

# Amplifying Patient Voice in Market Access

## Chief Patient Officer Summit 2024

Jamie Culp, Value and Access Lead, DKI Health  
Phil Gattone, CEO, NBDF

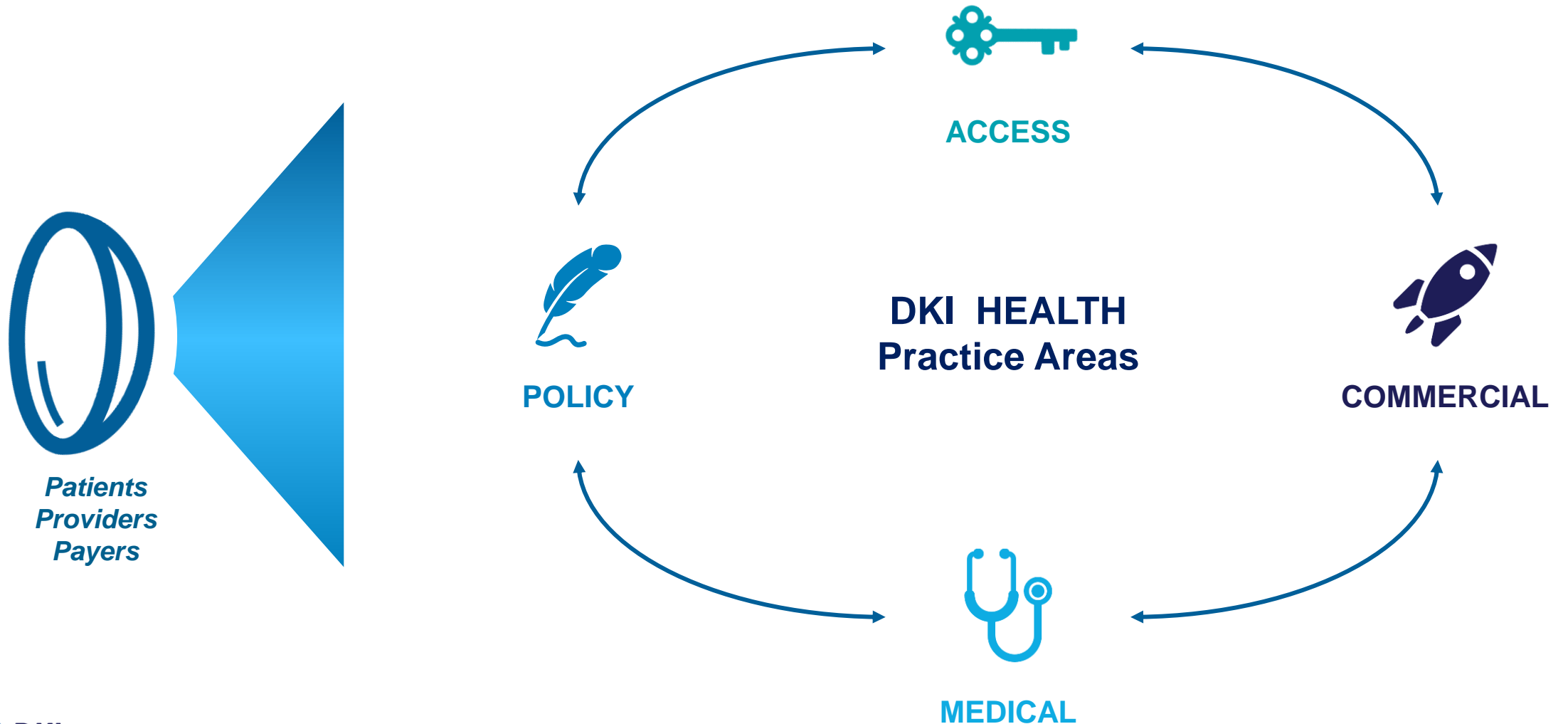
15 July 2024

Confidential

# Agenda

- Introductions
- Patient Access Challenges
- Impacting Access through Patient Voice: Colorado PDAB
- A Multi-Stakeholder Collaboration to Improve Patient Access to Medicine: NBDF and the Comprehensive Care Sustainability Collaborative
- Takeaways

**DKI Health is a trusted advisor in Life Sciences, providing a strategic view of your key stakeholders and how to engage them.**



# Our Provider, Patient, and Caregiver Advisory Council brings strategic and tactical patient insights to advance shared objectives.



**Vision:** Empower patients and caregivers to impact industry and government strategy that enhances patient-centered and equitable care.



**PHIL GATTONE**  
CEO, National Bleeding Disorders Foundation



**DENISE SMITH**  
Executive Director, National Association of Community Health Workers



**JEN GRAND-LEJANO**  
Government Relations Director, American Cancer Society Cancer Action Network



**ALISHA LEWIS**  
CEO, Genèsic (Sickle Cell Disease)



**COURTNEY BUGLER**  
President and CEO, ZERO Prostate Cancer



**ARYA SINGH**  
Spinal Muscular Atrophy Patient and Author, *Courageous Calla and the Clinical Trial*



**CHRISTIAN JOHN LILLIS**  
CEO, Peggy Lillis Foundation (C. Diff. infection)



**MARY KEMP**  
Director, Grassroots Organizing, American Cancer Society Cancer Action Network



**NEDA MILEVSKA KOSTOVA**  
President, IAPO P4PS Observatory



**SUE KOOB**  
CEO, Preventive Cardiovascular Nurses Association



**JOE NADGLOWSKI**  
President and CEO, Obesity Action Coalition

# OUR MISSION

The National Bleeding Disorders Foundation (NBDF) is dedicated to finding cures for inheritable blood and bleeding disorders and to addressing and preventing the complications of these disorders through research, education, and advocacy, enabling people and families to thrive.

# NUESTRA MISIÓN

La Fundación Nacional de Trastornos Hemorrágicos (NBDF, por sus siglas en Inglés) trabaja para encontrar la cura de los trastornos de la sangre y hemorrágicos hereditarios, así como para tratar y prevenir las complicaciones de estos trastornos a través de la investigación, educación y apoyo, permitiendo que las personas y las familias prosperen.



