

**Laboratory Annual Notice**

**Date**:    January 1, 2025

**To**:         Gundersen Boscobel Area Hospital and Clinics Medical Staff; Gundersen Boscobel Area Hospital

 and Clinics Associate Staff

**From**:    Dr. Christopher Cogbill, MD, Laboratory Medical Director; Judy Dayton, Ancillary Services

 Manager, Gundersen Boscobel Area Hospital and Clinics Laboratory

**cc**:          Kari Adank, Vice President, Compliance; Taryn Zubich, Director of Compliance (GLMC); Peter

 Weidenheim, Director of Compliance (Critical Access Hospitals)

To comply with the Office of Inspector General Compliance Guidance for Laboratories and the Medicare requirements, Gundersen Boscobel Area Hospital and Clinics Laboratory must send an annual notice to providers who use our testing services.

As required, this annual notice includes the following:

**Medical Necessity Requirements**

Laboratory tests arereimbursed under federally funded programs if they are deemed “medically necessary” for the diagnosis and treatment of the patient. The Centers for Medicare and Medicaid Services (CMS) has developed national and local coverage decisions that identify those tests that CMS determined will be covered under the Medicare program. Coverage for these services is based on the diagnosis / sign / symptom you assign to the office visit. CMS’ National Coverage Decisions (NCDs) and Local Medical Review Policies (LMRP) can be accessed at <https://www.cms.gov/medicare-coverage-database/search.aspx>.

Providers may order any laboratory tests, including screening tests that they believe are appropriate for the treatment of their patients. Tests that are considered screening tests are generally not covered. Therefore, it is a requirement that a diagnosis or symptom is linked to each test ordered.

**Advance Beneficiary Notice (ABN) or Notice of Denial of Medical Coverage (NDMC)**

Advance Beneficiary Notices are used when you believe that Medicare may not cover an ordered service.  ABN (CMS-R-131) Form Approved OMB No. 0938-0566 is the only written notice recognized by Medicare to satisfy the requirement for alerting Part B fee-for-service beneficiaries when they may be financially liable for an item or service that Medicare will likely deny. The Notice of Denial of Medical Coverage is used when you believe that Medicare Part C (Medicare Advantage) may not cover an ordered service. Each Medicare Part C plan is required to have its own NDMC and cannot use the Medicare approved ABN. Gundersen Health System uses a Senior Preferred Notice of Denial Medical Coverage.

Before the specimen is collected, the patient should be notified, in writing, of the possibility that payment will be denied. A valid ABN or NDMC must include written estimates for the cost of services. An ABN or NDMC is never required in emergent or urgent care cases.

The ABN form provides a space to write the test(s) that are ordered and a check-off list of the reasons the claim may be denied. The ABN form must be completed with this information before the patient is asked to sign. Patients cannot be asked to sign a blank or incomplete form. Patients do not need to sign the Senior Preferred Notice of Denial Medical Coverage. The patient’s name, the patient or guarantor’s signature, and the date of service must be on the form. The ABN or NDMC should onlybe used when you believe that “medical necessity” requirements may not be met. The patient must be given a copy of the ABN or NDMC form and a copy should be kept at your facility. In order to meet these requirements, our ABN/NDMC forms print when the test(s) are ordered in the computer system. After the patient signs the ABN or has been provided an SP-NDMC, a copy is given to the patient and then the original is scanned back into the computer system as a document.

**Panels/Profiles**

Gundersen Boscobel Area Hospital and Clinics Laboratory offers a small number of disease oriented test groups, often referred to as profiles or panels that are found in the American Medical Association’s *CPT* codebook. It should be noted that tests that make up the panels can be ordered separately. If all tests that make up a designated panel in the *CPT* codebook are ordered separately, the panel code will be billed.

This letter informs providers that if a customized profile is used, it may result in the ordering of tests for which Medicare may deny payment.

