

# 2024 Annual Notice to Providers



The United States Department of Health and Human Services (DHHS) Office of Inspector General (OIG) has requested that all clinical laboratories annually provide their providers with the following information. Additionally, the Federal government has requested that all laboratories inform you of certain government policies that apply to physicians and other individuals authorized by law to order laboratory tests. Please take a few minutes to review this information. We value your business and appreciate the opportunity to serve your laboratory needs in conjunction with these initiatives.

## Guidance on Medical Necessity

When placing orders, providers are required to consider medical necessity, frequency of testing, and specificity to the patient according to individual payor guidelines.

**It is the responsibility of the provider to ensure medical necessity is documented in the patient's medical record.**

Physicians and other authorized ordering parties should only order AMA-defined Organ/Disease Panels when all components are medically necessary. Payment for individual components of AMA defined Organ/Disease Panels will be rejected if not medically necessary. The Medicare Clinical Laboratory Fee schedule may be viewed and downloaded using the following link: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html>. Customized profiles may result in ordering component tests that are not covered, reasonable, or necessary may not be billed to Medicare and are, therefore, discouraged. Physicians and other authorized ordering parties should order individual tests or a less inclusive profile when not all the tests are medically necessary for an individual patient. The OIG takes the position that physicians and other authorized individuals may be subject to civil monetary penalties if they order medically unnecessary tests. Any individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies under civil, criminal, and administrative law.

### Toxicology

Presumptive testing should be conducted initially, and direct definitive tests avoided unless:

- Presumptive testing is unavailable for the analyte in question.
- Presumptive results are inconsistent with clinical history.

Further guidance can be viewed using the following link: [LCD - Controlled Substance Monitoring and Drugs of Abuse Testing \(L35006\) \(cms.gov\)](#)

### Genomics

With the continued expansion of testing availability in molecular pathology, cytogenetics, and genetics, many procedures are not covered services due to failing to meet medical necessity as they do not affect the clinical management of the patient. Certain tests may be subject to medical review and pre-authorization.

Further guidance can be viewed using the following link: [MCD Search Results \(cms.gov\)](#)

## National and Local Coverage Determinations

The Centers for Medicare and Medicaid Services (CMS) has developed National Coverage Determinations (NCDs), which provide direction for medical necessity on selected tests. CMS has authorized Novitas Solutions, the Medicare Part B carrier for Pennsylvania and New Jersey, to develop Local Coverage Determinations (LCDs), which may supplement or be in addition to the NCDs, and to give directions for medical necessity on selected tests. LCDs may not contradict NCDs. A complete list of laboratory NCDs and LCDs may be viewed using the following link: <https://www.cms.gov/medicare-coverage-database>.

## Advanced Beneficiary Notice (ABN)

A valid diagnosis is required for each laboratory test ordered. Medicare reimbursement may be denied for certain tests (e.g., screening, non-covered, medically unnecessary, experimental, research only, non-FDA-approved tests), diagnoses, or ordering frequencies. When Medicare is likely to deny payment, the patient must be notified prior to specimen collection.

If the patient chooses to have the testing performed, they must sign an Advanced Beneficiary Notice (ABN) confirming their understanding that they will be responsible for payment. It is the responsibility of the physician and other authorized ordering party to obtain a properly completed ABN when the patient is serviced in his/her office.

## ICD-10-CM Codes

Section 4317 of the Balanced Budget Act of 1997 requires the physician or authorized ordering party to submit a diagnosis to the laboratory for submission of a Medicare claim. It is the responsibility of the physician or authorized ordering party to document the diagnosis in the patient's medical record. Information about ICD-10-CM Codes may be viewed using the following link: <https://www.cms.gov/Medicare/Coding/ICD10/index.html>.

## Authorized to Order Laboratory Testing

The ordering individual is aware that the clinical laboratory may only bill Medicare and Medicaid for tests ordered by a licensed physician or other individual authorized by law to order laboratory tests. If your license has been revoked or suspended, it is your responsibility to immediately notify the laboratory.

## Questions?

The physician or authorized ordering party may contact a customer service representative to ensure proper test ordering. A representative may be reached at (877) 402-4221. Technical specialists or consultants in various areas of expertise are available upon request.

## AMA RECOGNIZED ORGAN/DISEASE PANELS

This table is designed to assure that providers are aware of and understand AMA defined Organ/Disease Panels and their applicable Medicare/Medicaid reimbursement rates, patient pricing and currently used Current Procedural Terminology (CPT) codes.

If individual components are ordered, HNL Lab Medicine will bundle as appropriate.

PANEL ORDER CODE	PANEL NAME & COMPONENTS	PANEL CPT CODE	MEDICARE ALLOWABLE	PA MEDICAID ALLOWABLE	NJ MEDICAID ALLOWABLE
AHEP	<b>Acute Hepatitis Panel</b> Hepatitis A Antibody, IgM (HAV Ab, IgM), Hepatitis B Surface Antigen (HbsAg), Hepatitis B Core Antibody, IgM (HbcAb, IgM), Hepatitis C (HCV) Antibody Screen	80074	\$47.63	\$52.66	\$30.00
BMP	<b>Basic Metabolic Panel (Calcium, Total)</b> Calcium, Carbon dioxide (CO2), Chloride, Creatinine, Glucose, Potassium, Sodium, Urea Nitrogen (BUN)	80048	\$8.46	\$9.36	\$9.30
CPMP	<b>Comprehensive Metabolic Panel</b> Alanine Aminotransferase (ALT), Albumin, Alkaline Phosphatase, Calcium, Carbon dioxide (CO2), Chloride, Creatinine, Glucose, Aspartate Aminotransferase (AST), Potassium, Protein, Total, Sodium, Bilirubin, Total Urea Nitrogen (BUN)	80053	\$10.56	\$11.69	\$10.50
ELEC	<b>Electrolyte Panel</b> Sodium, Potassium, Chloride, Carbon dioxide (CO2)	80051	\$7.01	\$7.00	\$5.90

PANEL ORDER CODE	PANEL NAME & COMPONENTS	PANEL CPT CODE	MEDICARE ALLOWABLE	PA MEDICAID ALLOWABLE	NJ MEDICAID ALLOWABLE
LFP	<b>Liver Function Panel (Hepatic Function Panel)</b> Alanine Aminotransferase (ALT), Albumin, Alkaline Phosphatase, Aspartate Aminotransferase (AST), Bilirubin, Direct, Bilirubin, Total, Protein, Total	80076	\$8.17	\$9.03	\$7.00
LIPAN	<b>Lipid Panel</b> Cholesterol, Total, Direct Triglyceride, HDL Cholesterol	80061	\$13.39	\$14.00	\$15.00
PN1	<b>Obstetrics Panel</b> ABO/RH(D) and Antibody Screen, CBC with Differential, Hepatitis B Surface Antigen, Rubella IgG Ab, Immune Status Syphilis Serology	80055	\$47.81	\$12.00	\$15.00
RFP	<b>Renal Function Panel</b> Albumin, Calcium, Carbon dioxide (CO2), Chloride, Creatinine, Glucose, Phosphorus, Potassium, Sodium, Urea Nitrogen (BUN)	80069	\$8.68	\$9.60	\$9.60