March 8, 2024

2024 Annual Notice to Physicians

Dear Physician/Client:

In accordance with the requirements of The Office of the Inspector General (OIG), this letter serves as the Caris Life Sciences® (Caris) annual notice to physicians and other qualified healthcare providers. The information below provides an overview of our policies and procedures and reflects our commitment to conducting business in accordance with federal, state and local laws, as well as adherence with program requirements for federal, state and private health plans. Additional details related to privacy policies, terms and conditions and other procedures can be found at www.CarisLifeSciences.com.

Clinical Consultant

Clinical operations and overall laboratory quality is led by Senior Vice President and Executive Medical Director, Matthew Oberley, MD, PhD. Caris medical staff, including Dr. Oberley, are available to assist with testing questions including ordering or result interpretation. Please contact Customer Support at 888-979-8669 or CustomerSupport@CarisLS.com to schedule a consultation.

Testing Options

No matter the specimen type, tissue or blood, comprehensive tumor profiling from Caris reveals a more complete molecular blueprint to decode cancer and guide more precise and individualized treatment decisions that may improve patient outcomes.

Tissue-based molecular profiling:

- **MI Profile™** (comprehensive testing): MI Tumor Seek Hybrid™ + IHCs and Other Tests by Tumor Type. Whole exome sequencing (WES) and whole transcriptome sequencing (WTS) analysis, plus additional tumor type relevant biomarker testing (IHC, ISH, etc.). Caris FOLFIRSTai™ is performed for mCRC cases and Caris GPSai™ is performed for CUP cases.
- **MI Tumor Seek Hybrid™** (next-generation sequencing only): WES and WTS analysis. Caris FOLFIRSTai is performed for mCRC cases and Caris GPSai is performed for CUP cases.
- **Caris FOLFIRSTai™**: an AI-powered chemotherapy response predictor that is intended to gauge a mCRC patient's likelihood of benefit from first-line FOLFOX+BV followed by FOLFIRI+BV, versus FOLFIRI+BV followed by FOLFOX+BV treatment.
- **Caris GPSai™**: an AI-powered cancer type similarity assessment that is intended to help identify the tumor of origin by comparing the molecular characteristics of the patient's tumor against other tumors in the Caris database.

Blood-based molecular profiling:

- **Caris Assure™**: Blood-based WES and WTS for pathogenic and likely pathogenic tumor-derived, incidental germline and incidental CHIP variant detection. Caris Assure is intended for patients with previously diagnosed solid malignant neoplasms where tissue is not available. RNA results are intended for investigational purposes only. This assay is not a replacement for comprehensive germline testing. Incidental pathogenic alterations detected in ACMG recognized cancer genes are reported. Negative results do not imply the patient does not harbor a germline mutation.

In certain localities, specific Caris tests or features may not be approved[1]. If such a test is ordered in those regions, Caris may alter 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 Testing

Reflex testing is additional testing that is automatically performed based on the initial results and is separately billed. Further information about Caris reflex testing can be found at www.CarisLifeSciences.com.

Caris Reporting

The Caris report outlines the molecular profile of the patient's tumor and aligns the biomarker results 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, necessary and meet specified 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.

Signed Requisitions

Although the provider signature is not required on laboratory requisitions, if signed the requisition will serve as acceptable documentation of a physician order for the testing. This will mitigate the risk of Caris reaching out to your staff to retrieve evidence of the signed test order in your patient chart, and so is strongly encouraged. In the absence of a signed requisition, documentation of your intent to order each laboratory test must be included in the patient's medical record and available to Caris upon request, as needed. Documentation must accurately describe the individual tests ordered; it is not sufficient to state "labs ordered". Upon request by Caris or its payors/auditors, ordering providers are required to provide any/all chart documentation (including physician signature) that reflect the actual lab order and supports the authenticity and medical necessity of the lab order(s) submitted.

Advance Beneficiary Notice (ABN)

Medicare will only pay for Part B Laboratory services that are determined to be reasonable and necessary. Caris 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 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 Caris' policy 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 to induce business reimbursed under the Medicare or Medicaid programs. Any form of kickback or inducement to secure Medicare or Medicaid referrals is 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. 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. MI Tumor Seek Hybrid, Caris Assure, Caris FOLFIRSTai, Caris GPSai, HLA Genotype, Homologous Recombination Deficiency (HRD) etc.