

A New Sphere of Influence: Formulary Strategies for Ultra-High-Cost Drugs and Cell/Gene Therapies (CGT)

30

YEARS

Introduction

Meet The Faculty

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 - University of Utah Health

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 - System Pharmacy Manager, Formulary and Drug Policy
 - University Hospitals Health System

Relevant Financial Relationship Disclosure

- No one in control of the content of this activity has a relevant financial relationship (RFR) with an ineligible company.
- As defined by the Standards of Integrity and Independence in Accredited Continuing Education definition of an ineligible company.

Learning Objectives

- Recommend which key organizational stakeholders are necessary for the implementation of ultra-high-cost and cell/gene therapies.
- Identify necessary resources and staff training for effective management of the rapidly evolving pipeline of high-cost therapies.

Outline

- Background (15 minutes)
- Case #1 (25 minutes)
- Additional background (15 minutes)
- Case #2 (25 minutes)
- Key take-aways (10 minutes)

Polling Slide

Has your organization implemented an ultra-high cost drug?

- A. Yes
- B. No

Polling Slide

Does your organization have a high-cost/similar committee?

- A. Yes
- B. No

What worries you about implementing ultra-high-cost drugs?

A word cloud turns open-text responses into a cloud of words whose size will depend on how many times they have been submitted by participants.

What words would you use to describe modern poetry?

A word cloud visualization showing the most common words used to describe modern poetry. The words are arranged in a cluster, with 'emotional' being the largest and most prominent. Other significant words include 'interesting', 'lyrical', and 'confessional'. Smaller words include 'objective', 'poignant', 'real', and 'humanistic'.

objective
poignant
lyrical
confessional
interesting
real
emotional
humanistic

Word clouds work best visually with short answers so advise your participants to use one to three words when using the word cloud to get the best results.

Background

Background

What do we call these products? (Definitions)

- Ultra high-cost (what is the number?)
- High-coordination (“invisible work”)

Example

- Example: Highly coordinated cell/gene therapy requiring multidisciplinary preparation, contracting (e.g. site, payor), implementation, clinical and financial monitoring in addition to the normal formulary process

Landscape

- PELA conference – new paradigm of ultra high-cost therapy
- Summit @ Pharmacy Futures
- Chief Pharmacy Leaders Consortium
- Vizient Cell, Gene & Specialty pharmacy symposium
- 30 cell/gene therapies on market
- Many products in the pipeline for gene therapy (clinical trial monitoring)

Global Status	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024
Preclinical	1,528	1,471	1,436	1,393	1,424
Phase I	270	301	314	318	341
Phase II	274	282	279	289	306
Phase III	33	35	34	35	35
Pre-registration	6	4	5	6	11
Total	2,111	2,093	2,068	2,041	2,117

Pipeline information used with permission from ManagedHealthcareExecutive.

- <https://www.ashp.org/-/media/assets/about-ashp/docs/PELA/ASHP-PELA-Virtual-Strategic-Directions-System-PT-Drug-Policy-High-Cost-Drugs-Whitepaper.pdf>
- Current FDA approvals for cell/gene therapy <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>
- <https://www.managedhealthcareexecutive.com/view/gene-therapy-s-pipeline-has-a-steady-flow-of-more-than-2-000-candidates>
- <https://www.vizientinc.com/newsroom/news-releases/2025/vizient-hosts-2025-cell-gene-and-specialty-pharmacy-symposium-to-advance-patient-care>
- <https://hmacademy.com/calendar>

Best practices

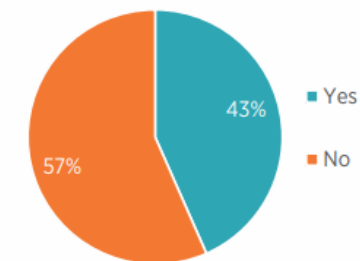
- Utilize formulary Pharmacy & Therapeutics process for evaluation and implementation
 - Intentionally connect teams for planning and discussion (avoid disparate discussion)
 - Multidisciplinary engagement
 - Site of care optimization
 - Assessing documentation/reporting abilities
 - Executive engagement
- Addressing areas that do not conform:
 - Site of care
 - Financial monitoring
 - Contracting for the site
 - Contracting for the drug
 - Contracting for payors by patient
 - Capacity (space to treat as well as financial)
 - Clinical monitoring

