Medical Necessity and Advanced Beneficiary Notice (ABN) Policy and Form

Billings Clinic Laboratory believes all health-care providers should order only appropriate tests for the diagnosis and treatment of their patients. It is the policy of Billings Clinic Laboratory to provide all health-care providers who utilize our laboratory services with the ability to order appropriate tests and to ensure that the convenience of ordering panels does not adversely impact the health-care providers ability to make a deliberate decision regarding which tests are medically necessary for the individual patient. **Ordering Health-Care Providers: Please exercise judgement when placing orders. You may order individual tests or a less inclusive panel when not all of the tests included in the panel or profile are medically necessary for the individual patient. You may decline reflex testing as well.**

National Coverage Determinations (NCDs) and Local Coverage Decisions (LCDs)

Medicare laws require that the program (Medicare) only pay for services that are reasonable and medically necessary for the treatment and diagnosis of Medicare beneficiaries. As a method of establishing the medical necessity for laboratory tests, Medicare has created medical coverage policies for certain laboratory tests. The policies come in 2 forms - NCDs and LCDs. NCDs establish national coverage while the local Medicare FI or Carrier establishes LCDs. The published NCD or LCDs give information as when payment is allowed. The Centers for Medicare & Medicaid Services (CMS) updates the NCDs quarterly. You may access current NCD information at www.cms.hhs.gov and current LCD information at www.medicare.bcbs.mt.com (Montana) and www.noridianmedicare.com (Wyoming).

Neither the NCDs or LCDs are intended to restrict a physician/nonphysician provider (NPP) from ordering any test he/she believes is medically necessary for a particular patient. The policies are intended to inform the ordering physician/NPP of the circumstances under which the Medicare program will allow payment. If Medicare denies payment for a test based on medical necessity, the provider may not bill a beneficiary for the test(s) unless it has informed the beneficiary of the likelihood of denial through the presentation of an advanced beneficiary notice (ABN) for option selection and signature.

Section 4317 of the Balanced Budget Act of 1997 requires the ordering physicians/NPPs to provide diagnostic information when placing orders for diagnostic tests such as laboratory tests. By policy, Billings Clinic Laboratory requires the diagnostic information for laboratory tests to be in the form of ICD-9 codes. The ICD-9 code(s) submitted with orders for diagnostic test(s) should be reflected in the patient's medical record. If the code(s) submitted with the order is not present as a "covered" code by the NCD or LCD, an ABN should be presented to the beneficiary or his/her authorized representative. The beneficiary or his/her representative must be able to receive and comprehend the ABN.

Billings Clinic Laboratory Policy related to NCDs, LCDs, and ABNs

When submitting orders for test(s) with NCD or LCD coverage, Billings Clinic Laboratory **requires submission of**:

- ICD-9 code(s) that meets Medicare criteria for coverage/payment for each test. The ICD-9 code is obtained FROM THE PATIENT'S MEDICAL RECORD THAT REFLECT THE PATIENT'S ACTUAL MEDICAL CONDITION **OR**
- A properly executed ABN proper for each NCD or LCD test and attached to the laboratory order form.

Failure to provide the above information will result in the following actions:

- Billings Clinic Laboratory staff may contact the ordering physician/NPP office requesting additional diagnostic information from the patient's medical record to support the medical necessity of the test(s) ordered **OR**
- Billings Clinic Laboratory staff may contact the ordering physician/NPP office requesting a copy of the properly executed ABN **OR**
- Submitting client is billed for services.

