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Portuguese consensus on first line treatment of moderate-to-severe psoriasis with a non-TNF inhibitor therapy – a delphi methodology

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ABSTRACT

Introduction: Psoriasis (PsO) is a common chronic, inflammatory, immune-mediated disease. In 2023, a 4.4% prevalence of PsO was reported in Portugal. Currently, Tumor Necrosis Factor inhibitors (TNFi) are the recommended first-line (1 L) biologic agents in Portugal given their lower cost. However, TNFi may not be suitable for several patients. In these patients, interleukin inhibitors (ILi) should be considered as they provide more effective outcomes and a better safety profile.

Methods: Qualitative interviews with PsO experts were conducted to identify PsO biologic treatment needs, resulting in an online survey to explore clinical cases focused on subpopulations of PsO. A delphi study evaluated consensus on clinical criteria to initiate non-TNFi therapy in seven predefined subpopulations of patients.

Results: This study highlights the benefit of starting non-TNFi therapy in all PsO predefined subpopulations. Patients with infection risk, mild heart failure and associated comorbidities, autoimmune diseases and family history of demyelinating disease consensually benefit from starting non-TNFi therapy in 1 L. Several risks associated with latent tuberculosis, advanced age and oncological disease were also evaluated.

Conclusion: Given the existence of various risks associated with TNFi usage, this clinical perspective overview of Portuguese experts in PsO treatment emphasizes the need for a tailored therapeutic framework in the management of PsO.

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KEYWORDS
Psoriasis; biologic therapy; TNF inhibitors; interleukin inhibitors; IL-23

Introduction

Psoriasis (PsO) is a common chronic, inflammatory, immune-mediated disease characterized by erythematous plaques with silvery scales that commonly appear on the scalp, elbows, and knees, although other areas of the skin may be affected [1]. This skin disorder affects 0.51% to 11.43% of the population [2]. In Portugal, a study conducted to assess psoriasis prevalence in 2023, determined the prevalence of psoriasis to be 4,4%, equating to approximately 440.000 affected individuals [3]. The same study suggested that psoriasis may be underdiagnosed in Portugal [3]. Visible plaques, skin symptoms and consequent discomfort trigger a negative cascade that markedly decreases patients' quality of life [3]. Disease burden is further increased by frequently associated comorbidities, such as metabolic syndrome and cardiovascular disease [2,3]. Psoriasis has a high burden on Healthcare systems, resulting from *'inaccurate or delayed diagnosis, a lack of access to care, and therapeutic options which are limited in their ability to achieve patient satisfaction'* [4].

Tumor necrosis factor inhibitors (TNFi) were the first biologic agents approved for the treatment of psoriatic disease [5]. The use of TNFi is mainly based on their wide availability, particularly TNFi biosimilars, which are less costly, offer greater access compared to biologic treatments and have improved efficacy vs traditional systemic therapies [6,7]. However, the increased risk of infection and potential for increased risk of malignancies associated with TNFi therapies have been described in the literature and remains a concern [8]. In addition, risks related to moderate to severe heart failure, multiple sclerosis and other demyelinating diseases have been described with TNFis [9]. The introduction of interleukin inhibitors (ILi), namely ILi-17, ILi-23, ILi-12/23 for psoriasis has broadened the therapeutic offer and made it possible to respond to limitations associated with topical and/or systemic therapy, namely the unsuccessful first-line with TNFi as recommended in European guidelines [7].

The British Association of Dermatologists (BAD) developed guidelines for biologic therapy for psoriasis in 2020, aiming to help healthcare practitioners (HCP) choose the best treatment option for their moderate-to-severe patients [9]. With regard to non-TNFi, IL-17i, such as secukinumab, ixekizumab and brodalumab, raise concerns in psoriasis patients with inflammatory bowel disease or recurrent candida infection, while such concerns

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have not been implicated with ustekinumab (IL-12/23i) or guselkumab and risankizumab (IL-23is) therapy [9].

