

## Medical Necessity

### ◇BACKGROUND

The 1965 Social Security Act [under Section 1862 (a) (1) (A)] requires that “*Medicare will cover only those services that are medically necessary. The Medicare program does not cover items and services that are not reasonable and necessary for the diagnosis or treatment of an illness, injury, or to improve the functioning of a malformed body member.*”

For an item or service to be **considered medically necessary**, it must be:

- Consistent with the symptoms or diagnosis of the illness or injury under treatment; **and**
- Necessary and consistent with generally accepted professional medical standards (i.e., not experimental); **and**
- Not furnished primarily for the convenience of the patient or provider; **and**
- Furnished at the most appropriate level that can be provided safely and effectively to the patient.

Therefore, Medicare may deny payment for a test the provider believes is appropriate, but which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the patient’s medical record does not support that the tests ordered were reasonable and necessary for a given patient. Tests submitted for Medicare reimbursement must meet program requirements or the claim may be denied.

The ordering provider should retain in the patient's medical record the history and physical examination notes documenting evaluation and management of one of the Medicare covered conditions/diagnoses, with relevant clinical signs/symptoms or abnormal laboratory test results, appropriate to one of the covered indications. The patient's medical record should further indicate changes/alterations in medications prescribed for the treatment of the patient's condition. There must be an order for each test documented in the patient's medical record. Documentation must be submitted to Medicare upon request. **The patient's medical record must include documentation to support medical necessity.**

### ◇MEDICAL RECORD DOCUMENTATION

- Title XVIII of the Social Security Act, section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.
- 42CFR410.32. Diagnostic tests may only be ordered by a treating physician or other authorized individual (or other treating practitioner) acting within the scope of their license and Medicare requirements.

Diagnosis codes and/or signs and symptoms must be supported by the patient's medical record:

- For each CPT code billed, there should be documentation that the service was performed
- Documentation must also substantiate the level of service billed
- Documentation should be written on a timely basis
- The medical records should be annotated by the provider who performed the service

### ◇ORGAN AND DISEASE ORIENTED PANELS

#### **Effective January 1, 1997**

In an effort to assist providers with ordering, the Centers for Medicare and Medicaid (CMS) and the American Medical Association (AMA) worked together to develop the "Organ and Disease Oriented Panels." The premise behind the development of these panels was to allow the provider to order tests that are medically necessary for a certain condition by ordering the appropriate panel rather than the individual tests. The strategy was to eliminate the old automated multi-channel panels and replace them with more clinically grounded groupings of tests. To use the organ or disease oriented code, the laboratory must perform each test listed under the panel. The laboratory is not allowed to make changes or substitutions in the test composition of the panels.

It is important to remember that even though CMS views the ordering of an Organ or Disease Oriented Panel as ordering an individual test, **there must be documentation in the patient’s medical record to support the medical necessity for each test within the panel.** Sanford Laboratories provides updated and new limited coverage information to clients as it becomes available. All claims are subject to post-payment review. If this occurs, our carrier may require the laboratory to produce documentation from the medical record that would support medical necessity for each test billed to Medicare.

