–9 scale (mean score in brackets); [b]Percentage of scores of 7–9 on a 9-point scale.

CR, clinical recommendation; PsA, psoriatic arthritis.

Table 4: Recommendations, Theme 4: Management

Consensus recommendation	Strength of recommendation[a]	Level of consensus[b]
Q11: What are the recommendations regarding use of steroids in patients with PsA?		
CR23: When making treatment decisions, consider disease activity, impact (function, QoL, participation) and comorbidities to optimise management.	9 (8.5)	95% n/N=19/20
CR24: Appropriate multidisciplinary team management (including AHPs) of patients with PsA is recommended for optimal care.	9 (8.7)	100% n/N=21/21
CR25: For guidance on pharmacological management of PsA, refer to national and international treatment recommendations.	9 (8.6)	100% n/N=19/19
CR26: The use of corticosteroids in PsA should be strictly minimised, with proactive consideration of alternative therapies.	8 (7.4)	75% n/N=15/20
CR27: Caution should be exercised in the tapering of steroids in people with PsA due to the significant risk of PsO flare associated with steroid withdrawal, and patients should be informed of this risk.	8 (8.0)	94.7% n/N=18/19
Q12: What are the recommendations regarding non-pharmacological management of PsA?		
CR28: Smoking cessation support is strongly recommended in line with current national guidelines.	9 (8.7)	96% n/N=24/25
CR29: Patients with PsA should be advised to undertake muscle strengthening and general aerobic exercise. The exercise activity should take into account current disease activity, comorbidities and patient preference.	9 (8.6)	100% n/N=27/27
Q13: What is the evidence base for early intervention?		
CR30: Prompt treatment of active inflammation is recommended to improve long-term outcomes. Referral and management within an early inflammatory arthritis clinic is recommended.	9 (8.6)	100% n/N=21/21

Q14: What are the recommendations regarding 'treating to target'? • **What domains should be measured/monitored when 'treating to target' for patients with PsA?**		
CR31: A treat-to-target management strategy is recommended in line with national and international recommendations.	9 (8.5)	100% n/N=24/24
CR32: Target selection should consider all disease manifestations in PsA. Minimal disease activity is the evidence-based multi-domain target for treatment in PsA.	9 (8.5)	100% n/N=24/24
CR33: There should be shared decision-making and alignment of patient and physician goals when discussing treatment options.	9 (8.7)	96.3% n/N=26/27
Q15: What does 'good' look like with regard to working with other specialities in the management of PsA? • **How should this be achieved in practice?** • **How should extra-articular manifestations be managed?**		
CR34: Collaborative working across key specialities (dermatology, gastroenterology, ophthalmology) is recommended to optimise outcomes for people with PsA; multidisciplinary clinics are recommended.	9 (8.4)	90.5% n/N=19/21

[a]Median score on a 1–9 scale (mean score in brackets); [b]Percentage of scores of 7–9 on a 9-point scale.

AHP, allied health professional; CR, clinical recommendation; PsA, psoriatic arthritis; PsO, psoriasis; QoL, quality of life.

Table 5: Implications for clinical practice, Themes 1–4

Theme 1: Diagnosis
Statements **CR1: Be aware that anyone with PsO or with a family history of PsO may develop PsA** **CR2: Be aware that axial disease may be present in a high proportion of PsA patients**
Implication for clinical practice
When considering a potential diagnosis of PsA, the following factors are associated with increased risk: • Nail PsO • Longer duration of PsO • Greater PsO severity • First-degree relative with PsA • Elevated BMI A thorough history and examination should include: • Family history • Axial symptoms • PsO in hidden sites, e.g. natal cleft, genitals, behind ears, scalp • History of related conditions, including IBD and uveitis
Statements **CR5: Questionnaire-based screening tools have moderate accuracy for screening for PsA, but the cost-effectiveness and number needed to screen has yet to be established** **CR6: Patient-completed screening tools may be useful in detecting PsA in patients with PsO, although they have limited specificity**
• NICE recommends an annual assessment for PsA in people with PsO • PEST is the most widely used screening tool and is quick to administer • For FCPs seeing patients with MSK in primary care, PEST is a reasonable screening tool, although it should be recognised that this has low specificity
Statements **CR7: Be aware that screening tools are not diagnostic tools, and cannot prove or exclude a diagnosis of PsA but may be useful in determining the need for referral to rheumatology.** **CR8: Consider referral of people with PsO who are screening test positive without other obvious explanation for symptoms, or those with persistent unexplained symptoms**