In this sense, the presence of comorbidities or associated conditions in subpopulations of psoriasis patients can also impact therapeutic success or failure, based on development of adverse reactions, poor adherence to treatment, and lack or loss of efficacy [10]. In 2020, a set of recommendations was published in Portugal, in which multiple subpopulations of patients were considered due to the impact of comorbidities on treatment success and the availability of new drugs to effectively manage them. By taking into consideration improvements in skin responses and a proper management of other comorbidities, dermatologists may be able to contribute for treatment algorithms updates and therefore avoiding suboptimal or unnecessary treatments [11]. New therapies with different mechanisms of action have been approved to treat moderate-to-severe psoriasis, allowing for additional opportunities for better disease control and potentially a better safety profile [9,12]. Effective management of the disease, taking into account comorbidities, patient adherence and preferences, biologic mechanisms of action and consequent efficacy and safety is of utmost importance for decreasing disease burden and guaranteeing treatment success [13].

Current management of psoriasis in daily clinical practice is highly variable and may be complicated by the lengthy and bureaucratic processes required for choosing and switching treatments. Development of national guidelines/recommendations for evaluating, managing and treating moderate-to-severe psoriasis patients with biologic therapies in routine clinical practice is essential for optimizing patient care [11] and effectively using healthcare resources while aiming to improve patients' quality of life.

Consequently, defining subpopulations of patients, based on specific clinical criteria, who may benefit from optimal first line therapies is essential to guaranteeing treatment choices with a greater chance of success. This study aims to define which patients with moderate to severe psoriasis would benefit more from starting a non-TNFi therapy, from a safety point of view, rather than TNFi as indicated by the National Commission on Pharmacy and Therapeutic.

Materials and methods

This study is based on two sequential phases. In the first phase, exploratory interviews were conducted with a panel of three experts (Professor Tiago Torres, Professor Maria João Paiva Lopes and Professor Sofia Magina) in the treatment and with up-to-date knowledge of psoriasis and its reality in Portugal (hereafter referred to as the Board). These interviews aimed to understand current therapeutic needs, related to institutional authorization to start non-TNFi therapies in defined patient subpopulations, and their therapeutic benefit. An online structured quantitative survey was conducted to analyze clinical cases of patients with moderate to severe psoriasis and (1) latent tuberculosis, (2) mild heart failure, (3) risk of/or recurrent infections, (4) risk of developing/ongoing malignancy and (5) advanced age. The survey aimed to quantify the level of benefit associated with initiating non-TNFi therapy, assess clinical criteria influencing treatment decisions, and identify the preferred first line therapeutic choice among non-TNFi options. A scale ranging from 1 to 3, indicating no benefit to major benefit was used, as well as multiple choice questions to define clinical criteria and optimal therapeutic choice for each subpopulation. The survey also assessed the main unmet needs in clinical practice. Anonymized data were self-reported and shared through

Table 1. Benefit level of initiating non-TNFi therapy in six subpopulations of patients with moderate-to-severe PsO.

Subpopulation	Min	Score (mean)	Max
Latent tuberculosis	3	**3**	3
Recurrent infections (*e.g.*, urinary and respiratory infections)	2	**2.9**	3
Personal history of oncological disease	1	**2.9**	3
Advanced age	2	**2.8**	3
Mild heart failure (NYHA I-II)	1	**2.6**	3
Family history of oncological disease	1	**2.4**	3

Note 1 – Level 1 (no benefit) to level 3 (major benefit).

Grupo Português de Psoríase da Sociedade Portuguesa de Dermatologia e Venereologia (GPP-SPDV), targeting a broader pool of PsO experts in Portugal.

Subsequently, a second phase involving a Delphi methodology – a highly regarded approach that utilizes an interactive process, characterized by rounds of voting, to achieve consensus on clinical matters in healthcare where there is limited guidance and/or a scarcity of evidence, was implemented [14,15]. In this second phase, the methodology was stratified into four phases: (1) the Board identified 25 statements lacking clinical consensus and developed a Delphi questionnaire (Table 1); (2) the questionnaire was then distributed to clinical experts in the field of PsO (GPP-SPDV members) through an online platform for the initial Delphi round. The panel was then asked to express their agreement or disagreement on each item using a Likert-type scale ranging from 1 to 5 (1 = strongly disagree to 5 = strongly agree) for a maximum of two rounds; (3) responses were then collected and analyzed for consensus; (4) common and conflicting viewpoints were identified.

At the end of Rounds 1 and 2, the median agreement score for each statement was calculated. Consensus for each statement was established if 75% of the responses were 4 or 5 for agreement on the Likert-type scale [14]. The methodology for this phase is shown schematically in Figure 1.

