

Advance Beneficiary Notice of Non-coverage (ABN)

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Advance Beneficiary Notice of Non-coverage

- An Advance Beneficiary Notice of Non-coverage or ABN, is an acknowledgment by the Medicare beneficiary that he/she has been notified that the services provided may be deemed as not medically necessary by Medicare and that he/she is responsible for payment if Medicare denies payment.

What is an ABN?

- CMS Form: CMS-R-131 (Exp. 01/31/2026)
- A National Coverage Determination (NCD) is a general outline of Medicare coverage which is applicable regardless of which Medicare Administrative Contractor (MAC) is administering claims for a region. Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) are specific to a MAC. LCDs and LCAs define Medicare coverage for items and services for which no NCD exists.

Advance Beneficiary Notice of Non-coverage

*When should a notice
be administered?*

- An ABN must be administered anytime a provider orders services which Medicare may not cover.
- The ABN must be administered prior to specimen collection or before services are provided.
- Medicare may not cover testing for the following reasons:
 - Does not pay for the test(s) for the patient's condition
 - The frequency limit for a test is exceeded
 - Test is considered experimental, investigational or for research use only

Advance Beneficiary Notice of Non-coverage

Why is the ABN administered?

- A properly administered ABN form protects the provider's right to collect payment from the beneficiary when claims are denied by Medicare as "not reasonable and necessary."
- Informs the Medicare beneficiary of the test(s) ordered and the estimated cost of those tests.
- If the ABN form is not completed properly, Medicare nor the beneficiary can be held responsible for payment.

Advance Beneficiary Notice of Non-coverage

How is an ABN administered?

- All areas of an ABN form must be completed prior to specimen collection and before services are provided for the ABN to be considered valid by Medicare.
- Failure to provide all required information will result in an invalid ABN form. Medicare nor the beneficiary can be held responsible for payment if the ABN form is invalid.

Advance Beneficiary Notice of Non-coverage

Step 1: Determine if the test is medically reviewed

- A list of applicable NCDs, LCDs and LCAs are available at:
<https://www.sanfordhealth.org/medical-services/laboratories>
Click on “Compliance” and scroll down to the “Printable Compliance Forms” section of the page and click on the appropriate link.
- Routine and screening tests are excluded by statute. An ABN is not required when a routine or screening diagnosis code is associated. Refer to the first section of the National Coverage Determinations PDF which provides a list of codes that are *never* covered by Medicare.

Advance Beneficiary Notice of Non-coverage

- The Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report (ICD-10-CM) is updated by the Centers for Medicare and Medicaid Services (CMS) four times a year on:
 - January 1st
 - April 1st
 - July 1st
 - October 1st
- Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) are added or updated periodically throughout the year by your Medicare Administrative Contractor (MAC).

Medically Reviewed Tests – Medicare Part B National Coverage Determinations (NCDs)

- Urine Culture, Bacterial
- HIV (Prognosis Including Monitoring)
- HIV (Diagnosis)
- Blood Counts
- Partial Thromboplastin Time (PTT)
- Prothrombin Time (PT)
- Serum Iron Studies
- Collagen Crosslinks, Any Method
- Blood Glucose Testing
- Glycated Hemoglobin/Glycated Protein
- Thyroid Testing
- Lipids Testing
- Digoxin Therapeutic Drug Assay
- Alpha-fetoprotein (AFP)
- Carcinoembryonic Antigen (CEA)
- Human Chorionic Gonadotropin (HCG)
- CA 125
- CA 15-3, CA 27.29
- CA 19-9
- Prostate Specific Antigen (PSA)
- Gamma Glutamyl Transferase (GGT)
- Hepatitis Panel/Acute Hepatitis Panel
- Fecal Occult Blood Test

Medically Reviewed Tests – Medicare Part B Local Coverage Determinations (LCDs) for Sioux Falls, Rapid City, Bismarck and Fargo Labs *

- B-Type Natriuretic Peptide (BNP) Testing
- Lab: Bladder/Urothelial Tumor Markers (UroVysion Test)
- Lab: Coenzyme Q10 (CoQ10)
- Lab: Controlled Substance Monitoring & Drugs of Abuse Testing
- Lab: Cystatin C Measurement
- Lab: Flow Cytometry
- Lab: Special Histochemical Stains & Immunohistochemical Stains
- Magnesium, Serum
- MDS FISH
- Measurement of Salivary Hormones
- MoIDX: Biomarkers in Cardiovascular Risk Assessment
- MoIDX: Blood Product Molecular Antigen Typing
- MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease
- MoIDX: Genetic Testing for Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin and MTHFR)
- MoIDX: HLA-DQB1*06:02 Testing for Narcolepsy
- MoIDX: Lab-Developed Tests for Inherited Cancer in Patients with Cancer
- MoIDX: MGMT Promotor Methylation Analysis
- MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer
- MoIDX: Molecular Diagnostic Tests (MDT)
- MoIDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing
- MoIDX: Next-Generation Sequencing for Solid Tumors
- MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies
- MoIDX: NRAS Genetic Testing
- MoIDX: Pharmacogenomics Testing
- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors
- MoIDX: Repeat Germline Testing
- Vitamin D Assay Testing

Medically Reviewed Tests – Medicare Part B Local Coverage Determinations (LCDs) for Bemidji Lab

- B-Type Natriuretic Peptide (BNP) Testing
- Biomarker Testing for Neuroendocrine Tumors/Neoplasms
- Biomarker Testing for Prostate Cancer Diagnosis
- Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases
- Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms
- Heavy Metal Testing
- Mass Spectrometry (MS) Testing in Monoclonal Gammopathy (MG)
- Molecular Pathology Procedures
- Multimarker Serum Tests Related to Ovarian Cancer Testing
- Multiplex Gastrointestinal Pathogen Panel (GPP) Test for Acute Gastroenteritis (AGE)
- RAST Type Tests (Allergy Testing)
- Respiratory Pathogen Panel Testing
- Urine Drug Testing
- Vitamin D Assay Testing

*** These lists may not be all inclusive. Refer to the Sanford Laboratories website for all LCDs for the Sioux Falls, Rapid City, Bismarck, Fargo and Bemidji regions.**

Medically Reviewed Tests – Medicare Part B Local Coverage Articles (LCAs) for Sioux Falls, Rapid City, Bismarck and Fargo Labs

- B-Type Natriuretic Peptide (BNP) Testing
- Influenza Diagnostic Tests
- Lab: Bladder/Urothelial Tumor Markers (UroVysion Test)
- Lab: Coenzyme Q10 (CoQ10)
- Lab: Controlled Substance Monitoring & Drugs of Abuse Testing
- Lab: Cystatin C Measurement
- Lab: Flow Cytometry
- Lab: Special Histochemical Stains & Immunohistochemical Stains
- Magnesium, Serum
- MDS FISH
- Measurement of Salivary Hormones
- MoIDX: BCR-ABL
- MoIDX: Biomarkers in Cardiovascular Risk Assessment
- MoIDX: Blood Product Molecular Antigen Typing
- MoIDX: FDA-Approved BRAF Tests
- MoIDX: FDA-Approved EGFR Tests
- MoIDX: FDA-Approved KRAS Tests
- MoIDX: Fragile X
- MoIDX: MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease
- MoIDX: Genetic Testing for Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin and MTHFR)
- MoIDX: HLA-DQB1*06:02 Testing for Narcolepsy
- MoIDX: HLA Testing for Transplant Histocompatibility
- MoIDX: Immunohistochemistry (IHC) Indications for Breast Pathology
- MoIDX: Lab-Developed Tests for Inherited Cancer in Patients with Cancer
- MoIDX: MGMT Promotor Methylation Analysis
- MoIDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker
- MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer
- MoIDX: Molecular Diagnostic Tests (MDT)
- MoIDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing
- MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies
- MoIDX: Next-Generation Sequencing for Solid Tumors
- MoIDX: NRAS Genetic Testing
- MoIDX: Pharmacogenomics Testing
- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors
- MoIDX: Repeat Germline Testing
- MoIDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer
- MoIDX: Testing of Multiple Genes
- MoIDX: TP53 Gene Tests
- Vitamin D Assay Testing

Medically Reviewed Tests – Medicare Part B Local Coverage Articles (LCAs) for Bemidji Lab

- B-Type Natriuretic Peptide (BNP) Testing
- Biomarker Testing for Neuroendocrine Tumors/Neoplasms
- Biomarker Testing for Prostate Cancer Diagnosis
- CPT Code 87641 (Infectious agent detection by nucleic acid [DNA or RNA]; Staphylococcus aureus, methicillin resistant, amplified probe technique)
- Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases
- Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms
- Heavy Metal Testing
- Mass Spectrometry (MS) Testing in Monoclonal Gammopathy (MG)
- Molecular Pathology Procedures
- Multimarker Serum Tests Related to Ovarian Cancer Testing
- Multiplex Gastrointestinal Pathogen Panel (GPP) Test for Acute Gastroenteritis (AGE)
- RAST Type Tests (Allergy Testing)
- Respiratory Pathogen Panel Testing
- Urine Drug Testing
- Vitamin D Assay Testing

*** These lists may not be all inclusive. Refer to the Sanford Laboratories website for all LCAs for the Sioux Falls, Rapid City, Bismarck, Fargo and Bemidji regions**

Advance Beneficiary Notice of Non-coverage

Step 2: Determine if
the diagnosis code is
covered

- If the test(s) ordered are medically reviewed by Medicare, i.e., a NCD, LCD, or LCA applies, and the diagnosis code (ICD-10-CM) is not excluded based on statute, determine if the diagnosis code is covered.
 - If the diagnosis code is covered, an ABN is not required.
 - If the diagnosis code is not covered, an ABN form must be completed.

Advance Beneficiary Notice of Non-coverage

Step 3: Completing the ABN

SANFORD
Laboratories

Advance Beneficiary Notice of Non-coverage (ABN)

Facility Name: _____
Address: _____
Phone: _____

A. Notifier: _____
B. Patient Name: _____
C. Identification Number: _____
DOB: _____

NOTE: If Medicare doesn't pay for lab test(s) below, you may have to pay.
Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the lab test(s) below.

Lab Test(s)	Reason Medicare May Not Pay:	Estimated Cost
	<input type="checkbox"/> Medicare does not pay for these tests for your condition <input type="checkbox"/> Medicare does not pay for these tests as often as this (denied as too frequent) <input type="checkbox"/> Medicare does not pay for experimental or research use tests	

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the lab test(s) listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

OPTIONS: Check only one box. We cannot choose a box for you.

OPTION 1. I want the lab 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 2. I want the lab 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 3. I don't want the lab 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.

Additional information: _____

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048).
Signing below means that you have received and understand this notice. You may ask to receive a copy.

Signature: _____	Date: _____
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You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you feel you've been discriminated against. Visit Medicare.gov/about-us/accessibility-nondiscrimination-notice.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form CMS-R-131 (Exp. 01/31/2026)
Form Approved OMB No. 0938-0566

Sanford Health
ABN Waiver - Laboratories

- Form CMS-R-131 (Exp. 01/31/2026) must be used. Earlier forms are considered invalid. The form number is located on the bottom left-hand corner of the ABN form.
- Detailed instructions for completing an ABN are available on the Sanford Laboratories website. Click on “Compliance” and scroll down to the “Printable Compliance Forms” section and click on the “Advance Beneficiary Notice of Non-coverage” link to locate instructions for completing an ABN.

Advance Beneficiary Notice of Non-coverage

Step 3: Completing the ABN

SANFORD
Laboratories

**Advance Beneficiary Notice
of Non-coverage (ABN)**

Facility Name: _____
Address: _____
Phone: _____

A. Notifier: _____
B. Patient Name: _____
C. Identification Number: _____
DOB: _____

NOTE: If Medicare doesn't pay for lab test(s) below, you may have to pay.
Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the lab test(s) below.

Lab Test(s)	Reason Medicare May Not Pay:	Estimated Cost
	<input type="checkbox"/> Medicare does not pay for these tests for your condition <input type="checkbox"/> Medicare does not pay for these tests as often as this (denied as too frequent) <input type="checkbox"/> Medicare does not pay for experimental or research use tests	

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the lab test(s) listed above.

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OPTION 2. I want the lab 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 3. I don't want the lab 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.

Additional Information:

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Form CMS-R-131 (Exp. 01/31/2025) Sanford Health
Form Approved OMB No. 0938-0566 ABN Waiver - Laboratories


Required Items

- Notifier (Lab name)
- Address and phone number for the facility
- Medicare Beneficiary's Full Name
- Name of lab test(s) that require an ABN
- Reason Medicare may not pay
(Check only one box)
- Estimated cost
 - The "Patient Fees to Use with ABNs" document is located on the Sanford Laboratories website. This document provides the cost for tests performed by Sanford Laboratories which require an ABN. If the test is not listed on this document, please contact the Sanford Laboratories Accounts Receivable department at 605-328-5485 for pricing information.
- The Medicare beneficiary or the beneficiary's representative must choose only one option.
- The Medicare beneficiary or the beneficiary's representative must sign the ABN form.
- The Medicare beneficiary or beneficiary's representative must date the ABN form.

Advance Beneficiary Notice of Non-coverage

Step 3: Completing the ABN

- The Identification number is *optional* per CMS but this field is ***required*** by Sanford Laboratories.
- If you choose to provide a patient ID number, use a number that is unique to the patient such as the E number (EPIC) or a medical record number associated with the patient's electronic medical record or chart. DO NOT use the beneficiary's Medicare ID number or Social Security Number (SSN).
- The Medicare beneficiary must receive a copy of the completed ABN form.

SANFORD Laboratories Advance Beneficiary Notice of Non-coverage (ABN) Facility Name: _____ Address: _____ Phone: _____		A. Notifier: _____ B. Patient Name: _____ C. Identification Number: _____ DOB: _____						
<p>NOTE: If Medicare doesn't pay for lab test(s) below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the lab test(s) below.</p> <table border="1"> <thead> <tr> <th>Lab Test(s)</th> <th>Reason Medicare May Not Pay:</th> <th>Estimated Cost</th> </tr> </thead> <tbody> <tr> <td></td> <td> <input type="checkbox"/> Medicare does not pay for these tests for your <u>condition</u> <input type="checkbox"/> Medicare does not pay for these tests as often as this (denied as too frequent) <input type="checkbox"/> Medicare does not pay for experimental or research use <u>tests</u> </td> <td></td> </tr> </tbody> </table>			Lab Test(s)	Reason Medicare May Not Pay:	Estimated Cost		<input type="checkbox"/> Medicare does not pay for these tests for your <u>condition</u> <input type="checkbox"/> Medicare does not pay for these tests as often as this (denied as too frequent) <input type="checkbox"/> Medicare does not pay for experimental or research use <u>tests</u>	
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<p>WHAT YOU NEED TO DO NOW:</p> <ul style="list-style-type: none"> • Read this notice, so you can make an informed decision about your care. • Ask us any questions that you may have after you finish reading. • Choose an option below about whether to receive the lab test(s) listed above. <p>Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.</p>								
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