**ORGAN AND DISEASE ORIENTED PANELS - as of January 1, 2017**

PANEL NAME & CODE	LIST OF TESTS
<b>Acute Hepatitis Panel CPT 80074</b>	<ul style="list-style-type: none"> <li>- Hepatitis A antibody (IgM) (86709)</li> <li>- Hepatitis B core antibody (IgM) (HBcAb) (86705)</li> <li>- Hepatitis B surface antigen (HBsAg) (87340)</li> <li>- Hepatitis C antibody (86803)</li> </ul>
<b>Basic Metabolic Panel CPT 80047</b>	<ul style="list-style-type: none"> <li>- Calcium, ionized (82330)</li> <li>- Carbon dioxide (82374)</li> <li>- Chloride (82435)</li> <li>- Creatinine (82565)</li> <li>- Glucose (82947)</li> <li>- Potassium (84132)</li> <li>- Sodium (84295)</li> <li>- Urea Nitrogen (BUN) (84520)</li> </ul>
<b>Basic Metabolic Panel CPT 80048</b>	<ul style="list-style-type: none"> <li>- Calcium (82310)</li> <li>- Carbon dioxide (82374)</li> <li>- Chloride (82435)</li> <li>- Creatinine (82565)</li> <li>- Glucose (82947)</li> <li>- Potassium (84132)</li> <li>- Sodium (84295)</li> <li>- Urea Nitrogen (BUN) (84520)</li> </ul>
<b>Comprehensive Metabolic Panel CPT 80053</b>	<ul style="list-style-type: none"> <li>- Albumin (82040)</li> <li>- Alkaline Phosphatase (84075)</li> <li>- ALT (SGPT) (84460)</li> <li>- AST (SGOT) (84450)</li> <li>- Bilirubin, total (82247)</li> <li>- Calcium (82310)</li> <li>- Carbon dioxide (82374)</li> <li>- Chloride (82435)</li> <li>- Creatinine (82565)</li> <li>- Glucose (82947)</li> <li>- Potassium (84132)</li> <li>- Sodium (84295)</li> <li>- Total Protein (84155)</li> <li>- Urea Nitrogen (BUN) (84520)</li> </ul>
<b>Electrolyte Panel CPT 80051</b>	<ul style="list-style-type: none"> <li>- Carbon dioxide (82374)</li> <li>- Chloride (82435)</li> <li>- Potassium (84132)</li> <li>- Sodium (84295)</li> </ul>
<b>Hepatic Function Panel 80076</b>	<ul style="list-style-type: none"> <li>- Albumin (82040)</li> <li>- Alkaline Phosphatase (84075)</li> <li>- ALT (SGPT) (84460)</li> <li>- AST (SGOT) (84450)</li> <li>- Bilirubin, Direct (82248)</li> <li>- Bilirubin, Total (82247)</li> <li>- Total Protein (84155)</li> </ul>
<b>Lipid Panel CPT 80061</b>	<ul style="list-style-type: none"> <li>- Cholesterol, serum, total (82465)</li> <li>- Triglycerides (84478)</li> <li>- HDL cholesterol, direct measurement (83718)</li> </ul>
<b>Obstetric Panel CPT 80081</b>	<ul style="list-style-type: none"> <li>- ABO blood typing (86900)</li> <li>- Rh blood typing (86901)</li> <li>- Antibody screen, RBC (86850)</li> <li>- Complete Blood Count (CBC) and automated differential WBC count (85025 or 85027 and 85004)</li> </ul> <p align="center"><b>OR</b></p> <ul style="list-style-type: none"> <li>- Complete Blood Count (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009)</li> <li>- Hepatitis B surface antigen (HBsAg) (87340)</li> <li>- HIV-1 antigen(s) and HIV-1 and HIV-2 antibodies (87389)</li> <li>- Rubella antibody (86762)</li> <li>- Syphilis test, qualitative (86592)</li> </ul>
<b>Renal Function Panel CPT 80069</b>	<ul style="list-style-type: none"> <li>- Albumin (82040)</li> <li>- Calcium (82310)</li> <li>- Carbon dioxide (82374)</li> <li>- Chloride (82435)</li> <li>- Creatinine (82565)</li> <li>- Glucose (82947)</li> <li>- Phosphorus, inorganic (phosphate) (84100)</li> <li>- Potassium (84132)</li> <li>- Sodium (84295)</li> <li>- Urea Nitrogen (BUN) (84520)</li> </ul>

Reference: American Medical Association, Current Procedural Terminology CPT 2017

## ◇ ROUTINE SCREENING

Medicare coverage does not usually include routine screening or experimental diagnostic testing based on the requirements for medical necessity. Screening is defined as examinations and/or diagnostic procedures performed in the absence of signs or symptoms. According to Medicare, **screening excludes** routine physical checkups (including tests performed in the absence of signs or symptoms) from the Medicare program. Screening is often performed based on patient age, and/or family history. **While performance of such examinations and tests may be considered good medical practice, they are not covered services under the Medicare program.** In certain situations, Medicare may through the legislative process, define tests that will be covered when performed as screening procedures.

