

Development and Implementation of a System-wide Process for High Value (Advanced) Therapeutics

Matt Rim, PharmD, MS, FASHP

Chief Pharmacy Officer, Northwestern Medicine

Brittany Karas, PharmD, BCPS

Medication-Use Policy Program Manager, Northwestern Medicine



2026 ICHP Annual Meeting

Statement of Disclosure

- The speakers no conflicts of interest with ineligible companies to disclose.



Objectives

- Describe emerging trends and challenges associated with high-value (advanced) therapeutics in health-system practice.
- Identify key components of a standardized, system-wide framework for evaluating, implementing, and monitoring advanced therapeutics.
- Discuss the role of multidisciplinary governance and stakeholder collaboration in supporting safe, timely, and sustainable adoption of advanced therapeutics.



2026 ICHP Annual Meeting

Advanced Therapeutics



- Cell and Gene therapies are moving from experimental medicine to routine care
- Initial approvals focused on hematology malignancies and rare diseases
- Pipeline is rapidly expanding into many different diseases
- Health systems prepare for infrastructure and processes

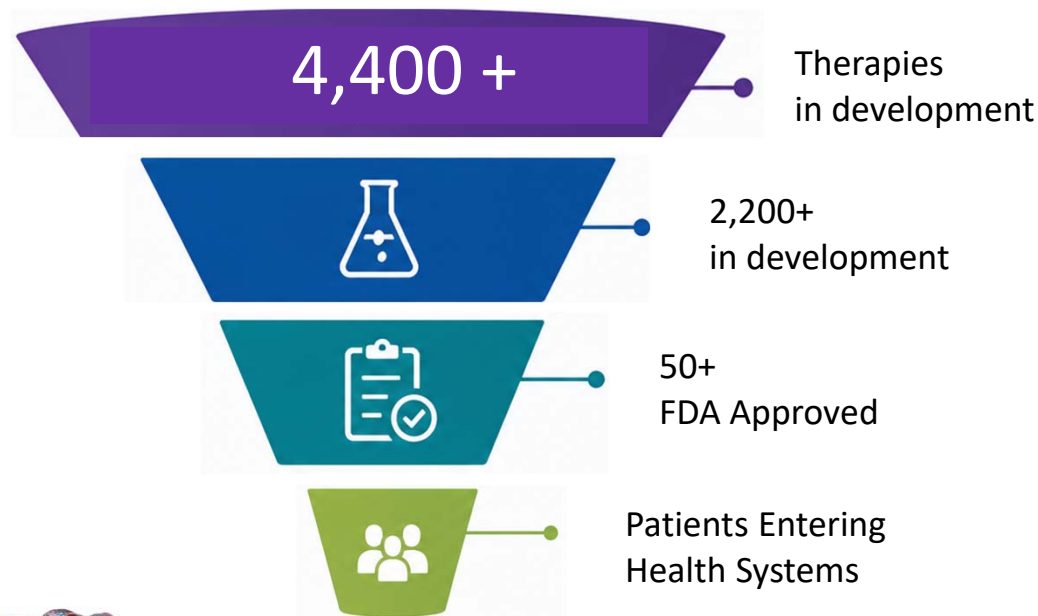
No longer “future medicine” – They are today’s strategic priority



2026 ICHP Annual Meeting

Cell and Gene Therapies Pipeline

The pipeline of cell and gene therapies continue to expand at an extraordinary pace^{1,2}



Examples of Approved Therapies

- CAR-T cell therapies
- Hemophilia
- Sickle Cell Disease
- Duchenne Muscular Dystrophy
- Retinal diseases

Future Indications

- Autoimmune diseases
- Heart failure
- Parkinson disease
- Type1 Diabetes
- And many more...



2026 ICHP Annual Meeting

1. Gene, Cell & RNA Therapy Landscape Report: Q2 2025 Quarterly Data Report. American Society of Gene +Cell Therapy. <https://www.asgct.org/uploads/files/general/Final-ASGCT-Citeline-Q2-2026.pdf> (accessed July 20, 2026)
2. Approved Cellular and Gene Therapy Products. FDA. <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products> (accessed July 20, 2026)

Drug Pipeline Resource (AJHP)

Recent and anticipated novel drug approvals (Q2 2026 through Q1 2027)



Supplementary material is available with the full text of this article at [AJHP online](#).