NATIONAL  
**BLEEDING DISORDERS**  
FOUNDATION  
*Formerly NHF*

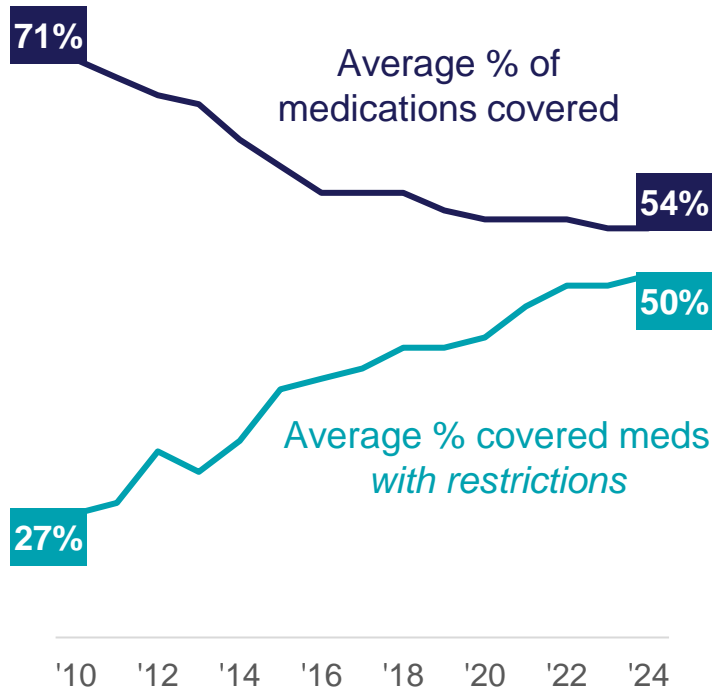
# Patient Access Challenges

# “Health insurers cover fewer drugs and make them harder to get.”



June 27, 2024

## Drug access, more or less Medicare PDP, 2010-2024



## When payers won't pay for prescribed treatments, others spend billions each year to narrow the gap

**\$24.8B**

Drugmaker spend to support patient access

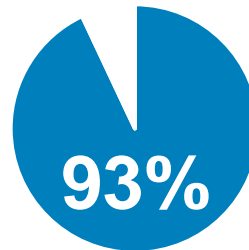
**\$26.7B**

Health provider spend navigating UM\*

**\$35.8B**

Patient out of pocket spend on drug cost sharing

## UM hurts patient care



Physicians (n=1000) say prior authorizations negatively impact patient clinical outcomes

“I continue to live with the effects of prior authorization. If I had been allowed to get the treatment I needed when I needed it most, I would still be able to drive a car, fly a plane, look through a telescope, see colors or walk without a cane. But I can't. I can never do those things again.”

—Ocean McIntyre  
14 weeks from diagnosis to treatment



\*UM: Utilization Management



Copyright © 2024 DKI Health. All rights reserved.

# Payers use a variety of tactics to restrict patient access, burdening stakeholders throughout the healthcare system.

## Tangled up in Red (Tape)

Requiring providers to meet and document additional requirements before covering treatment.

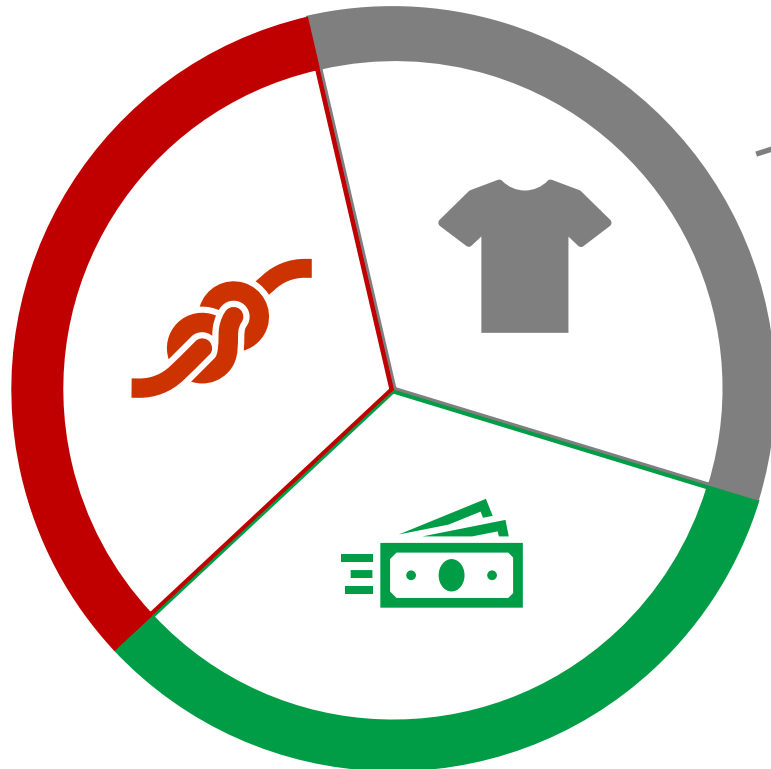
### Examples



Prior Authorization\*



Step Therapy\*



## 1 Size Fits

Limiting provider and patient choice to payer-preferred treatment(s).

### Examples

Formulary Exclusion



Non-Medical Switching



## Pass the Buck

Shifting treatment costs to others, e.g., drugmakers.

### Examples

Co-pay Accumulator



Alternative Funding



\*Some UM tactics include multiple burdens: PA and ST also limit provider and patient choice (1 Size Fits).



# Tactics emerge as Payers and Pharma engage in decades-long cost-sharing fight.



Payers

Copays and  
coinsurance



Pharma

**So patients  
will value  
their care.**

***Prevents  
access for  
patients!***

# Tactics emerge as Payers and Pharma engage in decades-long cost-sharing fight.



Payers

*Higher healthcare costs to increase their profits!*

Copays and coinsurance



Copay Assistance (PAP)



Pharma

Right treatment for patients regardless of ability to pay.

# Tactics emerge as Payers and Pharma engage in decades-long cost-sharing fight.



Payers



Pharma

Copays and coinsurance



Copay Assistance (PAP)

“Mitigate the market distortion coupons create.”

Copay Accumulator  
Copay Maximizer



“Just a scheme to increase their profits!”



# As the fight goes on, patients pay a heavy price.



Payers



Patients



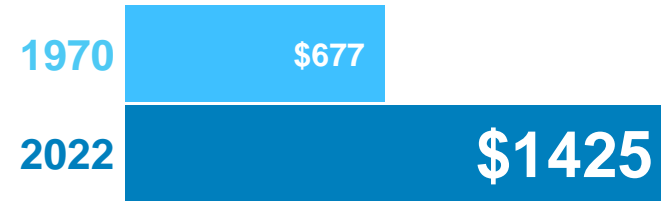
Pharma



Change in premiums as % of compensation, 1988 to 2019, US employer health plans

**\$220,000,000,000**

US medical debt



Out of pocket (OOP) health spend per-person, US (constant 2022 USD)

**500,000+**

Medical debt-related bankruptcies, US annually

# Alternative Funding Programs (AFP): can we all just agree they're bad?

## “Alternative” funding in 5 easy steps

1. Plan excludes drug(s) from formulary.
2. Plan contracts outside vendor, e.g. Payer Matrix, SHARx to administer excluded drug(s).
3. AFP vendor helps disguise patient as “uninsured” to apply for PAP funds (some vendors will contact drugmaker **as the patient**).
4. **/IF/ patient is approved**, drugmaker pays drug and pharmacy costs, while plan incurs no direct drug costs.
5. Plan pays AFP vendor fee of up to **30%** of PAP funding value.

## Common ground on AFP



### Pharma

“The AFP model is **based on deception**... puts profit first, patients last.”

–*BIO*



### Providers

“AFP vendors come between the patient and the practice, throwing up **unnecessary roadblocks and delays**.”

