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Annual Physician Notice as Required by the Office of the Inspector General

Pathology Consultants, P.C. dba Open Sky Laboratory, (OSL) is committed to conducting business in adherence with all applicable federal and state laws, and to comply with the program requirements of federal, state, and private health plans. In accordance with the Office of the Inspector General Compliance Program Guidance for Clinical Laboratories, published on August 24, 1998, we are providing the following information about Medicare requirements:

Medical Necessity

Physicians and other individuals authorized to order tests should only order tests that are medically necessary for the diagnosis or treatment of the patient. The Federal Office of Inspector General (OIG) takes the position that when medically unnecessary tests are ordered which result in false claims to Medicare, the physician may be subject to civil penalties under the False Claims Act. Medicare does not pay for screening tests except for certain specifically approved procedures that have frequency limits. Medicare also may not pay for non-FDA approved tests or those considered to be experimental. The medical necessity for tests performed must be documented in the patient's medical record. For OSL to bill tests to Medicare, the ordering clinician **must include the specific ICD-10 diagnosis code(s) for each test ordered.** OSL will not bill Medicare for tests that are not covered, are unreasonable, or unnecessary.

Advance Beneficiary Notice of Non-coverage (ABN)

If there is reason to believe that Medicare will not pay for a test, the patient (Medicare beneficiary) should be informed. The patient should sign a properly completed Advance Beneficiary Notice of Noncoverage (ABN) to indicate that he/she is responsible for the cost of the test if Medicare denies payment.

To be accepted by Medicare, the ABN must be completed by the patient before a service is provided. The ABN must include the patient's first and last name (middle initial also if on the beneficiary's Medicare card), laboratory test name(s), reason for possible denial, estimated cost, signature of patient, and the date signed. The patient must also choose one of the following options:

- Option One: "I want the **Test(s)** 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 Two: “I want the **Test(s)** 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 Three: “I don’t want the **Test(s)** listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**”

The signed ABN notifies the Medicare beneficiary that Medicare is likely to deny payment for a specific service, the reason why, and that the patient is responsible for payment if Medicare denies payment. ABNs should not be used for every patient encounter. ABNs should be used only if you have reason to believe Medicare will deny payment based on your patient’s diagnosis, or if you believe the test may exceed frequency limits. OSL includes an official ABN form on the website, http://tests.openskylaboratory.com/OSLTestCatalog/Collect/OSL_ABN.pdf OSL will not bill Medicare beneficiaries for tests performed that are denied as medically unnecessary unless an ABN has been signed by the patient.

Medicare’s National Coverage Determinations (NCDs) and the Local Coverage Determinations (LCDs)

NCDs were developed via a negotiated rulemaking process that involved Medicare officials and representatives of clinical labs, physician, consumer, and hospital groups. The NCDs promote consistency and standardization of medical necessity nationwide. The Medicare Administrative Contractor (MAC) has Local Coverage Determinations (LCDs) for additional tests that are not among the NCDs. Both the NCDs and LCDs specify whether a service is reasonable and necessary, what documentation will support the need for the service, and limit coverage to specific medical diagnosis.

The list of laboratory tests that have a NCD can be found on this website:

<https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=190&sortBy=chapter> .

LCDs can be found on the Noridian Medicare Part B website:

<https://med.noridianmedicare.com/web/jeb/policies/lcd/active>

Organ and Disease Oriented Panels

Organ and disease related panels will only be billed and paid by Medicare when **all** components are medically necessary and are reasonable to treat or diagnose an individual patient.

Per CMS, claims submitted with individual lab tests that are part of a specific panel will be returned to the provider as unable to be processed. Providers should refer to the NCCI Policy Manual Chapter 1, Section N – Laboratory Panel and Chapter 10, Section C – Organ or Disease Oriented Panels for complete billing and coding information.

[2025 Medicare NCCI Policy Manual – Chapter 1 REVISED FINAL](#)
[Medicare NCCI 2025 Coding Policy Manual – Chapter 10](#)

Medicare National Limitation Amounts

Medicare National Limitation Amounts for CPT codes are published by CMS each year. See Link for the most common tests/CPT codes OSL bills Medicare.

<https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/files>

Medicaid reimbursements are equal to or less than the amount of Medicare reimbursement.

Reflex Tests

A list of tests performed in our laboratory that may result in “reflex” test orders may be found on the Laboratory Test Catalog:

http://tests.openskylaboratory.com/OSLTestCatalog/Collect/Reflex_Tests.pdf

These reflex tests are consistent with regional and national standards of practice in an attempt to provide appropriate or useful information to the clinician. Our laboratory will generate an order for the appropriate additional reflex test(s). The option of ordering any one of these tests without the reflex is available.

CPT Codes

The CPT Codes published by OSL in our electronic handbook are provided for informational purposes only. The codes reflect our interpretation of CPT coding requirements based on AMA guidelines published annually. OSL assumes no responsibility for billing errors due to reliance on CPT codes published by OSL.

Clinical Consultants

The following Pathology Consultants, P.C. pathologist, serves as Open Sky’s clinical laboratory consultant:

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For questions, call OSL at 701-532-1895