Rachel Joseph, PharmD, BCPS, 340B ACE, Northwestern Medicine, Chicago, IL, USA

Michelle Sabbah, PharmD, BCTXP, Northwestern Medicine, Chicago, IL, USA

Farah Barada, PharmD, MBA, DPLA, Northwestern Medicine, Chicago, IL, USA

Khushali Sarnot, PharmD, Northwestern Medicine, Chicago, IL, USA

Andrew M. Levitsky, PharmD, BCPS, IPD, Analytics, Aventura, FL, USA

Purpose: Health-system pharmacists play a crucial role in monitoring the pharmaceutical pipeline to manage formularies, allocate resources, and optimize clinical programs for new therapies. This article aims to support pharmacists by sharing new and anticipated novel drug approvals.

Summary: Selected drug approvals anticipated in the 12-month period covering the second quarter of 2026 through the first quarter of 2027 are reviewed. The analysis emphasizes drugs expected to have significant clinical and financial impact in hospitals and clinics, as selected from among 60 novel drugs awaiting US Food and Drug Administration (FDA) approval. This year's pipeline features novel therapies for various disease states, including rare and inherited genetic disorders and immunologic and inflammatory diseases, and continued advancements in both targeted oncology and gene therapies.

Table 1. Selected Drugs and Biologicals That Have Already or May Receive FDA-Approved Labeling in 2026 and 1Q 2027^a

Drug or biological	Manufacturer	Indication	Route(s)	Type of application	Approval or PDUFA date ^b
Orforglipron	Eli Lilly; Chugai	Obesity	Oral	NDA	Approved Apr 2026
Doravirine/islatravir	Merck & Co (MSD)	HIV-1 infection	Oral	NDA	Approved Apr 2026
Lunsotogene parvec-cw ^a	Regeneron; Decibel Therapeutics	Otoferlin-related hearing loss	Otic injection	BLA	Approved Apr 2026
Bulevirtide	Gilead	Hepatitis D	SC	BLA	Approved May 2026

Joseph R, Sabbah M, Barada F, Sarnot K, Levitsky AM, Rim MH. Recent and anticipated novel drug approvals (Q2 2026 through Q1 2027). *Am J Health-Syst Pharm* 2026; 00:1-11.



2026 ICHP Annual Meeting

Pharmacy is uniquely positioned to lead



Health System Pharmacy

- ✓ Medication-use policy
- ✓ Formulary management
- ✓ Clinical oversight/med safety
- ✓ Pharmacy operations
- ✓ Financial stewardship
- ✓ Procurement
- ✓ Access

Pharmacy brings the expertise, infrastructure, and enterprise view necessary to ensure safe, effective and sustainable access



2026 ICHP Annual Meeting

Preparing Health Systems for Advanced Therapies

How does a health system prepare before the first patient arrives?



1. GOVERNANCE

Establish clear oversight & decision-making frameworks



2. CLINICAL REVIEW

Evaluate clinical evidence and appropriate use



3. FINANCIAL ASSESSMENT

Assess financial impact & risk



4. OPERATIONAL READINESS

Design workflows, care pathways
- Site of care



5. SUPPLY CHAIN

Sourcing, contracting, procuring products



6. REGULATORY COMPLIANCE

Address regulatory compliance details



7. EDUCATION & COMPETENCIES

Develop a plan for staff education



8. MULTIDISCIPLINARY COLLABORATION

Engage stakeholders for buy-in



9. ONGOING OVERSIGHT

Monitor outcomes, safety, access & performance



Create the foundation for a sustainable, high quality & financially responsible advanced therapy program



