



A New Sphere of Influence: Formulary Strategies for Ultra-High-Cost Drugs and Cell/Gene Therapies (CGT) 2025 ASHP Conference for Pharmacy Leaders

Case 1 – Organizational Gap Analysis – Infrastructure and Stakeholders

Part 1: Infrastructure

Does your organization have a process to decide should versus can?

- Does your organization have a definition for ultra-high cost / high coordination drugs?
- Who is involved in triaging and prioritizing which products/patients, etc, to implement?
- Is there a threshold of total drugs/patients you will provide?
- Is there a process to triage and prioritize which products/patients, etc, to implement?

Part 2: Stakeholders analysis

Review the Table on the next page and fill in for your organization. This list is not meant to be all inclusive, so add in additional rows as needed for your organization. Consider the stakeholder's primary role, review of bringing a product into the organization, or facilitating implementation details.

- Review your stakeholder table. Do you know all of them?
- Which stakeholders are needed to review/implement a high-cost product?
 - What does each stakeholder groups need to know?
 - Who is ultimately responsible for the patient?
 - Who does the patient call if they need something?
 - Note any gaps you notice below – use this list to prioritize identifying / meeting these contacts in your organization.

Table. Potential Key Stakeholders Involved in Reviewing and Implementing High Coordination / Ultra High-Cost Medications

Stakeholder	Your Organization’s Contact	Their Involvement – Review / Implementation / Both
Purchasing department		
Revenue cycle/integrity		
Accounting/Billing		
Contracting		
Managed care		
Informatics/EMR		
Pharmacy operations		
Cell lab		
Sterile processing		
Executives at the site		
Finance		
340b		
Supply chain		
Specialty pharmacy		
Nursing and nursing education		
Legal		
Employee health		
Patient access and prior authorization		
Ethics		
Clinical leaders		
Other:		
Other:		
Other:		
Other:		

Case 2 - Identifying Necessary Resources

Consider the following questions with regard to either Hepzato Kit™ or Lyfgenia™ (or both if you have time). Each product will have specific nuances, but this list will help you understand any potential gaps in resources.

- What pharmacy resources are needed?
 - Does your organization have a process to decide should versus can?
 - Do you have a process for adding additional work to pharmacy team?
 - If you are not adding resources – what work are you stopping or deprioritizing?
 - How is the product procured?
 - What are the storage and preparation requirements for this product?
 - Is there a REMS program?
 - Is specific pharmacy training provided? How long does it take and how many staff require training?

- Have you assessed the following?
 - Contracting for the site
 - Contracting for the drug
 - Contracting for payors by patient
 - Capacity (space to treat as well as financial cash on hand to support purchases)
 - Required documentation and reporting for access
 - Site of care optimization (complexities of payors) Will there be any inpatient days? Outpatient administration? Impact for billing.
 - Patient flow (Who manages the patient if inpatient? Who does the patient call with problems when outpatient?)
 - What will the EMR build look like?

- After you have started providing the product:
 - What is the expectation for financial monitoring?
 - What is the expectation for clinical monitoring?
 - How will you assess if you should continue providing the therapy?
 - When does providing therapy potentially stop?

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