BELAY DIAGNOSTICS

1375 W Fulton St., Suite 530
Chicago, IL 60607
contact@belaydiagnostics.com
P: 331-320-0155
F: 800-501-9246

Sample Collection – Min 6 mLs of CSF
Date*: (MM/DD/YY)
Time*: XX:XX am/pm
Kit # _____
Lumbar Puncture Tube Collection # :
○ #1 ○ #2 ○ #3 ○ #4

Belay Lab Use Only

***Required fields; otherwise, testing may be delayed** ○ **ARUP Sample**

PATIENT INFORMATION

Last Name*	Middle Name	**First Name***
Date of Birth* (MM/DD/YY)	Sex at birth: ○ Male ○ Female	MRN
Phone	**Email Address***	
Street Address*		
City*	**State***	**Zip***

Ancestry (select all that apply):
○ White/Non-Hispanic ○ Hispanic/Latino ○ Middle Eastern
○ Asian ○ Black/African American ○ Other:

ORDERING CLINICIAN INFORMATION

Clinician Name*	**NPI #***
Account#/Clinic/Institution*	Phone #
Street Address	Email
City	State / Zip
Additional Recipient	Email or Fax

BILLING INFORMATION

Place of Service*
○ **Inpatient**
○ **ER**
○ **Outpatient**
○ **Non-Hospital**

To prevent processing delays, please complete the '**Patient History**' section below **in full**; attach patient's insurance information and/or face sheet to support accurate billing.

PROVISIONAL DIAGNOSIS*

Example: Glioma

ORDER CHOICE* & SPECIMEN REQUIREMENTS

○ **Summit™ 2.0 + Ascent™**
○ **Summit™ 2.0 + Ascent™ + Vantage™**
○ **Summit™ 2.0** **Does not include chromosomal arm-level & focal loss/gain (Ascent™)**
○ **Ascent™**
○ **Vantage™**

Collect min 6mLs CSFin a sterile tube via:
○ Lumbar Puncture ○ Ommaya reservoir ○ Ventricular Catheter
○ Aspiration of CSF Space ○ Ventricle ○ Cistern ○ Other

SUMMIT™ 2.0 COMPREHENSIVE GENOMIC PROFILE

SNVs, MNVs, Indels – **520 GENES**
CNVs *(gene-level amplification)* – **62 GENES**
Fusions – **28 GENES**
Key Biomarkers – **TMB, MSI**

For specifications, see Summit 2.0 Comprehensive Genomic Profile at **bit.ly/3lSrneX** or scan this code:

ASCENT™ TEST

Chromosome arm-level and focal loss/gain

VANTAGE™ TEST

***MGMT* promoter methylation status**

PATIENT HISTORY

Is the patient either (check all that apply): ○ Recurrent ○ Relapsed ○ Refractory ○ Metastatic ○ Advanced stage/grade ○ Other:

Cancer History Questions	Yes	No	Unk
Is test ordered to guide clinical decision-making for current stage/grade of cancer treatment?	○	○	○
Is test ordered to assess treatment plans due to suspected resistance or progression?	○	○	○
Is patient seeking systemic treatment and/or clinical trial participation based on test results?	○	○	○
Does patient have a history of cancer? *(If "Yes", complete Primary Cancer Data section at right)*	○	○	○
Has patient undergone tissue biopsy/resection? *(If "Yes", attach pathology/cytology report)*	○	○	○
Is tissue biopsy/resection infeasible or contraindicated for this patient?	○	○	○
Has genomic profiling on tumor been completed for patient? *(If "Yes", attach report)*	○	○	○
Has patient received/currently receiving chemotherapy?	○	○	○
Has patient received/currently receiving radiotherapy?	○	○	○
Was CSF cytology testing performed? *If "Yes", the results are:* ○ *Negative* ○ *Positive*	○	○	○

Primary Cancer Data (complete if answered "yes" to history of cancer):

○ Brain
○ Breast
○ Colon
○ Kidney
○ Lung
○ Lymphoma
○ Melanoma
○ Prostate
○ Other (please specify):

CA Stage/Grade:

Date of DX: (MM/DD/YY)

○ **Pathology Report Attached**
○ **Genomic Profiling Report Attached**
○ **Relevant Clinical Notes Attached**

ICD10/Diagnostic Codes: https://www.icd10data.com/ICD10CM/Codes/R00-R99/R90-R94/R94-/R94.02

