January 27, 2015

Valued Client,

We are committed to promoting awareness of, and adherence to, Medicare policies. In accordance with the Office of Inspector General's (OIG) Compliance Program Guide for Clinical Laboratories, this letter will provide you with the following information about Medicare requirements.

**Medicare Medical Necessity Policy**

Medicare will only cover tests that meet all “Medicare coverage, coding, and medical necessity requirements”. Medicare may deny payment for a test that the physician believes is appropriate, such as a screening test, but which does not meet the Medicare definition of medical necessity. Screening or Investigational Use Only tests are not generally covered by Medicare with some exceptions. *The OIG takes the position that a physician who orders medically unnecessary tests for which Medicare or MediCal reimbursement is claimed may be subject to civil penalties.*

**2015 Medicare Clinical Laboratory Fee Schedule**

Outpatient clinical laboratory services are paid based on a fee schedule in accordance with Section 1833(h) of the Social Security Act. Payment is the lesser of the amount billed, the local fee for geographic area, or a national limit. In accordance with the statute, these national limits are set at a percent of the median of all local fee schedule amounts for each laboratory test coded. Each year, fees are updated for inflation based on the percentage change in the Consumer Price Index. However, legislation by Congress can modify the update to the fees. Co-payments and deductibles do not apply to services paid under the Medicare Clinical Laboratory Fee Schedule.

Medicaid reimbursement will be equal to, or less than, Medicare reimbursement.

The 2015 Medicare Clinical Laboratory Fee Schedule can be viewed and downloaded at: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html)

**Medicare Organ or Disease-Oriented Panels**

The AMA panels were developed for coding purposes only and should not be interpreted as clinical parameters. The test listed with each panel identify the defined components of that panel.

Each component in an AMA-defined panel must be medically necessary. Each component must be performed and reported as described in CY-CPT Manual in order to file claims using that Panel CPT code.
These panels, their components, 2015 Medicare Automated Test Panel (ATP) Allowable Reimbursements, and criteria for payment submission are listed as an attachment.

**Medical Laboratory Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs).**

These policies define the medical conditions through the inclusion of a list of ICD-9 (diagnosis) codes for which these tests are covered or reimbursed by Medicare. HIPAA regulations require ICD-9 code(s) to be present on each claim filed. These codes must also be documented in the patient's medical record.

**Frequency Limitations for Laboratory Tests**

Certain laboratory tests have specific frequency limitation requirements. These limitations may apply to tests from the laboratory LCDs and NCDs or Statute.

**Medicare Preventive Screening Laboratory Tests**

Certain preventive screening laboratory tests are covered benefits for Medicare patients. Benefit coverage is specific for each service, covered diagnosis codes, coverage requirements, and frequency limitations.

**Billing Information**

Physicians or authorized ordering providers must submit diagnosis information with the laboratory order. Diagnosis information supplied should accurately describe the patient's condition on the date of service as documented in the patient's medical record.

Medicare guidelines require the interpreting physician code using the ICD-9-CM code that provides the highest degree of accuracy and completeness for the diagnosis resulting from the test, or for the sign(s)/symptom(s) that prompted the ordering of the test. It is the providers' responsibility to select and provide these codes. The laboratory does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff.

It is important to note that diagnosis codes often require more than 3 digits. These are composed of codes with three, four, or five digits. Codes with three digits are included as the heading of a category of codes that may be further subdivided by the use of 4th and 5th digits to provide greater specificity. Assign 3-digit codes only if there are no 4-digit codes with that code category. Assign 4-digit codes only if there are no 5-digit subclassification for that category. Assign the 5-digit subclassification code for those categories where it exists.

**PECOS - Medicare Ordering and Referring Information**

The Affordable Care Act requires all physicians or other eligible non-physician practitioners (NPPs) to enroll in the Medicare Program to order/refer items or services for Medicare beneficiaries. This includes those physicians and other eligible NPPs who do not and will not send claims to a Medicare Administrative Contractor for the services they furnish.

Information on the requirement and how to enroll is available at: [http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html) or contact your sales representative.
Reflex testing

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate for patient care. There are two types of reflex testing protocols – required and optional reflex tests.

(a) Required Reflex Tests
Laboratory tests which, if positive, require additional separate follow-up testing in order to have clinical value. Reflex tests required by state, regulatory or accreditation standards are also considered to be of this type.

(b) Optional Reflex Tests
Laboratory tests where the initial test results may have clinical value without the additional reflex testing.

A list of reflex testing options follows.

Clinical Consultant/Medical Director
The laboratory’s Medical Director and other pathologists are available to discuss appropriate testing and test ordering.

Supplies Prohibited by Stark Law
Per CMS Regulations and Stark Law, our laboratory can only provide supplies that are used solely to collect, transport, process, or store specimens referred to our laboratory. Attached is a list of supplies that we are not able to distribute. We will be closely monitoring supply usage to comply with this regulation.

Attachments
The pages that follow will provide you and your staff with additional resources. References have been provided for the complete text and additional applicable information.

- 2015 Medicare Clinical Laboratory Fee Schedule
- AMA-Defined Organ or Disease Oriented Panels and their components
- General Health and OB Panel payment limitations
- Automated Chemistry Tests, CPT codes and Medicare National Limitation Amounts
- Medicare Laboratory Local Coverage Determinations (LCDs)
- Medicare Laboratory National Coverage Determinations (NCDs)
- Frequency Limitations for Laboratory Tests
- Medicare Preventive Screening Laboratory Tests
- Reflex tests
- Requisition Requirements
- ABN Requirements
- ABN Instructions
- Supplies Prohibited by CMS and Stark Law

Please review this notice with all respective staff.
NOTIFICATION FOR MEDICARE LAB TESTING

Medicare Clinical Laboratory Fee Schedule:

View and download the Medicare Clinical Laboratory Fee Schedule at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/CL podiumLabFeeSched/cli lab.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/CL podiumLabFeeSched/cli lab.html)

Medicaid reimbursement will be equal to, or less than Medicare reimbursement.

The CPT Manual may be purchased from the American Medical Association by calling 800-621-8335 or by visiting [http://www.ama-assn.org](http://www.ama-assn.org)

AMA-Defined Organ or Disease Oriented Panels:

Organ and disease oriented panels will only be paid by Medicare when all the component tests of the panel are medically necessary.

**Basic Metabolic Panels (BMP) (80048):**
- Calcium
- Carbon Dioxide (CO₂)
- Chloride
- Creatinine
- Glucose
- Potassium
- Sodium
- Urea Nitrogen (BUN)

**Basic Metabolic Panel (BMP) (80047):** Contains Ionized Calcium, instead of Calcium

**Comprehensive Metabolic Panel (CMP) (80053):**
- Albumin
- Bilirubin, Total
- Calcium
- Carbon Dioxide (CO₂)
- Chloride
- Creatinine
- Glucose
- Phosphatase, Alkaline
- Potassium
- Protein, Total
- Sodium
- Transferase, Alanine Amino (ALT), (SGPT)
- Transferase, Aspartate Amino (AST), (SGOT)
- Urea Nitrogen (BUN)

**Electrolyte Panel (80051):**
- Carbon Dioxide (CO₂)
- Chloride
- Potassium
- Sodium

**Lipid Panel (80061):**
- Cholesterol, Total
- HDL Cholesterol (direct measurement)
- Triglycerides

**Hepatic Function Panel (80075):**
- Albumin
- Bilirubin, Total
- Bilirubin, Direct
- Phosphatase, Alkaline
- Protein, Total
- Transferase, Alanine Amino (ALT), (SGPT)
- Transferase, Aspartate Amino (AST), (SGOT)

**Renal Function Panel (80069):**
- Albumin
- Calcium
- Carbon Dioxide (CO₂)
- Chloride
- Creatinine
- Glucose
- Phosphorus, Inorganic
- Potassium
- Sodium
- Urea Nitrogen (BUN)

**Acute Hepatitis Panel (80074):**
- Hepatitis A Antibody (HAV) IgM
- Hepatitis B Antibody (HBc) IgM
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis C Antibody (HCV Ab)

**General Health Panel (80050):**
- CMP
- TSH
- CBC

**NOTE:** Medicare does not pay for the General Health Panel. There is no benefit category. Medicare patients will be responsible for payment to the laboratory for the General Health Panel.

