

BUILDING TOWARD INSTITUTIONAL PREPAREDNESS¹

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 Explore²



PROGRAM
MANAGER



NURSE
COORDINATOR

- Science behind gene therapies being researched



ESTABLISHING THE STRUCTURE

Site Preparedness²

01

CONSIDER INSTITUTIONAL PROCESSES THAT MAY AFFECT THE PATIENT JOURNEY



PROGRAM
MANAGER



What does the patient's journey look like and how might that inform preparation?

- Finance and procurement department requirements
- Roles for the prescriber and multidisciplinary team members
- Content within consent forms
 - Shared decision-making approach between patient and provider
 - Detailed discussion and understanding of product attributes, risks, and unknowns
 - Time commitment for** posttreatment appointments, laboratories, and medication
 - Considerations for** posttreatment needs, eg, family planning, lifestyle changes
 - Need for translator support if English is not the patient's primary language
- Logistic planning** to ensure treatment arrival coincides with patient arrival
- Documentation and nursing notes required of infusion nurses

Other considerations for your institution:

02

SEEK OUT PARTNERS IN YOUR INSTITUTION, UNDERSTAND THEIR ROLE, AND DETERMINE THE APPROPRIATE TIME TO ENLIST THEIR SUPPORT



Q. Who do I need to work with to help prepare the institution?

Potential partners

- Personnel submitting any insurance-required paperwork, eg, a prior authorization, (if different from prescriber) and/or finance department

Role

Determine if additional team members or documents are required to obtain coverage, eg, specialty pharmacy case manager

- Infusion and pharmacy teams

Discuss the general day of infusion logistics and details for each case

- Specialist at referral and/or follow-up site (if different from prescriber)

May have added insight on product attributes

- Clinical coordinator at referral and/or follow-up site

May support multidisciplinary team in ensuring execution of posttreatment care and follow-up

May be aware of potential patient nuances that impact access to care, eg, travel, lodging

Other partners within your institution and their role:



MOVING DAY

Pre- to Postinfusion (Peri-infusion)



Q. What happens immediately around the day of infusion?

01

POTENTIAL PREINFUSION ACTIVITIES

- Documentation of eligibility, eg, genetic tests, antibody titers
- Notify pharmacy point of contact overseeing administration orders
- Notify nurse manager overseeing infusion team staffing, bed management, and scheduling
- Preinfusion and infusion appointments
- Patient and caregiver notification of location/date/time of infusion and all pre- and postinfusion appointments
- Patient consent forms, eg, procedural consent, legal consent and prescriber-patient expectations contract
- Any required laboratory tests

Other considerations for your institution:



MOVING DAY

Pre- to Postinfusion (Peri-infusion)

02

POTENTIAL DAY OF INFUSION ACTIVITIES

- Confirm patient signed any consent forms and contracts
- Ensure copies of all consent forms are distributed to necessary staff and/or uploaded into EMR
- Confirm patient is traveling to infusion site and their estimated time of arrival
- Confirm pharmacy is preparing the treatment
- Ensure pharmacy contact has documented treatment was dispensed to infusion site
- Consider having a crash cart or medications for infusion-related reactions readily available
- Ensure infusion team has documented treatment administration in EMR
- Confirm patient received postinfusion instructions and they understand any follow-up appointments and laboratory testing requirements
- Disseminate discharge plan to prescriber care and the HCP overseeing patient care (if different from prescriber)

Other considerations for your institution:

03

POTENTIAL POSTINFUSION ACTIVITIES

- Monitor and confirm patient adherence to any postinfusion appointments and laboratory work
- Regularly check in with patient and monitor for adverse events
- Support patient and address questions as needed

Other considerations for your institution:

CLICK OR SCAN



References: 1. Petrich J, et al. *J Pharm Pract.* 2020;33(6):846-855.
2. Pipe SW. *Haemophilia.* 2021;27(suppl 3):114-121.

FOR ADDITIONAL INFORMATION PLEASE CONTACT:

