

Development and Validation of a Claims-based Algorithm for Moderate-to-Severe Atopic Dermatitis Using U.S. Real-World Data

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Introduction/Background: Real-world data (RWD) source such as insurance claims data, provides the opportunity to draw on the experience of thousands of patients treated in routine clinical practice to better understand the relationships between exposures and outcomes. Nonetheless, conducting studies on atopic dermatitis (AD) using such data is challenging because it is an episodic condition with a heterogenous clinical presentation. Furthermore, although there are ICD-10-CM diagnosis codes for AD, the codes do not specify disease severity. Consequently, the potential for misclassification of AD diagnosis and severity is high.

Objective: To develop and validate a claims-based algorithm for moderate-to-severe AD (MTS-AD) using medical records.

Methods: This study was conducted within the Optum Research Database, a U.S. claims database from a large, commercial health plan affiliated with Optum. The study protocol was approved by the BRANY Institutional Review Board. Patients with at least one diagnosis code for AD (ICD-10-CM: L20*) between 28 March 2017 and 30 November 2019 were identified. Within this source population, several candidate

claims-based algorithms were applied to identify patients with MTS-AD. The candidate algorithms included proxy measures for MTS-AD, such as number of AD diagnoses, number and types of AD therapies, and specialty of the treating provider. Among patients who met one or more candidate algorithms for MTS-AD, a subset was randomly selected for medical record review. Additionally, charts of a random sample of patients from the source population were reviewed to assess the sensitivity. Following deidentification, the charts were adjudicated by a dermatologist with expertise in AD diagnosis and treatment to confirm the presence of MTS-AD. Using the adjudicated medical charts as the “gold standard”, the positive predictive value (PPV) of each candidate algorithm was calculated and compared to a pre-specified threshold of $\geq 70\%$.

Results: Overall, 278 medical records were sought and 200 were adjudicated, including 100 records among patients meeting a candidate algorithm for MTS-AD and 100 records among patients in the random sample. For the initial set of MTS-AD algorithms, which included ≥ 1 AD diagnosis as a criterion in each candidate algorithm, the PPVs ranged from 38-100%. For the algorithms with PPVs that met or exceeded the threshold of 70%, only 6 patients met the algorithm criteria. The MTS-AD algorithms were then modified to require ≥ 2 AD diagnoses as a criterion; the PPVs of the revised algorithms ranged from 57-100%. The final algorithm selected for MTS-AD had a PPV of 76% (95% CI: 53% - 90%) and a sensitivity of 35% (95% CI: 21% - 52%). This final algorithm included the following criteria: 1) ≥ 2 claims with an ICD-10-CM code for AD from any physician and either ≥ 1 dispensing of dupilumab or ≥ 2 dispensings of high potency topical corticosteroids¹ or systemic immunosuppressants²; or 2) ≥ 2 claims

¹ Including amcinonide (0.1%), betamethasone dipropionate (0.05%), betamethasone valerate (0.1%), clobetasol propionate (0.05%), desoximetasone (0.25%), diflorasone diacetate (0.05%), fluocinonide (0.05%), halcinonide (0.1%), halobetasol propionate (0.05%), mometasone furoate (0.1%).

² Including azathioprine, cyclosporine, methotrexate, or mycophenolate.

with an ICD-10-CM code for AD from a dermatologist or allergist and ≥ 3 dispensings of medium potency topical corticosteroids³, topical tacrolimus, phototherapy, or oral/parenteral corticosteroids (Figure).

Conclusions: A claims-based algorithm for identifying patients with moderate-to-severe AD was successfully developed and validated using RWD from a U.S. claims database. This validated moderate-to-severe AD algorithm is available for use in future studies within administrative databases, including those seeking to evaluate the safety or effectiveness of AD therapies in the post-marketing setting.

Keywords: validation, algorithm, moderate-to-severe atopic dermatitis, medical records, claims

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Figure. Final algorithm for moderate-to-severe atopic dermatitis

³ Including betamethasone valerate (0.1%), desoximetasone (0.05%), flucinolone acetonide (0.025%), hydrocortisone butyrate, hydrocortisone valerate, mometasone furoate, prednicarbate, triamcinolone acetonide (0.1%).

