ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

150 N. 18th Avenue
Phoenix, AZ 85007
602.417.4000

KATIE HOBBS
GOVERNOR

ROBERTA HARRISON
INTERIM DIRECTOR

P&T Committee
Written Public Testimony
May 19, 2026

Name*
David E. Delawder
Company or Organization*
NAMI Southern Arizona
Business Address*
6122 E 22nd St, 85711
Business City*
Tucson
Business State*
AZ
Preferred Email Address*
ddelawder@namisa.org
Phone*
520-622-5582
Check here if you are representing or speaking on behalf of any company/organization.
True
Check here if you are a private practice physician not affiliated with any manufacturer/organization.
False
Check here if you are a member of the public not affiliated wit h any manufacturer/organization.
True
Please check the box of the statement that best applies
I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee.
If yes, name organizations and roles:
National Alliance on Mental Illness of Southern Arizona, Executive Director.
Summary of Testimony*
Members of the AHCCCS Pharmacy and Therapeutics Committee,

Thank you for your time and I would like to address the committee as a person who has experienced many failed medication prescriptions during mental health treatment and as Executive Director of The National Alliance on Mental Illness (NAMI) of Southern Arizona speaking on behalf of our member families.

For many people with mental health conditions, medication is an essential part of their treatment and can be a valuable tool in overall well-being and they should have access to the full range of evidence-based mental health treatment options to successfully manage their condition.

While medication may not be part of every individual's treatment plan, it can be an important tool for managing symptoms that allow a person to stay engaged in or return to daily life activities or engage in their treatment.

Lack of access to mental health medications can worsen symptoms and lead to a greater likelihood of emergency room visits, hospitalizations, suicidal ideation, homelessness, and incarceration.

Step-therapy and therapeutic substitution is often promoted as a cost-savings strategy, but there is evidence that it can increase rates of hospitalizations and visits to the emergency room.

NAMI Southern Arizona believes people affected by mental health conditions should have access to the full range of evidence-based treatment options, including medications, to support their well-being.

NAMI Southern Arizona also opposes policies that reduce access to prescription psychiatric medications without clinical or evidence-based justification.

When it comes to your family needing life-saving treatment, would you want Managed Care Organization step-therapy protocols limiting access to the treatment your Doctor recommends for your child?

For members of NAMI Southern Arizona, the answer to that is "No."

Thank you for your time and what you do,
David E. Delawder
Drug/product*
Cobenfy
Therapeutic Drug Class*
Muscarinic agonist/(atypical anti-psychotic)
Testimony Format*
Written
Are you an employee or principal member of a company that is testing, producing, marketing, re-selling or distributing health care goods or services?
No
Do you receive currently, or have you received in the past 12 months, payments from a company for any of the following or similar work you provided: speakers' bureau, consultant, grant/research, etc.
No
In your presentation, will you discuss any products or services that were developed by a commercial interest (e.g. pharmaceutical company or devise manufacturer) with which, within the past 12 months, you, your spouse, or your partner have had a financial relationship?

No

Will you be discussing off-label use(s) of a medication? If so, identify the medication, off-label use, YES NO and manufacturer.

No

Do you have any other kind of financial interest in products or services you will be discussing?

No

If you answered “Yes” to any of the above, please list the commercial interest(s) and define your relationship(s) (e.g., founder, chief medical officer, speakers’ bureau, consultant, research support, stocker holder, royalties, or similar).

Name*

Amy Eby, DNP, CPNP

Company or Organization*

Banner Medical Group

Business Address*

1450 S. Dobson Rd Suite B221

Business City*

Mesa

Business State*

AZ

Preferred Email Address*

amy.eby@bannerhealth.com

Phone*

480-827-5370

Check here if you are representing or speaking on behalf of any company/organization.

True

Check here if you are a private practice physician not affiliated with any manufacturer/organization.