Advanced Beneficiary Notice (ABN)

Medicare Program A-00-43 and AB-02114 provide specific information about ABNs. You may also access updated information about ABNs on the CMS website: www.cms.hhs.gov. ABN is defined as a written notice given to a Medicare beneficiary, before services are furnished, when a provider believes that Medicare will not pay for some or all of the services. An ABN may be given to a beneficiary or their representative when they can receive it and comprehend its content. A provider may not bill a Medicare beneficiary for a service that is denied by Medicare without having evidence that it has informed the beneficiary of the likelihood of denial through the presentation of an ABN for the beneficiary's (or his/her representative's) review, choice selection, and signature. CMS issues standard ABN forms. One form is specific for laboratory tests, and one form is a general form. Either is acceptable for laboratory test(s) when properly completed. Health-care providers should present the ABN when appropriate. Attach the properly executed ABN form to the laboratory requisition when submitting laboratory orders. The following table contains

general guidelines on ABN presentation. This information is provided to Billings Clinic Laboratory customers to aid them in meeting the government's requirements concerning the use of ABNs. Please refer to the CMS website for further information regarding ABNs.

ABN SHOULD Be Executed When:	ABN SHOULD NOT Be Executed When:
Medicare is expected to deny payment (entirely or in part) for items or services because they are not reasonable and necessary under Medicare program standards (medical necessity denial)	The physician or supplier expects Medicare to pay
Certain screening tests (mammogram, Pap smear, PSA, etc.) have frequency limits. ABNs may be given every time these tests are ordered	The physician or supplier "never know whether or not Medicare will pay" but has no reason to expect Medicare will not pay
Medicare is expected to deny payment for medical equipment and supplies because it is not a covered service	If the item or services is NOT a Medicare benefit (eg, routine physical and tests in absence of signs or symptoms, etc.)
If the ordered tests are for research or investigational use only	If Medicare is expected to deny payment for an item or service which is a Medicare benefit because it does not meet a technical benefit requirement (eg, ambulance services denied due to an unapproved destination, etc.)

Additional Information

For additional information or questions about the contents of this catalog, its use or purpose, or to make suggestions to improve it, please call Billings Clinic Laboratory at 1-866-232-2522.

Advanced Beneficiary Notice (ABN)—Form

Billings Clinic

2800 10th Avenue North
PO Box 37000
Billings, MT 59107-7000

(A) **Notifier(s):**
(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.

(D)_____	***(E)*** **Reason Medicare May Not Pay:**	***(F)*** **Estimated Cost:**

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:**

Metals Analysis-Collection and Transport

Due to the methodologies used for metals testing, a significantly abnormal result for an analyte not ordered may be identified. When sample integrity is not in question, a comment will be added to the report to notify the physician of the abnormal analyte, so the appropriate test may be added, if desired.

Periodically, requests are received for metals testing on tissue types that have not been validated or are not appropriate. The only metals tests that can be routinely ordered on tissue specimens are #8350 “Iron, Liver Tissue”; #8687 “Copper, Liver Tissue”; and #89302 “Gadolinium, Dermal Tissue.” The laboratory will not accept requests for any other metals testing without advanced approval from the laboratory director. Such testing is performed on a research basis for clinical uses only; the laboratory does not perform testing for legal or forensic studies.

Analyses for trace metals at Mayo Clinic and Mayo Medical Laboratories are performed in an ultra-clean laboratory environment using a system of positive-pressure filtered air to prevent specimen contamination due to dust. This allows for detection of many metals at the sub-part-per-billion concentration range. Contamination control must be practiced during specimen collection to provide a specimen that will yield clinically useful results. We recommend and strongly urge the use of a specific set of blood collection tubes for specimen collection and that phlebotomists carry out the proven techniques described below.

The Metals Laboratory at Mayo Clinic has tested numerous blood collection tubes and has found most of them introduce contamination when used for trace metal specimen collection. Standard red-topped evacuated clot tubes and all plastic syringes with black rubber seals are grossly contaminated with zinc, and all contain varying amounts of heavy metals (lead, mercury, cadmium, nickel, chromium, and others). All rubber stoppers (except the royal blue-top Monoject Trace Element Blood Collection Tubes) have significant concentrations of aluminum in the rubber, which is carried into the specimen on the puncturing needle, contaminating the specimen. Most evacuated tubes for plasma or whole blood collection that are not specifically designed for trace metal specimen collection contain anticoagulants contaminated with trace metals. These problems have been noted in numerous publications.[1-3]

We require the use of EDTA as an anticoagulant for whole blood specimens. Other anticoagulants (heparin, for example) are effective only for 24 to 36 hours. Frequently, transportation time to Rochester exceeds this time; heparinized specimens frequently arrive partially clotted, making analysis and interpretation of results difficult.

