

The Changing Economics of Allergy Immunotherapy

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American
College
of Allergy, Asthma
& Immunology

LEARNING OBJECTIVES

- Verbalizes the challenges allergist face regarding payment for allergy extracts
- Explain why cost comparisons of extracts are difficult
- Verbalize the role PBM's play.

The Advocacy Council is like
air-conditioning on a hot
summer day - only missed if
we're not working!



The Advocacy Council Today: Who Are We?

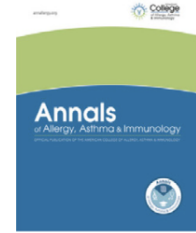


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Contents lists available at [ScienceDirect](#)



Perspective

The future of health care A look forward for the allergist

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Healthcare- A Look Forward....



Cost comparisons are difficult



- We all pay different amounts for our extracts
- We are all paid differently by commercial insurance companies
- We all mix extracts differently
- A medical procedure may be profitable in some parts of the USA, and not in others
- Since Medicare is a national plan, you would think it would be a good basis for comparison
- Private insurance payment rates are often pegged to Medicare

What is a (or is the) GPCI??



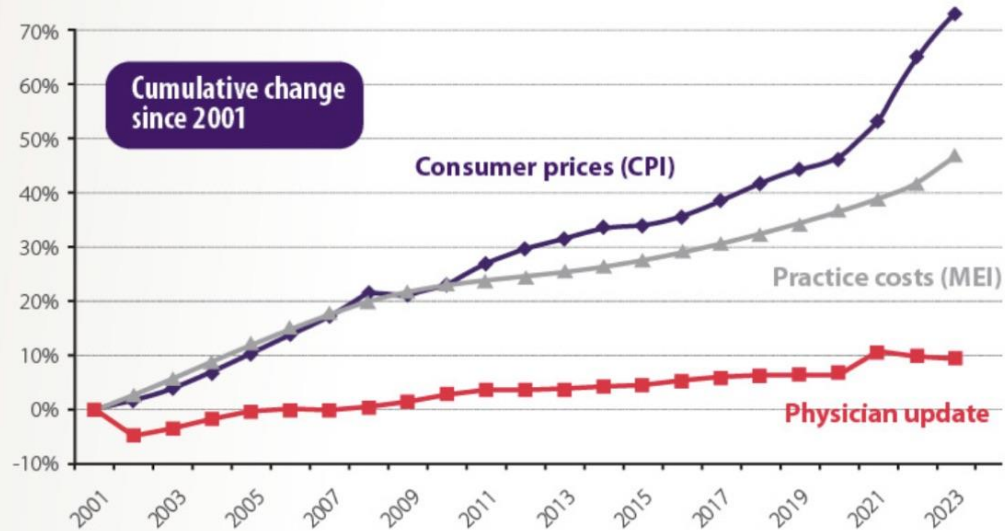
- Medicare's Geographic Practice Cost Index
- What does it mean for us?
- The GPCI has been established in 1989 for every Medicare payment locality for each of the three components RVU components.
- The GPCIs are applied in the calculation of a Medicare payment schedule amount by multiplying the RVU for each component times the GPCI for that component.
- Creates significant disparities in payments



Medicare physician payment is NOT keeping up with inflation.

Medicare updates compared to inflation (2001–2023)

Adjusted for inflation in practice costs, Medicare physician payment declined 26% from 2001 to 2023.

