

BUILDING TOWARD INSTITUTIONAL PREPAREDNESS^{1,2}

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



PREPPING THE LAND

Educational Topics to Explore³

- Types of investigational gene therapies available or in clinical trials, eg, gene editing, cell therapy, and gene transfer
- The risks and benefits of the specific gene therapy
- The different approaches to discussing and setting expectations regarding gene therapy with patients and their caregivers
- Nearby centers that can provide gene therapy and determine if your institution's and their electronic medical records are able to "communicate" with one another
- The postinfusion follow-up processes that may be requested by their institution providing gene therapy, so you are prepared to answer your patients' and the caregivers' questions, eg, "How many appointments are expected?" "How long will they be there?" "Can they do telehealth consultations?", etc



ESTABLISHING THE STRUCTURE

Site Preparedness³

01

IDENTIFY WHICH INSTITUTIONS ARE PROVIDING GENE THERAPY TREATMENT

- Identify a point of contact who may be able to address tasks identified below

02

COORDINATION OF CARE MAY REQUIRE MORE RESOURCES FOR PATIENTS WHO ARE REFERRED TO A DIFFERENT INSTITUTION TO RECEIVE GENE THERAPY

- Availability and person-hours needed from the referral team
- Identify if it is the referral site or the dosing site who determines patient eligibility

Possible tasks for the coordination of care:

- Determining the patient's payer requirements for the referral process
- Is the treating institution in network?
- Will the patient need a prior authorization prior to being referred or only before treatment?
- Coordinating and scheduling follow-up appointments and laboratory work
- Maintaining communication with the patient, pharmacy, payer, and tertiary clinic
- Discussing potential changes the patient should be aware of and when to call the clinic
- Conducting appointment reminders and periodic check-ins with the patient



ESTABLISHING
THE STRUCTURE

Site Preparedness³ (cont'd)

03

COORDINATE WITH THE INSTITUTION PROVIDING
GENE THERAPY TO DETERMINE THEIR REQUIREMENTS

Consider asking the following questions:

- What do they need from your clinic in order to start the process?
- How do they determine the patient's eligibility to receive gene therapy?
- Who will be responsible for conducting preliminary tests and obtaining prior authorization for treatment?

Other considerations for your institution:



MAINTAINING
AND ASSESSING

Follow-up Care Day 1 and Onward⁴

01

NOW THAT THE PATIENT HAS RECEIVED THEIR GENE THERAPY, YOUR
CLINIC MAY COORDINATE AND ORGANIZE FOLLOW-UP PROCESSES

- Regular monitoring as outlined by the care plan from the institution administering gene therapy
 - Identify methods to ensure patient compliance with these frequent follow-up visits and lab work
 - Continue to manage patient expectations, eg, adverse events, onset, variability, duration of effect
 - Reinforce the importance of follow-up visits and possible adherence to lifestyle modifications
 - Explore the role a social worker or counselor plays in providing psychosocial support, eg, impact of gene therapy on patient's identity
- Medications prescribed, as outlined by the care plan
- Ongoing conversations with the patient, caregiver, and multidisciplinary treatment team to proactively address any mental health, social, or medical complications that may arise

Other considerations for your institution:

CLICK OR SCAN



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. Pipe SW. *Haemophilia.* 2021;27(suppl 3):114-121. 4. Sidonio RF, et al. *Blood Rev.* 2021;47:100759. doi: 10.1016/j.blre.2020.100759. Epub 2020

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

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