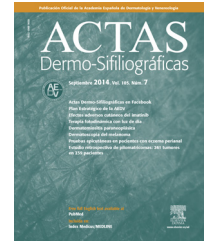




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## CONSENSUS DOCUMENT

# Evidence-Based Guidelines of the Spanish Psoriasis Group on the Use of Biologic Therapy in Patients With Psoriasis in Difficult-to-Treat Sites (Nails, Scalp, Palms, and Soles)<sup>☆</sup>



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**PALABRAS CLAVE**

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**Abstract** Psoriatic lesions affecting the scalp, nails, palms, and the soles of the feet are described as difficult-to-treat psoriasis and require specific management. Involvement of these sites often has a significant physical and emotional impact on the patient and the lesions are difficult to control with topical treatments owing to inadequate penetration of active ingredients and the poor cosmetic characteristics of the vehicles used. Consequently, when difficult-to-treat sites are involved, psoriasis can be considered severe even though the lesions are not extensive. Scant information is available about the use of biologic therapy in this setting, and published data generally comes from clinical trials of patients who also had moderate to severe extensive lesions or from small case series and isolated case reports. In this article we review the quality of the scientific evidence for the 4 biologic agents currently available in Spain (infliximab, etanercept, adalimumab, and ustekinumab) and report level I evidence for the use of biologics to treat nail psoriasis (level of recommendation A) and a somewhat lower level of evidence in the case of scalp involvement and palmoplantar psoriasis.

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**Directrices del grupo español de psoriasis (GEP) basadas en la evidencia para el uso de medicamentos biológicos en pacientes con psoriasis en localizaciones de difícil tratamiento (uñas, cuero cabelludo, palmas y plantas)**

**Resumen** El término de psoriasis en localizaciones de difícil tratamiento se emplea para hacer referencia a la psoriasis localizada en el cuero cabelludo, las uñas, las palmas y las plantas y que requiere un manejo diferenciado. A menudo los pacientes presentan un importante impacto físico y emocional, unido a la dificultad para controlar adecuadamente sus lesiones con tratamientos tópicos, debido a una insuficiente penetración de los principios activos y la escasa cosmetización de los vehículos empleados. Esta circunstancia justifica que la psoriasis en estas localizaciones pueda ser considerada grave, a pesar de su extensión limitada. La experiencia con terapias biológicas en estas localizaciones es escasa, en general en el contexto de ensayos clínicos de formas extensas de psoriasis moderada y grave, junto con series limitadas o casos aislados. En el presente artículo se presenta la calidad de la evidencia científica para los 4 agentes biológicos disponibles en España (infliximab, etanercept, adalimumab y ustekinumab) siendo de nivel I en el caso de la psoriasis ungueal (nivel de recomendación A) y algo inferior en la psoriasis del cuero cabelludo y palmoplantar.

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## Introduction

The Spanish Psoriasis Group of the Spanish Academy of Dermatology and Venereology (AEDV) has published an update of their evidence-based guidelines on the treatment of psoriasis with biologic agents.<sup>1</sup> To complement those guidelines, this article reviews the scientific evidence available on the treatment of psoriasis in difficult-to-treat sites, such as the nails, scalp, palms and soles. As there is currently no evidence in the literature regarding the efficacy and safety of biologic therapy in the treatment of flexural and genital psoriasis, the treatment of these sites will not be discussed.

The term difficult-to-treat psoriasis has been used by several authors in recent years to refer to psoriasis (usually psoriasis vulgaris) localized to the scalp, palms/soles, and nails, which requires special attention because it is often associated with a significant physical and emotional impact on the patient, and sometimes even functional impairment.<sup>2-4</sup> Many authors also include in this group psoriasis localized to areas of sensitive skin, such as the face, skin folds, and genitals.<sup>2,3,5</sup> Psoriasis in difficult-to-treat sites also requires special treatment because topical medications are often ineffective and disagreeable to use so that systemic

therapy is generally prescribed.<sup>2-5</sup> In some patients, lesions at these sites are the only manifestation of the disease and they display a marked resistance to conventional therapies.

Very few controlled trials have evaluated the efficacy and safety of systemic therapy (classic or biologic) in the management of psoriasis in these sites. In general, the evidence available is obtained from subanalyses of trials involving patients with psoriasis and/or psoriatic arthritis (PsA) in which the involvement of the nails, scalp, palms or soles is also assessed. In addition to the usual tools for assessing the severity of psoriasis—the Psoriasis Area and Severity Index (PASI), the Body Surface Area (BSA), and the Physician Global Assessment (PGA)—several scales have been designed specifically to measure the severity of psoriasis affecting difficult-to-treat sites, such as the Nail Psoriasis Severity Index (NAPSI) and the modified target NAPSI in the case of nail psoriasis.<sup>6,7</sup> The Psoriasis Scalp Severity Index (PSSI)<sup>8</sup> and the Palmoplantar Pustular Psoriasis Area Severity Index (PPPASI)<sup>9</sup> are both variants of the PASI. In order to assess the impact of psoriasis on the patient's quality of life, we have tools that measure the overall psychological and social impact of the disease; these include the Dermatology Life

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