National Alliance of Healthcare Purchaser Coalitions
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2020 Annual Forum

Total Cost of Care Management: A Focus on Rare Disease
Monday, November 9, 2020 | 3:45 PM – 4:45 PM ET

Cheryl Larson
MODERATOR
President & CEO
Midwest Business Group on Health

Kollet Koulianos
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National Hemophilia Foundation

Jeff Blake
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Alliant Employee Benefits

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Sr. Director
Therapeutic Policy and Advocacy
Takeda

#NatAllForum

Total Cost of Care Management: A Focus on Rare Disease

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Midwest Business Group on Health

The source for leading health benefits professionals

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About MBGH

Since 1980 – One of the nation's leading and largest non-profit coalitions of HR/health benefits professionals

4M Lives – Represent 135 mid, large & jumbo self-insured public & private companies

$12B – Annual employer member spend on health care costs

Community of Your Peers – A sharing and friendly environment to help you collaborate, benchmark and learn

Using Our Collective Voice – Serving as catalysts for change to improve the cost, quality and safety of your health benefits

Specialty/Orphan Drugs & Rare Diseases

- A rare disease generally affects fewer than 200,000 people in U.S.
- Over 6,800 with an estimated 25 to 30 million Americans affected
- Examples include Cystic Fibrosis, Huntington's Disease, Duchenne Muscular Dystrophy and Hemophilia
- Considerable progress has been made in recent years to diagnosis, treat and prevent many rare diseases; much more needs to be done as there is no treatment for the vast majority
- Orphan Drug Act of 1983 provided incentives for drug companies to develop treatments; in 25 years FDA has approved more than 340 treatments

Specialty/Orphan Drugs & Rare Diseases

- There is a robust pipeline for orphan drugs during a time of economic pressures
- AHIP 2019 report indicates the price of orphan drugs is increasing at a far more rapid pace than other specialty and traditional drugs and off label use is adding to the cost
- Payers and purchasers are showing increased levels of concern and scrutiny over coverage
- Strategies for orphan drugs are similar to those applied for other expensive biologics/specialty drugs and expected to intensify
- Few if any employers have strategies in place to impact cost of the drug or total cost of treatment; intermediaries also increase costs to the plan

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https://www.ajmc.com/view/panelists-discuss-community-based-approaches-to-mitigate-costs-improve-sdoh-outcomes

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Today's Stakeholder Panel: Hemophilia

- Hemophilia consistently ranks among the top-10 high cost claims conditions
- Only about 20,000 Americans have this condition
- Average annual cost of medication alone is more than $270,000 per patient; if complications arise the yearly cost can soar well over $1M
- Major factors impacting the cost of care include: site of care; medication management; prescription/adherence management
- Other significant cost issues include waste and misuse of clotting factor
  - Stockpiling – fear of patient running out of medication
  - Lack of oversight of on how much is sent to patient
  - Waste of clotting factor by PBMs and specialty pharmacies