- Thorough assessment by a rheumatologist (incorporating clinical, laboratory and imaging factors combined with context) is the gold standard for making a diagnosis
- Classification criteria alone are not diagnostic and should not be used as checklist
- PEST is only intended for patients with PsO, but due to its low specificity more than half of patients who screen positive do not have PsA
- Screening questionnaires can help raise awareness of PsA among patients with PsO

Statement

CR10: Imaging alone cannot diagnose or exclude PsA and must be considered in context

- Extra-articular manifestations and enthesitis may be difficult to assess clinically
- If using imaging, be aware of alternative causes of apparent inflammation in/around the joint, including mechanical tendonitis or osteoarthritis
- If inflammatory axial disease is a concern, MRI may be required
- Plain radiography alone cannot confirm or exclude a PsA diagnosis

Theme 2: Disease assessment

Statements

CR13: Holistic patient assessment should include an assessment of disease activity, functional impairment and broader impact from a patient perspective.

CR14: Routine and regular use of patient-reported outcome measures is recommended

- PsA has a very broad impact on QoL (which includes pain, fatigue, ability to work, etc.) and there is a need to capture the patient perspective in terms of assessments
- Impact on QoL may not only be due to PsA symptoms but also concomitant conditions, e.g. fibromyalgia, which need to be identified and managed to determine a treatment approach through shared decision-making
- The use of PROMs in PsA has been associated with better self-management, self-efficacy and outcomes. PsAID-12 or a similar tool should be considered as an adjunct for routine monitoring
- PsAID-12 responses to individual questions can be more useful to measure total impact of disease than a total score
- Best practice is both collecting PROMs and using them to facilitate effective communication and shared decision-making
- Results of PROMs should be available to patients and physicians. It is good practice to collect and monitor PROMs as a matter of routine (either via a hospital PROMs system or external digital tool)

- PROMs that are collected should be reflective of the individual patient and of local needs (e.g. linguistically)

Statement

CR15: If auditing quality of care, consider including patient-reported experience measures

- When collecting feedback on patients' experience, including shared decision-making and goal setting, tools such as the Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure (CQRA PREMS) questionnaire may be useful

Statement

CR16: As a minimum, HCPs caring for someone with PsA should include assessment of joints, enthesitis, spine, skin and comorbidities

- Assess 66/68-joint count, not just 28-joint count
- As a minimum, assess enthesitis using the Leeds Enthesitis Index and also consider other symptomatic areas
- Assess inflammatory spinal symptoms and consider appropriate investigations
- Assess skin disease activity – consider BSA and refer to dermatology if >3 palms
- Encourage all clinicians assessing patients with PsA to ask about high-impact sites (genitals, scalp, nails and natal cleft)
- No formal assessment is required for comorbidities, but patients should be asked about relevant signs and symptoms
    - Key comorbidities include metabolic syndrome, diabetes and non-alcoholic fatty liver disease
    - EULAR CV guidelines include PsA; CV risk is recommended to be assessed every 5 years
- Consider using digital tools to collect and monitor patient outcomes

Statement

CR17: Imaging may be used as an adjunct to support clinical decision-making in terms of whether to change/escalate therapy

- Ultrasound/MRI can complement clinical assessment of disease activity
- Structural changes in the context of PsA can identify patients at risk of progression

Theme 3: Comorbidities

Statement **CR18: Given the limited data on the management of many common comorbidities in the PsA population, we recommend using appropriate condition-specific recommendations to guide management of problems such as hyperlipidaemia, hypertension, diabetes, etc.**
Recommended comorbidities to be assessed and managed include: • Cardiovascular disease • Metabolic syndrome • Diabetes • Liver disease • Chronic infections • Bone health • Fibromyalgia • Reproductive health • Mental health Relevant guidance for the management of comorbidities includes the following: • NICE obesity guidelines • EULAR CV guidelines (which recommend a CV risk assessment for patients with PsA every 5 years) • GRAPPA treatment recommendations
Statement **CR19: Treatment of comorbidities in patients with PsA should utilise a multidisciplinary team management approach incorporating primary care and appropriate specialists in secondary care**
• It is recommended that rheumatologists support primary care colleagues and liaise closely with other specialities regarding comorbidities • Liaison with other specialities needs to be effective and timely
Statement **CR20: In PsA patients who are overweight/obese, a proactive approach to weight loss should be considered following national guidelines and local services** **CR21: In PsA patients who are depressed, proactive management should be considered following national guidelines and local services**

- Comorbidities that directly impact the disease include mental health conditions and obesity (vs conditions impacting health overall, such as cardiovascular disease)
- Clinicians should be aware of NICE guidelines for obesity (treatments and treatment eligibility criteria have been updated)
- Clinicians should be aware of NICE guidelines for the treatment and management of depression and anxiety
- Clinicians should be aware of adverse event profiles and contraindications of pharmacological therapies, and should refer to the SmPC of specific therapies for guidance

Statement

CR22: Be aware that some comorbidities (depression, fatty liver disease) have implications for pharmacological management of PsA and should be considered before therapy initiation.

- Depression may need to be considered in the context of therapy selection for PsA to avoid potential drug toxicity
- Appropriate monitoring is necessary with potentially hepatotoxic PsA disease-modifying drugs

Theme 4: Management

Statement

CR25: For guidance on pharmacological management of PsA, refer to national and international treatment recommendations

- Recommended guidelines include those from BSR, EULAR and GRAPPA
- It is useful for rheumatologists to have an awareness of the topical armamentarium for PsO and be familiar with common, effective topical preparations
- Refer to NICE guidance for topical treatment recommendations for PsO

Statement

CR26: The use of corticosteroids in PsA should be strictly minimised, with proactive consideration of alternative therapies

- There is very convincing evidence around the toxicity profile of steroids over long-term use. Even at low doses, long-term use is associated with multiple adverse outcomes and contributes to burden of comorbidity
- There is a role in some patients for IM or IA use, but this should be minimised and ideally reserved for those who are already initiated on other biologic or systemic therapies

Statement **CR27: Caution should be exercised in the tapering of steroids in people with PsA due to the significant risk of PsO flare associated with steroid withdrawal, and patients should be informed of this risk**
• Even in people with mild PsO, the highest risk of skin flare is in patients not on concomitant therapies for their PsO • When there is a need to control active joint disease or inflammation, IM or local joint injections may be preferable to oral steroids because of a lower risk of flare, but be aware that withdrawal may cause a reaction in the skin
Statement **CR28: Smoking cessation support is strongly recommended in line with current national guidelines**
• The BSR PsA guidelines 2022 provide helpful guidance on this topic • Provide appropriate signposting to encourage patients to quit smoking
Statement **CR29: Patients with PsA should be advised to undertake muscle strengthening and general aerobic exercise. The exercise activity should take into account current disease activity, comorbidities and patient preference**
• There is a lack of evidence to support recommendation of specific types of exercise for specific patient disease phenotypes • There are general benefits of cardio/resistance exercise (MH, fall risk/balance, muscle strength) that may outweigh the risk of worsening symptoms in the presence of musculoskeletal manifestations • HIIT exercise may be beneficial, and showed benefit and no worsening in patients with stable disease
Statement **CR30: Prompt treatment of active inflammation is recommended to improve long-term outcomes. Referral and management within an early inflammatory arthritis clinic is recommended**
• Patients with quicker diagnosis and who receive earlier treatment do better across inflammatory arthritides in general • In PsA, the disease phenotype can evolve and worsen over time – early therapy may alter the disease course

- There may be underestimation of the extent and severity of subclinical disease (detected by imaging but not examination). Thorough assessment is required, particularly in oligoarticular disease

Statements

CR31: A treat-to-target management strategy is recommended in line with national and international recommendations.

CR32: Target selection should consider all disease manifestations in PsA. Minimal disease activity is the evidence-based multi-domain target for treatment in PsA

- Treat-to-target is recommended by both BSR and EULAR PsA guidelines
- Data show that use of a treat-to-target approach can improve clinical outcome, QoL and reduce radiographic damage
- Clinics should be set up in a way that facilitates a treat to target approach.
  When considering target selection and measurement:
  - Take the patient's shoes off and conduct a full 66/68-joint count (not just 28-joint count)
  - The Leeds enthesitis index is quick, easy and PsA specific
  - MDA is the gold standard
  - Measure disease activity AND impact (PsAID/PRO)

Statement

CR33: There should be shared decision-making and alignment of patient and physician goals when discussing treatment options

- Any goal should be in the context of the patient's needs and any risks associated with treatment

Statement

CR34: Collaborative working across key specialities (dermatology, gastroenterology, ophthalmology) is recommended to optimise outcomes for people with PsA; multidisciplinary clinics are recommended.

- A good working practice would include having named contacts within relevant specialities who are available for timely contact for referrals or discussions
- There is a need to work with the appropriate colleagues depending on the patient – individualised care for each individual

- Close collaborative working in an MDT clinic can help to upskill rheumatologists in the long term

BMI, body mass index; BSA, body surface area; BSR, British Society for Rheumatology; CQRA, Commissioning for Quality in Rheumatoid Arthritis; CR, clinical recommendation; CV, cardiovascular; EULAR, European Alliance of Associations for Rheumatology; FCP, first contact practitioner; GRAPPA, Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; HCP, healthcare professional; HIIT, high-intensity interval training; IA, intra-articular; IBD, inflammatory bowel disease; IM, intramuscular; MDA, minimal disease activity; MDT, multidisciplinary team; MH, mental health; MRI, magnetic resonance imaging; MSK, musculoskeletal; NICE, UK National Institute for Health and Care Excellence; PEST, Psoriasis Epidemiology Screening Tool; PsA, psoriatic arthritis; PsAID, Psoriatic Arthritis Impact of Disease questionnaire; PREM, Patient Reported Experience Measure; PRO, patient-reported outcome; PROM, patient-reported outcome measure; PsO, psoriasis; QoL, quality of life; SmPC, Summary of Product Characteristics.

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

Cosentyx® secukinumab

1,000,000 patients treated globally, and counting*[4]

100+ clinical trials*[5]

8+ years of real-world evidence[1–3]

8 indications[1–3]

Click here to visit our HCP portal and learn more

Real-world evidence shows a consistent safety profile over 6 years[6,7]

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

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

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

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

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

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

Cosentyx® (secukinumab) licensed indications in rheumatology: Cosentyx, alone or in combination with methotrexate, is indicated for the treatment of active **psoriatic arthritis** in adult patients when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate; active **ankylosing spondylitis** in adults who have responded inadequately to conventional therapy; active **non-radiographic axial spondyloarthritis** with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active **enthesitis-related 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 **juvenile psoriatic arthritis** in patients 6 years or older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.[1,2]

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

*Patients prescribed Cosentyx for any indication since launch.

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

Abbreviations: AE, adverse event; AS, ankylosing spondylitis; EIAR, exposure-adjusted incidence rate; HCP, healthcare professional; IBD, inflammatory bowel disease; MACE, major adverse cardiac event; PsA, psoriatic arthritis; PsO, plaque psoriasis; PY, patient year.

References: 1. Cosentyx® (secukinumab) GB Summary of Product Characteristics; **2.** Cosentyx® (secukinumab) NI Summary of Product Characteristics; **3.** European Medicines Agency. European public assessment report. Available at: https://www.ema.europa.eu/en/documents/overview/cosentyx-epar-medicine-overview_en.pdf [Accessed February 2024]; **4.** Novartis Data on File. Secukinumab – Sec008. 2023; **5.** Novartis. Novartis Cosentyx® positive 16-week PREVENT results advance potential new indication for patients with axial spondyloarthritis. Available at: https://www.novartis.com/news/media-releases/novartis-cosentyx-positive-16-week-prevent-results-advance-potential-new-indication-patients-axial-spondyloarthritis [Accessed February 2024]; **6.** Novartis data on file. Cosentyx Periodic Safety Update Report (PSUR); 26 December 2019 – 25 December 2020. 22 February 2021; **7.** Deodhar A, et al. Arthritis Res Ther 2019;21(1):111.

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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. 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. 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UK | 290802 | June 2023

Adverse Event Reporting:

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