

# Advance Beneficiary Notice (ABN) Information For Adaptive Biotechnologies Tests

In cases where a patient covered by Medicare (not Medicare Advantage) receives services that do not meet the coverage criteria outlined in the relevant National Coverage Decision (NCD), Local Coverage Decision (LCD), or Local Coverage Article (LCA), the Centers for Medicare & Medicaid Services (CMS) requires patients to complete and sign an Advance Beneficiary Notice (ABN) prior to receiving testing services. It is the policy of Adaptive Biotechnologies to ensure a completed ABN is obtained from Medicare beneficiaries for non-covered lab tests prior to collection of specimen(s) for testing.

**Q: What is an ABN?**

**A:** The ABN notifies Medicare patients of their potential financial responsibility for services ordered by their healthcare provider.

**Q: What will happen if Medicare denies a claim for an Adaptive Biotechnologies test?**

**A:** In the event that Medicare denies a claim, the patient will be billed for clonoSEQ® testing at the list price. For eligible patients with financial need, Adaptive offers the Adaptive Assist™ Patient Support Program to help facilitate access to clonoSEQ testing services. Adaptive Biotechnologies is committed to providing guidance and support during each step of the insurance and billing process.

**Q: Are Medicare advantage patients required to complete an ABN?**

**A:** No. An ABN is not required for Medicare Advantage patients. Please refer to the patient's specific Medicare Advantage plan for related benefit guidelines.

**Q: What is the process for submitting an ABN on behalf of a patient?**

- A:**  Review the table below to assess whether or not a patient requires an ABN for the clonoSEQ testing service being requested. You can access the full coverage policy details for clonoSEQ via the [CMS website](#). Visit [www.clonoSEQ.com/ordering](http://www.clonoSEQ.com/ordering) for more information or to download an ABN form.
- Encourage patients interested in financial assistance to learn more about the Adaptive Assist Patient Support Program. Patients can download an application at [www.Adaptive-Assist.com](http://www.Adaptive-Assist.com) or for more information can call our Patient Support Team at 1-855-236-9230, Monday to Thursday 9AM to 7PM and Friday 9AM to 5PM EST.
- Submit the completed and signed ABN form with the specimen sent for testing. Completed forms can be uploaded to the Adaptive Diagnostics Portal, included in the shipping box with a sample sent for testing, or faxed to our Clinical Services team at 1-866-623-4408.

Test	Medicare Coverage Criteria
The clonoSEQ Assay	clonoSEQ is covered by Medicare for testing performed on bone marrow or blood* specimens from patients with B-cell acute lymphoblastic leukemia (B-ALL), multiple myeloma, or chronic lymphocytic leukemia.

**Q: What if a patient refuses to sign the ABN?**

**A:** In accordance with Medicare guidance, if the patient refuses to sign the ABN and wants to proceed with testing, a witness should annotate the ABN indicating the patient's refusal to sign (list witness). The patient may be held financially liable as the test will not be covered by Medicare.

Instructions for completing the ABN are provided by CMS and are available on the CMS website at [www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html](http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html).

**Still have questions? Contact Adaptive's Clinical Services Team at 1-888-552-8988 or [clinicalservices@adaptivebiotech.com](mailto:clinicalservices@adaptivebiotech.com).**

For important information about the FDA-cleared intended uses of clonoSEQ, including test limitations, visit [clonoSEQ.com/technical-summary](http://clonoSEQ.com/technical-summary).

\*clonoSEQ is not FDA approved or cleared for testing on peripheral blood specimens in myeloma or B-ALL patients. Available as a CLIA validated LDT only.