–*Ashley Sumrall, MD, FACP, FASCO*



### Advocates

“We strongly urge Payer Matrix to **stop identifying as either a ‘Patient Advocacy Company’ or a ‘Leading Patient Advocate’**... Payer Matrix advocates for employer cost savings which lead to profits for Payer Matrix, not employees’ health.”

–*30+ patient advocacy organizations*



### Payers

**80% saw significant challenges**. Said one pharmacy director at a large national payer, “There will likely be regulation coming... **Not sustainable**.”

–*MMIT payer interviews*

# Artificial Intelligence: new tool, same tactics?

Payers have been low-key on AI use and plans, but a 2023 STAT Investigation provides insights on usage to date and cautions for the future.

2011



Tom Scully, former CMS Administrator under George W. Bush, founds naviHealth. Their product, nH Predict, recommends “a **custom treatment regimen** and care setting for each patient,” including when to discharge.

To predict needs, the algorithm **compares patient measures to millions of medical records**.

2020



**May:** UnitedHealthGroup (UHG) acquires naviHealth for ~\$2.5B.

“Things changed after (UHG) took over. Instead of it being a tool that was used to anticipate a length of stay, it became a tool that **you’d better make it happen or there’s consequences.**”

—Former naviHealth case manager

**August:** Dolores Millam breaks her leg, is admitted to a nursing home. **HCP orders that she stay off it at least six weeks; nH Predict says 15 days.**

On Day 18, United cuts off payment. Millam still requires 24-hour care, stays **three months**—and is billed \$40,000 on discharge.

**November:** Judge orders United to pay for Millam’s treatment in full.

2023

UHG / naviHealth sets target for Medicare Advantage (MA) patient rehab stays of **±1% of days predicted by algorithm**: former staff say missing targets exposed them to discipline and/or **firing, regardless of Medicare coverage rules.**

“UnitedHealth was using the unregulated algorithm in making life-altering coverage decisions... as part of a plan that boosted profits at the expense of patients: UnitedHealth **pressured clinical employees to follow the algorithm’s length-of-stay determinations, even when they, and the patients’ own clinicians, disagreed.**”

—STAT

2023-24



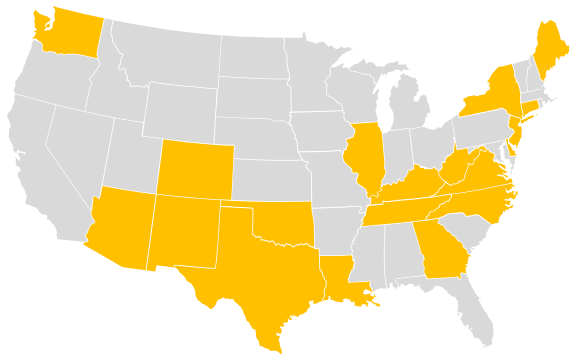
Following STAT reporting and US Congress calls for action, CMS issues MA plan **algorithm limitations, disclosure requirements, and oversight / audits** to follow.

# Patients and advocates champion pro-access policies in court and legislatures: the work is ongoing.



## Big wins

**Oct 2023:** Federal court ends HHS rule allowing copay accumulators on drugs that lack generic equivalents; case brought by **patient groups and three patients receiving copay assistance.**



As of March 2024, 19 states have banned copay accumulators in state-sponsored programs. State laws regulating these and other UM, such as step therapy and prior authorization, have **passed following multi-year advocate campaigns.**



## Miles to go

Federal Legislation	The Safe Step Act	The Help Ensure Lower Patient Copays Act
<b>Introduced</b>	2017	2021
<b>Status</b>	In committee	In committee
<b>Would require</b>	Standards, exceptions, and reporting for step therapy protocols.	Plans to apply payments by, and on behalf of, enrollees toward cost-sharing.
<b>Advocacy</b>	<b>200+</b> patient and provider organizations, including <b>National Psoriasis Foundation</b> , which leads coalition on federal step therapy reform. Sponsors steptherapy.com with information and tools.	<b>All Copays Count Coalition</b> , comprising <b>80+</b> organizations, educates the public and lobbies at all government levels to protect copay assistance.

# **Impact Access through Patient Voice: Colorado PDAB and Trikafta**



# Colorado PDAB Trikafta review shows power of patient voices in drug access—and value to drugmakers.



**1998:** Aurora Biosciences (Vertex acquisition, 2001) and Cystic Fibrosis Foundation Therapeutics (CFFT) launch R&D collaboration.

**2000-2016:** CFFT funds Vertex \$150M for CF drug development, including Trikafta, in exchange for sales royalties.

**2014, 2020:** CFFT sells Vertex royalty rights for >\$3.8B.



Colorado is third US state to form Prescription Drug Affordability Board (PDAB).



Vertex provides CFF \$5.77M in annual grants and licensing, more than any other company.



**Aug:** PDAB selects 5 drugs for review, including Trikafta.

**Sep - Oct:** CFF publicly lobbies PDAB, touting benefits of Trikafta, PAP. CF patients, including CFF members, speak at PDAB meetings: nearly all oppose price cap.

**Dec:** **PDAB votes unanimously to not cap Trikafta price.**

“Public meeting for patients and caregivers... was particularly raw, a lot of feelings expressed by **patients impacted by Trikafta**... I can't begin to tell you how touching those stories were, **how impactful**.”

—Catherine Harshbarger, CO PDAB

**Feb 2024:** PDAB votes to impose first price cap: on Enbrel, a drug costing less than 1/4 of Trikafta.

# A Multi-Stakeholder Collaboration to Improve Patient Access to Medicine

Philip Gattone, MEd  
President and Chief Executive Officer  
National Bleeding Disorders Foundation