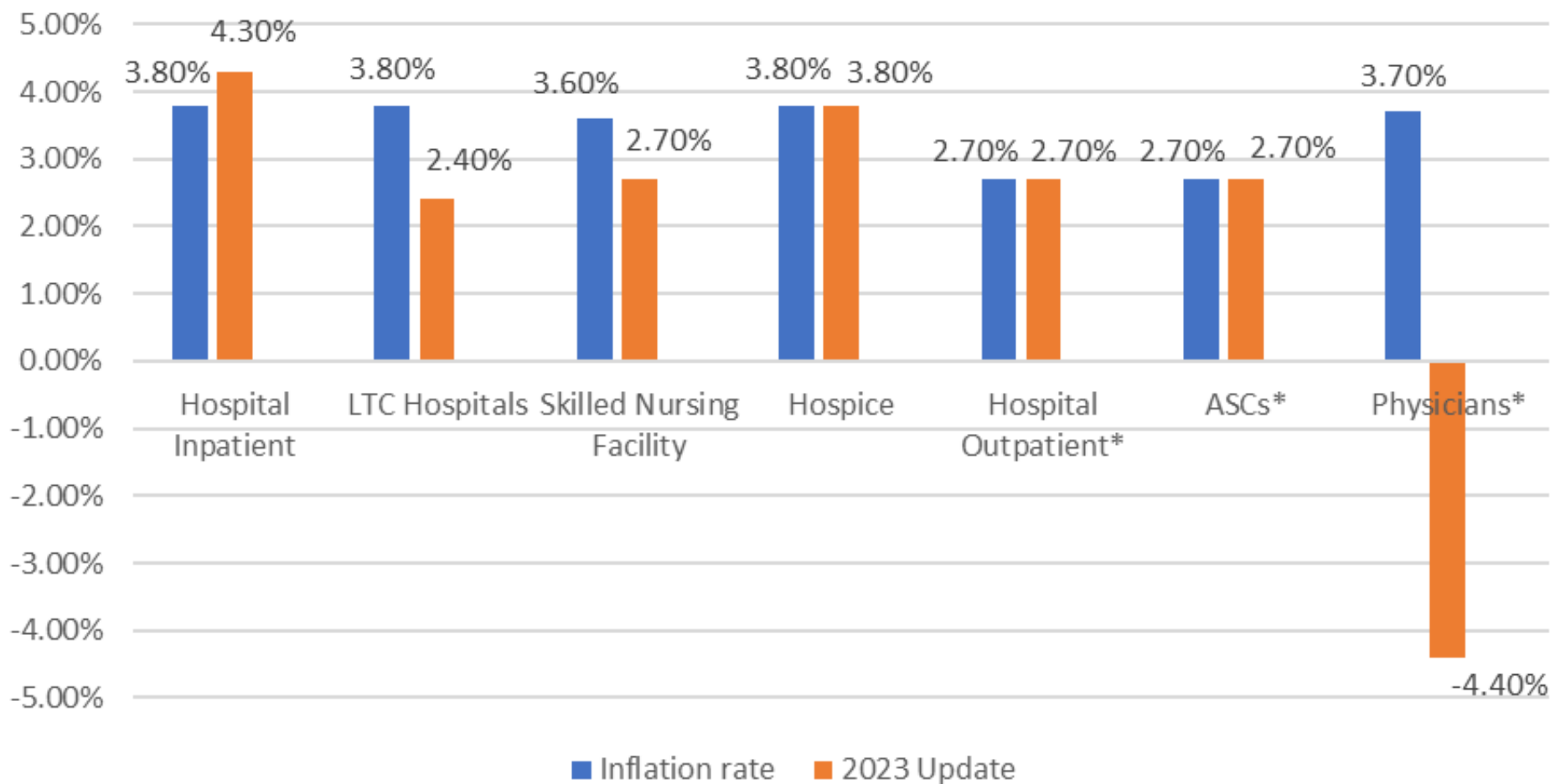


Sources: Federal Register, Medicare Trustees' Reports, Bureau of Labor Statistics, Congressional Budget Office.

Updated April 2023

We need to fix Medicare physician payment NOW.

Medicare Provider Updates for 2023



What does an extract cost?

- Comparison based on list prices from leading manufacturer 2024 of 50 ml bottle
 - Cat 10K BAU \$2070
 - Mite Mix 5K AU of each \$2184
 - Pollen 1:20 \$910
-
- So, a 5ml bottle of concentrated extract has up to \$218 -\$91

What does Medicare Pay?

- Only pays for concentrate vial, no dilutions
- Pays by the ml, not the “dose”
- Average base price per ml is \$17.68
 - Effected by the GPCI and annual conversion factor
 - Combines the facility and non-facility price
- Base payment is \$88.40
- It appears we are loosing money on extracts.

Venom Supply Issues

- ALK announced March 1, 2018, leaving the venom market
 - After October 2016 announcement of supply problems
- Venom Immunotherapy Codes for 2017
 - Increased 16%-39% for 2017 - phased-in over the next 4-years
 - AC work in submitting invoices
 - Done prior to the current shortage & price increases
- Receipts submitted in 2018 were insufficient to justify additional increases.
 - Still monitoring and will request change in RVU when justified.
- Venom antigens (95145-95149) increase by 9-12% in 2019 (& 2020) direct contact with CMS
- Annals published perspective article in 2019
- Medicare base payment indexed closely to average acquisition price
- Geographic Practice Cost Index (GPCI)
 - Some make money, some break even, some lose money.



Know your costs



- Know what you are paying for extracts
- Know what you are being paid for extracts
- Factors driving increased cost
 - USP
 - Medical Inflation
 - Audits on 95165 and 95117

USP Chapter 797 revision



- **Allergen extract is restored as a separate section of the proposed chapter**
 - **Section 21 – available in the Allergen Extract Mixing Toolkit - college.acaai.org/extract**
- **Confirmed previous allergen extract compounding requirements**
 - Personnel training and evaluation.
 - Hygiene and garbing.
 - Updated documentation requirements.
- **Options**
 - Dedicated Allergenic Extracts Compounding Area (AECA) or Primary Engineering Control (PEC)

The regulations regarding Allergen Extracts are NOT the same as the regulations for CSP 1 and 2
- **BUD (by use date) remains 12 months**



USP: Allergenic Extracts Compounding Area (AECA)



- **The requirements for an AECA include:**
 - Dedicated area
 - No carpeting
 - Impervious surfaces
 - No outside doors or openable windows
 - A visible perimeter
 - Additional reasonable expectations for sterile compounding in the physician office
- **Documentation requirements for:**
 - Compounding procedures
 - Temperature logs for refrigeration
 - Prescription set documentation
- ***Laminar flow hood is not required***



Key points of the USP Chapter 797 revision



- Compounding staff will be required to be trained and regularly evaluated on aseptic and compounding technique (mostly reflecting existing requirements)
- Additional requirements
 - Fingertip testing
 - Thumb sampling
- BUD (by use date) remains 12 months
- Large compounders may oppose our separate section
- What happens if I don't participate in USP?



Our Allergen Extract Mixing toolkit - everything you need to implement the new USP 797 rule!

college.acaai.org/extract



- Step by step guides
- Staff competency assessments
- How to implement the new standards webinar
- Allergen Extract Quiz
- FAQs, logs, forms and more



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Main drivers of expense in our health care delivery system



Technological advances in medicine

Rising cost of health care

Rising Cost of Health Care vs Shifting Health Care



The only year over year comparisons we have in health care are from the aggregators:

- Health insurance companies
- Government payers
- Employers

When policy makers discuss lowering the cost of health care, they are really discussing on lowering how much the aggregators spend on health care.

