Patient information for the nAbCyte™ Hemophilia B Testing Program

1. What is the purpose of the nAbCyte Hemophilia B Testing Program?

A: The nAbCyte™ Anti-AAVRh74var HB-FE Assay (nAbCyte Assay) helps to determine if you are eligible for treatment with the Pfizer® hemophilia B gene therapy.

2. Will there be a cost to me for the nAbCyte test?

A: The nAbCyte test program is currently available to eligible patients at no cost. Insurance will not be billed, and Pfizer will cover the cost of testing for eligible patients prescribed the diagnostic test by their health care provider (HCP), to include shipping, specimen processing, and reporting of results through the nAbCyte testing program. You are eligible for the program if your doctor or HCP is considering prescribing Pfizer's gene therapy to you for treatment. Patients and health care providers must not submit any claims to any insurance provider or government health care program for reimbursement for costs through the program.

3. How do I get tested through the nAbCyte Hemophilia B Testing Program?

A: Your doctor or HCP must first order the nAbCyte test, then he or she will collect a blood sample and send that sample to Labcorp for testing.

4. What will happen after I have my blood collected?

A: nAbCyte test results will be sent to your ordering HCP within approximately 7-10 days from the time the sample is received at the lab. Results will also be sent to Labcorp Patient™. You should consult your HCP for any questions or follow-up regarding test results.

5. Can I have a copy of my results?

A: Test results are sent to Labcorp Patient™. You can login or register for an account at patient.labcorp.com or download the mobile app.

6. What do the nAbCyte test results mean?

A: The nAbCyte test is a companion diagnostic test that detects antibodies to the AAVRh74var capsid called neutralizing antibodies. These antibodies may impact your eligibility for Pfizer's hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec-dzkt). The nAbCyte test is approved as a Humanitarian Use Device (HUD) by the FDA.

7. What is a Humanitarian Use Device (HUD)?

A: A HUD is a medical device that is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in no more than 8,000 individuals in the United States per year.

The nAbCyte test is classified as a Humanitarian Use Device (HUD) by the FDA. It is authorized by federal law for use as a companion diagnostic in the selection of patients to receive the Pfizer hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec-dzkt). A HUD that meets the HDE standard for approval is exempt from the requirement of establishing a reasonable assurance of effectiveness that would otherwise be required. FDA approval of the device is based on, among other criteria, evidence that the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The nAbCyte™ AAVRh74var HB-FE assay is FDA approved as a Humanitarian Use Device for use as a companion diagnostic in the selection of patients to receive the Pfizer hemophilia B gene therapy, BEQVEZ™ (fidanacogene elaparvovec-dzkt). The effectiveness of this device for this use has not been demonstrated.

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