4<sup>th</sup> Annual Chief Patient Officer Summit  
July 15, 2024  
Boston, MA

 **Comprehensive Care  
Sustainability Collaborative**  
National Bleeding Disorders Foundation

*Provided by*



*In Partnership with*



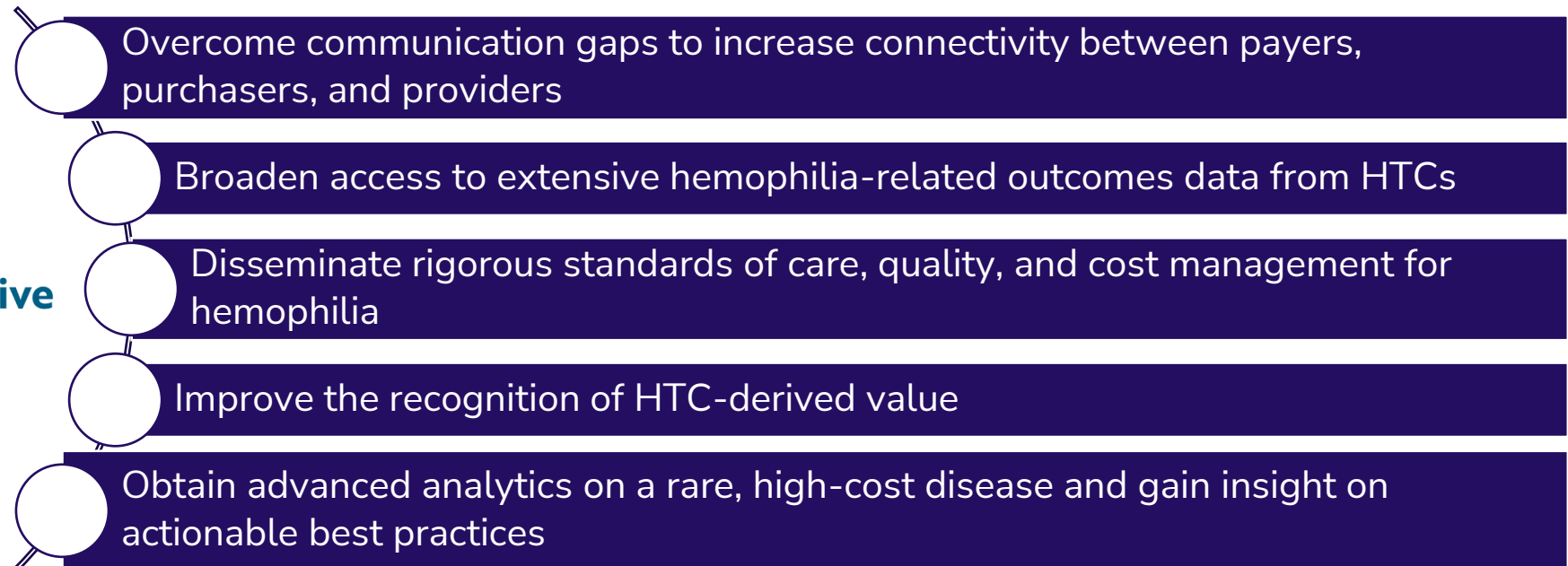
CCSC is supported by charitable donations from founding supporter Takeda, and additional support from BioMarin, Biotechnology Innovation Organization, Bleeding & Clotting Disorders Institute, CSL Behring, Genentech, Inc., Gulf States Hemophilia and Thrombophilia Center, Louisiana Center for Bleeding and Clotting Disorders, Sanofi, and Spark Therapeutics.

Copay Accumulator Adjustment Program (CAAP) Outreach is supported by AbbVie, Inc.

# CCSC: A Hemophilia Quality Improvement and Cost Management Initiative Sponsored by NBDF



- Formed in 2014 with a prominent group of Hemophilia Treatment Center (HTC) directors, clinicians, and administrators along with payer/managed care medical and pharmacy directors
- Goal is to augment the sustainability of HTCs through the following:



# The First Step: Defining Common Goals



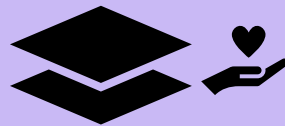
Communication gaps between payers and providers



Evidence-based high-quality care must be reimbursable



Benefit designs and care coordination strategies should optimize both cost-effectiveness and patient outcomes



Data sharing is vital to achieving common goals



Advocacy groups can connect payers and providers



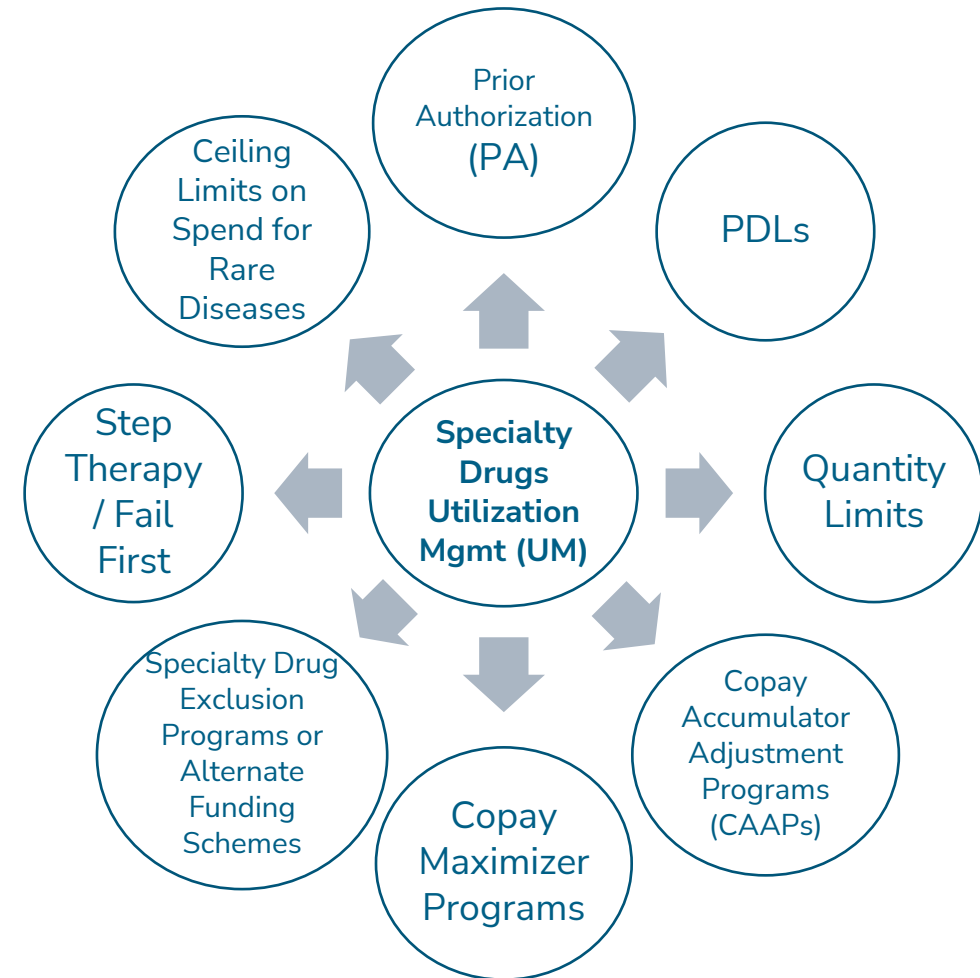
# The Importance of Access and Coverage to High Quality Care – Patient Advocacy Perspectives



The importance of access and coverage to high quality care starts with the people we serve.

For the patients and families we serve, navigating how to access care, let alone high quality and reimbursable care, is challenging.

Navigating care at an individual level is complex.