When multiple blood specimens are scheduled for collection from 1 patient, the trace metal specimens should be collected first; once the phlebotomy needle has punctured another rubber stopper, it is contaminated and should not be used for trace metal specimen collection.

Always use an alcohol swab to cleanse the venipuncture site. Avoid iodine-containing disinfectants. Use only stainless steel phlebotomy needles.

Do not collect specimens from patients who have received gadolinium-, iodine-, or barium containing contrast material within 96 hours. Gadolinium, iodine, and barium are known to interfere with most metals tests.

Serum

Blood specimens for serum testing should be drawn in the plain, royal blue-top Monoject® Trace Element Blood Collection Tube, product #8881-307006 (Supply T184). Allow the specimen to clot for 30 minutes; then centrifuge the specimen to separate serum from the cellular fraction. Remove the stopper. Carefully pour the serum into a 7-mL Mayo metal-free, screw-capped, polypropylene vial (Supply T173), avoiding transfer of the cellular components of blood. **Do not** insert a pipet into the serum to accomplish transfer, and **do not** ream the specimen with a wooden stick to assist with serum transfer. Place the cap on the polypropylene vial tightly, attach a specimen label, and send specimen to the laboratory at refrigerated or frozen temperature. All specimens to be stored more than 48 hours should be frozen.

Whole Blood

A specimen for whole blood testing should be drawn in a royal blue-top Monoject® Trace Element Blood Collection Tube, product #8881-307022 (Supply T183), containing EDTA as an anticoagulant. Leave the specimen in the tube, attach an identification label, and send the specimen to the laboratory at cool temperature. Alternatively, pediatric specimens can be drawn in a Becton-Dickinson MICROTAINER®, product #5973, with EDTA anticoagulant. Specimens to be stored more than 48 hours should be stored at 4° C and sent refrigerated.

Urine

Clean, plastic container(s) with no metal cap(s) or glued insert(s) must be used for urine collection. Send specimen in a plastic, 13-mL urine tube or a clean, plastic aliquot container with no metal cap or glued insert.

Do not collect urine specimens in the environment in which exposure is likely to occur. It is important that dust from clothing not contribute to the specimen contents.

Do not collect urine in metal-based containers such as metal urinals or pans.

Do not collect or transport urine in colored containers because of metals found in dyes.

Tips to Control Contamination

1. Keep patient specimen area clean and free of dust.
2. It is best to use the Monoject® evacuated blood tubes (Supply T183 or T184), vials, and needles.
3. **Do not** touch specimen with utensils unless they have been acid-washed.
4. Dialysis patients on heparin may form an uncoagulated serum when centrifuging. Pour off serum as soon as possible, invert the clot tube, and repeat centrifugation step to separate cellular fraction if more serum is needed.
5. **Do not** leave serum on cells more than 60 minutes. Centrifuge and pour serum into metal-free vial.

References

1. Moyer TP, Mussmann, GV, and Nixon, DE: Blood-collection device for trace metal and ultra-trace metals specimens evaluated. Clin Chem 1991;37:707-714

2. Boeynaems JM, De Leener A, Dessars B, et al: Evaluation of a new generation of plastic evacuated blood-collection tubes in clinical chemistry, therapeutic drug monitoring, hormone, and trace metal analysis. Clin Chem Lab Med 2004;42:67-71

3. Rodushkin I and Odman F: Assessment of the contamination from devices used for sampling and storage of whole blood and serum for element analysis. J Trace Elem Med Biol 2001:14-40-45