### Laboratory screening tests which Medicare covers under defined conditions:

Type	ICD-10	Test(s) Performed	CPT/HCPCS Codes Associated	Frequency <i>if</i> covered by Medicare Part B	Reference
Colorectal Cancer Screening	Z12.11	FOBT or FIT  Stool DNA Test	G0328	> A screening fecal occult blood test (FOBT) <u>or</u> fecal immunochemical test (FIT) are covered once every 12 months if you are 50 or older  > A stool DNA test is covered once every 3 years for individuals who meet <u>all</u> of these conditions: - Age 50 – 85 with no signs or symptoms of colorectal disease including lower GI pain, blood in stool, i.e. positive FOBT or FIT - No personal history of adenomatous polyps, colorectal cancer, inflammatory bowel disease, including Crohn’s Disease and ulcerative colitis. - No family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer.	<a href="https://www.medicare.gov/coverage/colorectal-cancer-screenings.html">https://www.medicare.gov/coverage/colorectal-cancer-screenings.html</a>
Prostate Cancer Screening	Z12.5	Prostate Specific Antigen (PSA)	G0103	> One time every 12 months for all men over 50	<a href="https://www.medicare.gov/coverage/prostate-cancer-screenings.html">https://www.medicare.gov/coverage/prostate-cancer-screenings.html</a>
Diabetes Screening	Z13.1	Glucose	82947	> One time every 12 months for individuals not diagnosed with pre-diabetes or never tested.  > Medicare Part B covers two times per year for individuals with any of the following risk factors: - High Blood Pressure - History of abnormal cholesterol and triglyceride levels - Obesity - History of high blood sugar  > Medicare Part B also covers if two or more of these apply to the beneficiary: - Age 65 or older - Overweight - Family history of diabetes (parents, brothers, sisters) - History of gestational diabetes or delivery of a baby weighing more than 9 pounds	<a href="https://www.medicare.gov/coverage/diabetes-screenings.html">https://www.medicare.gov/coverage/diabetes-screenings.html</a>
Cardiovascular Screening	Z13.6	Lipid Panel, Cholesterol, Lipoprotein & Triglycerides	80061, 82645, 83718, 84478	> 5 years after last covered screening test (Patients diagnosed with prior cardiovascular disease are not eligible for this benefit)	<a href="https://www.medicare.gov/coverage/cardiovascular-disease-screenings.html">https://www.medicare.gov/coverage/cardiovascular-disease-screenings.html</a>
HIV Screening	Z11.4 Z72.89	HIV-1 and / or HIV-2 by EIA, ELISA or Rapid Ab Test	G0432, G0433, G0435	> One time every 12 months for individuals who met the guidelines below: - 15-65 years old - Younger than 15 or older than 65, and at increased risk - Pregnant (covered up to 3 times during a pregnancy)	<a href="https://www.medicare.gov/coverage/hiv-screenings.html">https://www.medicare.gov/coverage/hiv-screenings.html</a>

In the absence of symptoms, physician or other authorized individual findings, or other evidence of disease or injury, tests are considered screening tests and are therefore **non-covered** services under Medicare. In such cases, the provider providing the non-covered service can bill the beneficiary without submitting a claim to Medicare. Submitting claims to Medicare for services that the provider knows are not covered by Medicare is considered fraudulent act. The provider may submit charges to Medicare in situations where the beneficiary wishes to have them submitted in order to obtain a Medicare denial so that the services may be submitted to a supplemental insurance company. This should be noted on the Medicare submission claim.

## ◇ LIMITED COVERAGE

Each Carrier (Part B coverage for physician's office or independent laboratory) and fiscal Intermediary (Part A coverage for hospital and skilled nursing home facilities) develops policies to define under which signs, symptoms, or diagnoses the services will be covered based on review of test utilization. These policies are called **Local Coverage Decisions (LCDs)**. Because test utilization patterns vary in different regions of the country and in different states, LCDs differ from the carrier in one state to the carrier in the next state. Since utilization in hospitals and nursing homes is different from those in the physician's office and independent laboratory, there may be different LCDs in the same state for the carrier and intermediary. **The Medicare contractor to which the laboratory billing the test service determines which LCDs apply to any given patient, regardless of the address of the patient and/or ordering physician or other authorized individual.**

**National Coverage Decisions (NCDs)** are policies developed by CMS at the national level. They are binding on all Medicare contractors and cannot be revised by local contractors. Local contractors can add frequency limits and may supplement an NCD where the NCD is silent on an issue. **National Coverage Decisions apply to all clinical laboratories throughout the United States.**

A listing of applicable NCDs and LCDs can be found on the Sanford Laboratories website at [sanfordlaboratories.org](http://sanfordlaboratories.org). *Click on the "NCDs and LCDs" sidebar to access the "NCDs and LCDs for Covered Signs, Symptoms, Diagnoses, & ICD-10 Codes."*

Please be aware it is not enough to link the procedure code to a correct payable ICD10-CM diagnosis code. The diagnosis must be present for the procedure(s) to be paid, but in addition, the procedure(s) must be reasonable and necessary for that diagnosis. Documentation within the beneficiary's medical record must support the necessity for the test(s) provided.

## ◇ ADVANCED BENEFICIARY NOTICE OF NONCOVERAGE FORM

When a test with limited coverage (NCD or LCD) is ordered, the laboratory is allowed to submit the test to Medicare for payment. If the payment is denied, the laboratory will be able to bill the beneficiary if an Advance Beneficiary Notice of Noncoverage Form was completed. The form regulations apply to participating and nonparticipating provider services that may be determined as not medically necessary. Under federal law, **providers must inform beneficiaries in writing before providing a service which Medicare may consider not medically necessary.** Advanced Beneficiary Notice of Noncoverage Forms also protect the provider's right to collect payment from the beneficiary when claims are denied by Medicare as "not reasonable and necessary."

### OMB Approved Advanced Beneficiary Notice of Noncoverage Form

The OMB-approved Form that is acceptable for use is the Form CMS 131 OMB 0938-0566 (Exp. 3/2020). A copy of the Advanced Beneficiary Notice of Noncoverage Form is available on the Sanford Laboratories website at [sanfordlaboratories.org](http://sanfordlaboratories.org). Click on the "NCDs and LCDs" sidebar and open the "Printable ABN Form" document.

### THE ADVANCED BENEFICIARY NOTICE OF NONCOVERAGE FORM MUST:

- Be obtained **PRIOR** to the beneficiary receiving the service (performing the procedure/test)
- Be verbally reviewed with the beneficiary or his/her representative, and any questions raised during the review must be answered prior to signing the ABN
- If the patient demands the service and refuses to sign the form, have a second employee in your lab or office witness the attempted administration of the form and the beneficiary's refusal to sign. Both employees should sign an annotation on the form attesting to having witnessed the attempted administration and the refusal to sign. If there is only one person at the draw station, the second witness may be contacted by telephone to witness the beneficiary's refusal to sign the form by telephone and may sign the form annotation at a later time.
- The unused patient signature line on the form may be used for the annotation and signatures. Writing in the margins of the form is also permissible. In this case, the patient may be billed for the services if Medicare denies the claim.

## INSTRUCTIONS FOR COMPLETING THE ADVANCED BENEFICIARY OF NONCOVERAGE FORM

CMS-R-131 OMB 0938-0566  
(Exp. 3/2020)

1. Always use black or blue ink and make sure each copy is legible and readable.
2. Determine if the test(s) ordered have a NCD or LCD. This information is available on the Sanford Laboratories website at [sanfordlaboratories.org](http://sanfordlaboratories.org). Click on the "NCDs and LCDs" sidebar to access the "NCDs and LCDs for Covered Signs, Symptoms, Diagnoses, & ICD-10 Codes."
3. **"Notifier"** – *REQUIRED* – Write the name, address and phone number of the entity administering the ABN. If the ABN form being used does not have the notifier information pre-populated on the upper left-hand corner of the document, the administrator of the ABN **MUST** provide this information. The notifier requirements are:
  1. Lab/Clinic Name
  2. Lab/Clinic Address
  3. Lab/Clinic Phone Number
4. **"Patient Name"** - *REQUIRED* - Print the name of the beneficiary (patient) as it appears on their Medicare card.
5. **"Identification Number"** – clearly indicate a unique identification number. Do not use the beneficiary's Medicare ID number or Social Security number. *This field is optional.*
6. **"Lab Tests(s):"** Box - *REQUIRED* – Write the name of the test(s) ordered (in line item fashion) that may not be covered by Medicare. A list of the medically reviewed NCD and LCD tests is available on the Sanford Laboratories website at [sanfordlaboratories.org](http://sanfordlaboratories.org). Click on the "NCDs and LCDs" sidebar to access the "NCDs and LCDs for Covered Signs, Symptoms, Diagnoses, & ICD-10 Codes."
7. **"Reason Medicare May Not Pay:"** Box - *REQUIRED* – Place an "X" in the box with the appropriate reason you believe Medicare may not pay for the "Lab Test(s)" ordered. The reasons are listed below:
  - o *Medicare does not pay for these tests for your condition;*
    - Example is a diagnosis is given, but does not meet medical necessity for the test ordered.
  - o *Medicare does not pay for these tests as often as this (denied as too frequent);*
    - Example is a PSA screen ordered more frequently than once per year
  - o *Medicare does not pay for experimental research tests;*
    - Exactly as specified above - ordered for research or experimental reasons.
8. **"Estimated Cost"** Box - *REQUIRED* - clearly indicate a good faith estimate of the *cost of each test* that may not be covered, or a *total estimate* of all tests that may not be covered. The cost for most tests are available on the Sanford Laboratories website at [sanfordlaboratories.org](http://sanfordlaboratories.org). Click on the "NCDs and LCDs" sidebar and open the "Patient Fees to use with ABNs" document.
9. **"Options:"** Box - *REQUIRED* - **Have the beneficiary or the beneficiary's representative complete this portion by placing an "X" in front of the appropriate option. THE BENEFICIARY OR REPRESENTATIVE MUST CHOOSE ONE OPTION--AND ONLY ONE. YOU CANNOT CHOOSE AN OPTION FOR THEM.**
  - o If the beneficiary or his/her representative wishes to receive some, but not all of the services on the Advanced Beneficiary Notice of Noncoverage Form, a new form should be filled out and reflected accordingly.
10. **"Additional Information:"** - you can enter any additional insurance information or any information for additional clarification for the beneficiary - *this field is optional*
11. **"Signature:"** - *REQUIRED* - The beneficiary or the beneficiary's representative must sign the form.
12. **"Date:"** - *REQUIRED* - The beneficiary or the beneficiary's representative must date the form.

## **FINALIZATION OF ADMINISTRATION OF THE ADVANCED BENEFICIARY NOTICE OF NONCOVERAGE PROCESS:**

If filling out the Sanford Laboratories 2-part ABN form, always give a copy of the completed form (yellow copy) to the patient. If using a copy of the ABN form available on the Sanford Laboratories website, ensure the patient gets a photocopy of the completed ABN form after they sign, date and all of the required items are entered as indicated above in the ABN Instructions section.

*Beneficiaries are aware that they are responsible for payment of routine or screening tests. Advanced Beneficiary Notice of Noncoverage Forms are not required for "routine or screening tests" as they are not covered services under Medicare; however, Medicare does cover a selection of screening tests as long as they are ordered under specific frequency criteria. For a list of the screening tests covered by Medicare, please see page 3 for test details and screening frequencies.*

When requesting that Sanford Laboratories bill Medicare, a valid ABN must accompany the sample and request. The laboratory submitting the claim to Medicare must have the form on file.

## **EXAMPLES OF UNACCEPTABLE ADVANCED BENEFICIARY NOTICE OF NONCOVERAGE FORM PRACTICES ARE:**

- Administering ABN forms for all claims and services (blanket forms)
- Failure to state on the ABN form the particular services which Medicare will likely deny
- Failure to complete the ABN form prior to providing the service (performing the test)
- Failure to provide the estimated cost information on the ABN form
- Administering an ABN form to a patient in a medical emergency or to a patient who is under great duress

**Clients and Providers who collect samples and order tests that may not be covered by Medicare will be held responsible for the testing charges if a valid Advanced Beneficiary Notice of Non-Coverage is not collected from the beneficiary.**