



## Annual Notice to Providers 2021

Dear Valued Client:

The Office of Inspector General for the U.S. Department of Health and Human Services (“OIG”) has requested that clinical laboratories annually send notices to physicians and practitioners authorized by law to order laboratory tests that are reimbursed by Medicare, Medicaid or another federally funded healthcare program (hereafter, “Federal Programs”). Accordingly, and as part of our corporate compliance program, Enzo is sending this to all physicians and practitioners who order tests from us. Please carefully review the information contained in this notice. If you have any questions, please contact Enzo at 800-522-5052 and ask to speak with either our Compliance Officer or Medical Director.

**Licensed Physicians/Excluded Providers.** Enzo may only bill for testing ordered by a licensed physician or practitioner authorized by law to order laboratory tests. It is your responsibility to stop ordering tests and to immediately notify us if: (a) your license has been revoked or suspended; (b) you have been excluded from the Federal Programs; or (c) if your enrollment in Federal Programs has been revoked or suspended.

**Medical Necessity and Diagnosis Codes.** Federal Programs will only pay for tests if the test is covered, reasonable, and medically necessary for the beneficiary, given his or her clinical condition. A medically necessary test is defined as one that is reasonable and necessary for the diagnosis or treatment of an illness or injury. Physicians/practitioners should only order those tests that they believe are medically necessary for the diagnosis and treatment of their patient. Federal Programs will deny payment for a test that is not necessary, such as most screening tests. In addition, your medical records must document the medical necessity for the tests ordered and, upon receipt of test results, updated to demonstrate how you used the information in the care and treatment of your patient.

The Centers for Medicare and Medicaid Services (CMS) has developed National Coverage Determinations (NCDs) that define medical necessity for certain tests. Local Coverage Determinations (LCDs) are also published by contractors, such as NGS. You should review the NCDs and LCDs – particularly the medical necessity requirements –for the tests that you order. NCDs and LCDs can be viewed at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.

In addition, physicians who order laboratory tests are required to provide diagnostic information at the time that the test is ordered. Enzo’s requisition forms have designated space for you to include these codes as required. The ICD-10 codes selected by you must be accurate and as specific as possible, based on the patient’s actual condition and information that is otherwise documented in the medical record. If you are ordering a test and cannot yet determine a diagnosis, you must provide the appropriate ICD-10 code that describes the patient’s signs and symptoms.

Providing complete and accurate diagnosis information at the time the test is ordered not only meets government requirements, but also minimizes the need for Enzo to contact you afterwards to request additional diagnostic information. The OIG requires that, when the diagnosis is unclear or

has not been provided, the laboratory “contact the ordering physician” to obtain the necessary information. Laboratories are prohibited from using diagnostic information provided by the physician from earlier dates of service (except for certain standing orders, as described below), and from inserting diagnosis codes based on their own evaluation of the patient’s probable or most likely diagnosis, or from speaking with a patient. If the information your office has provided to Enzo is inadequate or incomplete, we will contact your office in accordance with OIG guidance.

Providing complete and accurate information is very important. The OIG takes the position that physician/practitioners who knowingly cause a false claim to be submitted to any federally funded program (for example, by ordering medically unnecessary tests) may be subject to sanctions or remedies available under civil, criminal and administrative law, such as the False Claims Act. Potential penalties also include exclusion from Federal Programs.

**American Medical Association (AMA) Defined Organ/Disease Panels.** These panels may only be ordered when all components are medically necessary. Physicians/practitioners should order individual tests or a less inclusive profile if all tests in a panel are not medically necessary for an individual patient. A list of the 2016 AMA defined Organ/Disease Panels and their detailed test components is provided with this letter.

**Customized Profiles.** Custom panels are available to physicians/providers. The scope of the panel is documented in writing prior to utilization and annual review and approval by the physician is required to continue a panel’s use. The OIG has noted that such profiles present the danger that, by defaulting to such a profile, the physician may in a particular case be ordering one or more medically unnecessary tests contained in the profile. The OIG takes the position that ordering unnecessary tests within a profile, even when done without a specific intent to defraud, may subject the ordering physician to civil penalties. The government, of course, will usually pay in the first instance for each test within the profile; but, if one or more of those tests is later determined to have been medically unnecessary for the specific patient, then the submission of the claim may be considered to have been improper or fraudulent. Thus, when using a customized profile to order test, you should ensure that each test within the profile is, in fact, medically necessary for each specific patient.