Currently we offer the following AMA defined panels:

Lipid Panel Lipoprotein Analysis CPT 80061

 Cholesterol, Total

HDL Cholesterol

Triglycerides

Electrolyte Panel CPT 80051

Carbon Dioxide

Chloride

Potassium

Sodium

Enteric Bacterial Panel CPT 87506

 Salmonella species/EIEC

 Shigella species

 Campylobacter species (jejuni and coli)

 Shiga Toxin-producing organisms (STEC, Shigella dysenteriae)

Other offered panels with their CPT’s:

Blood Culture Identification Panel CPT 87150 per organism

 Gram Positive: E. faecalis, E. faecium, L. monocytogenes, Staph spp., S. aureus, S. epidermidis,

 S. lugdenesis, Strep spp., S. agalacticae (Gp B), S. pneumoniae, S. pyogenes (Gp A)

 Gram Negative: Acinetobacter calcaceticus baumanii complex, B. fragilis group, H. influenzae,

 N. meningitidis, P. aeruginosa, S. maltophilia, E. cloacae complex, E. coli, K. aerogenes,

 K. oxytoca, K. pneumoniae group, Proteus spp., Salmonella spp., S. marcescens

 Yeast: C. albicans, C. auris, C. glabrata, C. krusei, C. parapsilosis, C. tropicalis,

 C. neoformans/gattii

 Antimicrobial Resistance Genes: CTX-M, KPC, mecA/C, MREJ, NDM, van A/B, IMP,

 Mcr-1, OXA-48-like, VIM

Joint Infection (JI) Panel CPT 87999 are identified using the BIOFIRE JI Panel:

 Gram Positive: Anaerococcus prevotii/vaginalis, Clostridium perfringens, Cutibacterim

 avidum/granulosum, Enterococcus faecalis, Enterococcus faecium, Finegoldia magna,

 Parvimonoas micra, Peptoniphilus, Peptostreptococcus anaerobius, Staphylococcus aureus,

 Staphylococcus lugdunensis, Streptococcus spp., Streptococcus agalacticae, Streptococcus

 pneumoniae, Streptococcus pyogenes.

 Gram Negative: Bacteroides fragilis, Citrobacter, Enterobacter cloacoe complex, Esherichia coli,

 Haemophilus influenzae, Kingella kingae, Klebsiella aerogenes, Klebsiella pneumoniae group,

 Morganella morganii, Neisseria gonorrhoeae, Proteus spp., Pseudomonas aeruginosa,

 Salmonella spp., Serratia marcescens.

 Yeast: Candida albicans

 Antimicrobial Resistance Genes: CTX-M, KPC, NDM, vanA/B, IMP, mecA/C and MREJ (MRSA),

 OXA-48 like, VIM.

Respiratory Panel, multiplex (BioFire Film Array) CPT 0202U

 Adenovirus

 Coronavirus 229E

 Coronavirus HKUI

 Coronavirus NL63

 Coronavirus OC43

 Middle East Respiratory Syndrome Coronavirus

 Severe Acute Respiratory Syndrome Coronavirus

 Human Metapneumovirus

 Human Rhinovirus/Enterovirus

 Influenza A H1-2009

 Influenza A H3

 Influenza B

 Parainfluenza Virus 1, 2, 3, and 4

 Respiratory Syncytial Virus

 Bordetella parapertussis (IS 1001)

 Bordetella pertussis (ptxP)

 Chlamydia pneumoniae

 Mycoplasma pneumoniae

Respiratory Panel, 4Plex CPT 0241U

 Covid 19

 Influenza A, B

 RSV

Respiratory Panel, INRSV CPT 87631

 RSV

 Influenza A, B

Other test order groups, such as Hepatitis Panel, are offered but do not include the exact makeup of tests that CMS specifies. In these cases, individual members of the test group are billed separately, and each component of a panel must have a diagnosis linked to it. Unless all components of the panel are “medically necessary”, according to Medicare’s (NCD)-LMRP-, the claim will be denied.

The Office of Inspector General takes the position that a provider should only order those tests which the provider believes are medically necessary for each patient; therefore, all components of a customized profile must be medically necessary, and will be reimbursed separately in accordance with the clinical laboratory fee schedule. A provider, who knowingly causes a false claim to be submitted by ordering a customized profile that all components are not medically necessary, may be subject to civil penalties.

**Medicare Reimbursement**

Critical Access Hospitals are reimbursed for laboratory services by a cost percentage.  At Gundersen Boscobel Area Hospital and Clinics; all payers are charged the same, and it is our understanding that the Medicaid reimbursement amount is equal to or less than the amount of Medicare reimbursement.

