BUILDING
TOWARD INSTITUTIONAL PREPAREDNESS[1,2]

PRESCRIBER **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

PREPPING THE LAND | Educational Topics to Explore[3]

- ☐ **Types of investigational gene therapies available or in clinical trials, eg, gene editing, cell therapy, and gene transfer**
- ☐ **The different approaches to discussing and setting expectations regarding gene therapy with patients and their caregivers**
- ☐ **The US Food and Drug Administration's Cellular and Gene Therapy Guidances**

ESTABLISHING THE STRUCTURE | Site Preparedness

01 IDENTIFY WHO AT YOUR INSTITUTION WILL LEAD EACH OF THESE STEPS[1]

- ☐ May also identify any local treatment centers that have already started gene therapy treatment or research to leverage their knowledge and experiences

02 ENGAGE HIGH-COST DRUG COMMITTEE AND OTHER ADMINISTRATORS TO SHAPE PROCESSES DEFINING RESPONSIBLE USAGE[4]

Members

- ☐ Physicians
- ☐ Pharmacy administrators
- ☐ Bioethics personnel
- ☐ Quality control managers
- ☐ Finance or billing managers

Information to facilitate discussions

- ☐ Completed medication request form
- ☐ Supporting references or additional supporting evidence
- ☐ Clinician notes from the electronic medical record

03 IDENTIFY AND PARTNER WITH HOSPITAL ADMINISTRATORS TO HELP DEFINE STANDARD OPERATING PROCEDURES[1]

- ☐ Specific standards required by your facility
- ☐ Manufacturer-specific Risk Evaluation and Mitigation Strategy guidelines
  - ○ Procedures and personnel in place for training or implementation
  - ○ Oversight of the different standards
- ☐ Procurement and contracts established prior to writing the prescription
  - ○ Certifications required from participating physicians, infusion staff, pharmacists, etc
- ☐ Billing codes
  - ○ Is the billing system at the facility updated accordingly to support accurate coding and billing procedures?

PRESCRIBER
Checklist

MOVING DAY | Pre- to Postinfusion (Peri-infusion)

01 POTENTIAL PREINFUSION ACTIVITIES

- ☐ Any required laboratory tests, eg, liver function, creatinine, complete blood count
- ☐ Patient preparedness (with clinical examination and ongoing education)
- ☐ Preinfusion medications, eg, systemic corticosteroids

Depending on the patient's access to support, transportation, and proximity to the infusion facility, they may need to have follow-up lab work and clinical examinations completed elsewhere. Determining this prior to or during infusion may help with coordination of continued care after the infusion is complete.

02 POTENTIAL PERI-INFUSION ACTIVITIES

Ideally the nurse coordinator, pharmacist, and infusion suite staff will have the day-of-infusion procedures under control.

As the prescriber, consider

- ☐ Being available for potential questions or infusion-related reactions that might require medical expertise

03 POTENTIAL POSTINFUSION ACTIVITIES

- ☐ Labs monitored on a regular basis (as determined by the gene therapy prescribed)
- ☐ Postinfusion medications (if necessary)
- ☐ Ongoing conversations with the patient, caregiver, and multidisciplinary treatment team to proactively address any mental, social, or medical complications that may arise

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. Pipe SW. *Haemophilia*. 2021;27(suppl 3):114-121. 4. Durvasula R, et al. *Am Health Drug Benefits*. 2018;11(2):65-73.

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

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