# CCSC Impact on Utilization Management (UM) Strategies



Magellan updated their UM strategies in bleeding disorders

Magellan asked NBDF to review the UM strategies prior to launch and NBDF provided feedback

Magellan incorporated NBDF feedback prior to releasing the updated documentation

# CCSC Improving Access to the Integrated Comprehensive Care Model



## CCSC Success with Getting HTC's In-network



- Worked with Pharmacy Director (also a CCSC advisor) to amend policies to **allow HTC's in-network**

## CCSC Worked with Purchasers of Health Care to Improve Access



- CCSC worked with UnitedHealthcare and BCBS to amend policies to improve the management of members living with bleeding disorders
- **Resulting in streamlined access to the right therapy**
- Letter of agreement (LOA) with Compass Rose
- LOA with Nationwide Children's in Ohio
- **Overcame exclusive specialty pharmacy contract with HTC pharmacy access through the medical benefit**





NATIONAL  
**BLEEDING DISORDERS**  
FOUNDATION  
*Formerly NHF*



# Takeaways

# Takeaways

1. Access challenges are not going away: payers will innovate new UM tactics and deploy the newest technologies to enhance them.
2. Patients and advocates can be a difference-maker in winning and maintaining access—*if* we understand and address their needs.
  - Establish deep and lasting relationships with advocates based on patient needs and shared goals.
  - Give: grants, time, energy, thinking, support.
3. Seek opportunities to collaborate with stakeholders—internal and external—including providers *and* payers.
  - Understand motivations and identify shared goals.
  - Be ready to communicate, share, and trust.





**JAMIE CULP**  
Lead, Value and Access (US)  
[jamie.culp@dkihealth.com](mailto:jamie.culp@dkihealth.com)

**PHIL GATTONE**  
CEO  
[pgattone@bleeding.org](mailto:pgattone@bleeding.org)

**Thank You!**

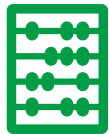


# APPENDIX

# Newer tactics to pass the buck: copay adjustment programs game PAPs, hurt patients in process (of course).

## Copay adjustment programs (CAAP) include

### Copay Accumulators



Copay assistance does not count toward deductible or OOP maximum.

### Copay Maximizers



Sets patient cost-sharing amount equal to copay assistance maximum.

### Studies say:

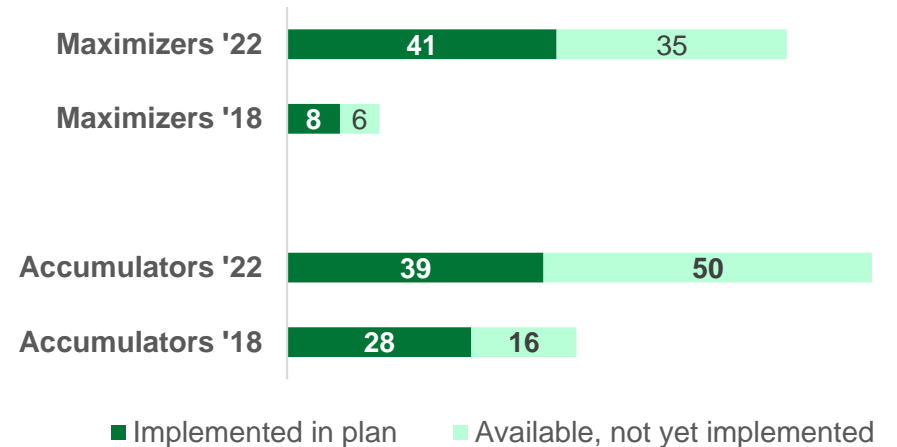
- Accumulators may drive lower treatment adherence.
- Accumulators and Maximizers may increase access disparities (Patients of Color are significantly more exposed to copay adjustment tactics).

### Patient experience:

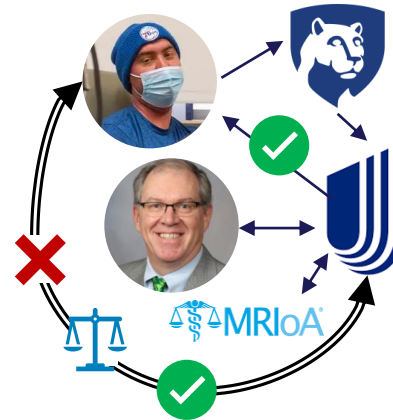
Jennifer Hepworth and her husband were stunned: their cost for their daughter’s cystic fibrosis medication payment had jumped from \$30 per month to \$3,500—equivalent to the family’s annual deductible. Hepworth paid because she didn’t want to stop giving her daughter a treatment that could extend her life.

***“We were struggling and everything went on credit cards.”***

### Copay adjustment grows: % of commercial beneficiaries in plans, 2018-22



# Christopher McNaughton vs UnitedHealthcare: UC patient fights disease and denials, wins coverage, exposes payer practices.



Chris McNaughton, a college student athlete, is diagnosed with severe UC. **Steroids and other drugs prescribed provide little relief, but are covered** under his parents' health plan.

Following multiple referrals, McNaughton travels 900 miles to Mayo Clinic, is treated by Dr. Edward Loftus Jr. In 2018, a high-dose combination of **vedolizumab and infliximab finally brings his UC under control.**

July: McNaughton enrolls at Penn State University (PSU), where his parents work; switches to UnitedHealthcare (UHC) student plan after being told **drugs will be covered.**

September: After covering two months of infusions, **UHC marks subsequent claims for year as "Pending". McNaughton and his family contact UHC twice,** are assured delay is for a simple records check.

January: **McNaughton's claims are denied,** owes >\$800,000. Family **appeals to PSU administrators.**

March: **UHC agrees to cover care** through August.

April - May: UHC conducts internal and external case reviews, claiming treatment regimen is not medically necessary and quashing opinions that disagree.

June: UHC informs McNaughton it **will not cover treatment regimen** after August.

August: **McNaughton sues UHC.**

September: **UHC agrees to cover** McNaughton's treatment for 2021-22 academic year.

In depositions, UHC staff admit **misrepresentations and weak bases for coverage denials.**

February: McNaughton and UHC **settle lawsuit.**

July: Chris McNaughton enrolls at PSU law school, plans to "represent patients who have had medical treatments denied by insurance companies."