False

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False

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If yes, name organizations and roles:

Summary of Testimony*

Currently there are only 4 companies that produce and supply Growth hormone in the current US marketplace. Only 1 of these 4 companies produce a preservative free, once a week growth hormone product in an autoinjector, making it easy to administer a preservative free option. Since my patient population includes children 0-21 years of age of which have autoimmune illnesses or are medically fragile it is imperative to have a preservative free option. The remaining options for treatment include a preservative called polyethylene glycol. This preservative can cause an allergic response. In these cases, I have limited treatment options often causing delays in treatment and a disparity of care. Children with Growth Hormone Deficiency can be on injections for over 13 years, some require lifelong treatment. Genotropin does make a preservative free option called the Miniquick. The Miniquick comes in a prefilled syringe and is administered as a daily injection. Many parents do not feel comfortable administering medication with a traditional syringe. This often causes anxiety and needle phobia with my pediatric patient. As a result, many families prefer going with the once a week preservative free option, Skytrofa. I am requesting that the AHCCCS P&T Committee please approve Skytrofa as a preservative free once a week Growth Hormone treatment option so that the disparity of treatment has been removed in my patient population.

Drug/product*

Skytrofa - once a week preservative free growth hormone with autoinjector.

Therapeutic Drug Class*

Growth Hormone
Testimony Format*
Written
Are you an employee or principal member of a company that is testing, producing, marketing, re-selling or distributing health care goods or services?
No
Do you receive currently, or have you received in the past 12 months, payments from a company for any of the following or similar work you provided: speakers' bureau, consultant, grant/research, etc.
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If you answered "Yes" to any of the above, please list the commercial interest(s) and define your relationship(s) (e.g., founder, chief medical officer, speakers' bureau, consultant, research support, stocker holder, royalties, or similar).

Name*

Miguel Tosado

Company or Organization *

Onvida Health Yuma, Arizona

Business Address *

Onvida Behavioral East 7200 East 31st Place

Business City*

Yuma

Business State*

AZ

Preferred Email Address*

mtosado@onvidahealth.org

Phone*

928-336-2090

Check here if you are representing or speaking on behalf of any company/organization.

Representation

Check here if you are a private practice physician not affiliated with any manufacturer/organization.

Please check the box of the statement that best applies*

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If yes, name organizations and roles:

Summary of Testimony *

The advances in availability of xanomeline and trospium chloride, Cobenfy, had been able to generate functioning individuals recovering and improving employability, family stability, decrease in incidence of psychiatric hospitalizations and an overall improvement never compared seen before with any other available antipsychotic medications. Two close testimonies call my attention as having one middle-aged adult male able to assist expanding their family business. Being able to return back to work had been so empowering for him and his family, thanks to the medication availability. Another patient testimony in a young lady able to improve her marital relationship, able to engage on her community group of friends' business had been also empowering and beneficial for her. Thanks for continuing easing the availability and coverage of this medication.

Drug/product*

xanomeline and trospium chloride, Cobenfy

Therapeutic Drug Class*

Antipsychotic.

Testimony Format **

Written

Name*
Jeffrey Baldwin
Company or Organization *
AMGEN
Business Address *
One Amgen Center Drive
Business City*
THOUSAND OAKS
Business State*
CALIFORNIA
Preferred Email Address*
jefbaldw@amgen.com
Phone*
8054474070
Check here if you are representing or speaking on behalf of any company/organization.
Representation
Check here if you are a private practice physician not affiliated with any manufacturer/organization.
Please check the box of the statement that best applies*
I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee.
If yes, name organizations and roles:
Amgen, Inc.
Sr. Manager, Medical Value & Population Health
Summary of Testimony *
Dear Arizona State Medicaid P&T Committee,

In response to the upcoming Pharmacy & Therapeutics Committee meeting posted agenda, Amgen kindly requests consideration of the following information for TEZSPIRE® (tezepelumab-ekko).

Summary: TEZSPIRE is a first-in-class biologic that blocks thymic stromal lymphopoietin (TSLP) and reduces multiple drivers of epithelial-driven inflammation across upper and lower airways. Importantly, TEZSPIRE is the first and only biologic for severe asthma without phenotypic or biomarker limitations within its approved label. TEZSPIRE significantly reduced asthma exacerbations vs placebo in clinical trials, which included a broad population of severe asthma patients irrespective of key biomarkers including blood eosinophil (bEOS) counts and allergic status. In patients with CRSwNP, TEZSPIRE significantly improved nasal polyp size, nasal congestion, loss of smell, and the need for nasal surgery or systemic corticosteroid use vs placebo.

Product Overview: TEZSPIRE® is a first-in-class biologic that blocks TSLP, an epithelial cytokine located upstream in the inflammatory cascade. TEZSPIRE is the first and only biologic for severe asthma without phenotypic (eosinophilic/allergic) or biomarker limitations within its approved label. (1)

Indications: TEZSPIRE is indicated as an add-on maintenance treatment for patients 12 and older with severe asthma. TEZSPIRE is not indicated for the relief of acute bronchospasm or status asthmaticus. TEZSPIRE is also indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP). TEZSPIRE is contraindicated in patients who have known hypersensitivity to tezepelumab-ekko or any of its excipients. (1)

Efficacy of TEZSPIRE in Severe Uncontrolled Asthma: PATHWAY and NAVIGATOR Studies
Overall Results: TEZSPIRE treatment resulted in significant improvements vs placebo in asthma exacerbation, lung function, asthma symptom control, and health-related quality of life. (1)
AAER Results: TEZSPIRE significantly reduced annualized asthma exacerbation rates (AAERs) vs placebo:

- In PATHWAY, the AAER reduction was 71% (90% confidence interval [CI], 54%–82%; P < 0.001) vs placeo; in NAVIGATOR, the AAER reduction was 56% (95% CI, 47%–63%; P < 0.001) vs placebo. (1)
  - PATHWAY AAER: 0.20 for TEZSPIRE + SOC (n = 137) vs 0.72 for placebo + SOC (n = 138); RR 0.29 (95% CI, 0.16–0.51);
  NAVIGATOR AAER: 0.93 for TEZSPIRE + SOC (n = 528) vs 2.10 placebo + SOC (n = 531); RR 0.44 (95% CI, 0.37–0.53).
  - NAVIGATOR AAER associated with hospitalizations/ED/urgent care visits:
  0.06 for TEZSPIRE + SOC (n = 528) vs 0.28 for placebo + SOC (n = 531); RR 0.21 (95% CI, 0.12–0.37).
- The AAER for exacerbations associated with hospitalization, or an emergency department/urgent care visit was reduced by 79% vs placebo (95% CI, 63%-88%). (1) Results are descriptive only and from the NAVIGATOR study.

TEZSPIRE Data Across Phenotypic Profiles and Biomarker Levels. Data presented are descriptive only. Reductions in the AAERs were observed across biomarker levels and clinically relevant subgroups, including bEOS levels, allergic status, and history of nasal polyps. (1)
TEZSPIRE has an established safety profile. Most common adverse reactions occurring in at least 3% of patients are pharyngitis, arthralgia, and back pain. (1)
Clinical Practice Recommendations: TEZSPIRE has been recognized in the Global Initiative for Asthma (GINA) recommendations as an add-on biologic therapy option for patients with type 2 (e.g. allergic and/or eosinophilic) and non-type 2 severe asthma. (2)
Efficacy of TEZSPIRE in Chronic Rhinosinusitis with Nasal Polyps (CRSwNP): WAYPOINT Study
Study Design: WAYPOINT (phase 3, N = 408) was a multicenter, parallel-group, double-blind, randomized, controlled, 52-week trial in patients aged 18 years or older on standard of care treatment with severe uncontrolled Chronic Rhinosinusitis with Nasal Polyps (CRSwNP). (1,3)
Overall Results: In the WAYPOINT study in adults with severe, uncontrolled CRSwNP, treatment with TEZSPIRE significantly reduced nasal polyp size, congestion severity, the need for systemic corticosteroids and sino-nasal surgery, and resulted in improved loss of smell versus placebo. (1,3)

