

## STATEMENT OF MEDICAL NECESSITY

The **Oncoguard™ Liver** test is a convenient single blood test that combines analysis of methylated DNA markers and the biomarker alpha fetoprotein with a sophisticated algorithm to help identify hepatocellular carcinoma (HCC) in at-risk patients.

**Patient Name:** \_\_\_\_\_ **Patient Date of Birth:** \_\_\_\_\_

**Insurance Payer Name:** \_\_\_\_\_ **Insurance Payer ID:** \_\_\_\_\_

**Ordering Physician Name:** \_\_\_\_\_ **Ordering Physician NPI:** \_\_\_\_\_

**Office Address:** \_\_\_\_\_

**Office Phone:** \_\_\_\_\_ **Office Fax:** \_\_\_\_\_

**CPT Code:** 81599

**Date of Specimen Collection:** \_\_\_\_\_ (MM/DD/YYYY)

**ICD-10 Code(s):** \_\_\_\_\_

### Symptoms/Clinical Findings:

- Cirrhosis of the liver       Hepatitis B infection (HBV)       Fatty liver disease  
 Other \_\_\_\_\_       Other \_\_\_\_\_       Other \_\_\_\_\_

### Prior History (check all that apply):

- Hepatitis B infection (HBV)       Hepatitis C infection (HCV)       Alcohol  
 Non-alcoholic fatty liver disease (NAFLD)       Genetic disorders: \_\_\_\_\_

**Authorized Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Routine surveillance plays an important role in diagnosing HCC in its early stages and is recommended in AASLD and NCCN guidelines. This diagnosis is indicative of the patient being at-risk for HCC. To confirm the need for a diagnostic follow-up for potential HCC, it is imperative to perform the Oncoguard Liver test.

	AASLD <sup>1</sup>	NCCN <sup>2</sup>
<b>Population:</b>	Cirrhosis and/or HBV (selected)	Cirrhosis and/or HBV (selected)
<b>Surveillance Method(s):</b>	Ultrasound +/- AFP	Ultrasound + AFP
<b>Frequency:</b>	Every 6 months	Every 6 months

1. Heimbach JK, et al. *Hepatology*. 2018;67(1):358-380. 2. NCCN Hepatobiliary Cancers, Version 1. 2021  
AASLD—American Association for the Study of Liver Diseases    NCCN—National Comprehensive Cancer Network