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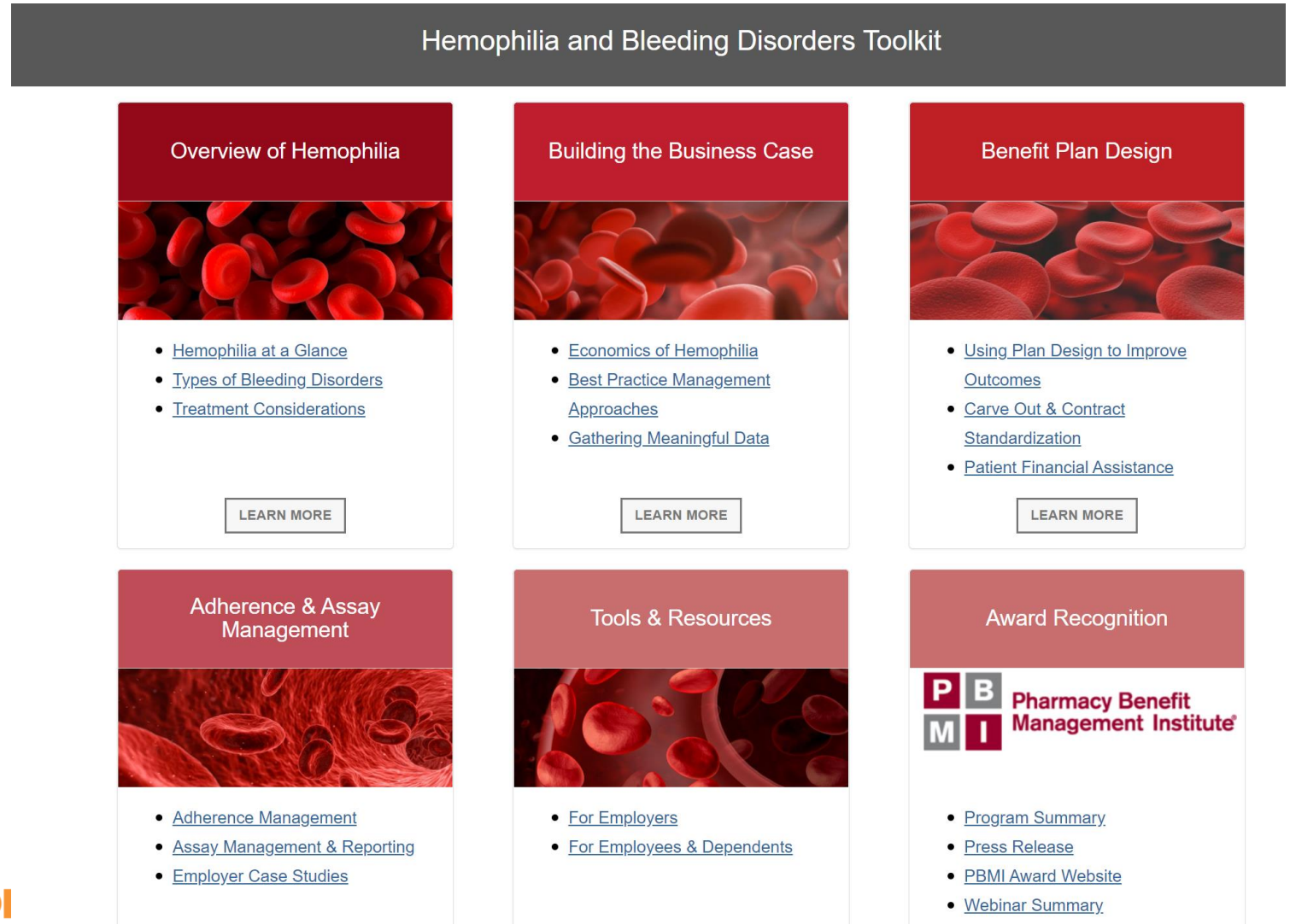
MBGH's Employer Toolkit on Hemophilia & Bleeding Disorders



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https://www.mbgh.org/www/resources/employertoolkits/hemophilia-toolkit

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Total Cost of Care Management: A Focus on Rare Disease

A Case Study on Hemophilia

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Faculty Panel

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President & CEO
Midwest Business Group on Health

Rodney Dickson
Sr. Director, Therapeutic Policy and Advocacy, Rare Disease
U.S. Public Affairs
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Jeff Blake, MBA
Senior Vice President, Payer Relations
Hemophilia Alliance

Kollet Koulianos, MBA
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Sal Morana, RPh, PhD
SVP, Pharmacy Practice Lead – Hospitals & Health Systems
Alliant Employee Benefits

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Objectives

- Discuss the unintended consequences resulting from plan design, utilization management strategies, exclusivity, etc. in the management of high cost diseases
- Identify high cost claimant cost levers
- Determine what data is key for analyzing vendor performance
- Using hemophilia as an example, illustrate the parallels in care management in other high cost diseases and discuss best practices to improve quality of care and contain costs

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Economics of Hemophilia

- Hemophilia consistently ranks among the top-10 high-cost claims conditions
  - ✓ Approx. 2.5 x Higher than Avg High-Cost Claimants
    - ✓ $270,000 Annually
  - ✓ 90% of Cost Associated with Treatment
- Disproportionate share driver of healthcare spend
- Three primary cost centers that have greatest impact on total cost of care
  - Provider / Site of Care
  - Medication Management
  - Prescription / Adherence Management

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Payers have several levers for managing specialty drug costs