**Chris McNaughton**  
Student at Penn State Law



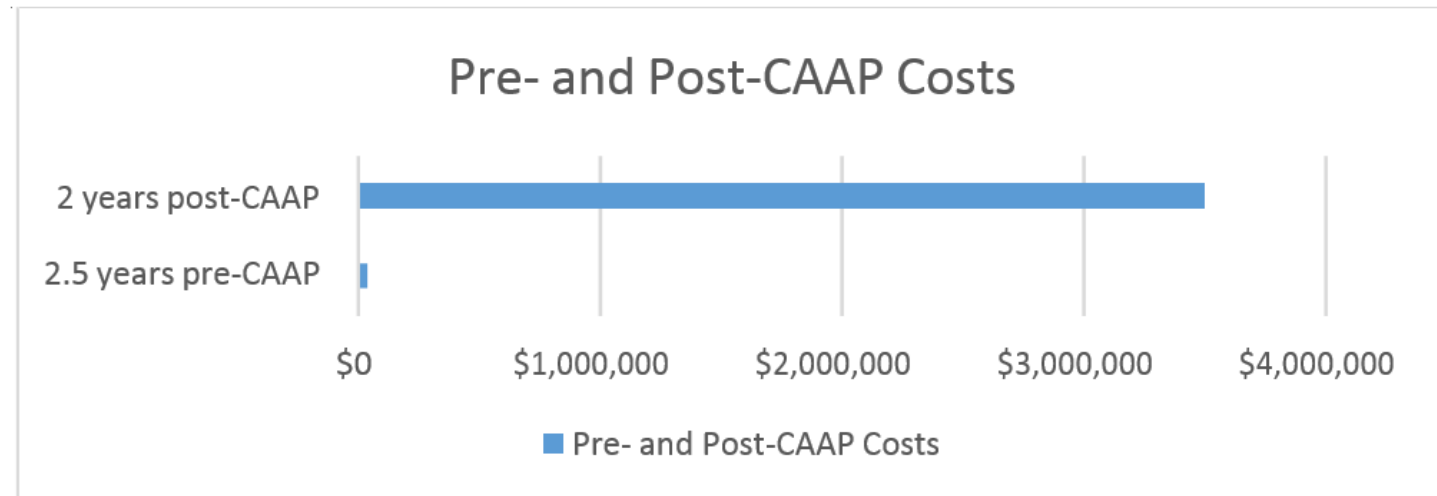
# Additional Cases

# Copay Accumulator Adjustment Programs (CAAP) Case Study – 23-year-old Male with Mild Hemophilia A



## COST

- In the 2.5 years prior to the implementation of CAAP, the patient specialty medication claims **totaled \$36,800**
- In the 2 years since the CAAP prevented the patient from accessing his treatments, his costs have **exceeded \$3,500,000** and counting





# Case Scenario: Male with Severe Hemophilia B



- Self-Funded Employer Plan
- Script: Dispense 55u/kg (90.9 kg) Factor IX replacement product
- Target dose 4,999.5 units
- Exclusive specialty pharmacy (SPP) contract rate \$1.35 per/iu
- Dosing schedule 3x/week and PRN for breakthrough bleeds

# SPP Actual Dispense Data Against HTC LOA Rate Cost Assay



TARGET MONTHLY UNITS	ACTUAL MONTHLY UNITS DISPENSED	MONTHLY ACTUAL \$1.35/UNIT	ANNUAL ACTUAL \$1.35/UNIT
60,000	62,880	\$84,888	\$1,018,656

TARGET MONTHLY UNITS	ACTUAL MONTHLY UNITS DISPENSED	MONTHLY ACTUAL \$1.08/UNIT	ANNUAL ACTUAL \$1.08/UNIT
60,000	62,880	\$67,910.40	\$814,924.80

**SPP**

**HTC**



# HTC Policies Lead to Total Savings

- All scripts 30 days with NO refills
- Will not approve order request from SPP before speaking to patient/caregiver at which time:
  - Care team confirms doses on hand.
  - Identifies if any breakthrough bleeds occurred.
  - Confirms if PRN doses were required and how many.
  - Provides inventory management reminders.
  - HTC documented delivery days and refill to soon attempts

ANNUAL PER UNIT SAVINGS	ANNUAL ASSAY MANAGEMENT SAVINGS	TOTAL ANNUAL COST SAVINGS
\$273,559.68	\$46,656	\$320,215.68



# References

# References

Slide #	References
7	<ol style="list-style-type: none"> <li>1. Lupkin S. Health insurers cover fewer drugs and make them harder to get. NPR. Published June 27, 2024. Accessed July 9, 2024. <a href="https://www.npr.org/2024/06/27/g-s1-6773/health-insurers-cover-fewer-drugs-and-make-them-harder-to-get">https://www.npr.org/2024/06/27/g-s1-6773/health-insurers-cover-fewer-drugs-and-make-them-harder-to-get</a></li> <li>2. Marsh T. The Big Pinch: Fewer Medications Covered, More Restrictions on Covered Drugs. GoodRx. Published March 16, 2020. Accessed July 9, 2024. <a href="https://www.goodrx.com/insurance/health-insurance/the-big-pinch-fewer-prescription-drugs-covered-more-insurance-restrictions">https://www.goodrx.com/insurance/health-insurance/the-big-pinch-fewer-prescription-drugs-covered-more-insurance-restrictions</a></li> <li>3. Howell S, Yin PT, Robinson JC. Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients. Health Affairs. 2021;40(8):1206-1214. doi:<a href="https://doi.org/10.1377/hlthaff.2021.00036">https://doi.org/10.1377/hlthaff.2021.00036</a></li> <li>4. Care Delays Associated with PA Treatment Abandonment due to PA. <a href="https://www.ama-assn.org/system/files/prior-authorization-survey.pdf">https://www.ama-assn.org/system/files/prior-authorization-survey.pdf</a></li> <li>5. Commentary G. California should end this health insurance tactic delaying urgent treatment. CalMatters. <a href="https://calmatters.org/commentary/2023/07/health-insurance-tactic-urgent-treatment/">https://calmatters.org/commentary/2023/07/health-insurance-tactic-urgent-treatment/</a>. Published July 7, 2023. Accessed July 9, 2024.</li> </ol>
9	<ol style="list-style-type: none"> <li>1. Gondek K. Prescription drug payment policy: past, present, and future. Health Care Financ Rev. 1994 Spring;15(3):1-7. PMID: 10137792; PMCID: PMC4193453. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193453/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193453/</a></li> </ol>
10	<ol style="list-style-type: none"> <li>1. Congressional Research Service. Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs) Updated September 12, 2022. <a href="https://crsreports.congress.gov/product/pdf/R/R44264">https://crsreports.congress.gov/product/pdf/R/R44264</a></li> </ol>