2026 ICHP Annual Meeting

Survey Results for Advanced Therapies

2024 Vizient Survey on Advanced Therapies

52% of institutions had a designated high-cost committee

21% were under development at time of survey

N = 77 organizations

2024 ASHP Survey on Strategic Directions in High-Cost Drug Management

43% of respondents had established a committee to manage high-cost drugs

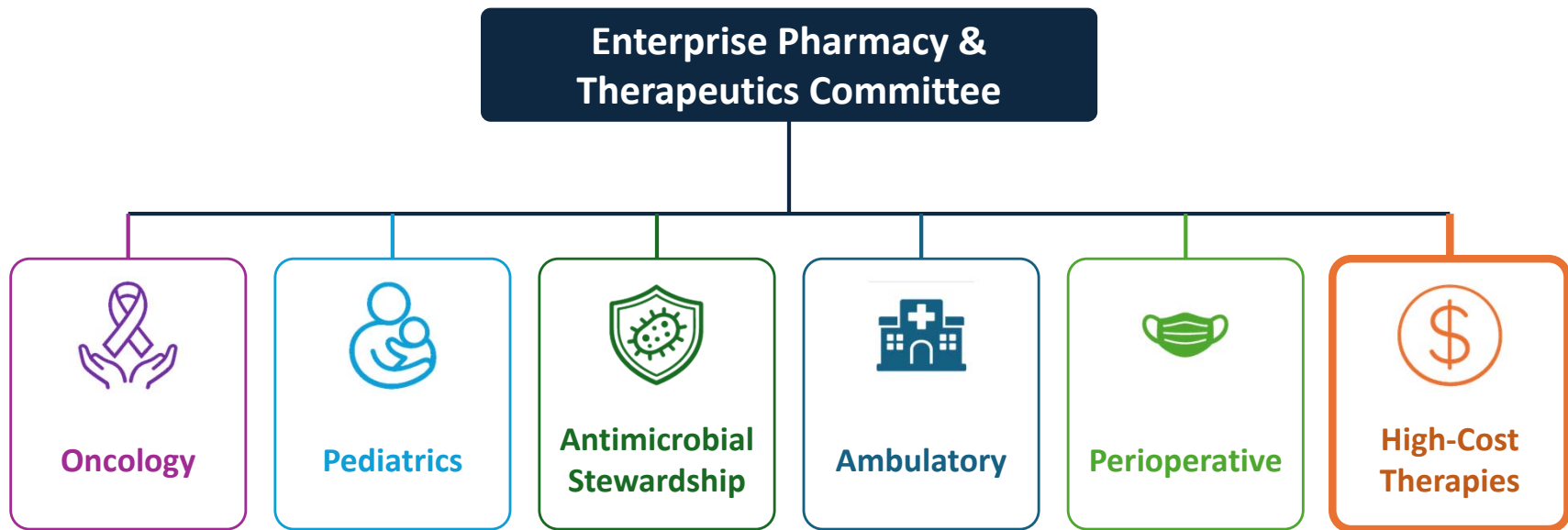
N = 58 individuals



2026 ICHP Annual Meeting

Vizient, Inc. Transforming Medication Management: The Role of Advanced Therapy Committees in Health Systems. Executive summary. Published December 2024. Accessed August 12, 2026
American Society of Health-System Pharmacists. Strategic Directions in System Formulary, Drug Policy, and High-Cost Drug Management: PELA® Virtual Conference Report. Published May 23, 2024. Accessed August 14, 2026