DOMAIN #5: THE NEW PARADIGM OF ULTRA-HIGH-COST THERAPIES

Most breakout participants are developing new processes or committee structures to manage and monitor ultra-high-cost drugs. Just over half of post-event survey respondents indicated that they had developed a separate committee for high-cost drugs (Figure 3). One organization created a separate cost center for ultra-high-cost drugs to separate the expenses from normal pharmacy business. (The response did not state whether separate personnel expenses were also associated with that cost center.) Thresholds defining ultra-high cost varied greatly across sites, and established thresholds changed over time or in certain situations. Organizational investment in infrastructure that ensures fiscal responsibility seems practical, given the substantial cost impact of these therapies. At some organizations, a separate committee evaluates specific requests for mega- or ultra-high-cost drugs to determine the feasibility and sustainability of the request, allowing for more timely, informed decisions. Two examples included the high-value-drug review” and CAR-T committees. In the absence of a formalized committee, high-cost drug assessments are often made on a case-by-case basis involving physicians and pharmacy personnel.

FIGURE 3

Do you have a committee(s) established to manage high-cost drugs at your organization?
(n=53)



Key Takeaways

- Engage the revenue cycle team to actively review claim denials and cash flow and to identify opportunities for improvement, particularly for ultra-high-cost drugs.
- Engage the informatics team to build functionality into the EHR that facilitates the prior authorization process.
- Build collaborative processes to proactively review drug requests and ensure timely access for patients.
- Consider establishing committees with the necessary expertise (clinicians, pharmacists, data/informatics, revenue cycle) to review ultra-high-cost drugs.
- Create communication mechanisms that keep senior leadership informed about the impact of ultra-high-cost drugs (positive or negative) and new roles for pharmacy.

The “invisible” work

- What is invisible work?
 - The work pharmacy takes on to get something done. Usually not resourced or anticipated.
 - What are you not doing to accomplish this visible work? Is this level of work sustainable or scalable?
- Products likely to require high amounts of invisible work generally have one or more of the following:
 - Multidisciplinary (multiple meetings required to onboard a single product)
 - Extensive preparation requirements
 - Contracting (to purchase AND to administer)
 - REMS
 - Clinical and financial monitoring

• <https://pubmed.ncbi.nlm.nih.gov/39828495/>

“Usual” process for new drugs



Clinical trials



FDA approval



P&T review, approval,
implementation



Contracting

High coordination medications break the “usual” process



Clinical trials,
Initial site
contracting
discussions



FDA approval



Executive
engagement,
capacity, etc

Site Contracting



Review
(Multiple levels
including P&T)

Drug
contracting



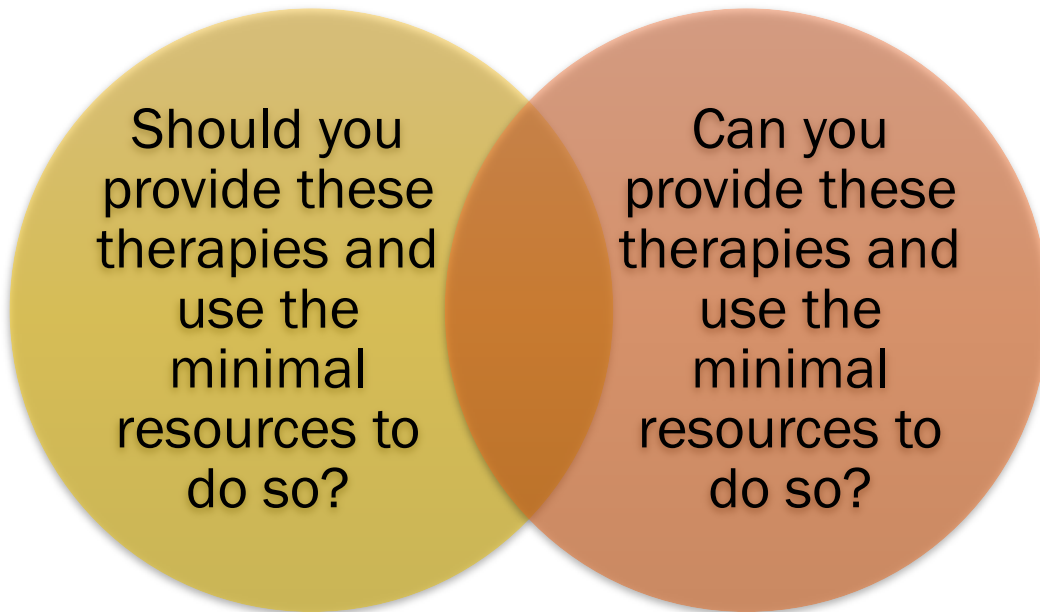
Normal
implementation
and

Specific patient
workflow
implementation



Monitoring
clinical and
financial
outcomes

Should vs. Can (ideally first step)



- Does your organization have infrastructure to decide “should” you offer a treatment vs. “can”?
- If every treatment is “can” you will run out of resources quickly
- Do you have the resources to absorb the invisible work?
- How are thresholds defined?
- If you are not adding resources – what work are you stopping?
- If you have started providing a product, when/if does provision stop?