Based on the patients' subpopulations previously considered, this Delphi exercise focused on 7 different subpopulations of patients with moderate-to-severe psoriasis and (1) latent tuberculosis, (2) advanced age, (3) risk of infections, (4) heart failure, (5) oncologic disease, (6) demyelinating disease, (7) lupus erythematosus or autoimmune disease.

A total of 32 statements were assessed, including 25 in Round 1 and 7 in Round 2.

Results

Phase I

Between June and July of 2023, 30 Portuguese psoriasis experts (approximately 85% of GPP-SPDV members) answered the online survey, of which 50% ($n = 15$) indicated working in both public and private health institutions. Most experts (90%, $n = 27$) reported following more than 20 patients currently being treated with biologic therapy. On average, 66% of their patients were being treated with non-TNFis. Physicians indicated that moderate-to-severe psoriasis patients with latent tuberculosis, recurrent infections, personal history of oncological disease and advanced age stood to benefit most from starting biologic therapy with a non-TNFi agent, namely an IL-17i or IL-23i. The main results are described in Tables 1 and 2.

Along with indicating the benefit of initiating non-TNFi therapy, experts also identified several limitations in clinical practice to prescribing non-TNFi biologics as first line treatment in these subpopulations. The most frequently cited limitations were related to the

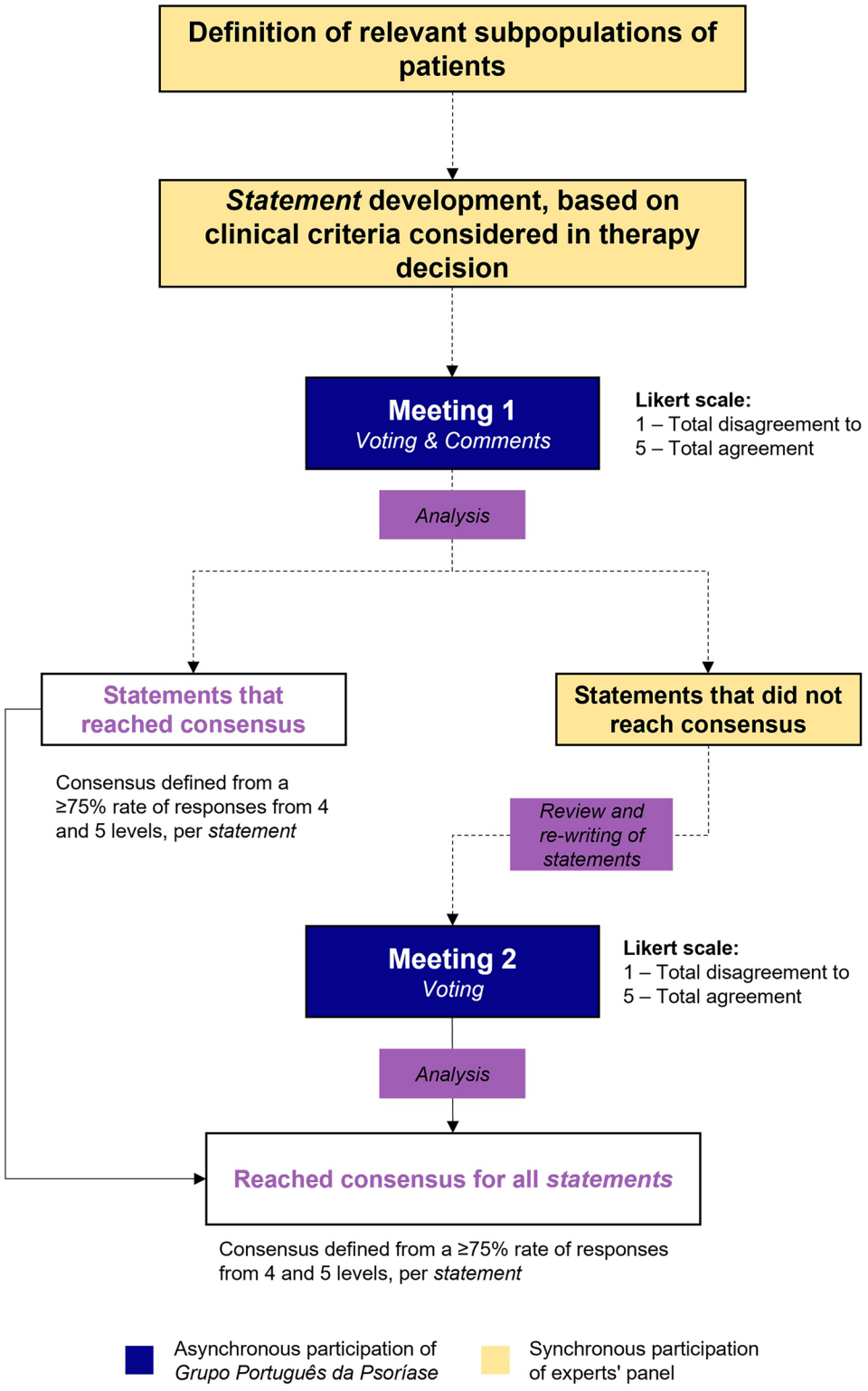

Figure 1. Flow diagram of the statement classification in terms of level of agreement or disagreement.

current process of therapeutic approval and the existing therapeutic recommendations from the Local and National Pharmacy and Therapeutic Committee in Portugal. Further, these limitations were often linked to financial constraints, and a reluctance to accept the clinical criteria which justify the preference for non-TNFi as first line therapy. Consequently, a Delphi panel was convened to establish specific clinical criteria for determining the benefits of initiating non-TNFi therapy within each patient subpopulation in Phase 2 of the current study.

Phase II

In the second phase of the study a Delphi panel was developed, considering 7 subpopulations of patients, and 25 statements

related to these. In the first round 18 statements reached consensus, with agreement among 75% to 95% of participants. In the second round, 7 statements were considered, of which 5 reached consensus. All results are listed in detail in Tables 3 and 4.

Discussion

