GUARDANT360 CDx

clientservices@guardanthealth.com | 1.855.698.8887
NPI # 1184045619 | CLIA # 05D2070300 | CAP Accredited # 8765297

Place Barcode Here

Guardant360 CDx Test Requisition & Statement of Medical Necessity

All shaded boxes REQUIRED

1. PATIENT INFORMATION

Last Name | First Name

DOB (yyyy/mm/dd) | Sex F M | Medical Record Number

Street Address

City | State | Country | Zip

Preferred Contact Phone Number | Email (We will email status updates of your test)

☐ New Guardant360 CDx Patient ☐ Existing Guardant360 CDx Patient

2. SPECIMEN INFORMATION

Collection Date (yyyy/mm/dd) | Name of Person Collecting Specimen

3. ICD-10 CODE(S)

4. STAGE (REQUIRED)

Patients not eligible for systemic therapy or Stage I/II not currently accepted

☐ Advanced Cancer (Stage IIIB/IV-NSCLC, Stage III/IV-other cancer types) ▸ Currently on Therapy? If yes, please list below

5. ORDERING PHYSICIAN (or other Licensed Medical Professional)

Last Name | First Name

Email

GHI-003381
OPS Guardian Medical Logistics

Phone: (314) 576-7766
Fax: (866) 458-3654

Medical Professional Consent

My signature constitutes a Certification of Medical Necessity, and I hereby authorize and order Guardant Health, Inc. (GH) to perform Guardant360 testing and curation for this patient as indicated on this requisition. If no test is selected, that indicates an order for Guardant360 CDx. I have reviewed the medical consent on the back of this form and will provide test interpretation to the patient as appropriate. *(continued on back)*

*A Guardant360 CDx test order report contains both the FDA-approved report with 55 genes and the professional services report with 74 genes including MSI-High

Medical Professional Signature | Date

X

6. TEST SELECTION (MUST choose one)

☐ Guardant360 CDx* (~7 day TAT)

☐ Guardant360 (~10 day TAT) Includes: Tumor Mutational Burden (TMB), *NTRK2, NTRK3 CHEK2, FANCA, KEAP1, MSH2, MSH6, PALB2, PMS2, RAD51D*

7. ADDITIONAL RECIPIENT

Medical Professional Name

Phone Number | Fax Number

8. DIAGNOSIS (MUST choose one)

Date of Original Diagnosis (yyyy/mm/dd)

BRAIN
- ☐ Glioblastoma
- ☐ Other Primary CNS Tumor ▸

BREAST
- ☐ Breast Carcinoma

GENITOURINARY
- ☐ Bladder Carcinoma
- ☐ Prostate Adenocarcinoma
- ☐ Renal Cell Carcinoma
- ☐ Renal Pelvis Urothelial Carcinoma

GI
- ☐ Appendiceal Adenocarcinoma
- ☐ Cholangiocarcinoma
- ☐ Colorectal Adenocarcinoma
- ☐ Esophageal Squamous Cell Carcinoma
- ☐ Gastric Adenocarcinoma
- ☐ Esophageal/Gastroesophageal Junction Adenocarcinoma
- ☐ (GIST) Gastrointestinal Stromal Tumor
- ☐ Hepatocellular Carcinoma
- ☐ Pancreatic Ductal Adenocarcinoma
- ☐ Pancreatic Neuroendocrine Tumor
- ☐ Other Gastrointestinal Tumor ▸

GYNECOLOGIC
- ☐ Cervical Squamous Cell Carcinoma
- ☐ Endometrial Carcinoma
- ☐ Ovarian Carcinoma

HEAD & NECK
- ☐ Squamous Cell Carcinoma

LUNG
- ☐ Adenocarcinoma (NSCLC)
- ☐ Large Cell Carcinoma (NSCLC)
- ☐ Squamous Cell Carcinoma (NSCLC)
- ☐ Lung Carcinoid/Neuroendocrine
- ☐ Small Cell Lung Carcinoma
- ☐ Other Lung Tumor ▸