Case #1

Think/pair/share – Case #1: Organizational gap analysis – Infrastructure and stakeholders

Infrastructure

- Review infrastructure questions for your organization

Stakeholder analysis

- Consider the questions for the example stakeholder groups listed

Share with
your group

Debrief after
15-20
minutes

Based on the first case, what did you find surprising in your organization's analysis?

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lyrical
confessional
objective
interesting
poignant
real
emotional
humanistic

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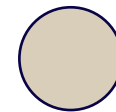
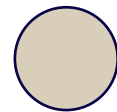
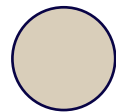
Additional background

University of Utah Health

■ Structure and Timeline

10/2023

New formulary status category “High Coordination”



4/2024

First meeting, Charter Oncology Strategic Oversight Committee (System P&T subcommittee)

8/2025

Scope changed for all therapies, not just Oncology

Co-Chairs:

- System Chief Medical Operations Officer
- Oncology Chief Clinical Officer

Members:

- Heme/Onc providers
- Pharmacy leadership
- Nursing leadership
- System contracting
- System finance
- System RCSS
- Ad-hoc providers based on product discussion

Key Areas before “yes”

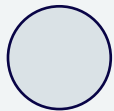
- Technically feasible
- Makes sense for our patients
- SCAs / financial

University Hospitals

■ Structure and Timeline

2024

New High cost drug/therapy subcommittee and scope (in tandem with P&T)



2025

- Additional drug planning
- Procedure
- Executive engagement
- Business planning



First high cost drug administration with new process
Aug 2024



Stakeholders:

- Clinical team provider
- Finance
- Revenue Cycle
- Managed Care
- Pharmacy (340b, IT, Operations, Supply Chain, Specialty, Formulary)
- Nursing leadership
- Legal
- Cellular lab
- Employee health plan
- Patient access
- Ethics

Key Areas before “yes”

- Difference between drug implementation and patient implementation

University Hospitals Experience

What worked well?

Two medications implemented

Multidisciplinary engagement

C-suite connectivity

Procedure

Business planning connectivity

What didn't?

Confusion on pharmacy involvement (Are these drugs?)

Epic needs from pharmacy (charging)

Clear expectations for single case agreements

Documentation of steps and needs

Should vs can (at first!)

Case #2



Think/pair/share- Case #2: Identifying necessary resources

Background:

- Hepzato
 - High dose melphalan delivered directly to liver for uveal melanoma
 - Must prepare and deliver melphalan in short window
 - Requires interventional radiology, anesthesia, perfusionist in same room x 2 +h
- Lovotibeglogene autotemcel (Lyfgenia)
 - Cell/gene therapy in sickle cell disease
 - Several conditioning steps required prior to administration
 - Multiple bags of cells/one dose

Asks:

- Consider the various questions in the case and building off your learnings from case 1 for one of the medications.

Debrief after 15-20 minutes

Think/pair/share- Case #2: Identifying necessary resources

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Case 2 questions

Review of what occurred (Debrief):

- Hepzato
 - Should vs. can
 - EMR needs
 - Location
 - Timing, which service line admits / follows?
 - Equipment storage
 - Contracting
- Lyfgenia
 - EMR needs
 - Capacity
 - Contracting by site and drug
 - Should vs can
 - Intentional connectivity

Based on the second case, did you identify a gap that you didn't think of in case 1?

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poignant
lyrical
confessional
interesting
real
emotional
humanistic

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Conclusion

Now let's get to work!

What structures
and decisions
might you need
to address?

What are your
next step
marching
orders?

Learnings from
the day

Key Takeaways

1. **Ultra-high-cost drugs are resource intensive** (*Are you ready for more invisible work?*).
2. **Strong connections within your organization are imperative for success** (*Have you made these connections?*).
3. **Structure with organizational stakeholders and engagement around the evolving pipeline are necessary for implementation** (*Does your organization have a plan?*).

QUESTIONS?