NPS and NCS Results: TEZSPIRE significantly improved the total Nasal Polyp Score (NPS) and Nasal Congestion Score (NCS) at week 52 vs. placebo: (1)
For NPS, the LS mean difference vs. placebo was -2.01 (95% CI:-2.33, -1.68; p<0.0001). For NCS, the LS mean difference vs. placebo was -0.95 (95% CI: -1.12, -0.78; p<0.0001). (1)

- NPS: LS mean change from baseline was -2.47 for TEZSPIRE + SOC (n=203) vs -0.47 for placebo + SOC (n=205)
- NCS: LS mean change from baseline was -1.76 for TEZSPIRE + SOC (n=203) vs -0.81 for placebo + SOC (n=205)

Safety profile of TEZSPIRE in CRSwNP: Most common adverse events occurring in ≥3% of patients are nasopharyngitis, upper respiratory tract infections, epistaxis, pharyngitis, back pain, influenza, injection site
reaction, and arthralgia. (1)

We respectfully request that TEZSPIRE be included on the State Preferred Drug List as a Preferred Agent for severe asthma and CRSwNP with coverage criteria aligned to the label with no phenotypic or biomarker requirements, to ensure equitable access for all eligible patients.

References: 1. TEZSPIRE® (tezepelumab-ekko) Prescribing Information. 2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. https://ginasthma.org/2025-gina-strategy-report/. Published 2025. Accessed 03/2026. 3. Lipworth BJ, et al. N Engl J Med. 2025; 392:1178-1188.

Drug/product*
TEZSPIRE® (tezepelumab-ekko)
Therapeutic Drug Class*
Cytokine and CAM Antagonists
Testimony Format **
Written

Name*

Sierra Wolter MD, FAAD

Company or Organization*

Phoenix Children's Hospital

Business Address*

5983 E Grant Rd Suite 201

Business City*

Tucson

Business State*

AZ

Preferred Email Address*

swolter@phoenixchildrens.com

Phone*

5202072318

Check here if you are representing or speaking on behalf of any company/organization.

False

Check here if you are a private practice physician not affiliated with any manufacturer/organization.

False

Check here if you are a member of the public not affiliated wit h any manufacturer/organization.

False

Please check the box of the statement that best applies

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If yes, name organizations and roles:

Summary of Testimony*

Executive summary:

I am a board-certified pediatric dermatologist practicing in Arizona caring for a significant number of children with severe atopic dermatitis statewide. Current step therapy requirements mandating trials of newer topical agents before dupilumab are clinically misaligned, delay effective care, and increase downstream costs. Early dupilumab initiation is also associated with reduced atopic march progression — including asthma and allergic rhinitis — a downstream benefit that mandatory delays forfeit. Allowing direct access when clinical criteria are met would better align coverage policy with evidence-based care, cost stewardship, and health equity.

Dear Pharmacy Benefit Management Leadership,

I am a board-certified pediatric dermatologist practicing in Arizona, caring for a significant number of children with moderate-to-severe atopic dermatitis statewide, including many patients covered under AHCCCS plans. I appreciate the opportunity to provide clinical input ahead of your policy review regarding step therapy requirements for dupilumab (Dupixent).

I support evidence-based utilization management. However, based on current data, treatment guidelines, and my clinical experience, requiring trials of tapinarof (Vtama) or roflumilast (Zoryve) prior to dupilumab in pediatric patients with documented severe atopic dermatitis is clinically misaligned and counterproductive.

Clinical concerns

Severe pediatric atopic dermatitis is not amenable to topical-only management Children with severe atopic dermatitis present with extensive body surface area involvement, intense pruritus, sleep disruption, and recurrent infection. Two distinct findings independently preclude effective topical therapy. Body surface area involvement exceeding 10% makes adequate coverage physically impractical — the quantity required, caregiver time burden, and real-world adherence failures at scale render topicals insufficient as a primary intervention. Open excoriations independently compromise skin integrity, making topical application painful, poorly tolerated, and potentially harmful regardless of BSA involved. Either finding alone predicts topical failure. Notably, neither tapinarof nor roflumilast is approved for severe atopic dermatitis, and neither has demonstrated efficacy comparable to systemic biologic therapy in this population. Mandating a trial under these conditions is not meaningful utilization management — it is a foreseeable failure with real consequences for the child.

