BILLING INFORMATION SHEET FOR HEALTHCARE PROFESSIONALS

We want you to be able to focus on the care of your patients, and to leave the insurance process to us. We are committed to doing all we can to help your patients manage any expenses related to our tests.

Biotheranostics believes every clinically eligible patient should have access to our tests, independent of their insurance or financial status. We accept all insurance plans and offer a patient assistance program for patients in need.

OUR PROCESS

1. This process starts with ensuring your patient's complete insurance information is provided on the Biotheranostics test requisition prior to sending it in to us.
2. We then contact the pathology department to have the specimen sent for testing. After the test is performed by us, the results are delivered to the ordering physician.
3. We bill the patient's insurance company. Biotheranostics Patient Advocates are available to discuss the billing process and options that may be available to your patients to help manage any out of pocket expenses.
4. The billing process will take several months and during this time your patient will receive a communication from the insurance company called an Explanation of Benefits (EOB). This is NOT A BILL.
5. In addition to the EOB from the insurance company, your patient will receive a welcome letter from Biotheranostics that outlines our billing and appeals process and contains an important document that they will need to sign and return to us. This Authorization of Representation form allows us to appeal to insurance companies on a patient's behalf.
6. The insurance company will send payment to us for the test. Your patient may be responsible for a deductible, co-payment, and/or co-insurance as indicated by the insurance plan and required by federal/state regulations. Our Patient Assistance Program is designed to help manage these out of pocket expenses and is based on household income and financial responsibilities.

IMPORTANT INFORMATION

IF YOUR PATIENT IS A MEDICARE BENEFICIARY

Medicare accepts CancerTYPE ID® and Breast Cancer Index℠ as medically necessary and covers the tests at a predetermined rate with no fees charged to the patient when specific criteria are met under a local coverage determination (LCD). See reverse side for details. In most cases Medicare will be billed directly. However, in certain situations with CancerTYPE ID® we are obligated to bill the hospital; the “14 Day Rule” is a regulation set by the Centers for Medicare and Medicaid Services (CMS) that requires laboratories, including Biotheranostics, to bill the hospital for clinical laboratory services and the technical component of pathology services provided to Medicare patients when services are ordered less than 14 days after the patient was discharged.

IF YOUR PATIENT IS INSURED BY COMMERCIAL INSURANCE

We accept all insurance plans, and are currently in network with a growing number of plans. In the event your insurance company sends payment to your patient, please have your patient forward the check to us. If an insurance company denies coverage, we will work on behalf of the patient to attempt to obtain coverage and will assist in pursuing any appeals on the patient's behalf.

IF YOUR PATIENT DOES NOT HAVE INSURANCE

Biotheranostics will bill patients directly for services ordered. Please inform you patients that they can apply for assistance through our Patient Assistance Program or Payment Plan.

PATIENT ASSISTANCE PROGRAM

Our Patient Assistance Program can help lower the bill for patients. This requires patients to provide a paystub, W-2 or other documentation of income.

PAYMENT PLANS

We offer a discounted “direct pay” price for patients who wish to pay cash for our testing. We offer a 6 month interest free payment plan option for patients who need to make payments in installments.

To discuss our Patient Assistance Program and eligibility requirements, contact our Patient Advocate Team at 1(877) 886-6739, select prompt 2.

MEDICARE LOCAL COVERAGE DETERMINATION (LCD) CRITERIA:

CancerTYPE ID®

CancerTYPE ID is covered as a once-in-a-life time benefit. The assay may be used to resolve an unknown primary tumor or to resolve a pathological diagnosis with 2 or more differential diagnoses. In the unlikely event of a second UPC, denied claims can be appealed through standard Medicare protocol.
Use of the CancerTYPE ID assay is limited to:

- Tumors for which a single specific site of origin has not been established or resolved by the combination of clinicopathologic studies and consultation with pathologists, radiologists and oncologists.
- Specimens, such as cytology cell blocks, where limited quantity of the specimen precludes standard pathologic workups

Breast Cancer Index℠ (BCI)

Coverage of the Breast Cancer Index (BCI) is limited to patients that meet the following criteria:

- Post-menopausal female with non-relapsed, ER+ breast cancer, and
- Was lymph node negative (LN-), and
- Is completing five (5) years of tamoxifen therapy, and
- Patient must be eligible for consideration of extended endocrine therapy based on published clinical trial data or practice guidelines, and
- Physician or patient is concerned about continuing anti-hormonal therapy because of documented meaningful toxicity or possible significant patient-specific side effects, and
- The test results will be discussed with the patient (including the limitations of the testing method, the risks and benefits of either continuing or stopping the therapy based on the test, and current cancer management guidelines).

CancerTYPE ID Intended Uses and Limitations

CancerTYPE ID is indicated for use in tumor specimens from patients diagnosed with malignant disease and is intended to aid in the classification of the tissue of origin and tumor subtype inconjunction with standard clinical and pathological assessment by a qualified physician. CancerTYPE ID is not intended to p edict patient survival benefit, t eatment efficacy or to distinguish between benign versus malignant lesions. Tumor types not included in the CancerTYPE ID reference database may exhibit RNA expression patterns that are similar to RNA expression patterns within the reference database. This test was developed and performance characteristics have been determined by Biotheranostics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician. Biotheranostics is certified under the Clinical Laboratory Imp ovement Amendments of 1988 as qualified to perform high-complexity clinical laboratory testing.

BCI Intended Uses and Limitations

The Breast Cancer Index (BCI) Risk of Recurrence & Extended Endocrine Benefit Test is indicated for patients diagnosed with estrogen receptor-positive (ER+), early-stage breast cancer, who are distant recurrence-free, and provides: 1) a quantitative assessment of the likelihood of both late (post-5 years) and overall (0-10 year) distant recurrence in lymph node-negative (LN-) patients treated with initial adjuvant endocrine therapy, and 2) prediction of likelihood of benefit from extended (>5 year) endocrine therapy in patients who are recurrence-free after an initial 5 years of adjuvant endocrine therapy. Test results require correlation with all other clinical findings for treatment decisions.
This test was developed and its performance characteristics determined by Biotheranostics. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician. Biotheranostics is certified under the Clinical Laboratory Improvement Amendments of 1988 to perform high complexity clinical laboratory testing.

Biotheranostics, Inc. | 9640 Towne Centre Drive | Suite 200 | San Diego, CA 92121 | www.Biotheranostics.com
US and International: +1 (858) 587-5870 | Fax: +1 (858) 587-5874 | Client Services: +1 (877) 886-6739