**Obstetric Panel (80055):**
- Complete Blood Count (CBC) with platelet and auto differential Antibody Screen, RBC, each serum technique
- Hepatitis B Surface Antigen (HBsAg)
- Rubella Antibody
- Syphilis test, qualitative (e.g. VDRL, RPR, ART)
- Blood typing, ABO
- Blood typing, Rh

**NOTE:** Medicare does not pay for the Obstetric Panel. There is no benefit category. Medicare patients will be responsible for payment to the laboratory for the Obstetric Panel.

**NOTE:** Medicaid Patients: For benefits, limitations and reimbursement please see provider manual.
Automated Chemistry Tests

Laboratory tests on the Medicare list of 23 automated chemistry tests (listed below) are bundled for payment by Medicare into specified groups (listed below) when ordered separately or in a panel (including AMA-defined chemistry panels) on the same date of service. Reimbursement for the groups may be found on the Medicare Clinical Lab Fee Schedule under ATP (Automated Test Panel).

<table>
<thead>
<tr>
<th>CPT</th>
<th>Procedure/Panel</th>
<th>2014 Medicare ATP Allowable Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Number of Tests: Allowable:</td>
</tr>
<tr>
<td>82040</td>
<td>Albumin</td>
<td>2</td>
</tr>
<tr>
<td>82247</td>
<td>Bilirubin, Total</td>
<td>3</td>
</tr>
<tr>
<td>82248</td>
<td>Bilirubin, Direct</td>
<td>4</td>
</tr>
<tr>
<td>82330</td>
<td>Calcium, Ionized (measured)</td>
<td>5</td>
</tr>
<tr>
<td>82310</td>
<td>Calcium, Total</td>
<td>6</td>
</tr>
<tr>
<td>82374</td>
<td>Carbon Dioxide (CO₂)</td>
<td>7</td>
</tr>
<tr>
<td>82435</td>
<td>Chloride</td>
<td>8</td>
</tr>
<tr>
<td>82465</td>
<td>Cholesterol, Total</td>
<td>9-10</td>
</tr>
<tr>
<td>82550</td>
<td>CK, Total</td>
<td>11</td>
</tr>
<tr>
<td>82565</td>
<td>Creatinine</td>
<td>12</td>
</tr>
<tr>
<td>82947</td>
<td>Glucose</td>
<td>13-16</td>
</tr>
<tr>
<td>82977</td>
<td>GGT</td>
<td>17-18</td>
</tr>
<tr>
<td>83615</td>
<td>LDH</td>
<td>19</td>
</tr>
<tr>
<td>84075</td>
<td>Phosphatase, Alkaline</td>
<td>20</td>
</tr>
<tr>
<td>84100</td>
<td>Phosphorus</td>
<td>21</td>
</tr>
<tr>
<td>84132</td>
<td>Potassium</td>
<td>22-23</td>
</tr>
<tr>
<td>84155</td>
<td>Protein, Total</td>
<td></td>
</tr>
<tr>
<td>84295</td>
<td>Sodium</td>
<td></td>
</tr>
<tr>
<td>84450</td>
<td>SGOT (AST)</td>
<td></td>
</tr>
<tr>
<td>84460</td>
<td>SGPT (ALT)</td>
<td></td>
</tr>
<tr>
<td>84478</td>
<td>Triglycerides</td>
<td></td>
</tr>
<tr>
<td>84520</td>
<td>BUN (Urea Nitrogen)</td>
<td></td>
</tr>
<tr>
<td>84550</td>
<td>Uric Acid</td>
<td></td>
</tr>
<tr>
<td>80053</td>
<td>Comprehensive Metabolic Panel (14 ATP)</td>
<td></td>
</tr>
<tr>
<td>80048</td>
<td>Basic Metabolic Panel (8 APT)</td>
<td></td>
</tr>
<tr>
<td>80069</td>
<td>Renal Function Panel (10 ATP)</td>
<td></td>
</tr>
<tr>
<td>80076</td>
<td>Hepatic Function Panel (7 ATP)</td>
<td></td>
</tr>
<tr>
<td>80051</td>
<td>Electrolyte Panel (4 ATP)</td>
<td></td>
</tr>
<tr>
<td>80061</td>
<td>Lipid Panel (2 ATP @ $7.10 + HDL Cholesterol @ $11.17 = $18.27 Total)</td>
<td>22-23</td>
</tr>
</tbody>
</table>
Medicare Laboratory Local Coverage Determinations (LCDs)

View the complete test of LCD's (diagnosis limits, frequency limits and non-covered services) at https://med.noridianmedicare.com/web/jeb/policies/lcd/active

Medicare Laboratory National Coverage Determinations (NCDs). (Negotiated Rulemaking)

View the NCD Coding Manual Releasing at http://www.cms.hhs.gov/Manuals/IOM/list.asp
Select section 100-03.

- Alpha-Fetoprotein (AFP)
- Blood Counts
- Carcinoembryonic Antigen (CEA)
- Collagen Crosslinks, Any Method
- Digoxin
- Fecal Occult Blood
- Gamma Glutamyl Transferase (GGT)
- Glucose
- Glycated Hemoglobin and Glycated Protein
- Hepatitis Panel, Acute
- Human Chorionic Gonadotropin (hCG)
- Human Immunodeficiency Virus (HIV)
- Iron Studies
- Lipids
- Pap Test
- Partial Thromboplastin Time (PTT)
- Prostate Specific Antigen (PSA)
- Prothrombin Time (PT)
- Screening for Sexually Transmitted Infections
- Thyroid Testing
- Tumor Antigen by Immunoassay – CA125
- Tumor Antigen by Immunoassay – CA15-3 and CA27.29
- Tumor Antigen by Immunoassay – CA19-9
- Urine Culture, Bacterial

View the NCDs at http://www.cms.hhs.gov/CoverageGenInfo/04_labNCDs.asp. Select NCD.

HIPAA Regulations Require ICD-9 Code(s) to be present on each claim filed.

View Additions, Revisions, and Deletions for ICD-9 Codes which became effective on October 1, 2008 at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/07_summarytables.asp

Medicare Part B National Correct Coding Initiative (NCCI) Edits: (Not a comprehensive list)

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 1</th>
<th>Column 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transferrin</td>
<td>Iron Binding Capacity</td>
<td>Lipid Panel, Total Cholesterol</td>
<td>Direct LDL (w/o elevated Trig)</td>
</tr>
<tr>
<td>Free T4</td>
<td>Total T4, T3 Uptake</td>
<td></td>
<td>Cholesterol</td>
</tr>
<tr>
<td>Free T3</td>
<td>Total T3</td>
<td></td>
<td>Triglycerides</td>
</tr>
</tbody>
</table>

Medicare does not pay for column 2 tests when ordered on the same day as column 1 tests.
View CCI Edits at http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/NCCI-Coding-Edits.html
<table>
<thead>
<tr>
<th>Laboratory Test(s)</th>
<th>National Coverage Determination (NCD)</th>
<th>Local Coverage Determination (LCD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Disease Screening</td>
<td>Lipid Testing: Lipid Panel OR One of each individual test every 5 years (60 months)</td>
<td>No more frequently than every two (2) months for any test, whether in a panel or separately ordered *</td>
</tr>
<tr>
<td></td>
<td>Lipid Panel (Total Chol, HDL, Trig) Cholesterol, Total HDL Cholesterol Triglycerides</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LDL Cholesterol, direct measurement 12 Hour Fasting required</td>
<td></td>
</tr>
<tr>
<td>Cervical or Vaginal Cancer Screening</td>
<td>For female beneficiaries: Low Risk (routine screen): One (1) every two (2) years (24 months)</td>
<td></td>
</tr>
<tr>
<td>Pap Test</td>
<td>High Risk One (1) every 12 months</td>
<td></td>
</tr>
<tr>
<td>Colorectal Cancer Screening</td>
<td>Fecal Occult Blood Once per year (1-3 simultaneous determinations) for beneficiaries who have attained age of 50 years</td>
<td></td>
</tr>
<tr>
<td>Diabetes Screening</td>
<td>Glucose, Quantitative, Fasting Pre-diabetes diagnosed = 2 screening tests per year (12 months)</td>
<td>One per month for Uncontrolled Diabetes Mellitus</td>
</tr>
<tr>
<td></td>
<td>Glucose, 2 Hour, post 75 gm load glucose Previously tested but not diagnosed with pre-diabetes or never tested before = 1 screening test per year (12 months)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Glucose Tolerance, 3 specimens w/75 gm load non-pregnant adults</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Glucose, by instrument approved for home use</td>
<td></td>
</tr>
<tr>
<td>Prostate Cancer Screening</td>
<td>Prostate Specific Antigen (PSA, Total) One (1) every twelve (12) months for male beneficiaries who have attained age of 50 years</td>
<td>Four (4) times a year For any test, whether in a panel or separately ordered *</td>
</tr>
<tr>
<td>Thyroid Testing:</td>
<td>Thyroxine, Total (Total T4) Thyroxine, Free (Free T4) Thyroid Stimulating Hormone (TSH) Thyroid Hormone (T3 or T4) uptake</td>
<td></td>
</tr>
</tbody>
</table>
FREQUENCY FOR LABORATORY TESTS
ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN) REQUIRED WITH EACH ENCOUNTER

<table>
<thead>
<tr>
<th>Laboratory Test(s)</th>
<th>National Coverage Determination (NCD)</th>
<th>Local Coverage Determination (LCD)</th>
<th>LCD Frequency Limit (Per Beneficiary Per Provider)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statue Frequency Limit (Per Beneficiary)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamins and Tests for Metabolic Function</td>
<td></td>
<td>Two per year (baseline and 6 months)</td>
<td></td>
</tr>
<tr>
<td>Carnitine (Total and Free)</td>
<td></td>
<td>Two per year (baseline and 6 months) for Statin therapeutic management</td>
<td></td>
</tr>
<tr>
<td>C-Reactive Protein, high sensitivity (hsCRP)</td>
<td></td>
<td>One per year OR more frequently with low platelets *</td>
<td></td>
</tr>
<tr>
<td>Fibrinogen Antigen</td>
<td></td>
<td>One per year OR more frequently with malabsorption syndromes or deficiency disorders *</td>
<td></td>
</tr>
<tr>
<td>Folic Acid, serum</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Homocysteine</td>
<td></td>
<td>Two per year (baseline and 6 months) for Statin therapeutic management</td>
<td></td>
</tr>
<tr>
<td>Lipoprotein-associated Phospholipase A2 (PLAC)</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin B1 (Thiamine)</td>
<td></td>
<td>One per year OR more frequently with malabsorption syndromes, deficiency disorders, or post-surgical malabsorption *</td>
<td></td>
</tr>
<tr>
<td>Vitamin B2 (Riboflavin)</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin B6 (Pyridoxal Phosphate)</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin C (Ascorbic Acid)</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin E (Tocopherol)</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin K</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin B12 (Cyanocobalamin)</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin D 1,25 Dihydroxy</td>
<td></td>
<td>One per year</td>
<td></td>
</tr>
<tr>
<td>Vitamin D 25 Hydroxy</td>
<td></td>
<td>One per year OR more frequently with Vitamin D deficiency *</td>
<td></td>
</tr>
</tbody>
</table>

* Refer to LCD Utilization Guidelines for acceptable reasons (ICD-9-CM codes) for more frequent testing. [https://med.noridianmedicare.com/web/jeb/policies/lcd](https://med.noridianmedicare.com/web/jeb/policies/lcd)

Advanced Beneficiary Notice of Noncoverage (ABN) is required at each encounter for frequency. The ABN must include the frequency limitation as the reason for which Medicare will deny coverage (column 2 on ABN). A patient who has an ABN and exceeds the frequency limitation may incur out-of-pocket charges. (Refer to CMS Publication 100-04, Chapter 30-Financial Liability Protections) [http://www.cms.hhs.gov/Manuals/IOM/list.asp](http://www.cms.hhs.gov/Manuals/IOM/list.asp)
<table>
<thead>
<tr>
<th>Laboratory Test(s)</th>
<th>Statutory Frequency Limit (Per Beneficiary)</th>
<th>Considered as preventive screening ONLY when the physician provides one of the ICD-9-CM “V” Codes published by Medicare for the test ordered.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular Disease Screening</strong></td>
<td></td>
<td>CMS Publication 100-4, Chapter 18, titled “Preventive and Screening Services” <a href="http://www.cms.hhs.gov/Manuals/IOM/list.asp">http://www.cms.hhs.gov/Manuals/IOM/list.asp</a></td>
</tr>
<tr>
<td>Lipid Testing:</td>
<td></td>
<td>V81.0 Special screening for ischemic heart disease</td>
</tr>
<tr>
<td>Lipid Panel</td>
<td>One (1) Lipid Panel</td>
<td>V81.1 Special screening for hypertension</td>
</tr>
<tr>
<td>OR Cholesterol, Total HDL Cholesterol</td>
<td></td>
<td>V81.2 Special screening for other and unspecified cardiovascular conditions</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>OR One (1) of each individual test every five (5) years (60 months)</td>
<td></td>
</tr>
<tr>
<td>12 Hour Fast required</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cervical or Vaginal Cancer Screening</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pap Test</td>
<td>For female beneficiaries:</td>
<td>Low Risk (routine screen):</td>
</tr>
<tr>
<td>Conventional collection OR</td>
<td>Low Risk (routine screen): One (1) every two (2) years (24 months)</td>
<td>V72.31 Routine gynecological exam</td>
</tr>
<tr>
<td>Liquid-based collection OR Liquid-based</td>
<td>High Risk screen: One (1) every twelve (12 months)</td>
<td>V76.2 Special screening for malignant neoplasms; cervix</td>
</tr>
<tr>
<td>image-guided Pap test</td>
<td></td>
<td>V76.47 Special screening for malignant neoplasms; vagina</td>
</tr>
<tr>
<td></td>
<td></td>
<td>V76.49 Special screening for malignant neoplasms; other sites</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High Risk Screen:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>V15.89 Other specific personal history presenting hazards to health; other</td>
</tr>
<tr>
<td></td>
<td></td>
<td>V81.3 Special screening for other and unspecified cardiovascular conditions</td>
</tr>
<tr>
<td><strong>Colorectal Cancer Screening</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fecal Occult Blood</td>
<td>One (1) per year (12 months) (1-3 simultaneous determinations) for beneficiaries who have attained age of 50 years</td>
<td>Although Medicare has not published a specific list of acceptable “V” screening codes for fecal blood screening, the physician should request the test with a screening code such as V76.51 (special screening for malignant neoplasms; colon).</td>
</tr>
<tr>
<td>Peroxidase activity (e.g., guaiac) OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin determination by immunoassay</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes Screening – Glucose Testing</strong></td>
<td></td>
<td>V77.1 Special screening for diabetes mellitus</td>
</tr>
<tr>
<td>Glucose, Quantitative, Fasting OR</td>
<td>Pre-diabetes diagnosed = 2 screening tests per year (1 screening test each 6 months)</td>
<td></td>
</tr>
<tr>
<td>Glucose, 2 Hour, post 75 gm load glucose</td>
<td>Previously tested and not diagnosed with Pre-diabetes or never tested before = 1 screening test per year (12 months)</td>
<td></td>
</tr>
<tr>
<td>OR Glucose Tolerance, 3 specimens w/75 gm load – non-pregnant adults</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HIV Testing</strong></td>
<td></td>
<td>All patients - Primary</td>
</tr>
<tr>
<td>Males or Non-Pregnant Females</td>
<td>One (1) annual voluntary HIV screening of Medicare beneficiaries at increased risk for HIV infection</td>
<td>V73.89 Screening for other specified viral disease</td>
</tr>
<tr>
<td>Pregnant Females</td>
<td>Pregnant Females Three (3) voluntary screening tests per pregnancy</td>
<td>Secondary as appropriate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>V22.0 Supervision of normal first pregnancy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>V22.1 Supervision of other normal pregnancy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>V23.9 Unspecified high-risk pregnancy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>V69.8 Other problems related to lifestyle</td>
</tr>
<tr>
<td><strong>Prostate Cancer Screening</strong></td>
<td></td>
<td>V76.44 Special screening for malignant neoplasms; prostate</td>
</tr>
<tr>
<td>Prostate Specific Antigen (PSA, Total)</td>
<td>One (1) every twelve (12) months For male beneficiaries who have attained age of 50 years</td>
<td></td>
</tr>
<tr>
<td>Laboratory Test(s)</td>
<td>Statutory Frequency Limit (Per Beneficiary)</td>
<td>Considered as preventive screening ONLY when the physician provides one of the ICD-9-CM &quot;V&quot; Codes published by Medicare for the test ordered.</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Sexually Transmitted Infections (STI's) (Effective 11/08/2011) Chlamydia and Gonorrhoeae | 1. Pregnant women who are ≤ 24 years old or younger when the diagnosis of pregnancy is known.  
   a. Repeat screening during the third trimester if high-risk sexual behavior has occurred since the initial screening test  
   2. Pregnant women at increased risk for STIs when diagnosis of pregnancy is known  
   a. Repeat screening during the third trimester if high-risk sexual behavior has occurred since the initial screening test  
   3. Non-pregnant women at increased risk for STIs – annually | Pregnant Women at increased risk  
   V74.5 Screening, bacterial-sexually transmitted AND  
   V69.8 Other problems related to lifestyle AND one of the following  
   V22.0 Supervision of other first pregnancy  
   V22.1 Supervision of other normal pregnancy  
   V23.9 Supervision of unspecified high-risk pregnancy  

Non-Pregnant Women at increased risk  
V74.5 Screening bacterial - sexually transmitted AND  
V69.8 Other problems related to lifestyle (This diagnosis code is used to indicate high/increased risk for STIs) |
| Syphilis | 1. Pregnant women when the diagnosis of pregnancy is known.  
   a. Repeat screening during the third trimester if high risk sexual behavior has occurred since the previous screening test  
   b. Repeat screening at delivery if high-risk behavior has occurred since the previous screening test  
   2. Men and non-pregnant women at increased risk for STIs-annually. | Pregnant Women  
   V74.5 Screening, bacterial-sexually transmitted AND one of the following  
   V22.0 Supervision of normal first pregnancy  
   V22.1 Supervision of other normal pregnancy  
   V23.9 Supervision of unspecified high-risk pregnancy  

Pregnant Women at increased risk  
V74.5 Screening, bacterial-sexually transmitted AND  
V69.8 Other problems related to lifestyle AND one of the following  
V22.0 Supervision of normal first pregnancy  
V22.1 Supervision of other normal pregnancy  
V23.9 Supervision of unspecified high-risk pregnancy  

Men and Non-Pregnant Women at increased risk  
V74.5 Screening, bacterial-sexually transmitted AND  
V69.8 Other problems related to lifestyle as secondary (This diagnosis code is used to indicate high/increased risk for STIs) |
| Hepatitis B Surface Antigen | 1. Pregnant women at the first prenatal visit when the diagnosis of pregnancy is known.  
   a. Re-screening at the time of delivery for those with new or continuing risk factors. | Pregnant Women  
   V73.89 Other specified viral diseases AND one of the following  
   V22.0 Supervision of normal first pregnancy  
   V22.1 Supervision of other normal pregnancy  
   V23.9 Supervision of unspecified high-risk pregnancy  

Pregnant Women at increased risk  
V73.89 Other specified viral diseases AND  
V69.8 Other problems related to lifestyle AND one of the following  
V22.0 Supervision of normal first pregnancy  
V22.1 Supervision of other normal pregnancy  
V23.9 Supervision of unspecified high-risk pregnancy |
## Reflex Testing Options

<table>
<thead>
<tr>
<th>Test</th>
<th>Condition</th>
<th>Reflexed Test(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody Screen</td>
<td>If Positive</td>
<td>Antibody Identification</td>
</tr>
<tr>
<td>Antibody Identification</td>
<td></td>
<td>Antibody Titer</td>
</tr>
<tr>
<td>If antibody is causative of HDFN (Prenatal Patients only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANA</td>
<td>If Positive</td>
<td>ANA Panel</td>
</tr>
<tr>
<td>Coccioidiodomyososis ID IgG &amp; IgM</td>
<td>If either Positive</td>
<td>Complement Fixation (CF) Titer</td>
</tr>
<tr>
<td>Clinical Drug Screen</td>
<td>If Amphetamine Positive</td>
<td>Drug Confirmation by GC/MS</td>
</tr>
<tr>
<td>Pre-Employment Drug Screen</td>
<td>If any drug Positive</td>
<td>Drug Confirmation by GC/MS</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>If patient &lt; 3 years old</td>
<td>Reducing Substances</td>
</tr>
<tr>
<td>Urine Chemistry</td>
<td>If abnormal</td>
<td>Urine Microscopy</td>
</tr>
<tr>
<td>Urine C&amp;S</td>
<td>If WBC, Nitrite, Bacteria, Leucocyte Esterase Abnormal</td>
<td>Culture and Sensitivity</td>
</tr>
<tr>
<td>RPR</td>
<td>If Reactive</td>
<td>Treponemal IgG/IgM &amp; RPR Titer</td>
</tr>
<tr>
<td>Treponemal IgG/IgM</td>
<td>If Positive</td>
<td>RPR</td>
</tr>
<tr>
<td>RPR/Treponemal</td>
<td>If results do not correlate</td>
<td>TP-PA</td>
</tr>
<tr>
<td>Platelet Aggregation Epinephrine</td>
<td>If EPI &gt;184 sec</td>
<td>Platelet Aggregation ADP</td>
</tr>
<tr>
<td>dRVVT Screen (Lupus Anticoagulant)</td>
<td>If prolonged</td>
<td>dRVVT Confirm with Ratio</td>
</tr>
<tr>
<td>HIV-1 &amp; 2 Antibodies</td>
<td>If Positive</td>
<td>Western Blot Confirmation</td>
</tr>
<tr>
<td>Hepatitis B Surface Ag Screen</td>
<td>If Positive</td>
<td>Hepatitis B Surface Ag Confirmation</td>
</tr>
<tr>
<td>Hepatitis B Core Ab (Total)</td>
<td>If Positive</td>
<td>Hepatitis B Core Ab-IgM</td>
</tr>
<tr>
<td>Hepatitis A Ab (Total)</td>
<td>If Positive</td>
<td>Hepatitis A Ab-IgM</td>
</tr>
<tr>
<td>CBC</td>
<td>Multiple Parameters</td>
<td>Manual Differential and/or Pathologist Review</td>
</tr>
</tbody>
</table>

Reflex Test Options, 2/13/14
**Advance Beneficiary Notice of Noncoverage (ABN)**

**NOTE:** If Medicare doesn't pay for __________ below, you may have to pay. Medicare does not pay for everything, even some care that you or your healthcare provider have good reason to think you need. We expect Medicare may not pay for the __________ below.

<table>
<thead>
<tr>
<th>Laboratory Test(s)</th>
<th>Reason Medicare May Not Pay:</th>
<th>Estimated Cost</th>
</tr>
</thead>
</table>

**WHAT YOU NEED TO DO NOW:**
- Read this notice, so you can make an informed decision about whether to accept, refuse, or appeal the claim.
- Ask us any questions you may have after you finish reading this notice. We may help you decide whether to receive the Medicare payment or to file an appeal. We can provide you with an estimated cost of the care you would have, but Medicare cannot.

**OPTION 1.** I want the __________ 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 __________ 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 do not want to be paid now. 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 also receive a copy.

**Signature:**

**Date:**

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 (03/11)  Form Approved OMB No. 0938-0566
Advance Beneficiary Notice of Noncoverage (ABN)

**What You Need to Do Now:**
1. Read this notice, so you can make an informed decision about whether to use any other insurance.
2. Ask us any questions that you may have.
3. Choose an option below about whether you want Medicare to pay for the services listed above.
   - **Option 1:** I want the D. You may ask to be paid now, but I agree that Medicare doesn't pay. I am responsible for any payment, which is sent to me on a Summary Notice (MSN).
   - **Option 2:** I want the payment, but I can appeal to have Medicare pay. You may ask to be paid now, but I do not bill Medicare. You agree to follow the directions on the MSN. If Medicare does pay, you will refund any amounts listed above, but do not bill Medicare. You are responsible for any co-pays or deductibles listed above.
   - **Option 3:** I don't want the payment, but I cannot appeal to see if Medicare would pay.

**H. Additional Information:**

This notice gives information, not an official Medicare decision. If you have any questions about this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-800-397-8620).

**J. Date:**

**Signature:**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a currently valid OMB control number. The time required to complete this information collection is 0935-0199. The time required to complete this information collection is 45 minutes per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of these time estimates or suggestions for improving this form, please write to the PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.
DISCLAIMERS

This booklet was current at the time it was published or uploaded onto the web. Medicare policy
cchanges frequently so links to the source documents have been provided within the document for
your reference.

This booklet was prepared as a service to the public and is not intended to grant rights or impose
obligations. This booklet may contain references or links to statutes, regulations, or other policy
materials. The information provided is only intended to be a general summary. It is not intended
to take the place of either the written law or regulations. We encourage readers to review the
specific statutes, regulations, and other interpretive materials for a full and accurate statement of
their contents.

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Your feedback is important to us and we use your suggestions to help us improve our educational
products, services and activities and to develop products, services and activities that better meet
your educational needs. To evaluate Medicare Learning Network® (MLN) products, services
and activities you have participated in, received, or downloaded, please go to http://go.cms.gov/
MLNProducts and in the left-hand menu click on the link called ‘MLN Opinion Page’ and follow
the instructions. Please send your suggestions related to MLN product topics or formats to
MLN@cms.hhs.gov.
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The Centers for Medicare & Medicaid Services (CMS) implemented the Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, to inform Part B and certain Part A Original Medicare beneficiaries when Medicare may deny payment for an item or service. This booklet provides information to help health care professionals understand the Medicare requirements for when and how to issue an ABN.

WHAT IS AN ABN?

An ABN, Form CMS-R-131, is a standardized notice you or your designee must issue to a Medicare beneficiary before providing certain Medicare Part B (outpatient) or Part A (limited to hospice, home health agencies [HHAs], and Religious Nonmedical Healthcare Institutions only) items or services. You must issue the ABN when:

- You believe Medicare may not pay for an item or service;
- Medicare usually covers the item or service; and
- Medicare may not consider the item or service medically reasonable and necessary for this patient in this particular instance.

Hospices, HHAs, and Durable Medical Equipment (DME) suppliers must also follow additional guidelines for ABN issuance (listed on pages 3–4).

You should only provide ABNs to beneficiaries enrolled in Original (Fee-For-Service) Medicare. ABNs allow beneficiaries to make informed decisions about whether to get services and accept financial responsibility for those services if Medicare does not pay. The ABN serves as proof the beneficiary knew prior to getting the service that Medicare might not pay. If you do not issue a valid ABN to the beneficiary when Medicare requires it, you cannot bill the beneficiary for the service and you may be financially liable if Medicare doesn’t pay.

You may also use the ABN as an optional (voluntary) notice to alert beneficiaries of their financial liability prior to providing care that Medicare never covers. ABN issuance is not required to bill a beneficiary for an item or service that is not a Medicare benefit and never covered.

Please note:
The information in this publication applies only to the Medicare Fee-For-Service Program (also known as Original Medicare).

What’s New?

Medical Necessity
Medicare defines medical necessity as services that are:

- Reasonable and necessary;
- For the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member; and
- Not excluded under another provision of the Medicare Program.

For information related to Medicare coverage, regulations, and processes, visit http://www.cms.gov/Medicare/Coverage/CoverageGenInfo on the CMS website.
How Do I Know When Medicare Might Not Pay?

Medicare limits coverage of certain items and services by the diagnosis. If the diagnosis on the claim is not one Medicare covers for the item or service, Medicare will deny the claim. An ABN must be issued prior to furnishing a usually covered item or service when the diagnosis doesn’t support medical necessity.

What Are Medicare Coverage Policies?

Limited coverage may result from National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). Medicare expects you to know both current NCDs and LCDs. NCDs describe whether Medicare pays for specific medical items, services, treatment procedures, or technologies. In the absence of an NCD, LCDs indicate which items and services Medicare considers reasonable, medically necessary, and appropriate. In most cases, the availability of this information indicates you knew, or should have known, Medicare would deny the item or service as not medically necessary.


ICD-9-CM Coding

All services reported to the Medicare Program by health care professionals must demonstrate medical necessity through the use of International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnostic coding carried to the highest level of specificity for the date of service. For dates of service on or after October 1, 2015, you will use the International Classification of Diseases, 10th Edition, Clinical Modification/Procedure Coding System (ICD-10-CM/PCS). For more information, visit http://www.cms.gov/Medicare/Coding/ICD10 on the CMS website.

What Are Frequency Limits?

Some Medicare-covered services are subject to frequency limitations. A frequency limit means Medicare will pay for only a certain quantity of a specific item or service in a given time period for a particular diagnosis. If you believe that an item or service may exceed frequency limitations, you must issue an ABN prior to providing the item or service to the beneficiary.