○	C 70.0 Malignant neoplasm of cerebral meninges	○	C 71.7 Malignant neoplasm of brain stem
○	C 70.1 Malignant neoplasm of spinal meninges	○	C 71.9 Malignant neoplasm of brain, unspecified
○	C 70.9 Malignant neoplasm of meninges, unspecified	○	C 72.0 Malignant neoplasm of spinal cord, cranial nerves and other parts of CNS
○	C 71.0 Malignant neoplasm of cerebrum, except lobes and ventricles	○	C 79.31 Secondary malignant neoplasm of the brain
○	C 71.1 Malignant neoplasm of frontal lobe	○	C 79.32 Secondary malignant neoplasm of cerebral meninges
○	C 71.2 Malignant neoplasm of temporal lobe	○	C 79.40 Secondary malignant neoplasm of unspecified part of nervous system
○	C 71.3 Malignant neoplasm of parietal lobe	○	C 79.49 Secondary malignant neoplasm of other parts of nervous system
○	C 71.4 Malignant neoplasm of occipital lobe	○	G 96.198 Other disorders of meninges, not elsewhere classified
○	C 71.5 Malignant neoplasm of cerebral ventricles	○	Other:
○	C 71.6 Malignant neoplasm of cerebellum		

MEDICAL NECESSITY AND ORDERING PROVIDER AUTHORIZATION

I am the patient's treating physician and my signature certifies: (1) I am authorized under applicable law to order the tests on this test requisition form; (2) the clinical information entered on this form is accurate and this test is medically necessary; (3) I have prepared documentation demonstrating the medical necessity of the test, included it in the patient's medical record, and will make it available to Belay upon request; (4) I will use the test results to inform my treatment decisions and medical management of the patient; (5) I have explained the nature, purpose, potential benefits, risks, and alternatives to the patient, and the patient has had the opportunity to ask questions regarding the test including the collection, use, and disclosure of their sample and health information; and (6) I have obtained informed consent from the patient to have the test performed using the consent form enclosed with this test requisition form, notified the patient they may receive a copy of this informed consent for their records, and will provide a copy of this informed consent to Belay upon request.

Ordering Clinician/Authorized Signature*: **Date*:**

○ **By checking this box, I confirm that I have discussed Belay's billing options, including if applicable the Assay Evolution Program Protocol, with the patient, and the patient requests that Belay provide the patient with additional information regarding such options.**

BELAY DIAGNOSTICS

INFORMED CONSENT FOR SAMPLE RELEASE, TESTING, AND FINANCIAL RESPONSIBILITY

Patient Full Name	Date of Birth* (MM/DD/YY)	MRN
Address	Email	Phone

Your healthcare provider intends to order Summit™, Ascent™, and/or Vantage™ (Test(s)) offered by Belay Diagnostics (Belay). By signing below, you acknowledge receipt of information regarding the financial responsibility, potential risks, benefits, and limitations of testing and provide your authorization as to the matters listed in this consent. If you have any questions or need additional information about Test(s), please consult your healthcare provider before signing this consent.

Test(s) Overview

Belay tests analyze cerebrospinal fluid samples for molecular biomarkers known to be associated with brain and spinal cord cancers. Summit analyzes gene level variants and fusions, along with TMB and MSI. Ascent evaluates chromosome arm-level loss/gain. Vantage evaluates *MGMT* promoter methylation status. The results of Summit, Ascent, and/or Vantage may assist your healthcare provider in choosing a treatment plan that is best for your medical condition. However, undergoing Test(s) does not guarantee that a successful treatment will be identified or that all relevant arm-level losses/gains, mutations, and methylation signatures will be found. Test(s) may not provide information about susceptibility to developing disease in the future, and a negative result does not rule out the presence of chromosome arm-level losses/gains, gene level alterations or methylation.

Financial Responsibility

Coverage for the Test(s) may be available through private or third-party health insurance plans. If insurance is used, Belay Diagnostics will submit a claim to your insurer. You are responsible for any amounts not covered by your insurance plan, including but not limited to deductibles, co-payments, co-insurance, or charges applied due to lack of coverage or denial of the claim. If your insurance does not cover the Test(s), or if your deductible has not been met, you may receive a bill for the remaining balance. Patients may elect to self-pay for the Test(s). Belay Diagnostics offers a substantially discounted self-pay rate and may provide financial assistance through the Belay Assistance Program (BAP) for eligible patients. To inquire about self-pay options, discounted pricing, or financial assistance, please contact our billing team at (331) 320-0155 or billing@belaydiagnostics.com prior to or following testing. Pricing, discount programs, and financial assistance eligibility are subject to change and may be modified by Belay Diagnostics at any time.

Sample Collection and Release

Belay will perform Test(s) using genomic material extracted from the patient's cerebrospinal fluid sample. By signing below you authorize Belay to work with your healthcare provider to obtain your sample and any information related to you or your medical condition that is relevant for Test(s). Performing the requested Test(s) may exhaust the sample that is sent to Belay, and additional Test(s) may not be possible unless you provide additional samples.