# References

Slide #	References
11	<ol style="list-style-type: none"> <li>1. New “Let’s Talk About Cost” Ads Highlight How Copay Accumulator Programs Leave Patients Financially Exposed. phrma.org. Accessed July 9, 2024. <a href="https://phrma.org/resource-center/Topics/Cost-and-Value/new-let-s-talk-about-cost-ads-highlight-how-copay-accumulator-programs-leave-patients-financially-exposed">https://phrma.org/resource-center/Topics/Cost-and-Value/new-let-s-talk-about-cost-ads-highlight-how-copay-accumulator-programs-leave-patients-financially-exposed</a></li> <li>2. AHIP Files Amicus Brief in Support of Copay Coupon Accumulators. AHIP. Accessed July 9, 2024. <a href="https://www.ahip.org/news/press-releases/ahip-files-amicus-brief-in-support-of-copay-coupon-accumulators">https://www.ahip.org/news/press-releases/ahip-files-amicus-brief-in-support-of-copay-coupon-accumulators</a></li> </ol>
12	<ol style="list-style-type: none"> <li>1. Himmelstein DU, Lawless RM, Thorne D, Foohey P, Woolhandler S. Medical Bankruptcy: Still Common Despite the Affordable Care Act. American Journal of Public Health. 2019;109(3):431-433. doi:<a href="https://doi.org/10.2105/ajph.2018.304901">https://doi.org/10.2105/ajph.2018.304901</a></li> <li>2. Rae M, Claxton G, Amin K, Wager E, Ortaliza J, Cox C. The burden of medical debt in the United States. Peterson-KFF Health System Tracker. Published February 12, 2024. <a href="https://www.healthsystemtracker.org/brief/the-burden-of-medical-debt-in-the-united-states/">https://www.healthsystemtracker.org/brief/the-burden-of-medical-debt-in-the-united-states/</a></li> <li>3. Hager K, Emanuel E, Mozaffarian D. Employer-Sponsored Health Insurance Premium Cost Growth and Its Association With Earnings Inequality Among US Families. JAMA Network Open. 2024;7(1):e2351644. doi:<a href="https://doi.org/10.1001/jamanetworkopen.2023.51644">https://doi.org/10.1001/jamanetworkopen.2023.51644</a></li> </ol>
13	<ol style="list-style-type: none"> <li>1. Fein AJ, Ph.D. Employers Expand Use of Alternative Funding Programs—But Sustainability in Doubt as Loopholes Close. <a href="https://www.drugchannels.net/2023/05/employers-expand-use-of-alternative.html">https://www.drugchannels.net/2023/05/employers-expand-use-of-alternative.html</a></li> <li>2. BIO.ORG GROWTH in ALTERNATIVE FUNDING PROGRAMS THREATENS PATIENT ACCESS to MEDICINES How Do AFPs Make It Harder for Patients to Access Medicines? Accessed July 9, 2024. <a href="https://www.bio.org/sites/default/files/2023-10/bio_afp_factsheet_v4_2.pdf">https://www.bio.org/sites/default/files/2023-10/bio_afp_factsheet_v4_2.pdf</a></li> <li>3. Re: Payer Matrix identifying itself as both a ‘Patient Advocacy Company’ and a ‘Leading Patient Advocate’ is untrue and misleading to consumers. CancerCare et al. August 17 2023. <a href="https://media.cancercare.org/documents/344/original/Response-to-Payer-Matrix_Final-8.17.23.pdf">https://media.cancercare.org/documents/344/original/Response-to-Payer-Matrix_Final-8.17.23.pdf</a></li> <li>4. Alternative Funding Programs. ONS Voice. Accessed July 9, 2024. <a href="https://voice.ons.org/news-and-views/alternative-funding-programs">https://voice.ons.org/news-and-views/alternative-funding-programs</a></li> <li>5. Payers Troubled by Rise of Alternative Funding Programs. MMITNetwork. Accessed July 9, 2024. <a href="https://www.mmitnetwork.com/thought-leadership/payers-troubled-rise-alternative-funding-programs/">https://www.mmitnetwork.com/thought-leadership/payers-troubled-rise-alternative-funding-programs/</a></li> </ol>

# References

Slide #	References
14	<ol style="list-style-type: none"> <li>1. DuBois; BS. Startup naviHealth ramps up for growth. The Tennessean. Accessed July 9, 2024. <a href="https://www.tennessean.com/story/news/2013/12/20/navihealth-ramps-up-growth-beefs-up-leadership-team/4143083/">https://www.tennessean.com/story/news/2013/12/20/navihealth-ramps-up-growth-beefs-up-leadership-team/4143083/</a></li> <li>2. Bannow T. Sen. Warren pushes for more data on Medicare Advantage coverage hurdles, denials. STAT. Published December 8, 2023. Accessed July 9, 2024. <a href="https://www.statnews.com/2023/12/08/medicare-advantage-more-data-warren-senators/">https://www.statnews.com/2023/12/08/medicare-advantage-more-data-warren-senators/</a></li> <li>3. AIAAIC - NaviHealth nH Predict post-acute care predictions. www.aiaaic.org. Accessed July 9, 2024. <a href="https://www.aiaaic.org/aiaaic-repository/ai-algorithmic-and-automation-incidents/navihealth-nh-predict-post-acute-care-predictions">https://www.aiaaic.org/aiaaic-repository/ai-algorithmic-and-automation-incidents/navihealth-nh-predict-post-acute-care-predictions</a></li> <li>4. Ross C. Denied by AI: How Medicare Advantage plans use algorithms to cut off care for seniors in need. STAT. Published March 13, 2023. <a href="https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/">https://www.statnews.com/2023/03/13/medicare-advantage-plans-denial-artificial-intelligence/</a></li> <li>5. Herman B. How UnitedHealth's acquisition of a popular Medicare Advantage algorithm sparked internal dissent over denied care. STAT. Published July 11, 2023. Accessed July 9, 2024. <a href="https://www.statnews.com/2023/07/11/medicare-advantage-algorithm-navihealth-unitedhealth-insurance-coverage/">https://www.statnews.com/2023/07/11/medicare-advantage-algorithm-navihealth-unitedhealth-insurance-coverage/</a></li> <li>6. Herman B. UnitedHealth pushed employees to follow an algorithm to cut off Medicare patients' rehab care. STAT. Published November 14, 2023. Accessed July 9, 2024. <a href="https://www.statnews.com/2023/11/14/unitedhealth-algorithm-medicare-advantage-investigation/">https://www.statnews.com/2023/11/14/unitedhealth-algorithm-medicare-advantage-investigation/</a></li> <li>7. Herman B. Medicare Advantage plans will have to stop denying required care, federal officials say. STAT. Published April 5, 2023. Accessed July 9, 2024. <a href="https://www.statnews.com/2023/04/05/medicare-advantage-denying-care/">https://www.statnews.com/2023/04/05/medicare-advantage-denying-care/</a></li> <li>8. 2024 Oversight Activities. CMS. October 24, 2023. <a href="https://www.documentcloud.org/documents/24083148-2024-cms-ma-utilization-management-oversight-activities">https://www.documentcloud.org/documents/24083148-2024-cms-ma-utilization-management-oversight-activities</a></li> <li>9. CMS Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F). February 6, 2024. <a href="https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf">https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf</a></li> </ol>