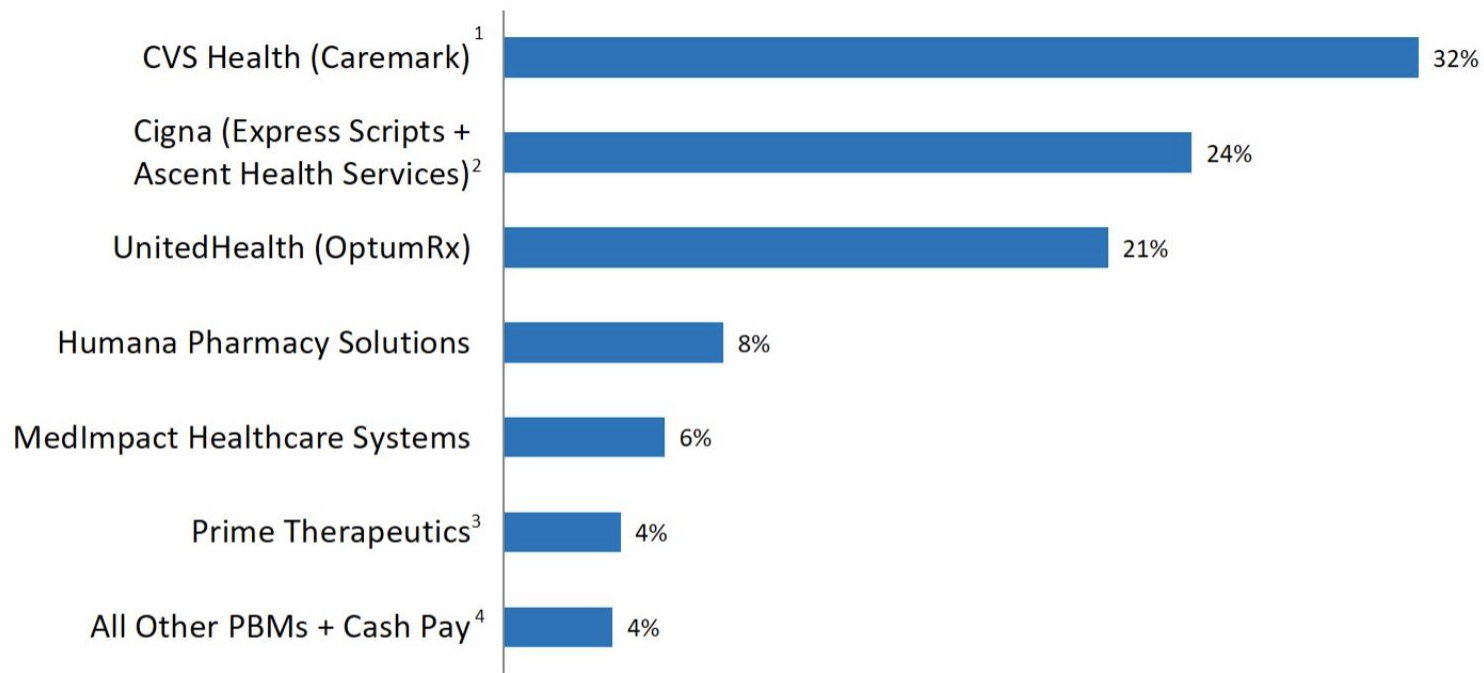
		REMOVE ✕	REMOVE ✕	REMOVE ✕	REMOVE ✕	REMOVE ✕	REMOVE ✕	REMOVE ✕	REMOVE ✕	REMOVE ✕
RANK ^	NAME	REVENUES (\$M)	REVENUE PERCENT CHANGE	PROFITS (\$M)	PROFITS PERCENT CHANGE	ASSETS (\$M)	MARKET VALUE — AS OF MARCH 31, 2021 (\$M)	CHANGE IN RANK (FULL 1000)	EMPLOYEES	CHANGE IN RANK (500 ONLY)
4	CVS Health	\$268,706	4.6%	\$7,179	8.2%	\$230,715	\$98,653.2	1	256,500	1
5	UnitedHealth Group	\$257,141	6.2%	\$15,403	11.3%	\$197,289	\$351,725	2	330,000	2
7	McKesson	\$231,051	7.8%	\$900	2547.1%	\$61,247	\$31,044	1	70,000	1
8	AmerisourceBergen	\$189,893.9	5.7%	\$-3,408.7	-498.5%	\$44,274.8	\$24,169.7	2	21,500	2
13	Cigna	\$160,401	4.5%	\$8,458	65.7%	\$155,451	\$83,976.1	-	72,963	-
14	Cardinal Health	\$152,922	5.1%	\$-3,696	-371.2%	\$40,766	\$17,840.3	2	48,000	2
23	Anthem	\$121,867	16.9%	\$4,572	-4.9%	\$86,615	\$87,908.9	6	83,400	6
24	Centene	\$111,115	48.9%	\$1,808	36.9%	\$68,719	\$37,169.6	18	71,300	18
36	Johnson & Johnson	\$82,584	0.6%	\$14,714	-2.7%	\$174,894	\$432,685.3	-1	134,500	-1
41	Humana	\$77,155	18.9%	\$3,367	24.4%	\$34,969	\$54,087.7	11	48,700	11