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UNDERSTANDING COST DRIVERS

Prescription Data

- Payers do not traditionally have access to prescription data; however, they can and should collect this information
- Having the actual prescription data provides the payer with transparency to verify assay management and per unit pricing

Cost per Unit

- Per unit prices differ among specialty/dispensing pharmacies
- HTCs are multidisciplinary, non-profit clinics recognized by the federal government that have access to discounted medications under the 340B Drug Pricing Program and may offer competitive and/or lower average pricing per unit

Assay Management

- NHF's Medical And Scientific Advisory Council (MASAC) Recommendation #188 states that factor should be dispensed within ±5% to ±10% of the prescribed target dose
- Payers and purchasers can and should require tighter assay management; in most cases, ±1% to ±2% of the target dose can be achieved

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The Right Care at the Right Time at the Right Place

RARE DISEASE CENTER OF EXCELLENCE MODEL

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Expert, High-Touch Medical Management

PROVIDER/SITE OF CARE

- Federally Recognized Hemophilia Treatment Centers (HTC's) of Excellence are recognized as the *GOLD STANDARD* in caring for patients with Hemophilia, vWD and other rare bleeding disorders by the World Federation of Hemophilia, National Hemophilia Foundation, Health Resources and Services Administration (HRSA), and Centers for Disease Control (CDC)
  - Hematologists with Sub-Specialization in Rare Chronic Bleeding Disorders on call 24/7/365
  - Prescribed Dosing Based on Science and Expertise
  - Proactive Medical Home
    - Integrated Expert Clinical Care Team (Provider, Nurse Practitioner, Nurse Care Coordinators, Physical Therapists, Social Workers)
      - Surgical Management (Medication Management, Scheduling, Training and in some cases On-site Nursing for clotting factor infusions)
      - Travel Planning
      - School IEP's
      - Home Inventory Management / Training
      - Coordinated Medical/Pharmacy/Patient Clinical Discussions and/or Concerns
      - Annual Home Visit (infusion review recertification, physical inventory inspection, home safety audit)
  - Specialized Coagulation Laboratories

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Medication Management

- Medical/Pharmacy Communication, Coordination and Documentation
- Assay Management
  - Target vs Actual Deviation[1]
- Emergency Response / Delivery
  - **24/7/365** Pharmacy
  - Close Proximal Location ONLY Mechanism to Avoid Unnecessary ER Visits[2]
- Close coordination/collaboration with medical provider team
  - **24/7/365** Provider Availability
- Adequate Data Collection/Reporting
- Dose Reviews
- NO Auto Filling
- Monthly Communication w Patient
- Bleed Logs

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1. HTC Annual Dispensation Review documented 19% lower dispensed units/kg in 2017
2. ER Avoidance Claims

Prescription Adherence Management

- Annual Patient Adherence Education
- Regular Collection/Review of Bleed Logs
- Home Inventory Management
  - Physical Onsite Home Inspection
    - Validate/Review Inventory
    - Proper Storage Review
    - Home Safety Inspection
    - Infusion Recertification
- Monthly Communication / Reconciliation to verify # PRN doses on hand, adherence, document ER visits/Hospitalizations, inventory management review (review/rotate stock)

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MEDICAL AND SCIENTIFIC ADVISORY COUNCIL GUIDELINES

188 Standards of Pharmacy Services

- Correctly filled and delivered within 48 hours from the time the order is received.
- If the pharmacy receives a call about an emergent situation, the treating physician to be notified immediately and patient should have access to the CFC within 12 hours of expressed need; with a goal of 3 hours where logistically possible.
- Filling of scripts within +/-5-10%.

MASAC 242 - Home Delivery & Refill Under State Emergency

- Patient should have 1 week of PRN doses on hand in case of emergency or natural disaster.