The results of this consensus study emphasize the clinical rationale of starting first-line non TNFi therapy in patients with moderate-to-severe psoriasis, in particular, sub-populations with latent tuberculosis, advanced age, oncological disease, risk of infection, heart failure, demyelinating disease, and lupus erythematosus/autoimmune diseases. It is important to note that moderate-to-severe psoriasis is associated with several well-established cardiovascular risk factors including obesity, hypertension, diabetes, dyslipidemia and metabolic syndrome, conditions that may impact treatment choice and overall therapeutic success [16].

Based on the results of the present study and recommendations from the current literature patients with moderate-to-severe psoriasis and a history of recurrent infections, immunosuppression panel, or chronic infections, should initiate non-TNFi therapies, in order to avoid adverse effects, worsening of disease, and noncompliance of therapy [9].

It is widely reported that patients treated with TNFi have an increased risk of latent tuberculosis infection (LTBI) reactivation or developing new onset tuberculosis infection, particularly in the first months of treatment [17]. In Portugal, there were 1521 reported cases of tuberculosis in 2021, a number that has been decreasing over time, but indicates a remaining public health concern [18]. Based on the findings of the present study, patients with psoriasis and latent tuberculosis could clearly benefit from initiating non-TNFi therapy. Moreover the literature suggests that therapies such as ILi-17 or ILi-23 should be preferred over TNF antagonists for patients with LTBI, who are considered to be at risk for developing complications related to TB prophylaxis therapy, avoiding the need to initiate any preventive strategy [5,9]. European recommendations drafted in 2021 suggest avoiding TNFis in patients with LTBI unless there are no other suitable treatment options [10,19].

Regarding cardiovascular disease, European and BAD recommendations suggest not using TNFis in patients with psoriasis and

Table 2. Non-TNFi Therapy preference, per subpopulation.

	Non-TNFi therapy preference	
Subpopulation	IL 23 inhibitors [% (*n*)]	IL 17 inhibitors [% (*n*)]
Latent tuberculosis	93% (28)	40% (12)
Personal history of oncological disease	97% (29)	40% (12)
Family history of oncological disease	97% (29)	53% (16)
Recurrent infections	93% (28)	40% (12)
Mild heart failure (NYAH I-II)	97% (29)	67% (20)
Advanced age	97% (29)	30% (9)

Table 3. Statements that reached consensus in this delphi panel, defining which subpopulations of patients must be initially treated with non-TNFi.

