

BUILDING TOWARD INSTITUTIONAL PREPAREDNESS^{1,2}

ACCESS AND DISTRIBUTION Checklist

Research into potential gene therapies for a range of conditions is ongoing. Institutions evaluating their interest and preparedness for any of these gene therapies may benefit from multidisciplinary partnerships and comprehensive process development. Identifying the right processes and champions in gene therapy preparedness may take time and may vary depending on the provider, institution, and potential gene therapy products. Timely and proactive exploration of institutional protocols may make the implementation process easier and more effective.

Note that any potential therapy will have its own specific attributes and requirements. The following content does not provide requirements or guidance for any specific gene therapies; rather, it provides general information for your evaluation and consideration. No gene therapies for hemophilia A or B have been approved for use or determined to be safe or effective.



PREPPING THE LAND

Educational Topics to Explore^{3,4}

- Explore manufacturer-specific information for each gene therapy under consideration at your site
- Seek and understand institutional policies (if available) that may pertain to gene therapies and/or high-cost therapies
- Consider reaching out to individuals responsible for other gene therapy programs within your institution



ESTABLISHING THE STRUCTURE

Site Preparedness^{3,4}

01

CONSIDER IDENTIFYING A CONTACT AT YOUR INSTITUTION RESPONSIBLE FOR ACCESS AND REIMBURSEMENT, WHO HAS:

- Familiarity with insurance plans and payer policies
- Ability to complete a benefits investigation
- Familiarity with prior authorization and letter of medical necessity
- Experience with manufacturers' hubs to assist with access and reimbursement

02

CONSIDER YOUR PAYER MIX AND HIGH-VOLUME COMMERCIAL PLANS

- Consider calling the payer and asking about gene therapy coverage criteria
- Do they cover any other existing gene therapies? What do those criteria look like?
- Is there any accreditation required?

03

CONSIDER ISSUES WITH ACCESS AND REIMBURSEMENT

- Understanding routes of access for gene therapy. These can vary depending on the payer:
 - Buy and bill through a specialty distributor
 - Traditional dispense through a specialty pharmacy
 - Bill to/Ship to model, eg, contract pharmacy relationship

03

CONSIDER ISSUES WITH ACCESS AND REIMBURSEMENT (CONT'D)

- ❑ Would you infuse gene therapy at your site (Home Treater), or would you refer your patients to another location (Infusion Location)?
 - **If you are going to infuse at your site**
 - Does your institution have an existing policy for gene therapy administration?
 - ▶ If not, consider starting to work with your multidisciplinary team to create a policy for gene therapy administration
 - **If you are going to refer patients**
 - Have you identified a potential Infusion Location?
 - Does the pharmacy meet any relevant criteria, eg, state or institution requirements, Health Resources & Services Administration status, etc? Note that any accreditations, listings, or contracting may take a prolonged amount of time
 - ▶ The Home Treater may be responsible for follow-up and long-term monitoring, as required for each individual gene therapy
 - Consider executing a contract with the Infusion Location
 - ▶ Consider identifying someone at your institution who could assist in contracting between Home Treater and Infusion Location for services rendered
 - ▶ Are there current relationships outside of the Home Treater or Infusion Location that can assist in the contracting process, eg, group purchasing organization, management entity/contract pharmacies, and/or national advocacy organizations?
 - **Payer networks**
 - Payers may be evaluating and preparing for potential gene therapies today to understand potential care pathways, eg, Home Treater, Infusion Home, etc

Other considerations for your institution:

CLICK OR SCAN



Additional Resources

References: 1. Petrich J, et al. *J Pharm Pract.* 2020;33(6):846-855. 2. Miesbach W, et al. *Haemophilia.* 2021;27:511-514. 3. Iorio A, et al. *Haemophilia.* 2018;1-6. 4. Academy of Managed Care Pharmacy. *JMCP.* 2020;26:1206-1213.