ANTHEM EARNINGS: OPERATING REVENUE JUMPED \$4B DUE TO INGENIORX REVENUES

- Despite the domestic spread of the coronavirus disease 2019 (COVID-19) during Q2 2020, Anthem Inc. reported an operating revenue of \$29.2 billion, an increase of \$4 billion largely attributed to success of IngenioRx.
- The company's pharmacy benefit manager recorded an operating gain of \$300 million during Q2 and an operating revenue of more than \$5.2 billion.

PBM Market Share, by Total Equivalent Prescription Claims Managed, 2020



1. Excludes Drug Channels Institute estimates of double-counted network claims for mail choice claims filled at CVS retail pharmacies.

2. Includes Cigna claims, which fully transitioned to Express Scripts by the end of 2020. Includes Ascent Health Services, which includes Kroger Prescription Plans and a partial year of Prime Therapeutics.

3. Excludes Drug Channels Institute estimates of 2020 claims for which Ascent Health Services handled rebate negotiations and pharmacy network contracting.

4. Figure includes some cash pay prescriptions that use a discount card processed by one of the 6 PBMs shown on the chart.

Source: [The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Drug Channels Institute, Exhibit 92. Total equivalent prescription claims includes claims at a PBM's network pharmacies plus prescriptions filled by a PBM's mail and specialty pharmacies. Includes discount card claims. Note that figures may not be comparable with those of previous reports due to changes in publicly reported figures of equivalent prescription claims. Total may not sum due to rounding.

Impact on Allergy

- Dramatic increase in audits of our codes – especially 95165.
- Application of Medicare MUE (limits per day) along with yearly limits.
- **Excessive requests for medical records**
- Application of limits on skin testing.
- Auditing allergy injections.
- PBMs increasingly flexing their muscles – influencing movement of biologics into Medicare Part D.
- Medical director often “Siloed out of decision making”.

Restrictions on 95165: Allergy Extracts



- CPT definition - Professional services for the supervision (*incident to*) of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
- Because of increased utilization (not necessarily by allergist or ENT) third party payers have annual caps on the number doses (e.g., 120)
- July 2016, Medicare began making public their MUE's (Medically Unlikely Edits)
 - 95165 is 30 doses per day.
 - Medicare does not follow the CPT definition, instead defines a dose as 1ml.
 - Does not pay for diluted vials made from the concentrated vial.

Restrictions on 95165: Allergy Extracts



- Many state Medicaid and some private payers have adopted the CMS policies.
 - Occurred after ACA when they became aware of CMS' rules by their involvement in running the Medicaid State Exchanges and Medicare Advantage plans.
- Cigna & Aetna nationally raised the annual limit to 150 after AC contacted them.
- The AC has helped individual practices/state societies advocate for 160 -170 doses.
- UHC's Optum360 sells artificial intelligence (AI) auditing services to multiple MCOs including Medicare Advantage & Medicaid Plans.

What is Optum?



Explore what Optum has to offer

Optum Care

Optum Care is a family of 60,000 doctors in 2,000 locations nationwide. We work together to help 20+ million people live healthier lives.

[Learn more >](#)

Optum Financial

Transforming how care is financed and paid for, accelerating a healthier future for all.