**Standing Orders and Reflex Tests.** In situations in which a patient is receiving an extended course of treatment, it may be necessary to create a standing order with the laboratory to have the same test conducted on a periodic basis. While such orders are not prohibited as a matter of law, the OIG notes that such orders have “too often in the past” led to “fraudulent and abusive practices.” Like any other order for tests that will be reimbursed by Federal Programs, each test must be medically necessary. As a result, once it is no longer necessary to conduct a test specified in a standing order, the order must be terminated. The OIG asks laboratories to verify the patient’s continuing need for a specified test. Accordingly, we will periodically contact you to conduct such verification.

Reflex confirmatory testing may be performed depending on the testing ordered by the physicians/providers. Reflex testing occurs when the initial test results are positive and/or inconsistent with expected results based on the patient’s prescribed therapy and indicate that a second related test is medically appropriate. It is the physicians/providers’ responsibility to ensure documentation is present in the patient’s medical record to support reflex testing.

**Advance Beneficiary Notice of Non-coverage.** If you deem it clinically appropriate to order a test that Medicare may find to be medically unnecessary and thus not reimbursable, we ask that you have the patient complete and sign a Medicare Advance Beneficiary Notice of Non-coverage form. This notice informs that patient that the test may not be covered by Medicare and that he or she thus may be liable for paying for the test. In cases in which medically unnecessary tests are performed for a Medicare patient, the patient generally may not be billed for the service without such a notice having been completed. You can find the Advance Beneficiary Notice of Non-coverage Form (CMS-R-131), instructions on using the form and more information from CMS on this topic here: <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN#:~:text=The%20Advance%20Beneficiary%20Notice%20of,payment%20is%20expected%20to%20be>

**Medicare Clinical Laboratory Fee Schedule.** Medicaid reimbursement amounts will be equal to or less than the amount of Medicare reimbursement. The Medicare Clinical Laboratory Fee Schedule may be viewed and downloaded at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/02clinlab.asp>.

**2021 AMA Recognized Organ/Disease Panel (eff. 1/1/2021)**

Panel Number	Panel Name and Components	Panel CPT	2021 Medicare Allowable <sup>1</sup>	2021 Medicaid Allowable <sup>2</sup>
90017	<b>ACUTE HEPATITIS PANEL</b>	80074	\$47.63	No published rate as Medicaid considers this a non-covered service.
	Hepatitis A Ab IgM      Hepatitis B Surface Ag Hepatitis B Core Ab IgM      Hepatitis C Ab			
7053	<b>BASIC METABOLIC PANEL</b>	80048	8.46	\$7.25
	Calcium, Total      Glucose			
	Carbon Dioxide      Potassium			
	Chloride      Sodium Creatinine      Urea Nitrogen			
7055	<b>COMPREHENSIVE METABOLIC PANEL</b>	80053	\$10.56	\$10.00
	Albumin      Phosphatase, Alkaline			
	Bilirubin, Total      Potassium			
	Calcium, Total      Protein, Total			
	Carbon Dioxide      Sodium			
	Chloride      ALT (SGPT)			
	Creatinine      AST (SGOT) Glucose      Urea Nitrogen			
9081	<b>ELECTROLYTE PANEL</b>	80051	\$7.01	\$6.04
	Carbon Dioxide      Potassium Chloride      Sodium			
93839	<b>GENERAL HEALTH PANEL</b>	80050	No published rate as Medicare considers this a non-covered service.	No published rate as Medicaid considers this a non-covered service.
	Comprehensive Metabolic Panel Complete Blood Count TSH			
93240	<b>HEPATIC FUNCTION PANEL</b>	80076	\$8.17	\$7.25
	Albumin      Protein, Total			
	Bilirubin, Total      ALT (SGPT)			
	Bilirubin, Direct      AST (SGOT) Phosphatase, Alkaline			
7100	<b>LIPID PANEL</b>	80061	\$13.39	\$6.04
	Cholesterol			
	HDL Cholesterol Triglycerides			
9778	<b>OBSTETRIC PANEL</b>	80055	\$47.81	No published rate as Medicaid considers this a non-covered service.
	Antibody Screen      Hepatitis B Surface Ag			
	Blood Typing, ABO      RPR			
	Blood Typing, Rh (D)      Rubella Ab Complete Blood Count			
96583	<b>RENAL FUNCTION PANEL</b>	80069	\$8.68	\$8.68
	Albumin      Glucose			
	Calcium, Total      Phosphatase, Alkaline			
	Carbon Dioxide      Potassium			
	Chloride      Sodium Creatinine      Urea Nitrogen			