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Case 1: AutoZone Beneficiary

- Patient has severe hemophilia B
- Patient prescribed 55u/kg (90.9 kg) of factor IX CFR – Target dose 4,999.5 units
- Dose schedule 3x/week and PRN for breakthrough bleeds
- SPP per unit cost $1.35

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SPP Actual Dispense Data Against HTC Cost Assay

SPP

TARGET MONTHLY UNITS	ACTUAL MONTHLY UNITS DISPENSED	MONTHLY ACTUAL $1.35/UNIT	ANNUAL ACTUAL $1.35/UNIT	ANNUAL COST FOR UNITS DISPENSED OVER TARGET @ $1.35/U
60,000	62,880	$84,888	$1,018,656	$46,656

HTC

TARGET MONTHLY UNITS	ACTUAL MONTHLY UNITS DISPENSED	MONTHLY ACTUAL $1.08/UNIT	ANNUAL ACTUAL $1.08/UNIT	ANNUAL COST FOR UNITS DISPENSED OVER TARGET @1.08/U
60,000	62,880	$67,910.40	$814,924.80	$37,324.80

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SPP Actual Data Against HTC Cost & Vial Availability Report

TARGET MONTHLY UNITS	ACTUAL MONTHLY UNITS DISPENSED	MONTHLY ACTUAL $1.35/UNIT	ANNUAL ACTUAL $1.35/UNIT	ANNUAL COST FOR UNITS DISPENSED OVER TARGET @ $1.35/U	
					SPP
60,000	62,880	$84,888	$1,018,656	$46,656	

TARGET MONTHLY UNITS	ACTUAL MONTHLY VIAL AVAILABILITY	MONTHLY COST $1.08/UNIT	ANNUAL ACTUAL $1.08/UNIT	TOTAL SAVINGS TO BE REALIZED	
					HTC
60,000	57,492	$62,091.36	$745,096.32	$320,215.68	

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HTC Policies and 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

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Additional savings realized from HTC Intervention and lack of MASAC compliance exposes plan and patient.

- 1/7 SPP request order – HTC contracted patient to confirm need. Pt states 3 doses on hand. Script sent. Pt confirmed receipt 1/12
- 1/30 SPP request order – HTC contact w pt. who states he has 6 doses on hand; however w past deliver delays would like to go ahead and get ordered. Script sent. Pt confirmed receipt 2/7
- 2/11 SPP request order – HTC contact w pt. who stated he just received last order 2/7 therefore not needed. HTC denied request*
- 3/11 SPP request order – HTC contact w pt. who stated 3 doses left on hand, confirmed time for reorder. Script sent. Pt confirmed receipt 3/16

All ordered to delivered outside MASAC recommendations

***$84,888 Saved as a result of the HTC Medication Management Protocol**

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Case 2: Patient Covered by a Self-Funded Employer

BACKGROUND

A patient covered by a self-funded employer was receiving clotting factor through a specialty pharmacy

The development of an inhibitor necessitated a therapeutic switch to a non-factor therapy that was priced higher

At the same time, the patient's care was transferred to the local HTC to more carefully manage the complications associated with the inhibitor

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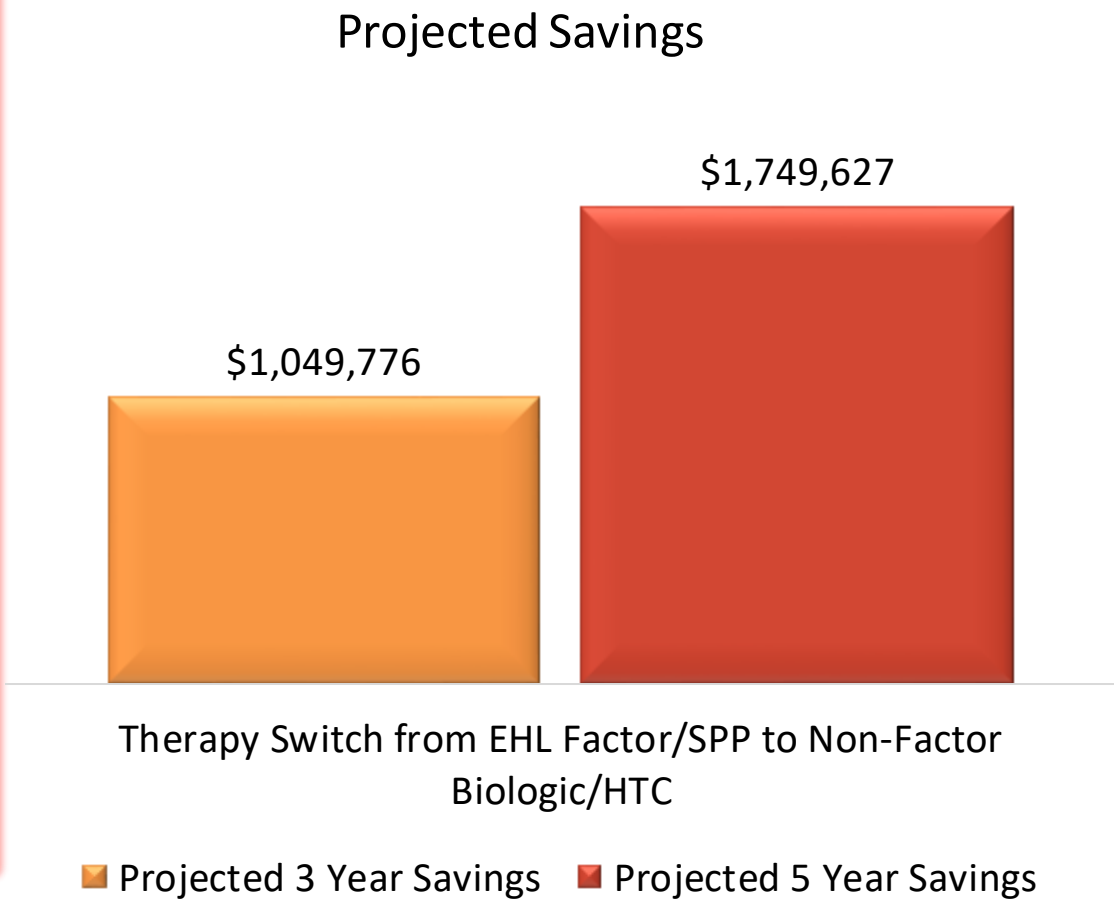
Patient Covered by a Self-Funded Employer

