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Assessing The Holistic Value Of Tirbanibulin For Treating Actinic Keratosis Using Multi-Criteria Decision Analysis (MCDA) In Three European Countries

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Introduction & Objectives:

Actinic keratosis (AK) is a common pre-malignant skin condition caused by cumulative ultraviolet radiation exposure, with an estimated global incidence rate of 1,928 cases per 100,000 people each year. If untreated, AK may progress to invasive squamous cell carcinoma. Diagnosis is primarily clinical, based on erythematous, scaly lesions on sun-exposed skin. Treatment options vary depending on lesion characteristics, patient preferences, and healthcare system factors. Tirbanibulin, a microtubule inhibitor, was approved by the US Food and Drug Administration (2020) and the European Medicines Agency (2021) for the topical treatment of non-hyperkeratotic, non-hypertrophic AK on the face and scalp. A Multi-Criteria Decision Analysis (MCDA) is a structured methodology that integrates multiple value dimensions into healthcare decision-making, enabling a holistic, transparent, and systematic evaluation of new interventions including both comparative and non-comparative criteria.

This study used the MCDA methodology to assess the holistic value of tirbanibulin and identify its key value drivers for AK treatment across Germany, Italy, and Spain. It aimed to capture the perspectives of clinicians, payers, and patients to facilitate evidence-based decision-making.

Materials & Methods:

The study adapted and validated the 10th edition of the Evidence and Value: Impact on Decision-Making (EVIDEM) MCDA framework with clinical experts for evaluating novel AK treatments 2, 3. As a result, 11 criteria from the EVIDEM core model were included. These were categorized into disease-related criteria (burden of disease, size of affected population, unmet needs), non-comparative treatment-related criteria (quality of evidence, alignment with expert consensus, type of therapeutic and preventive benefits), and comparative treatment-related criteria (comparative efficacy, safety, patient-reported outcomes, and cost consequences). The

comparator selected for the comparative criteria was 5-fluorouracil 4% (5FU 4%), an antimetabolite chemotherapy widely used for AK treatment and approved for the target population of tirbanibulin.

The study included 18 participants, with six clinicians, six payers, and six patients equally distributed among the three countries. Each stakeholder group comprised two dermatologists, two payer representatives (regional primary healthcare pharmacists from Spain and Italy and representatives from sickness insurance funds in Germany), and two patients with AK diagnosis.

The MCDA process was conducted in two phases. To ensure objectivity, both treatments were anonymized using coded identifiers. In Phase 1, participants independently assigned a relative weight (on a scale of 1–5) to each criterion based on its perceived importance in assessing an AK treatment. These weights were then discussed in an online session to align perspectives and validate the criteria prioritization. In Phase 2, participants were presented with an evidence matrix containing clinical, economic, and patient-centered data for tirbanibulin and 5FU 4% (for comparative criteria). Participants independently scored each criterion based on the available evidence, followed by an online meeting to refine their assessments.

Results:

The findings will be submitted as they become available.

Conclusion:

The findings will provide insights into the key value drivers of tirbanibulin to help inform decision making.