If you do not know the number of times the beneficiary got a service within a specific time frame, you can try to get this information from the beneficiary or other providers involved in his or her care. Otherwise, contact your Medicare Administrative Contractor (MAC). For your MAC contact information, visit http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map on the CMS website. Alternatively, you may use the Health Insurance Portability and Accountability Act (HIPAA) Eligibility Transaction System (HETS) (270/271) to determine if a Medicare beneficiary met the frequency limits from another provider during the calendar year. For more information on HETS 270/271, visit http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/HETSHelp on the CMS website.
Key Points For Health Care Providers

- You must issue an ABN to the beneficiary prior to providing care that Medicare may not cover because it is not medically reasonable and necessary in this particular case.
- In situations where the ABN is required:
  - Medicare permits you to bill the beneficiary after the beneficiary signs a valid ABN indicating his or her choice to get the item or service and accept financial liability, and
  - If you do not issue an ABN or Medicare finds the ABN invalid, you may not bill the beneficiary for the services, and you may be financially liable if Medicare does not pay.
- You may not use ABNs to charge a beneficiary for a component of a service when Medicare makes full payment through a bundled payment.
- Medicare prohibits you from using an ABN to transfer liability to the beneficiary when Medicare would otherwise pay for items and services.
- When you issue the ABN as a voluntary notice, the beneficiary does not check an option box or sign and date the notice.
- The ABN is issued for items and services covered under Part B. It is only issued for Part A care provided by hospices, HHAs, and Religious Nonmedical Healthcare Institutions.

WHEN MUST I ISSUE AN ABN?

Mandatory ABN Uses

You must issue an ABN when:

- You expect Medicare to deny payment for an item or service because it is not reasonable and necessary under Medicare Program standards;
- Medicare considers the care to be custodial care;
- Outpatient therapy services are in excess of therapy cap amounts and do not qualify for a therapy cap exception;
- A patient is not terminally ill (for hospice providers only); or
- Home health services requirements are not met: for example, the individual is not confined to the home or does not need intermittent skilled nursing care (for HHA providers).

Refer to the “What Claim Reporting Modifiers Do I Use?” section at the end of this booklet for information on claim modifiers associated with mandatory ABN use.

Common reasons for Medicare to deny an item or service as not medically reasonable and necessary include care that is:

- Experimental and investigational or considered “research only”;
- Not indicated for diagnosis and/or treatment in this case;
- Not considered safe and effective; or
- More than the number of services Medicare allows in a specific period for the corresponding diagnosis.

Additional mandatory requirements apply to DME suppliers. DME suppliers must issue an ABN before providing the beneficiary with items or services if:
- The provider violated the prohibition against unsolicited telephone contacts;
- The supplier has not met supplier number requirements;
- The supplier is a non-contract supplier providing an item listed in a competitive bidding area; or
- Medicare requires an advance coverage determination.

**WHEN MAY I ISSUE A VOLUNTARY ABN?**

**Voluntary ABN Uses**

Medicare does not require ABNs for statutorily excluded care or for services Medicare never covers. However, in these situations, you may issue an ABN voluntarily. Refer to the “What Claim Reporting Modifiers Do I Use?” section at the end of this booklet for information on claim modifiers associated with voluntary ABN use.

**Examples of Medicare Program exclusions include:**
- Charges made to the Medicare Program for services furnished by a physician or supplier to his or her immediate relatives or members of his or her household;
- Cosmetic surgery, unless required for prompt repair of accidental injury or for improvement of a malformed body member;
- Eye exams for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses in the absence of disease or injury to the eye;
- Hearing aids and routine hearing examinations;
- Personal comfort items;
- Routine dental services (that is, care, treatment, filling, removal, or replacement of teeth);
- Routine foot care (that is, cutting or trimming corns or calluses, unless inflamed or infected; routine hygiene or palliative care or trimming of nails);
- Routine immunizations (except influenza, pneumococcal, and hepatitis B vaccinations; specific regulations regarding beneficiary responsibility apply for these services);
- Services furnished or paid by government institutions;
- Services resulting from acts of war; and
- Supportive devices for the feet.
WHEN AM I PROHIBITED FROM ISSUING AN ABN?

What Is the Routine Notice Prohibition?
Medicare prohibits you from issuing ABNs on a routine basis (that is, where there is no reasonable basis to expect that Medicare may not cover the item or service). You must ensure a reasonable basis exists for noncoverage associated with the issuance of each ABN. As long as proper evidence supports each ABN use, you will not be violating the routine notice prohibition.

What Are Some Exceptions to the Routine Notice Prohibition?
ABNs may be routinely issued in the following circumstances:
- Experimental items and services;
- Items and services with frequency limitations for coverage;
- Medical equipment and supplies denied because the supplies had no supplier number or the supplier made an unsolicited telephone contact; or
- Services that are always denied for medical necessity.

What About a Beneficiary in a Medical Emergency or Under Great Duress?
You should not obtain an ABN from a beneficiary in a medical emergency or under great duress (that is, compelling or coercive circumstances). ABN use in the emergency room or during ambulance transports may be appropriate in some cases for a medically stable beneficiary with no immediate health issues.

HOW DO I ISSUE A VALID ABN?

When Do I Issue an ABN?
Three triggering events may prompt you to issue an ABN. They are:
- Initiations;
- Reductions; and
- Terminations.

Initiations
An initiation occurs at the beginning of a new patient encounter, start of a plan of care, or beginning of treatment. If you believe at initiation that Medicare will not cover certain otherwise covered items or services because they are not reasonable and necessary, you must issue an ABN prior to the beneficiary receiving the noncovered care.

May I Use an ABN to Bill a Beneficiary for Services Denied Due to a Medically Unlikely Edit (MUE)?
No, you cannot use an ABN to shift liability and bill the beneficiary for the services denied due to an MUE. For more information on MUEs, visit http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html on the CMS website.
Reductions

A reduction occurs when a component of care decreases (for example, frequency or duration of a service). An ABN should not be issued every time there is a reduction in care. You must issue an ABN prior to delivery of care if a reduction occurs, but the beneficiary wants to continue to receive the care that is no longer considered medically reasonable and necessary.

Terminations

A termination is the discontinuation of certain items or services. You only need to issue an ABN at termination if the beneficiary wants to continue receiving care that is no longer medically reasonable and necessary.

**Who Issues the ABN when Multiple Entities Render Care?**

When multiple entities render care, Medicare does not require you to issue separate ABNs. Any party involved in the delivery of care can issue the ABN when:

- There are separate “ordering” and “rendering” providers (for example, a physician orders a laboratory test and an independent laboratory delivers the ordered tests);
- One health care provider delivers the “technical” component and the other the “professional” component of the same service (for example, radiological test that an independent diagnostic testing facility renders and a physician interprets); or
- The entity that obtains the signature on the ABN differs from the entity that bills for the service (for example, when one laboratory refers a specimen to another laboratory, which then bills Medicare for the test).

In these situations, you may enter the names of more than one entity in the header of the ABN as long as the beneficiary can clearly identify whom to contact for billing questions.

**NOTE:** Regardless of who issues the ABN, Medicare holds the billing entity responsible for effective issuance.

**How Do I Format an ABN?**

You must issue the ABN in the standardized notice format, and it cannot exceed one page in length. However, Medicare permits attachments for listing additional items and services. If you use an attachment sheet, the attachments must allow for clear matching of the items or services in question with the reason that a denial is expected and cost estimate information.