RESULTS OF SPP TO HTC SWITCH

	Treatment Type and Dose	Specialty Pharmacy Monthly Cost	HTC Monthly Cost	Annual Savings
	EHL Factor Infuse 4,000 Units M / Th and PRN	$69,480.45	$62,354.00	**$85,522.20 EHL Factor Prophy Dosing**
	Non-Factor Biologic Loading Dose	$71,424	$57,700	**$13,724.00 Non-Factor Biologic Loading Doses**
	Non-Factor Biologic Maintenance Dose	$49,996.80	$40,320	**$116,112 Non-Factor Biologic Maintenance Prophy Dosing**
Savings from therapy switch from EHL Factor/SPP to Non-Factor Biologic/HTC		$833,765.40 EHL Factor/SPP	$483,840.00 Non-Factor Biologic/HTC	**$349,925.40 Annual Savings***



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*When switching from EHL Factor dispensed by specialty pharmacy provider (SPP) to Non-Factor Biologic dispensed by HTC. Savings are a result of cost per unit only. Additional savings may be realized with HTC assay management; however, data was not available at time of presentation.

Case 3: Background

COPAY ACCUMULATOR ADJUSTMENT PROGRAMS (CAAPs) ARE BECOMING INCREASINGLY POPULAR AND ARE BEING ROLLED OUT AS A ONE-SIZE-FITS-ALL SOLUTION

CAAPs pose a risk of significant unintended consequences for patients with chronic/rare diseases, such as hemophilia

- 43% of individuals with private insurance are enrolled in high-deductible health plans (HDHPs)
- 1/3 of employers ONLY offer HDHPs
- Median household income: $61,372 (US Census Bureau, 2018)
- 63% of the population cite not having $500 for emergencies (Forbes, 2018)
  - Individual deductible/max out of pocket (OOP) - $7,900
  - Family deductible/max OOP - $15,800

Many patients with chronic/rare disease depend on copay assistance as a lifeline to access their life saving treatments

CAAPs no longer allow patient copay assistance dollars to count towards a members deductible/out of pocket

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CAAP Case Study – 23-year-old Male with Mild Hemophilia A

BACKGROUND

- July 6, 2017—Patient developed a knee/joint bleed
  - Patient called his PBM/Specialty Pharmacy to order replacement clotting factor (infusible specialty medication to treat bleeds)
  - Health plan implemented Copay Accumulator Adjustment Program
  - Available manufacturer copay assistance dollars had been exhausted earlier in the year.
  - PBM notified patient his $6,500 deductible would be required before they could dispense
  - As a newly married college graduate, he had no way to pay the $6,500 leaving him unable to access his specialty medication so that he could treat his bleed
  - The patient experienced prolonged bleeding into his knee and developed additional bleeds that went untreated for 40 days

