Value & Adoption of Novel Assessments for Drugs

Translating patient value to commercial value in the development of digitally measured **nocturnal** scratch

NOCTURNAL SCRATCH



Digital Measures Development

www.dimesociety.org/tours-of-duty/digital-measures-nocturnal-scratch

A project by the



Key Insights

- & -
- Drug developers should work with patients to collect evidence that nocturnal scratch
 is relevant to their experience with atopic dermatitis. Drug developers must
 demonstrate that nocturnal scratch offers unique information about disease burden
 in atopic dermatitis beyond existing visual assessments and patient reported
 outcomes.
- Payers will be more willing to accept digital measure of nocturnal scratch if drug developers can show that it is correlated with existing endpoints and payer-relevant outcomes, including health care utilization and patient quality of life.
- Whether digitally measured nocturnal scratch is developed for use in clinical practice
 will affect its value as an endpoint. Payers are more likely to value digitally measured
 nocturnal scratch if they can track it in their patient populations in real-time, but
 payers may also tie utilization management to digital nocturnal scratch thresholds
 and limit patient access to treatments.

Patient Considerations



- Evidence in the medication approvals needs to translate into clinical significance for the patients in terms of daily living or experience
- Access to digital technologies should not limit patient inclusion in trials to ensure representative population
- Digital technologies may also reduce barriers to participation in trials



Action Items

- Engage with patients to demonstrate that nocturnal scratch is relevant to their experience with AD, distinct from itch and skin appearance
- ✓ Establish a minimal clinically important difference in nocturnal scratch outcome
- ✓ Provide technological resources (e.g., pre-paid data plans) to reduce patient barriers to participating in trials



Pharma Considerations



- Need to demonstrate that nocturnal scratch offers unique information about disease burden in AD beyond existing ClinROs & PROs
- At the same time, nocturnal scratch should relate to existing endpoints and payer-relevant outcomes, such as QoL
- The "first mover" disadvantage vs. opportunity for collaboration

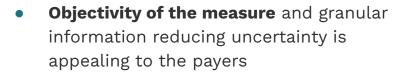


Action Items

- ✓ **Demonstrate** that improvements in digitally-measured nocturnal scratch relate to improvements in both general AD and dermatology-specific quality of life measures
- ✓ Provide evidence on unique information provided by the new measure
- ✓ Draw from pre-competitive measure development work by DiMe and partners

Payer Considerations





- Evidence leading to cost savings and decreased healthcare utilization is a large consideration for payers
- Payers may tie utilization management to nocturnal scratch thresholds and limit patient access to treatments



Action Items

- Demonstrate that improvements in digitally measured nocturnal scratch lead to reductions in health care utilization and spending
- ✓ Evaluate the benefits of introducing digital measure into clinical practice vs. the risks of potential development of new utilization management guidelines tied to the measure



Additional Relevant Resources:

- Modeling Potential Increases in Drug Utilization Following
 Successful Deployment of Digitally
 Measured Nocturnal Scratch
- Modeling Potential Increases in Drug Utilization Following Successful Deployment of Digitally Measured Nocturnal Scratch
- DiMe: <u>3Ps of Digital Endpoint</u>
 Value



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