You must use a visually high-contrast combination of dark ink on a pale background, and the print should be readable to the beneficiary.
Medicare permits limited customization, such as preprinting information in certain blanks of the ABN. For more information, refer to the “Medicare Claims Processing Manual,” Chapter 30, Section 50 at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf on the CMS website.

**How Do I Effectively Issue an ABN?**

Medicare considers issuance of an ABN effective when the notice is:

- Issued (preferably in person) to and comprehended by a suitable recipient;
- Completed on the approved, standardized ABN with all required blanks completed;
- Provided far enough in advance of potentially noncovered items or services to allow sufficient time for the beneficiary to consider available options;
- Explained in its entirety with all questions related to the ABN answered; and
- Signed and dated by the beneficiary or his or her representative after he or she selected one option box on the ABN.

If you issue ABNs on an electronic screen, you must ask the beneficiary if he or she prefers a paper version and issue a paper ABN if that is preferred. Regardless of whether the ABN is signed electronically or on paper, you must give the beneficiary a paper copy.

**To Whom Should I Issue an ABN?**

You should issue the ABN to:

- The Medicare beneficiary; or
- The Medicare beneficiary’s representative for the purposes of getting notice under applicable State or other law.

You and the beneficiary must each retain one copy of the signed ABN. If you maintain Electronic Medical Records (EMRs), you may scan the signed hard copy for retention.

**How Do I Issue an ABN Other Than In Person?**

In circumstances when issuing an ABN in person is not possible, you may issue an ABN through the following means and according to HIPAA policies:

- Direct telephone;
- E-mail;
- Mail; or
- Secure fax machine.
When you do not issue the ABN in person, document the contact in the beneficiary’s records. For Medicare to consider the issuance of an ABN effective, the beneficiary should not dispute such contact. You must follow telephone contacts immediately by either a hand-delivered, mailed, e-mailed, or faxed ABN. The beneficiary or the beneficiary’s representative must sign and retain the ABN and send a copy of the signed ABN to you for retention in the beneficiary’s record.

Keep a copy of the unsigned ABN on file while awaiting receipt of the signed ABN. If the beneficiary fails to return a signed copy, document the initial contact and subsequent attempts to obtain a signature in appropriate records or on the ABN.

**HOW DO I COMPLETE AN ABN?**

For the ABN and instructions on its use, visit [http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html](http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html) on the CMS website. You can find an example of an ABN on page 11 of this booklet.

The ABN consists of 5 sections and 10 blanks, which must appear in the following order from top to bottom. The letters refer to the corresponding blanks in the ABN form that you or the beneficiary must complete. The letters are for guidance purposes and should be removed from the ABN prior to issuance.

**Notifier(s) (A)**
- Place your name, address, and telephone number at the top of the ABN.
- If the billing and notifying entities differ, you may give the name of more than one entity in the notifier area. However, the beneficiary must be able to identify which entity to contact for billing questions.

**Patient Name (B)**
- You must enter the first and last name of the beneficiary getting the ABN. You should also use the middle initial if it appears on the beneficiary’s Medicare card.

**Identification Number (C)**
- This field is optional and can include an identifier such as a medical record number or date of birth.
- Medicare numbers, Health Insurance Claim Numbers (HICNs), or Social Security Numbers (SSNs) must not appear on the ABN.

**Body (D)**
- List the general description of what you believe may not be covered by Medicare on the blank lines of the “NOTE.” A commonly used descriptor for blank D is “Items/services.”

**Table (D, E, F)**
- **Blank (D)**
  - For the table header, insert the same general description language as used in the “D” blanks in the paragraph above.
In the table, list the specific items or services you believe to be noncovered.
- For upgrades, list the excess component(s) of the item or service for which you expect a denial.
- For repetitive or continuous noncovered care, specify the frequency and/or duration of the item or service.
- For reduction in service, provide enough additional information so beneficiaries understand the nature of the reduction.

**Reason Medicare May Not Pay (E)**
- Explain in beneficiary-friendly language why you believe Medicare may not cover each item or service. Commonly used reasons for noncoverage are:
  - Medicare does not pay for this test for your condition.
  - Medicare does not pay for this test as often as this (denied as too frequent).
  - Medicare does not pay for experimental or research use tests.

**NOTE:** To be a valid ABN, at least one reason must apply to each item or service listed. You may apply the same reason for noncoverage to multiple items.

**Estimated Cost (F)**
- You must complete the Estimated Cost block to ensure the beneficiary receives all available information to make an informed decision about whether to obtain potentially noncovered services.
- You must make a good faith effort to insert a reasonable estimate for all the items or services listed. In general, Medicare expects the estimate will fall within $100 or 25 percent of the actual costs, whichever is greater. Examples of acceptable estimates include, but are not limited to, the following:
  - For a service that costs $250:
    - “Between $150–$300”; or
    - “No more than $500.”
- You can bundle routinely grouped multiple items or services into a single-cost estimate.

**Options (G)**
The beneficiary, or his or her representative, must choose only one of the three options listed. Medicare does not permit you to make this selection. (However, home health agencies caring for dual eligibles may direct beneficiaries on option selection in accordance with State directives. For more information, see [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8597.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8597.pdf).)

**If the beneficiary chooses Option 1:**
The beneficiary wants to get the item or services at issue and accepts financial responsibility. He or she agrees to make payment now, if required. **You must submit a claim to Medicare that will result in a payment decision that the beneficiary can appeal.**

**NOTE:** If the beneficiary needs a Medicare claim denial for a secondary insurance plan to cover the service, the beneficiary should select Option 1.
If the beneficiary chooses Option 2:
The beneficiary wants to get the item or services at issue and accepts financial responsibility. He or she agrees to make payment now, if required. When the beneficiary chooses this option, you do not file a claim, and there are no appeal rights.

You will not violate mandatory claims submission rules under Section 1848 of the Social Security Act (the Act) when you do not submit a claim to Medicare at the beneficiary’s written request.

If the beneficiary chooses Option 3:
The beneficiary does not want the care in question and cannot be charged for any items or services listed. You do not file a claim, and there are no appeal rights.

Additional Information (H)
You may use this space to provide additional clarification or information that may be useful to the beneficiary. For example:

- A statement advising the beneficiary to notify his or her health care provider about certain tests ordered but not received;
- An additional dated witness signature; or
- Other necessary annotations.

Medicare assumes you made annotations on the same date as that appearing with the beneficiary’s signature unless you include a separate date with the annotation.

Signature and Date Box (I, J)
Once the beneficiary reviews and understands the information contained in the ABN, the beneficiary, or his or her representative, should complete the Signature and Date box.

Signature (I)
The beneficiary, or the beneficiary’s representative, must sign the ABN to indicate he or she got the ABN and understands its contents. If a representative signs, he or she should indicate “representative” after his or her signature and print the name if it isn’t legible.

Date (J)
The beneficiary, or the beneficiary’s representative, must write the date he or she signed the ABN. If the beneficiary experiences physical difficulty writing and requests assistance in completing this box, the notifier may insert the date.

Beneficiary Refuses to Complete or Sign the ABN
If the beneficiary refuses to choose an option or refuses to sign the ABN, you should annotate the original copy of the ABN indicating the refusal to sign or choose an option. You may list any witnesses to the refusal on the ABN, although Medicare does not require this. If a beneficiary refuses to sign a properly issued ABN, you should consider not furnishing the item or service unless the consequences (health and safety of the beneficiary or civil liability in case of harm) prevent this option.
A. Notifier:
B. Patient Name:
C. Identification Number:

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for D. ________ 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 D. ________ below.

