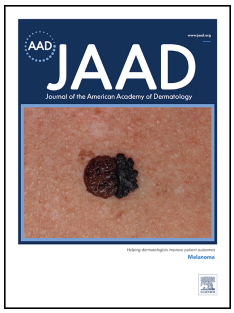

Focused update to the Guidelines of Care for the Management of Actinic Keratosis: Executive Summary

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Key Points

- The focused guideline update considers the evidence on the use of topical tirbanibulin to treat Actinic Keratosis (AK).
- A strong recommendation for the use of topical tirbanibulin was added to the list of recommended therapies for AK.

Summary

Actinic keratoses are keratinocyte neoplasms occurring on skin that has had long-term exposure to ultraviolet radiation. Actinic keratosis (AK) is one of the most common conditions treated by dermatologists in the United States.[1] In 2021, the AAD published guidelines addressing the management of AK and provided recommendations for the use of various available AK treatments, including topical agents, cryosurgery, and photodynamic therapy.[2] The purpose of the update is to incorporate new evidence for the use of a recently U.S Food and Drug Administration-approved topical, tirbanibulin, for the treatment of AK into the AAD's existing guidance on the management of AK.

A systematic review identified two phase III randomized, double-blinded, parallel-group, placebo-controlled trials, including 702 adult participants.[3] Both trials compared a standard regimen of topical tirbanibulin 1% applied once daily to a 25cm^2 treatment field containing 4-8 AKs on the face or scalp for five consecutive days to vehicle.

On day 57, participants treated with tirbanibulin experienced higher rates of complete and partial clearance of AKs in the treatment area (pooled complete clearance rates 174/353 [49.3%]; pooled partial clearance rate 255/353 [72.2%]) than those treated with the vehicle (pooled complete clearance rate 30/349 [8.6%]; pooled partial clearance rate 63/349[18.1%]). The most common adverse events reported through day 57 of the phase III trials were application site

pruritus (reported in 9.1% of tirbanibulin-treated participants vs 6.0% of vehicle-treated participants) and pain (reported in 9.9% of tirbanibulin-treated participants vs 3.2% of vehicle-treated participants).[3] Severe local skin reactions were rare with less than 1% of tirbanibulin-treated participants experiencing severe vesiculation, pustulation, erosion, or ulceration by day 57 and no vehicle-treated participants experiencing these severe reactions. No participants in either arm of the trials discontinued treatment due to treatment-related adverse events.[3]

The Work Group determined that the overall balance of benefits and potential harms as reported at 57 days favors using tirbanibulin for the management of AK on the face and scalp and that the certainty of the available short-term evidence is high. Although the Work Group recognizes that cost may be prohibitive without adequate insurance coverage and other strongly recommended treatments for AK may be available for lower cost, they concluded that the use of tirbanibulin is likely acceptable to patients and providers, and feasible to implement especially considering the abbreviated duration of tirbanibulin treatment compared to the duration of other available topical agents for AK.

The Work Group acknowledges that the current recommendation is based on the available short-term efficacy and safety evidence specific to the management of AKs on the face and scalp. The future availability of long-term safety data may impact the direction or strength of the recommendation. Consult the full focused update publication for a detailed discussion of the evidence and rationale for the recommendation. [Citation pending]

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90