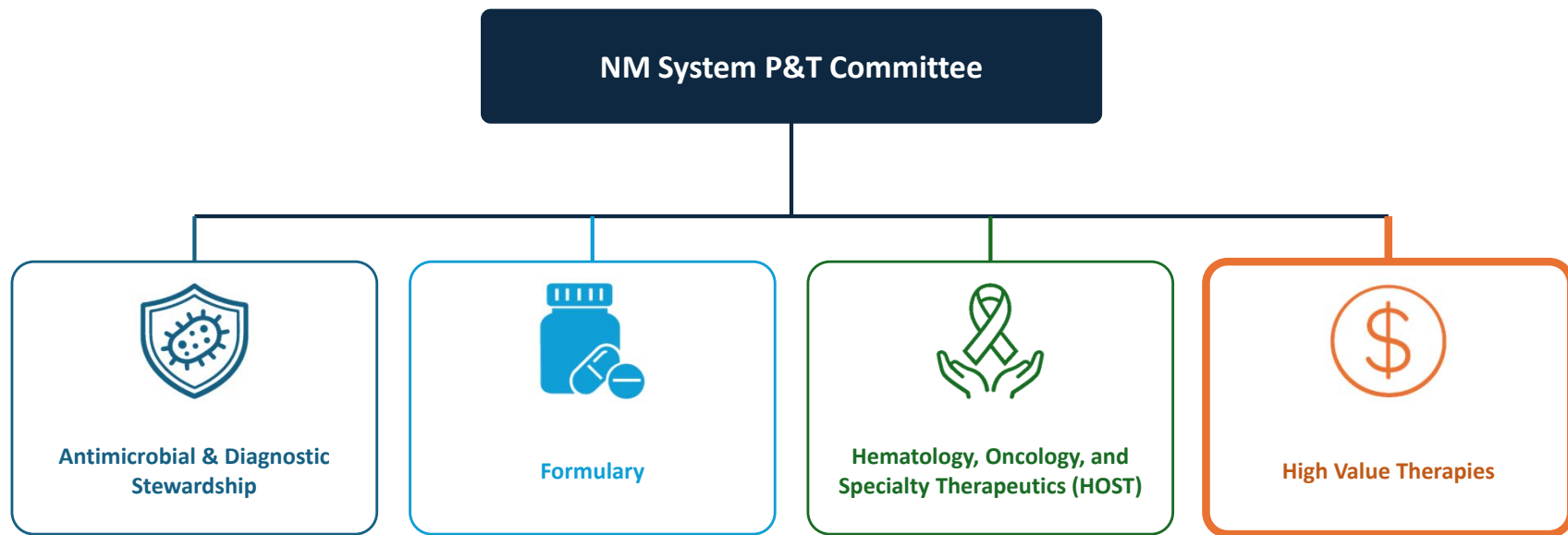
Governance Structures



2026 ICHP Annual Meeting

Vizient Center for Pharmacy Practice Excellence Expert Panel. Enterprise P&T Committee Best Practice Considerations. Vizient, Inc. Published December 2025. Accessed August 12, 2026

NM System P&T Committee Structure



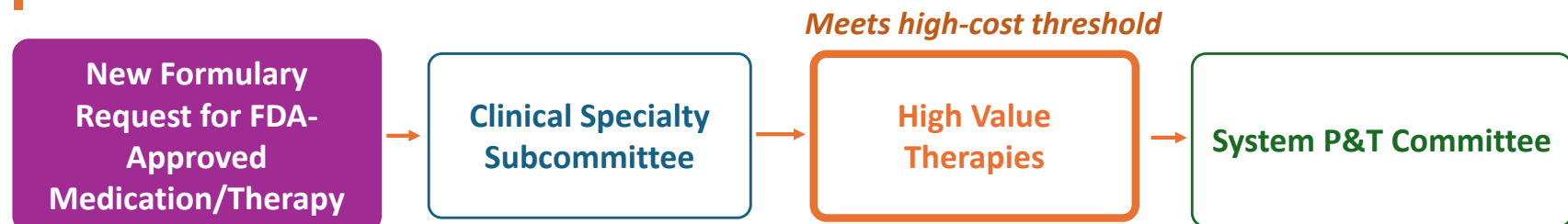
2026 ICHP Annual Meeting

New Formulary Reviews: Two Pathways

STANDARD REVIEW



HIGH-COST REVIEW



2026 ICHP Annual Meeting

Defining High-Cost?

No universal definition

Institutions often arbitrarily select high-cost threshold and should consider reevaluating as necessary

Cost thresholds

- >\$5,000, >\$10,000 per dose
- >\$100,000 per therapy course
- Annual cost to patient
- Annual cost to health system

“High-Coordination”

Complexity of care, not cost alone, can drive committee review

NM High Value Therapy Threshold

Therapies $\geq$ \$10,000 per dose and with an expected budget impact to the organization of >\$1 million annually



American Society of Health-System Pharmacists. Strategic Directions in System Formulary, Drug Policy, and High-Cost Drug Management: PELA® Virtual Conference Report. Published May 23, 2024. Accessed August 14, 2026

2026 ICHP Annual Meeting

NM High Value Therapies Stakeholders

CO-CHAIRS

- Chief Pharmacy Officer
- Associate Director of Clinical Operations, Cancer Center

Physician Leadership

Pharmacy Leadership

Access

Managed Care Contracts
& Payer Relations

Finance

Procurement Services

Pharmacy Strategic
Sourcing

Revenue Assurance

Stem Cell Transplant &
Cell Therapy Operations

Cellular Therapy Lab

Medication-Use Policy



2026 ICHP Annual Meeting

Formulary Evaluation: High Value Therapies

Typical Formulary Review



Efficacy



Safety



Cost / Cost-effectiveness

New High Value Therapies Factors to Consider



Clinical &
Operations



Sourcing &
Procurement



Managed care
contracts



Reimbursement



Revenue Cycle



Site of care



Overall impact to
the organization



2026 ICHP Annual Meeting

Implementation Considerations



Same considerations as new typical formulary medications (eg, Epic build, smart pump)



Gap in the current medication-use process needs to be addressed



Authorized treatment center designation



Individually manufactured therapies have added coordination complexities



Training and education of multidisciplinary staff



2026 ICHP Annual Meeting

Post Implementation and Monitoring

Clinical Review

Similar to post P&T approval reviews for traditional medications

- Utilization and appropriateness
- Safety
- Clinical outcomes

Financial Review (Revenue Cycle)

NEW: continuous, real-time review of financial outcomes

- Improving necessary documentation
- Confirming payment, if applicable
- Follow up on denials



2026 ICHP Annual Meeting

Case Example: Nadofaragene Firadenovec

High-risk, BCG-unresponsive, non-muscle invasive bladder cancer

Gene therapy

Historical P&T review

Met high-value threshold

\$60,900

WAC per dose

\$243,600

Per patient annually

8

Estimated patients per month



2026 ICHP Annual Meeting

ADSTILADRIN (nadofaragene firadenovec-vncg). Package insert. Ferring Pharmaceuticals Inc.; 2026. Accessed August 12, 2026.