<table>
<thead>
<tr>
<th>D.</th>
<th>E. Reason Medicare May Not Pay</th>
<th>F. Estimated Cost</th>
</tr>
</thead>
</table>

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 D. ________ 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.

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

☐ OPTION 1. I want the D. ________ 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 D. ________ 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 D. ________ listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

H. 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 also receive a copy.

I. Signature: ___________________________  J. Date: ___________________________

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 (03/11)  Form Approved OMB No. 0938-0566
WHAT DO I DO WITH THE ABN?

In general, you should keep the ABN for 5 years from the date-of-care delivery when no other requirements under State law apply. Medicare requires you to keep a record of the ABN in all cases, including those cases in which the beneficiary declined the care, refused to choose an option, or refused to sign the ABN. Electronic retention of the ABN is acceptable. You may scan the signed version of the ABN for the electronic medical record and give the paper copy to the beneficiary.

What If the Beneficiary Changes His or Her Mind?

After completing and signing the ABN, if the beneficiary changes his or her mind, you should present the previously completed ABN to the beneficiary and request he or she annotate the original ABN. The annotation must include a clear indication of his or her new option selection along with his or her signature and date of annotation. In situations where you cannot present the ABN to the beneficiary in person, you may annotate the form to reflect the beneficiary’s new choice and immediately forward a copy of the annotated ABN to the beneficiary to sign, date, and return.

NOTE: In either situation, you must provide a copy of the annotated ABN to the beneficiary as soon as possible.

When Do I Need to Issue Another ABN for an Extended Course of Treatment?

You may issue a single ABN to cover an extended course of treatment if the ABN identifies all items and services and the duration of the period of treatment for which you believe Medicare will not pay. If the beneficiary receives an item or service during the course of treatment that you did not list on the ABN and Medicare may not cover it, you must issue a separate ABN.

A single ABN for an extended course of treatment remains valid for no more than 1 year. If the extended course of treatment continues after a year’s duration, you must issue a new ABN.

May I Collect Payment from the Beneficiary?

A beneficiary’s agreement to be responsible for payment on an ABN means the beneficiary agrees to pay for expenses out of pocket or through any insurance other than Medicare. You may bill and collect funds for noncovered items or services immediately after the beneficiary signs an ABN. If Medicare ultimately denies payment, you retain the funds collected.

If Medicare pays all or part of the claim for items or services previously paid by the beneficiary or if Medicare finds you liable, you must refund the beneficiary the proper amount in a timely manner. Medicare considers refunds timely when made within 30 days after you get the Remittance Advice from Medicare or within 15 days after a determination on an appeal if you or the beneficiary files an appeal.

If you do not issue a valid ABN to the beneficiary when required by Medicare, you cannot bill the beneficiary for the service and you may be financially liable.
WHAT IF I FAIL TO ISSUE A MANDATORY ABN OR ISSUE A DEFECTIVE ABN?

You will likely be financially liable for items or services if you knew, or should have known, Medicare would not pay for a usually covered item or service and you fail to issue an ABN or issue a defective ABN. In these cases, you cannot collect funds from the beneficiary, and Medicare requires you to make prompt refunds if you previously collected payment.

WHAT CLAIM REPORTING MODIFIERS DO I USE?

The following are claim modifiers associated with ABN use. For specific instructions on filing claims associated with ABNs, refer to the “Medicare Claims Processing Manual,” Chapter 1, Section 60 at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ctm104c01.pdf on the CMS website.

GA Waiver of Liability Statement Issued as Required by Payer Policy, Individual Case
Use this modifier to report when you issue a mandatory ABN for a service as required and it is on file. You do not need to submit a copy of the ABN, but you must have it available on request.

GX Notice of Liability Issued, Voluntary Under Payer Policy
Use this modifier to report when you issue a voluntary ABN for a service Medicare never covers because it is statutorily excluded or is not a Medicare benefit. You may use this modifier in combination with modifier GY.

GY Item or Service Statutorily Excluded, Does Not Meet the Definition of Any Medicare Benefit
Use this modifier to report that Medicare statutorily excludes the item or service or the item or service does not meet the definition of any Medicare benefit. You may use this modifier in combination with modifier GX.

GZ Item or Service Expected to Be Denied as Not Reasonable and Necessary
Use this modifier to report when you expect Medicare to deny payment of the item or service due to a lack of medical necessity and no ABN was issued.
RESOURCES

For more information on ABNs, refer to the table below.

ABN Resources

<table>
<thead>
<tr>
<th>Resource</th>
<th>Description and Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Coverage</td>
<td>The MCD assists you with the latest information related to NCDs and LCDs, local policy articles, and proposed NCD decisions. For the MCD, visit <a href="http://www.cms.gov/Medicare-Coverage-Database">http://www.cms.gov/Medicare-Coverage-Database</a> on the CMS website. For information related to coverage and important links, visit the Medicare Coverage Center at <a href="http://www.cms.gov/Medicare/Coverage/CoverageGenInfo">http://www.cms.gov/Medicare/Coverage/CoverageGenInfo</a> on the CMS website. The online CMS Internet-Only Manuals (IOMs) include CMS’ program issuances, day-to-day operating instructions, policies, and procedures based on statutes, regulations, guidelines, models, and directives. For the NCD Manual, visit the IOM web page at <a href="http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html">http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html</a> on the CMS website.</td>
</tr>
<tr>
<td>Resource</td>
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</table>
The Medicare Learning Network® (MLN), a registered trademark of CMS, is the brand name for official information health care professionals can trust. For additional information, visit the MLN's web page at http://go.cms.gov/MLNGenInfo on the CMS website.
Supplies Prohibited by Stark Law

- Bags, Baggies/zip lock (other than specimen bags)
- Bags, Red biohazard for regulated medical waste disposal
- Bandage, Band-Aid
- Bandage, Coban wrap
- Brushes, disposable biopsy
- Catheter kits
- Cotton balls, swabs, Q-tips, gauze
- Cover slips
- Emergency eyewash stations
- Gloves, disposable, rubber/latex
- Glucometer and test strips
- Goggles, safety glasses, splash shields, masks
- Gowns, Examination
- Hazardous material labels
- K-Y / lubricating jelly
- Lab coats
- Magazine subscriptions
- Microscope slides
- Needles, aspiration (reusable or disposable)
- Needles, biopsy
- Needles, butterfly
- Needles, injection (reusable or disposable; large and small)
- Needles, prostate biopsy
- Paper, copier
- Paper, examination table
- Paper, other disposable paper supplies, i.e. facial tissue, cups, towels
- Parafilm
- Phlebotomy chairs
- Reagents for in-office testing
- Refrigerators
- Rubber bands
- Sharps container
- Snare
- Soap, antibacterial
- Soap, germicidal
- Speculums
- Surface disinfectant products
- Syringes
- Tape, hypoallergenic, including paper and transparent
- Test kits, on-site testing, i.e. fecal occult blood, pregnancy, (NOTE: "kits" comprised solely of collection devices are allowable, such as for O&P)
- Test tube racks
- Tongue blades
- Tourniquets (for Physician Office Labs)
- Urine cups (non-sterile, without lid)
- Urine dip sticks
- Wipes, alcohol
- Wipes, Betadine
- Wipes, other similar skin preparation products

References:
1. California Clinical Laboratory Association, 2001 Guidance
2. Office of the Inspector General, Department of Health & Human Services
3. Centers for Medicare & Medicaid Services Advisory Opinions
4. Code of Federal Regulations
5. New York Regulations, Subpart 34-2