SARCOMA
- ☐ Sarcoma, please specify ▸

SKIN
- ☐ Basal Cell Carcinoma
- ☐ Squamous Cell Carcinoma
- ☐ Melanoma

THYROID
- ☐ Thyroid Carcinoma

OTHER
- ☐ Carcinoma of Unknown Primary (CUP)
- ☐ Other ▸

9. RELEVANT CLINICAL HISTORY (ALL REQUIRED for medical coverage determination)

1. The patient is seeking further treatment and is: ☐ Newly diagnosed (Stage III/IV) ☐ Not responding to therapy
2. Has the patient received a Guardant360 CDx report since their most recent progression? ☐ No ☐ Yes
3. Is tissue-based comprehensive genomic profiling (CGP) from a recent biopsy feasible? ☐ No ☐ Yes
4. Has tissue-based CGP from a recent biopsy been performed with a non-QNS result? ☐ No ☐ Yes
5. Has tissue-based CGP from a recent biopsy already returned an actionable result? ☐ No ☐ Yes

Please see the back page of this form for details regarding Medicare coverage criteria

10. BILLING INFORMATION Please attach a copy of the front and back of the patient's insurance card and/or the patient face sheet

Patient Status (Medicare only) ☐ Hospital Inpatient ☐ Hospital Outpatient ☐ Non-Hospital Patient

☐ Insurance (please fill in below) ☐ Medicare - Part B ☐ Medicaid ☐ Hospital/Institution ☐ Self-Pay (Please contact Client Services for billing information)

Primary Insurance | Insured Name | Policy # | Group #

Patient Relationship to Insured ☐ Self ☐ Spouse ☐ Child ☐ Other | Insured DOB

GENERAL COMMENTS:

GUA4403807

D-000354 R5

GUARDANT360 CDx [illegible] T 1.855.698.8887

Test Requisition & Statement of Medical Necessity

5. Medical Professional Consent (continued from front)

As may be required by applicable state laws and regulations, I have supplied information to the patient regarding somatic genomic testing and the patient has given consent for this testing to be performed by GH and for the results to be reported back to me. I understand that GH is relying only on the diagnosis or diagnosis code that I provide on the test requisition form in providing information about potential therapeutic options and clinical trials associated with the reported genomic testing results, and that an incorrect diagnosis or diagnosis code would adversely affect the relevance of the information provided by GH. I understand that I remain free to make medical decisions on how to use the results of Guardant360 CDx in my management of this patient. I have obtained in writing the patient's data privacy consent to transmit the health data on this requisition form for the purpose of processing this order and performing the Guardant360® CDx test. I authorize GH to select the most appropriate test [illegible] Physicians www.guardant360CDx.com/AnnualNotice.

I hereby authorize GH to release test results and relevant medical information to the patient's third party payer when necessary as part of the reimbursement process. I have obtained the patient's consent for GH to submit claims and, if necessary, to appeal claims on the patient's behalf to pursue reimbursement, as well as for GH to receive payment directly from the patient's insurance carrier. With respect to tests reimbursed by Medicare, Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose an individual patient. With respect to tests reimbursed by Medicare, Medicaid or other third party payers, I attest that Guardant360 testing is medically necessary and the results will be used in the management of the patient's condition. I agree to provide a copy of relevant clinical history and medical records in order to support a request from a health plan at no cost to Guardant Health. I acknowledge that patients who are United States residents may be enrolled in Guardant Access [illegible] Financial Assistance Program only if they sign the assignment of benefits form.

I understand that fusions in the [illegible] gene are only available in the Guardant360 CDx test.

For Medicare Beneficiaries Only

If **Guardant360 CDx** is ordered, a Medicare Advance Beneficiary Notice (ABN) must be submitted for any Medicare patient for whom has previously had a Guardant360 CDx test and has not progressed since the previous test was performed. If **Guardant360** is ordered, a Medicare Advance Beneficiary Notice (ABN) must be submitted for any Medicare patient for whom the questions in Section [illegible] on the previous page are marked in the following manner: [illegible] patients, an ABN is required if (1) question 2 is marked "Yes" or (2) if question 5 is marked "Yes" or (3) if tissue based CGP from a recent biopsy was feasible but not performed [illegible] solid tumor patients other than NSCLC, an ABN is required if any question is marked "Yes"; all CNS patients require an ABN. ABN forms that have been pre-populated with Guardant Health's test information can be obtained from Guardant Health Customer Service, Guardant360 CDx product website www.Guardant360CDx.com/ABN or inside the Guardant360 CDx kit. Completed ABN forms can be sent to Guardant Health with the kit sample, via fax at 888.974.4258, or emailed to billing@guardanthealth.com.