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CAAP Case Study – 23-year-old Male with Mild Hemophilia A

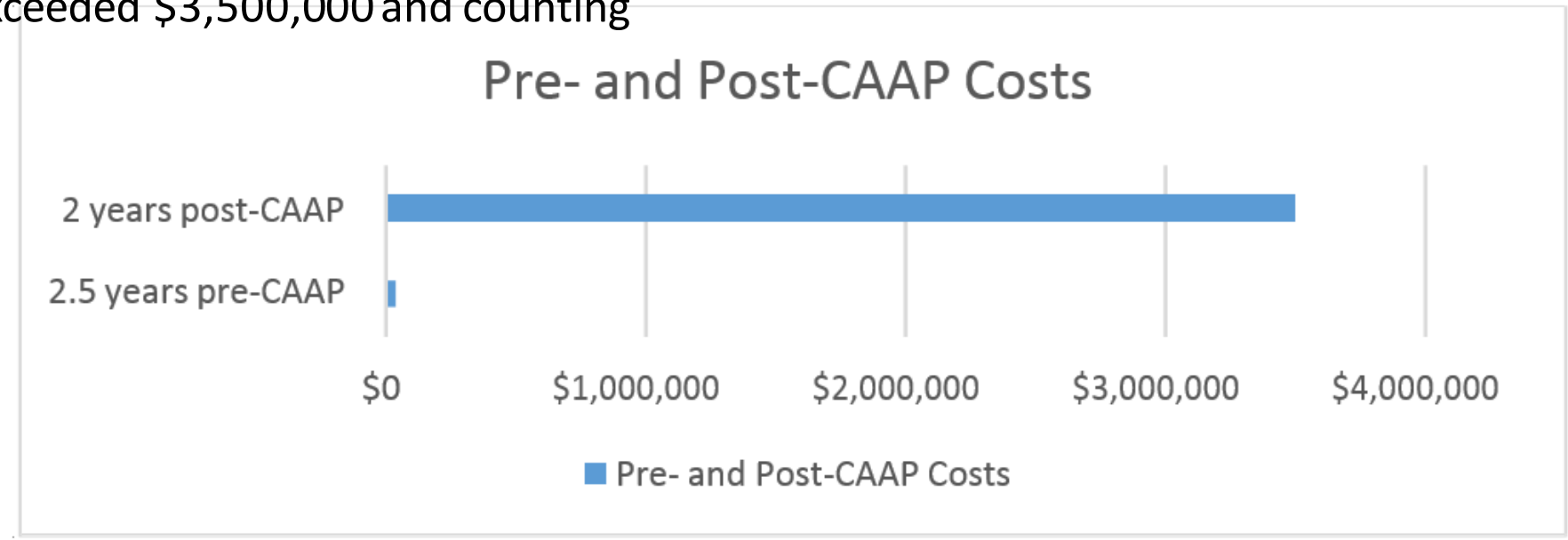
INTERVENTION

- With assistance from NHF and his wife's tenacity the patient finally received his clotting factor
  - As a result of multiple unresolved bleeds, patient developed what is known as a target joint in his knee and hip area.
  - Prior to the implementation of the CAAP program, his mild diagnosis required him to only infuse clotting factor replacement when he experienced bleeds, known as on demand, which in his case was no more than 5 times a year.
  - After experiencing prolonged untreated bleeds, the patient is left with permanent arthropathy, continued bleeding in his target joints, and went from rarely requiring clotting factor infusions to regular high dose infusions to manage bleeds and resulting pain
  - The patient was hospitalized multiple times, required a surgery, and is currently wheel chair dependent because weight bearing to painful

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



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Panel Discussion

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Summary

- These cases exemplify the importance of expert, multidisciplinary management offered by the rare disease COE model
- In addition to cost savings achieved through optimal medical management, some HTCs may offer additional savings through reduced per-unit pricing and rigorous assay management
- Special case scenarios, such as the use of innovative technology and the avoidance of harmful CAAP programs, are other situations in which a total cost of care strategy demonstrates value

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Question and Answer Session

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Closing Comments

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