



April 26, 2022

Annual Notice to Physicians 2022

Dear Physician/Client:

The Office of the Inspector General (OIG) has issued guidance that recommends laboratories provide notices to physicians and other ordering providers annually as part of their compliance plan. Caris Life Sciences® (Caris) is issuing this notice in accordance with this recommendation. We are committed to conducting business in accordance with all federal, state and local laws, and in adherence with program requirements for all federal, state and private health plans. This letter serves as continuing education for ordering providers on our policies and procedures as they relate to these expectations.

Clinical Consultant

Caris medical staff, including Medical Director Dr. Matthew Oberley, are available to assist with reference testing questions, including ordering and interpretation. Please contact Customer Support at 888-979-8669 or CustomerSupport@CarisLS.com to schedule a consultation.

Test Ordering

Comprehensive tumor profiling from Caris assesses DNA, RNA and Proteins with multiple technologies to reveal a more complete molecular blueprint to guide precise and individualized treatment decisions and improve patient outcomes.

- MI Profile™ – Multi-platform, solid tumor biomarker analysis. Whole Exome Sequencing (DNA) and Whole Transcriptome Sequencing (RNA), including molecular signature analysis of LOH, MSI, and TMB, as well as HLA Genotyping, pyro sequencing, IHC, and *in situ* hybridization. Caris FOLFIRSTai™ will be performed for mCRC cases.
- MI Tumor Seek™ – NGS analysis. Whole Exome Sequencing (DNA) and Whole Transcriptome Sequencing (RNA). Includes molecular signature analysis of LOH, MSI, and TMB, as well as HLA Genotyping. Caris FOLFIRSTai will be performed for mCRC cases. Additional Immuno-Oncology IHC biomarkers can be added: PD-L1 and MMR (MLH1, MSH2, MSH6, PMS2).
- Caris GPSai™ – Cancer type similarity assessment consisting of algorithmic analyses of the genomic (DNA) and transcriptomic (RNA) characteristics of the tumor as compared to more than 20 distinct tumor types in the Caris database. Only available if MI Profile or MI Tumor Seek is ordered.

In certain localities, a given Caris test may not be approved¹. If the test is ordered in those regions, Caris may change the order to a version that is approved (if available), which may include some features ordered by the provider. Alternatively, Caris may cancel the ordered test and the ordering provider will be notified.



Reflex Laboratory Tests

Based on the submitted sample and after initial assessment, reflex testing may be automatically performed for limited tissue cases, and separately billed. Further information about Caris reflex testing can be found on the Caris website (www.CarisLifeSciences.com).

Caris Reporting

The Caris report aligns the molecular profile of the patient's tumor to a list of relevant therapeutic agents associated with potential benefit or potential lack of benefit. The report is designed to provide the key biomarker and therapeutic information in an easy to interpret front page, with details of all testing performed and references supporting the therapeutic association provided later in the report. After testing, the Caris report can be delivered via the practice's EMR, fax, email (MI Portal credentials required), Caris+ App or MI Portal.

Medical Necessity

Medicare pays for services that are reasonable and necessary and meet specified Medicare coverage criteria for the beneficiary's unique medical condition.

As a participating Medicare provider, Caris has the responsibility to make good faith efforts to ensure that all tests requested are performed and billed in a manner that is consistent with federal and state statutes and regulations. The OIG takes the position that ordering providers authorized by law to order clinical laboratory tests for Medicare beneficiaries share the burden of ensuring that only medically necessary services are ordered and billed to Federally funded programs. Providers who submit false claims may be subject to sanctions or remedies available under civil and administrative law.

The Caris Test Requisition Form (TRF) includes a comprehensive set of attestations to determine the coverage status for Medicare services. Completion of the "Relevant Clinical History" section of the TRF enables appropriate determination of coverage for rendered services.

Laboratory claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary, given his or her clinical condition, as defined by CMS.

Advance Beneficiary Notice (ABN)

Medicare will only pay for Part B Laboratory services that are determined to be reasonable and necessary. We may need to obtain an Advance Beneficiary Notice (ABN) and/or provide a Notice of Non-Coverage to a beneficiary/patient in advance of what is believed to be a non-covered laboratory service (as determined by the Centers for Medicare and Medicaid Services (CMS) guidelines and/or the fiscal intermediary, and/or other third-party payers).



Medicare Reimbursement Fee Schedule

Medicare reimburses laboratory services based upon a published fee schedule. Medicaid FFS programs typically reimburse based on a fee schedule and the reimbursement is typically equal to or less than the amount Medicare reimburses.

Medicare Coverage Determinations

Services rendered by Caris Life Sciences are typically documented in either Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs). LCDs and NCDs have sections describing what medical conditions are covered and the ICD-10 codes that are covered. All clinical orders sent to Caris must include at least one ICD-10 code and should include all appropriate ICD-10 codes which describe the patient's unique medical condition.

Prohibited Referrals and Inducements

It is the policy of Caris to comply with both the Physician Self-Referral Law (Stark) and the Anti-Kickback Statute. If a financial relationship exists between a physician (or their immediate family member) and a laboratory, the Stark Law prohibits the physician from referring Medicare beneficiaries to the laboratory, and the laboratory cannot bill Medicare for any services referred by the physician unless the financial relationship between the parties falls into one of the law's exceptions. The Anti-Kickback Statute prohibits the knowing or willful offer, payment, solicitation, or receipt of remuneration in order to induce business reimbursed under the Medicare or Medicaid programs. Any form of kickback or inducement to secure Medicare or Medicaid referrals is strictly prohibited.

Patient Privacy

Under the Health Insurance Portability and Accountability Act (HIPAA), Caris is a healthcare provider and a covered entity. We are committed to compliance with all HIPAA privacy and security standards. A copy of our Notice of Privacy Practices is available at www.CarisLifeSciences.com/privacy-us.

Thank you for your time and attention to these important concepts. If you have any questions or require any further information, please contact me directly at 866-771-8946.

Thank you,

Ginger Appleberry
SVP, Chief Compliance Officer and Deputy General Counsel
Caris Life Sciences

1. Caris FOLFIRSTai, Caris GPSai, HLA Genotype, etc.