Patient Assignment of Benefits Form (required)

ASSIGNMENT OF BENEFITS

I hereby assign and convey all applicable health insurance benefits and/or insurance reimbursement, as well as all rights and obligations that I have under my health plan, to Guardant Health for services performed by Guardant Health. I appoint Guardant Health as my authorized representative to:

- File medical claims with my health plan.
- File appeals and grievances with my health plan.
- File appeals or grievances with an external review committee at a state insurance board, independent review organization, Office of Personnel Management, Department of Labor or equivalent agency.
- File a complaint regarding inaccurate claims processing, appeal processing or pricing to CMS or their agent regarding my Medicare Part C plan.
- Release medical and insurance information necessary to process claims or appeals.
- Obtain medical records related to services provided by Guardant Health when it is required to process a claim or appeal.
- Collect payment of any and all medical benefits and insurance proceeds directly from my health plan (including Medicare and Medicaid).
- Resolve any insurance related matter regarding a service provided by Guardant Health directly with my health plan.

I acknowledge and agree that I remain responsible for applicable co-payments, deductibles and co-insurance as required by my medical and/or other healthcare benefits plans. If I receive payment of medical and/or other health benefits on account of services provided by Guardant Health, I shall pay Guardant Health the full amount of that payment.

AUTHORIZATION RELEASE

I hereby authorize Guardant Health to:

- Release any information necessary to my health benefit plan (or its administrator) regarding my illness and treatments;
- Process and submit insurance claims generated in the course of examination or treatment; and
- Allow a photocopy of my signature to be used to process insurance claims, payment, grievances or appeals. This authorization will remain in effect until revoked by me in writing.

OUT-OF-NETWORK DISCLOSURE AND PATIENT CONSENT

I understand that Guardant Health services may be designated as an out of network service by some insurance plans. As a result, there may be costs associated with these services that are not covered by my insurance plan. I hereby consent for out of network services to be provided by Guardant Health.

You may visit **www.guardanthealth.com/insurance** for a list of insurance plans that consider Guardant Health services as in network. Guardant Health will provide, upon request, the estimated amount that Guardant Health expects to bill for services associated with out of network plans.

ERISA AUTHORIZATION

I hereby designate, authorize, and convey to Guardant Health, to the full extent permissible under law and under any applicable insurance policy and/or employee health care benefit plan, the following:

- The right and ability to act as my Authorized Representative in connection with any claim, right, or cause of action against my health plan that I may have under such insurance policy and/or benefit plan; and
- The right and ability to act as my Authorized Representative to pursue such claim, right, or cause of action in connection with said insurance policy and/or benefit plan (including, but not limited to, the right and ability to act as my Authorized Representative with respect to a benefit plan governed by the provisions of ERISA as provided in 29 C.F.R. §2560.503-1(b)(4)) with respect to any healthcare expense incurred as a result of the services I received from Provider and, to the extent permissible under the law, to claim on my behalf, such benefits, claims, or reimbursement, and any other applicable remedy, including fines. I understand I can revoke this authorization in writing at any time.

ELIGIBILITY FOR FINANCIAL ASSISTANCE

I hereby consent Guardant Health to evaluate my eligibility for the Guardant Health Financial Assistance Program.

A photocopy of this Authorization shall be as effective and valid as the original.
This form is not an Advanced Beneficiary Notification (ABN).
If you have any questions, please do not hesitate to contact us at 1.855.698.8887 or clientservices@guardanthealth.com.

X	PRINT NAME OF PATIENT	DATE
SIGNATURE OF PATIENT	EMAIL	