Subpopulation	*Statement*	Agreement level
Latent tuberculosis	Patient with latent tuberculosis.	85%
	Patient with latent tuberculosis and at risk of failure to adhere to prophylactic therapy for tuberculosis.	85%
	Patient with latent tuberculosis and at risk of tuberculosis reactivation by epidemiological risk context.	80%
	Patient with latent tuberculosis and at risk of developing adverse effects to prophylactic therapy for tuberculosis.	90%
	Patient with latent tuberculosis with risk factors for toxicity to antibacilar therapy.*	95%
	Patient at high risk of contact (professional or otherwise) with tuberculosis.*	76%
Advanced age	Patient aged 65 or over with an associated risk of developing a neoplastic/infectious disease.	95%
	Patient aged 65 or over with associated comorbidities.	90%
	Patient aged 65 or over, with associated comorbidities that increase the risk of infection or oncological disease.*	90%
Oncological disease	Patient with previous personal history of cancer (<5 years).	95%
	Patient with previous personal history of cancer (>5 years).	80%
	Patient with active cancer disease.	80%
	Patient with a hereditary risk of developing an oncological disease.	90%
	Patient with active cancer disease with metastasization or significant risk of metastasization.*	75%
Risk of infection	Patient with recurrent infections (e.g., urinary, respiratory, prostatitis…).	80%
	Immunosuppressed patient (transplanted).	90%
	Patient with chronic infections (HIV, Hepatitis B, Hepatitis C).	90%
Heart failure	Patient with mild heart failure (NYHA classification I or II) and associated comorbidities.	85%
Demyelinating Disease	Patient with a family history of demyelinating disease.	90%
Lupus erythematosus and autoimmune diseases	Patient with active lupus erythematosus.	90%
	Patient with high titers of nuclear antibodies.	75%
	Patient diagnosed with another autoimmune disease.	80%

Note 2 – Statements with an asterisk (*) reached consensus in the second round of this Delphi panel.

Table 4. Statements that did not reached consensus in this Delphi panel.

Subpopulation	*Statement*	*Agreement level*
Latent tuberculosis	Patient with latent tuberculosis undergoing prophylactic therapy for tuberculosis.	65%
Advanced age	Patient aged 65 or over.	65%
Oncological disease	Patient with a family history of cancer.	45%
	Patient at risk of developing cancer due to exposure to risk environments / factors (e.g., smokers, risky working conditions).	55%
	Patient with a family history (direct relative) of cancer disease.*	57%
	Patient with a family history (direct relative) of hematological oncological disease (e.g., lymphoma, leukemia).*	67%
Heart failure	Patient with mild heart failure (NYHA classification I or II).	65%
Lupus erythematosus and autoimmune diseases	Patient with a family history of autoimmune diseases.	60%
	Patient with a family history of lupus erythematosus.	50%
	Patient with a family history (direct relative) of lupus erythematosus*	71%

Note 3 – Statements with an asterisk (*) were considered in the second round of this Delphi panel.

advanced congestive heart failure [9,10]. As a consequence, the possibility of including patients with mild heart failure among those who would benefit from non-TNFi therapy was also assessed. Findings suggest that patients with mild heart failure coupled with other comorbidities should initiate other therapy (non-TNFi), to better manage all diseases and achieve therapeutic success.

A family history of demyelinating disease, such as multiple sclerosis – which affects up to 8.000 people in Portugal – was identified as an important reason for initiating non-TNFi therapy in this study. This aligns with previous recommendations against using TNF antagonists in psoriasis patients diagnosed with multiple sclerosis or other demyelinating diseases [10].

A systematic review of the literature by Battista et al. (2024) determined that patients with psoriasis and cancer or a previous history of cancer are usually excluded from clinical trials [20]. The same study describes, in line with guidelines, the consideration of biologic therapy in cancer patients in remission for at least 5 years, and reconsidering first line use of conventional psoriasis therapies [20]. The results from the current study highlight the need to consider personal history of cancer, an active state of cancer, the hereditary risk of developing cancer and the presence of metastatic disease when choosing psoriasis treatment. Family history of cancer and environmental risk did not reach consensus among participants in this study, although more than half indicated the benefit of considering these factors when selecting treatment for such patients.

Recent literature suggests that conventional systemic drugs are often avoided in elderly patients with psoriasis due to their higher rates of comorbidities and potential drug interactions, whereas phototherapy treatments may prove unsuitable for those with limited mobility or dependence on caregivers [21,22]. The challenges in treating patients older than 65 years of age are severely impacted by the development of immunosenescence, a progressive immune system impairment associated with aging (increasing susceptibility to infections and cancers) [21]. It is also important to note that patients aged 65 years of age or older are frequently excluded from randomized clinical trials (RCTs), potentially leading to undertreatment and a lack of established guidelines for patients in this age group [22–25]. Given this, the current study highlights the need to properly address treatment in patients over 65 years of age, in light of how their associated comorbidities, and higher risk of infections or oncologic disease can impact therapeutic success, in particular with TNFi therapies. Despite limited safety and efficacy data, biologics are commonly prescribed for elderly patients [21], as acknowledged by the participants in the current study.

Patients with moderate-to-severe psoriasis and other previously diagnosed autoimmune disease (such as lupus erythematous), based on results from this study and the literature, may benefit from starting non-TNFi therapy, given evidence for contraindications or safety signals associated with this class of biologics [11].

In line with the results of the present study, it is important to highlight the role of HCPs and their specialized considerations. According to this study, allowing HCPs to select the treatment that best suits each patient's clinical profile will result in greater therapeutic benefit. Despite the possibility of higher initial costs, this approach may ultimately lead to greater efficacy, increased likelihood of sustaining treatment and clinical improvements, as well as better tolerability and safety outcomes. It is worth to mention that in Spain, the Spanish Society of Rheumatology (SER) has issued a statement stressing the importance to *'preserve the right of physicians to prescribe a specific drug which has been selected taking into account the individual characteristics and circumstances of each patient without, of course, ignoring the economic impact of such decisions'* [26]. The SER also considers the role of hospital authorities to ensure that all biologic and biosimilar drugs funded by the Spanish health system for the management of rheumatic diseases are made available in all the hospitals in the National Health System [26].

In Portugal, these circumstances are not always guaranteed (as described in the first part of the study by the experts involved). Confidence in clinical decision-making, supported by the present study and international literature, may help facilitate changes in the in the current Portuguese healthcare system to ensuring that the optimal treatment is provided in a timely manner for subpopulations of moderate to severe psoriasis patients with special considerations.

Study limitations

Despite the high rate of participation from GPP-SPDV experts in this study, the total number of participants can be considered small. Although development of the statements for the Delphi exercise was based on the clinical experience of three Portuguese clinical experts, some relevant patient sub-populations may have been excluded from consideration.

Conclusion

The present study provides an overview of the clinical perspective of Portuguese psoriasis experts regarding biologic therapeutic decision making in light of risk factors associated with TNFis use. Patients with moderate to severe psoriasis who have latent tuberculosis, advanced age and associated comorbidities, a history of or active cancer, risk of or ongoing infection, mild heart failure, or a family history of demyelinating diseases require special attention and recommendations, representing relative contraindications that should be properly managed. Such patients may benefit from a more comprehensive assessment of the safety profile of different classes of biologic agents. Currently, the prescription of a wider range of biologic agents in first line treatment for psoriasis is limited mainly due to financial factors. However, a more tailored approach to treatment could provide significant benefits, as it may enhance patient outcomes and reduce overall healthcare costs in the long term.

Disclosure statement

Maria João Paiva Lopes: AbbVie, Almirall, Boehringer Ingelheim, Janssen, Leo-Pharma, Eli Lilly, Novartis, Pfizer, Sanofi-Genzyme, Viatris Sofia Beatriz Loureiro Marques Vasconcelos Magina Silva Ramos: Sofia Magina reports consulting and speaker fees from Abbvie, Almirall, Janssen-Cilag, Leo- Pharma, Lilly, Novartis, and Pfizer Tiago Costa Ferreira Torres: Tiago Torres has received consultancy and/or speaker's honoraria from and/or participated in clinical trials sponsored by AbbVie, Amgen, Almirall, Amgen, Apogee Therapeutics, Arena Pharmaceuticals, Biocad, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Fresenius-Kabi, Johnson & Johnson Innovative Medicine, LEO Pharma, Eli Lilly, MSD, Mylan, Novartis, Pfizer, Samsung-Bioepis, Sanofi-Genzyme, Sandoz, STADA and UCB.

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