# References

Slide #	References
15	<ol style="list-style-type: none"> <li>1. Court strikes down HHS rule that allowed insurers to not count copay assistance. HIV+Hepatitis Policy Institute. <a href="https://hivhep.org/press-releases/court-strikes-down-hhs-rule-that-allowed-insurers-to-not-count-copay-assistance/">https://hivhep.org/press-releases/court-strikes-down-hhs-rule-that-allowed-insurers-to-not-count-copay-assistance/</a></li> <li>2. Amicus Briefs Filed in Suit to End Policy That Prohibits Copay Assistance from Counting toward Patients' Out-of-Pocket Spending Harmful Insurer &amp; PBM Policy Increases Prescription Drug Costs for Patients. Accessed July 9, 2024. <a href="https://hivhep.org/wp-content/uploads/2023/02/HIV-Hep-DLC-DPAC-Litigation-Amicus-Briefs-press-release-2.10.23.pdf">https://hivhep.org/wp-content/uploads/2023/02/HIV-Hep-DLC-DPAC-Litigation-Amicus-Briefs-press-release-2.10.23.pdf</a></li> <li>3. Congress. Congress.gov   library of Congress. Congress.gov. Published 2023. <a href="https://www.congress.gov/">https://www.congress.gov/</a></li> <li>4. Step Therapy Homepage   Learn More About NPF. Step Therapy. Accessed July 9, 2024. <a href="https://steptherapy.com/">https://steptherapy.com/</a></li> <li>5. Federal Advocacy. www.psoriasis.org. Accessed July 9, 2024. <a href="https://www.psoriasis.org/federal-advocacy/">https://www.psoriasis.org/federal-advocacy/</a></li> <li>6. Take Action. AllCopaysCount. Accessed July 9, 2024. <a href="https://allcopayscount.org/take-action/">https://allcopayscount.org/take-action/</a></li> </ol>
17	<ol style="list-style-type: none"> <li>1. Vertex and Cystic Fibrosis Foundation Therapeutics to Collaborate on Discovery and Development of New Medicines to Treat the Underlying Cause of Cystic Fibrosis   Vertex Pharmaceuticals. Vertex Pharmaceuticals. Published 2024. <a href="https://investors.vrtx.com/news-releases/news-release-details/vertex-and-cystic-fibrosis-foundation-therapeutics-collaborate">https://investors.vrtx.com/news-releases/news-release-details/vertex-and-cystic-fibrosis-foundation-therapeutics-collaborate</a></li> <li>2. Vertex snares \$75M windfall in revised CFF deal; Ex-Celgene R&amp;D prez Daniel starts advisory group. Endpoints News. <a href="https://endpts.com/vertex-snares-75m-windfall-in-revised-cff-deal-ex-celgene-rd-prez-daniel-starts-advisory-group/">https://endpts.com/vertex-snares-75m-windfall-in-revised-cff-deal-ex-celgene-rd-prez-daniel-starts-advisory-group/</a></li> <li>3. Document. www.sec.gov. Accessed July 9, 2024. <a href="https://www.sec.gov/Archives/edgar/data/875320/000087532016000096/a8-kxcfftxoctober2016.htm">https://www.sec.gov/Archives/edgar/data/875320/000087532016000096/a8-kxcfftxoctober2016.htm</a></li> <li>4. Cystic Fibrosis Foundation Royalty Sale Will Be Transformational for People with CF   Cystic Fibrosis Foundation. www.cff.org. Accessed July 9, 2024. <a href="https://www.cff.org/press-releases/2014-11/cystic-fibrosis-foundation-royalty-sale-will-be-transformational-people-cf">https://www.cff.org/press-releases/2014-11/cystic-fibrosis-foundation-royalty-sale-will-be-transformational-people-cf</a></li> <li>5. A Message From Our CEO   Cystic Fibrosis Foundation. www.cff.org. Published November 2, 2020. <a href="https://www.cff.org/node/871">https://www.cff.org/node/871</a></li> <li>6. Reid S. STATEMENT: Colorado Becomes Third State With Prescription Drug Affordability Board. Patients For Affordable Drugs Now. Published June 16, 2021. <a href="https://patientsforaffordabledrugsnow.org/2021/06/16/colorado-third-state-pdab/">https://patientsforaffordabledrugsnow.org/2021/06/16/colorado-third-state-pdab/</a></li> <li>7. Industry Contributions   Cystic Fibrosis Foundation. www.cff.org. <a href="https://www.cff.org/about-us/industry-contributions">https://www.cff.org/about-us/industry-contributions</a></li> </ol>



# References

Slide #	References
17	<ol style="list-style-type: none"> <li>8. SEC Filing   Vertex Pharmaceuticals. Vrtx.com. Published 2023. <a href="https://investors.vrtx.com/node/31666/html">https://investors.vrtx.com/node/31666/html</a></li> <li>9. Prescription Drug Affordability Review Board   DORA Division of Insurance. doi.colorado.gov. <a href="https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board">https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board</a></li> <li>10. CF Foundation Provides Comments to Colorado’s Prescription Drug Affordability Board on Its Review of Trikafta   Cystic Fibrosis Foundation. www.cff.org. Accessed July 9, 2024. <a href="https://www.cff.org/statements/2023-10/cf-foundation-comments-colorado-pdab-trikafta">https://www.cff.org/statements/2023-10/cf-foundation-comments-colorado-pdab-trikafta</a></li> <li>11. Zhang RC, Silverman Ed. Amgen’s rheumatoid arthritis drug Enbrel targeted for first-in-the-nation price limit in Colorado. STAT. Published February 23, 2024. <a href="https://www.statnews.com/pharmalot/2024/02/23/amgen-enbrel-rheumatoid-arthritis-price-limit-colorado/">https://www.statnews.com/pharmalot/2024/02/23/amgen-enbrel-rheumatoid-arthritis-price-limit-colorado/</a></li> <li>12. Colorado moves to cap price of arthritis drug Enbrel in first-in-the-nation action by state affordability board. The Denver Post. Published February 23, 2024. <a href="https://www.denverpost.com/2024/02/23/enbrel-price-cap-colorado-prescription-drug-affordability-board/">https://www.denverpost.com/2024/02/23/enbrel-price-cap-colorado-prescription-drug-affordability-board/</a></li> </ol>
29	<ol style="list-style-type: none"> <li>1. What You Need to Know: Accumulators, Maximizers, and People With CF   Cystic Fibrosis Foundation. www.cff.org. <a href="https://www.cff.org/support/what-you-need-know-accumulators-maximizers-and-people-cf">https://www.cff.org/support/what-you-need-know-accumulators-maximizers-and-people-cf</a></li> <li>2. Sherman BW, Epstein AJ, Meissner B, Mittal M. Impact of a co-pay accumulator adjustment program on specialty drug adherence. The American Journal of Managed Care. 2019;25(7):335-340. <a href="https://pubmed.ncbi.nlm.nih.gov/31318506/">https://pubmed.ncbi.nlm.nih.gov/31318506/</a></li> <li>3. Ingham M, Sadik K, Zhao X, Song J, A Mark Fendrick. Assessment of racial and ethnic inequities in copay card utilization and enrollment in copay adjustment programs. Journal of managed care &amp; specialty pharmacy. 2023;29(9):1084-1092. doi:<a href="https://doi.org/10.18553/jmcp.2023.23021">https://doi.org/10.18553/jmcp.2023.23021</a></li> <li>4. Appleby J. When Copay Assistance Backfires on Patients. KFF Health News. Published March 15, 2024. <a href="https://kffhealthnews.org/news/article/drugmaker-copay-assistance-backfires-patient-deductibles/">https://kffhealthnews.org/news/article/drugmaker-copay-assistance-backfires-patient-deductibles/</a></li> <li>5. Fein AJ, Ph.D. Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow. Accessed July 9, 2024. <a href="https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html">https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html</a></li> </ol>

# References

Slide #	References
30	<ol style="list-style-type: none"><li data-bbox="300 337 2400 444">1. Armstrong D, Rucker P, Miller M. UnitedHealthcare tried to deny coverage to a chronically ill patient. He fought back, exposing the insurer's inner workings. ProPublica. Published February 2, 2023. <a href="https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis">https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis</a></li><li data-bbox="300 458 970 494">2. LinkedIn Profile: Christopher McNaughton</li></ol>