[Learn more >](#)

Optum Rx

We help people take charge of managing and ordering their medications to get the most out of their prescription benefits.

[Learn more >](#)



\$30B

Roughly \$30 billion in annual health plan and employer savings through Optum Payment Integrity Solutions.



No. 1

Optum Financial is the No. 1 HSA provider in the U.S.



130M

We empower over 130 million people to live healthier lives.



\$6.4B

\$6.4B invested annually in technology and innovation.



1.3B+

1.3 billion prescriptions filled through Optum Rx.



3.5M+

Over 3.5 million Veterans and Military service members served.



Pre-pay solutions

Click the toggles below to learn more about the value levers that you can take advantage of throughout the claims lifecycle to reduce costs and improve relationships.



Claim editing

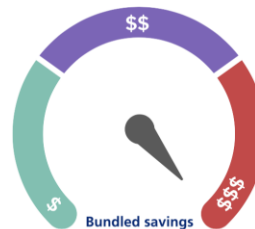
Claim pricing

Claim coding – Specialty drugs

COB avoidance

Provider education

Claim review



\$7B+

generated in annual savings for health plans with Optum cost-avoidance and



Optum

Realize cost savings with our payment integrity solutions.

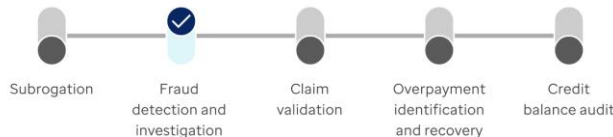
To meet cost-reduction goals, health plans need to:

- Improve payment integrity
- Prevent fraud, waste and abuse
- Increase focus on third-party liability
- Improve administrative efficiency



Post-pay solutions

Click the toggles below to learn more about the value levers that you can take advantage of throughout the claims lifecycle to reduce costs and improve relationships.



Subrogation

Fraud detection and investigation

Claim validation

Overpayment identification and recovery

Credit balance audit



Fraud detection and investigation

To maximize the detection of suspect claims, health plans need a comprehensive approach to identifying and auditing fraud, waste and abuse. Through the use of solutions like advanced detection analytics, provider education and case management, health plans can decrease provider abrasion while increasing the recovery of improper payments.



What is an Allergist to do???



- Document everything!
 - Emails, letters, phone calls – date, time and name of person to whom you spoke
- Get the guidelines in writing.
- Ask exactly what they are expecting to be documented.
 - Not one size fits all or shotgun approach
 - Up to 8 data points for an allergy injection
- They often “move the goal post” after you “kick”
- Webinar - Everything you wanted to know about CPT 95165 - <https://bit.ly/2KjN187>
- Correct Documentation Helps Reduce Denials - <https://education.acaai.org/correct-documentation>
- Hire an experienced health care attorney
- New Consensus Statement from allergy organizations
- Looking at a more “global” approach
 - Similar to DASH

Profitable Options Many Allergists are Providing



- **Oral Immunotherapy (OIT) for food allergy**
 - ACAAI webinar on coding for approved product - <https://college.acaaai.org/new-oit-coding-recommendations/>
- **Integrative Medicine**
 - ACAAI committee on the topic
- **Off-label Sublingual Immunotherapy (SLIT) drops**
 - An on-label product has gained little traction in the USA
 - Wide perception it competes with SCIT.
- **These all share common benefits and drawbacks**
 - High public demand
 - Services & goods purchased outside of insurance; bigger mark up than service covered by insurance
 - Relative lack of peer reviewed evidence of efficacy
 - Generally, consider safe
- **Are these options that many of us will select?**

Step Therapy & PA Issues



- Advocacy Council joined a coalition that includes several physician and patient organizations in supporting both Federal and state legislation designed to address step therapy issues.
- Many states have enacted legislation that promises to restrict the ability of insurers to impose unreasonable step therapy requirements.
- Close alliance with AfPA

Questions?



THANK YOU!



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The College's vision helps you navigate the future.

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