



Biologic and Nonbiologic Systemic Agents and Phototherapy for Treatment of Chronic Plaque Psoriasis: Comparative Effectiveness Review Number 85

U. S. Department of Health and Human Services, Agency for Healthcare Research and Quality

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Psoriasis is a common, chronic, autoimmune inflammatory skin disease affecting 2 to 3 percent of the worldwide population. The onset of psoriasis predominantly occurs early in adulthood (between the ages of 15 and 25 years) but may affect individuals at any age. The course of psoriasis is marked by chronic and acute phases with a wide variety in relapse and clearance rates. Total health care costs of psoriasis are estimated at \$11.25 billion annually. This economic burden, along with the clinically relevant reductions in quality of life experienced by many patients with psoriasis, underscores the need for prompt, effective, and sustained disease management. Among several clinical psoriasis phenotypes, chronic plaque psoriasis is the most frequent, accounting for all but 10 percent of cases. Chronic plaque psoriasis, also known as psoriasis vulgaris, often appears as well-demarcated, erythematous plaques covered with silvery white scales that vary in size up to several centimeters. Different parameters determine disease severity such as the degree of body surface area (BSA) involved, activity of the lesions, the location of lesions in sensitive areas, duration of disease, treatment failures, and the impact on quality of life. While disease localized to nonsensitive areas of skin may be managed effectively with topical agents, patients with more widespread disease often require systemic treatment. The American Academy of Dermatology has published guidelines for the treatment of psoriasis and suggest use of either biologic or nonbiologic systemic agents or phototherapy with ultraviolet B (UVB) or with psoralen plus ultraviolet A (PUVA) therapy in patients with widespread disease. Biologic therapies for psoriasis use genetically engineered drugs that target specific steps in the pathogenesis of psoriasis involving T cells and cytokines. Currently, three biologic TNF-alpha inhibitors (infliximab, etanercept, and adalimumab), and one anti-IL 12/23 agent (ustekinumab) have approval from the Food and Drug Administration (FDA) for psoriasis treatment. Nonbiologic systemic therapies may be effective but can be associated with significant short-term and longterm adverse events (hepatotoxicity, nephrotoxicity, hypertension, dyslipidemia, malignancy, and teratogenicity). Phototherapy, although considered to be one of the safer therapeutic options, requires strict compliance, and the long-term toxicity associated with it includes photocarcinogenesis. The objective of this comparative effectiveness review (CER) is to examine the benefits and harms of biologic systemic agents compared with nonbiologic systemic agents or phototherapy in patients with chronic plaque psoriasis. The Key Questions addressed in this review include: Key Question 1. In patients with chronic plaque psoriasis, what is the comparative effectiveness of systemic biologic agents and systemic nonbiologic agents (between-class comparisons on an individual drug level) or phototherapy when evaluating intermediate (plaque BSA measurement, PASI, Patient's Assessment of Global Improvement, PGA, and individual symptom improvement) and final health outcomes (mortality, HRQoL and other patient-reported outcomes, MACE, diabetes, and psychological comorbidities)? Key Question 2. In patients with chronic plaque psoriasis, what is the comparative safety of systemic biologic agents and systemic nonbiologic agents (between-class comparisons on an individual drug level) or phototherapy (hepatotoxicity, nephrotoxicity, hematologic toxicity, hypertension, alteration in metabolic parameters, injection site reaction, malignancy, infection, and study withdrawal)? Key Question 3. In patients with chronic plaque psoriasis treated with systemic biologic therapy, systemic nonbiologic therapy, or phototherapy, which patient or disease characteristics affect intermediate and final outcomes?

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