Disclosure of Results

Belay will report the results of Test(s) to the patient's healthcare provider, who will discuss results and next steps with the patient. Based on results, the healthcare provider will determine if any follow-up testing is appropriate. The results and other data and information generated during the performance of Test(s) maybe used and disclosed in a manner consistent with our Notice of Privacy Practices, which can be found at belaydiagnostics.com/privacy-practices. Belay is under no ongoing obligation to update,revisit,or later re-evaluate Test(s) results after those results have been made available to your healthcare provider through Test(s) reports described above.

Privacy, Sample Retention, and Secondary Data Use

Belay Diagnostics may use and disclose health information as permitted by law, as described in our Notice of Privacy Practices, and may request and exchange health information electronically through secure health information networks (HINs), including TEFCA-enabled networks such as CommonWell Health Alliance. HINs enable secure electronic sharing of health information by your healthcare providers for purposes allowed under HIPAA. You may opt out of HIN use at any time by contacting contact@belaydiagnostics.com. Opting out will not affect testing but will limit medical record exchange, reducing Belay's ability to obtain insurance coverage or payment for Test(s), and may result in delays in services.

◯ **New York Residents Only: I authorize Belay to retain my specimen for potential future testing, for research ordered by my healthcare provider and/or for quality control purposes. If this box is not checked, unused specimen will be destroyed 60 days after testing is completed. Opting in or out will not impact the quality of care or testing you receive.**

By signing this consent below, you nevertheless authorize the use of your sample, results, and other data and information generated during the performance of Test(s) for the purposes described in this consent. At the end of the testing process, Belay may choose to destroy or return your sample, maintain it for a future Test(s) ordered by your healthcare provider, or convert it into "Residual Information and Materials" (as defined below) and retain it indefinitely.

Belay may redact information that directly identifies you from your sample, the results of Test(s), other data and information generated during performance of Test(s), and other health or demographic information that Belay receives about you to create "Residual Information and Materials." Belay may maintain and use the Residual Information and Materials for any purpose permitted by federal and state law, including but not limited to:

- Ongoing development of testing methodologies to aid in improved diagnosis of primary and metastatic brain cancers.
- Performing quality assurance, test validation, and other operations purposes.
- Conducting commercial development and research, including performing additional analyses using the Residual Information and Materials for scientific and/or research purposes.
- Aggregating the Residual Information and Materials with similar residual information from other individuals, which may be used to create, or be disclosed to, databases or datasets that are solely or jointly owned by Belay or may be submitted to public databases to advance medical research.

The Residual Information and Materials may also be shared with third-parties, including, but not limited to, pharmaceutical and medical device companies, hospitals and universities, and other entities. You are not entitled to compensation for the use of the Residual Information and Materials or rights to any products or discoveries resulting from use of the Residual Information and Materials. Notwithstanding the foregoing, Belay will retain any of your identifiable or de-identified data as required by applicable federal or state laws or regulations.

Acknowledgement

By signing below, I confirm that I have read this consent in its entirety, understand it, and have had the opportunity to speak with my healthcare provider about Test(s) including the cost and financial responsibility, purpose, risks, benefits, and testing alternatives. I understand that I may raise any future questions or concerns related to Test(s) or this consent with my healthcare provider at any time. I request that my Test(s) proceed and authorize my sample to be taken and released for the performance of Test(s). I further authorize Belay to maintain, use, and disclose my sample and any information related to my Test(s) as described in this consent.

I agree that I will be solely responsible for the full cost of Test(s). I agree and acknowledge that I am requesting this testing for the purpose of informing my diagnosis and/or further treatment if indicated by the results. I acknowledge my financial responsibility as described above.

I agree that Belay may contact me at the email address or telephone number listed above for any additional information relating to my medical history that may be required for Test(s). I also understand that this consent is voluntary, treatment from my healthcare provider is not conditioned upon it, and I may opt out of it at any time by contacting Belay at contact@belaydiagnostics.com or by calling +1 (331) 320-0155.

Patient or Representative/Guardian Signature*	**Date***
Representative/Guardian Printed Name and Relationship to Patient (If Applicable)*	

◯ **By checking this box, I am requesting an application for the BelayAccess™ program through which financial assistance may be available to certain patients on the basis of need.**

Clear Form

A. Notifier:

B. Patient Name: **C. Identification Number:**

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for **D. Summit/Ascent/Vantage** below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider has good reasons to think you need. We expect Medicare may not pay for the **D. Summit/Ascent/Vantage** below.

D. Test(s)	E. Reason Medicare May Not Pay	F. Estimated Cost
Summit 2.0	Not covered under Medicare guidelines	$ 3,200
Ascent	Not covered under Medicare guidelines	$ 1,200
Vantage	Not covered under Medicare guidelines	$ 275

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D. Summit/Ascent/Vantage** listed above.

  Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you

☐ **OPTION 1.** I want the **D. Summit/Ascent/Vantage** listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the **D. Summit/Ascent/Vantage** listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed**.

☐ **OPTION 3.** I don't want the **D. Summit/Ascent/Vantage** listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048). Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:	J. Date: