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

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Statement of Disclosure

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

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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.

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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

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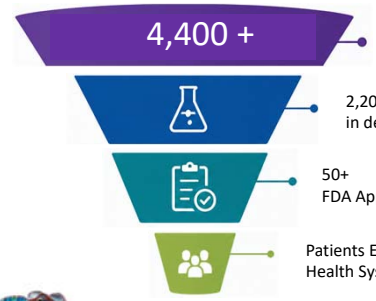
Cell and Gene Therapies Pipeline

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…

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)

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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.

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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-cwha[c]	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.

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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

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Preparing Health Systems for Advanced Therapies

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

1. GOVERNANCE	2. CLINICAL REVIEW	3. FINANCIAL ASSESSMENT	4. OPERATIONAL READINESS	5. SUPPLY CHAIN	6. REGULATORY COMPLIANCE	7. EDUCATION & COMPETENCIES	8. MULTIDISCIPLINARY COLLABORATION	9. ONGOING OVERSIGHT
Establish clear oversight & decision-making frameworks	Evaluate clinical evidence and appropriate use	Assess financial impact & risk	Design workflows, care pathways - Site of care	Sourcing, contracting, procuring products	Address regulatory compliance details	Develop a plan for staff education	Engage stakeholders for buy-in	Monitor outcomes, safety, access & performance

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

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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

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

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Governance Structures

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

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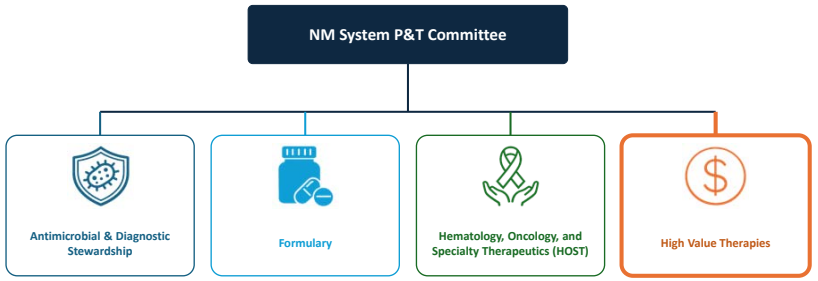
NM System P&T Committee Structure



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New Formulary Reviews: Two Pathways

STANDARD REVIEW

New Formulary Request for FDA-Approved Medication/Therapy → Clinical Specialty Subcommittee → System P&T Committee

HIGH-COST REVIEW

New Formulary Request for FDA-Approved Medication/Therapy → Clinical Specialty Subcommittee → *Meets high-cost threshold* → High Value Therapies → System P&T Committee

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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 ≥ $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

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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

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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

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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

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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

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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	$243,600	8
WAC per dose	Per patient annually	Estimated patients per month

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

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Case Example: Nadofaragene Firadenovec

Formulary Evaluation

- More complex preparation than others and biosafety precaitopms
- 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

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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

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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

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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

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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.

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