Delayed access causes avoidable morbidity — and falls hardest on Medicaid families

Severe atopic dermatitis is associated with pain, sleep deprivation, impaired school functioning, psychosocial distress, and secondary infection. Delaying effective systemic therapy prolongs meaningful suffering during a critical period of development. This burden falls disproportionately on AHCCCS-enrolled families, who are less likely to have the resources, time, and caregiver capacity to execute twice-daily topical regimens across large body surface areas in young children — and fewer options to navigate urgent care or pharmacy appeals when disease flares during the delay. Step therapy requirements that are merely inconvenient for higher-resource families function as a de facto access barrier for the population this program exists to serve.

Step therapy increases downstream utilization and cost

In my practice, most children with severe disease predictably fail topical step therapy. Required trials generate months of additional high-cost topical prescriptions, repeated specialty visits, antibiotic courses, systemic corticosteroid bursts, and urgent care visits — after which the majority are approved for dupilumab regardless. The result is higher cumulative cost without avoiding biologic initiation.

Delayed initiation forfeits a disease-modifying opportunity

Atopic dermatitis is the entry point for the atopic march — the sequential development of asthma, allergic rhinitis, and food allergy. A 2024 population-based cohort study (n = 4,384 propensity-matched pediatric patients) found that dupilumab-treated children had a 32% lower risk of atopic march progression, a 40% lower risk of asthma, and a 31% lower risk of allergic rhinitis compared to those on conventional therapy — with the greatest protective effect in the youngest children. For a Medicaid plan, this is a direct cost argument: each of these conditions generates its own ongoing claims burden. Delaying dupilumab in children who will ultimately receive it anyway may forfeit the window in which it could have prevented additional chronic disease.

Evidence base

Dupilumab is FDA-approved for children as young as 6 months with moderate-to-severe atopic dermatitis, with robust long-term safety and efficacy data in pediatric populations. AAD guidelines support systemic therapy including biologics for patients with moderate-to-severe disease inadequately controlled with topical therapy.

Selected references

Paller AS et al. Dupilumab in children aged 6 months to 5 years with uncontrolled atopic dermatitis. N Engl J Med.2022.

Simpson EL et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. N Engl J Med. 2016.
Sidbury R et al. Guidelines of care for the management of atopic dermatitis. J Am Acad Dermatol.
FDA Prescribing Information for Dupixent (dupilumab).
Chia-Yu Chu et al. Reduced atopic march risk in pediatric atopic dermatitis patients prescribed dupilumab versus conventional immunomodulatory therapy. J Am Acad Dermatol. 2024.
Paller AS et al. Dupilumab is efficacious in young children with atopic dermatitis regardless of type 2 comorbidities. Advances in Therapy. 2024.

Recommendation
For pediatric patients with documented severe atopic dermatitis, I recommend allowing direct access to dupilumab without mandatory topical trials when any of the following criteria are met:
- Body surface area involvement greater than 10%
- Presence of open excoriations or compromised skin barrier precluding safe topical application
- Both findings present concurrently

Each criterion independently identifies a patient for whom topical step therapy is not a reasonable clinical option. These thresholds are clinically meaningful, objectively documentable at the point of care, and preserve appropriate utilization oversight while eliminating the most harmful delays — including the window in which early dupilumab initiation may prevent progression to additional chronic atopic disease.

I appreciate your consideration and would welcome the opportunity to provide further clinical input during your policy review.
Sincerely,
Sierra Wolter MD
Pediatric Dermatologist
Division of Dermatology
Phoenix Children's Medical Group
Drug/product*
Dupilumab
Therapeutic Drug Class*
Biologic
Testimony Format*
Written
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