Case Example: Nadofaragene Firadenovec



Formulary Evaluation

- More complex preparation than others and biosafety precautions
- Site of care challenges — how to treat patients now and the ideal future state



Implementation

- Training of pharmacy and nursing staff in new identified SOC
- Coordination of pre-certification



Monitoring & Post-Implementation

- Commercial payor challenge requiring site-of-care pivot
- Revenue cycle review of Medicare claims to assure payment
- New complex, high-value therapies requested for similar indication



2026 ICHP Annual Meeting

Audience Question 1

Which best describes the current state of the cell and gene therapy landscape?

- A. More than 50 products are FDA approved, with thousands therapies in the development pipeline
- B. Approvals have plateaued, with fewer than 10 products on the market
- C. The pipeline remains limited to hematologic malignancies and rare diseases
- D. Most products remain investigational with no FDA approvals to date



Audience Question 2

Beyond efficacy, safety, and cost-effectiveness, which additional factors are uniquely evaluated during a high-value therapy review?

- A. Wholesale acquisition cost of the product
- B. Managed care contracts, reimbursement, revenue cycle, and site of care
- C. Prescriber preference and marketing materials
- D. Nothing additional as the criteria are identical to a standard review



2026 ICHP Annual Meeting

Audience Question 3

Why should managed care and revenue cycle partners be engaged before a high-value therapy is approved?

- A. To negotiate the wholesale acquisition cost with the manufacturer
- B. To determine clinical efficacy and safety
- C. To confirm payer coverage, site-of-care requirements, and payment before financial risk is assumed
- D. To provide staff training on administration



2026 ICHP Annual Meeting

Conclusion

An immediate strategic priority

Advanced therapeutics have moved from experimental to routine care, and a rapidly expanding pipeline is bringing more patients into health systems.

A standardized, system-wide framework

A defined high-value threshold and dedicated subcommittee extend formulary review to sourcing, site of care, payors, and revenue cycle.

Governance and continuous monitoring

Multidisciplinary governance with ongoing clinical and financial review after implementation is essential to safe, timely, and sustainable access.



2026 ICHP Annual Meeting

References

1. Gene, Cell & RNA Therapy Landscape Report. Q2 2025 Quarterly Data Report. American Society of Gene +Cell Therapy. Accessed July 20, 2026. <https://www.asgct.org/uploads/files/general/Final-ASGCT-Citeline-Q2-2026.pdf>.
2. Approved Cellular and Gene Therapy Products. FDA. Accessed July 20, 2026. <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>.
3. Joseph R, Sabbah M, Barada F, Sarnot K, Levitsky AM, Rim MH. Recent and anticipated novel drug approvals (Q2 2026 through Q1 2027). *Am J Health-Syst Pharm* 2026; 00:1-11.
4. ASHP Center for Next-Generation Therapeutics. Cell and Gene Therapy. Accessed July 20, 2026. <https://www.ashp.org/pharmacy-practice/resource-centers/ashp-center-for-next-generation-therapeutics/cell-and-gene-therapy>.
5. Vizient, Inc. Transforming Medication Management: The Role of Advanced Therapy Committees in Health Systems. Executive summary. Published December 2024. Accessed August 12, 2026
6. American Society of Health-System Pharmacists. Strategic Directions in System Formulary, Drug Policy, and High-Cost Drug Management: PELA® Virtual Conference Report. Published May 23, 2024. Accessed August 14, 2026.
7. Vizient Center for Pharmacy Practice Excellence Expert Panel. Enterprise P&T Committee Best Practice Considerations. Vizient, Inc. Published December 2025. Accessed August 12, 2026.
8. ADSTILADRIN (nadofaragene firadenovec-vncg). Package insert. Ferring Pharmaceuticals Inc.; 2026. Accessed August 12, 2026.



2026 ICHP Annual Meeting

Development and Implementation of a System-wide Process for High Value (Advanced) Therapeutics

Matt Rim, PharmD, MS, FASHP

Chief Pharmacy Officer, Northwestern Medicine

Brittany Karas, PharmD, BCPS

Medication-Use Policy Program Manager, Northwestern Medicine



2026 ICHP Annual Meeting