**CPT or HCPCS Codes**

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| Gundersen Health System will maintain detailed, up-to-date billing codes, policies and procedures to ensure accuracy of billing for all laboratory services. Compliance, Revenue Cycle, LIS and Laboratory is charged with responsibility to accurately maintain all information necessary for coding and billing of laboratory services.  Details can be found in RevCycl-1005 (Laboratory Coding and Chargemaster Maintenance) |  |

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<https://gndrsn-gundersen.policystat.com/policy/10027089/latest/>

**Reflex Testing Protocols**

In a limited number of predefined circumstances and based on initial test results, additional subsequent laboratory tests will be performed. These are referred to as reflex testing protocols. When performed, the reflex tests are billed to the patient. If the patient’s condition does not warrant the additional testing, providers have the option to contact the lab and cancel the automatic reflex test. The following is a list of additional tests that laboratory staff automatically performs after a positive initial test result:

***Blood Bank*:**

Positive antibody screens will reflex to antibody identification testing, including a DAT and relevant antigen typing, including an ABO/Rh and/or red cell genotyping. If antibody identification may not be completed by the hospital blood bank, further testing will be sent to the reference lab.

When a clinically significant antibody is identified and red cell products are ordered, reflex testing will include antigen typing of donor cells and a Coombs crossmatch for each red cell product.

Positive DAT (Coombs) tests will reflex additional testing based on patient history. This may include an antibody eluate or auto adsorption.

For patients requiring partial or full antigen matching of transfused red cell units, reflex testing will include red cell genotyping of the patient, and serologic antigen typing of donor cells. For sickle cell and thalassemia patients, serologic testing of the patients’s red cells for Rh (D, C, c, E, e) an d K antigens may be performed if a transfusion is requested before red cell genotyping is completed.

Positive fetal bleed screens on Rh-negative Rho (D) Immune Globulin candidates will reflex to a fetal hemoglobin stain.

For patients with discrepant or potential variant expression of Rh(D)typing, molecular Rh(D) typing may be reflexed. This may include weak RhD genotyping and/or partial RhD analysis by the reference laboratory.

An antibody titer will reflex an antibody ID if the antibody is currently demonstrating reactivity, or an antibody screen if the antibody is currently not demonstrating reactivity or is not demonstrating reactivity at the correct phase or in the correct method to titer.

***Chemistry:***

TSH <0.4 will reflex a Free T4.

***Urinalysis****:*

A positive Protein, Occult Blood, Leukocytes, or Nitrites is reflexed to a microscopic examination. When the color of the urine specimen is red, amber, or green or the specimen is turbid, a microscopic exam is also reflexed. If urine Dipstick Only is ordered, the microscopic exam is not performed for positive dipstick tests.

A urine with a greater than 1+ reaction for leukocytes, nitrites or bacteria will reflex to a culture.

***Hematology****:*

A manual peripheral blood differential is performed whenever indicated by pathologist approved instrument flags.

A Body Fluid or CSF Cell Count and Diff with large mononuclear cells present, reflexes to a pathologist review.

***Immunology:***

Hepatitis A Total result positive tests will reflex to Hepatitis IgM to be performed.

ANA positive tests will reflex to ANA titer to be performed.

A positive syphilis test will reflex to an RPR.

***Microbiology****:*

The following positive cultures reflex to antibiotic susceptibility testing:

Wound and fluid cultures growing small to large numbers of pathogens, a CSF culture with any growth, positive blood culture, urine culture with pathogenic growth, and respiratory cultures growing large number of pathogens.

Wound, tissue, fluid, or sputum cultures reflex to a gram stain.

Bone marrow cultures reflex to routine, AFB, and fungal cultures.

C. difficle antigen positive, C. difficle toxin negative tests will reflex to a C. difficle PCR.

Cryptococcal antigen positive tests will reflex to a Cryptococcal antigen titer.

Negative Streptococcus pyogenes (Group A) screens reflex to a Strep culture if the patient is less than 18 years old.

All Invalid molecular method influenza or covid-19 testing will reflex to a test by PCR.

HPV positive tests will reflex to HPV 16 18/45 Genotype.

***Cytology:***

A negative PAP test when HPV High Risk is positive will reflex to a HPV Genotype.

**Specimens submitted for pathology review**

Surgical and cytology specimens submitted for pathology review will be processed and evaluated with the use of routine macroscopic and microscopic techniques, and, when applicable and medically necessary, special/ancillary stains or other diagnostic laboratory studies will be performed on the specimen.  Utilization of any special/ancillary stains or other studies are at the discretion of the pathologist responsible for the diagnostic assessment and will be used in an effort to establish an accurate and complete diagnosis.  Microscopic examination is with very rare exception required for all tissue specimens submitted, unless specifically exempted according to Gundersen Health System policy Lab-2500. If a submitting provider wishes to limit or otherwise restrict the use of special/ancillary stains or other studies on a particular specimen submitted to the laboratory for pathologic evaluation, this request should be made in writing and should accompany the specimen upon its submission to the pathology department.

**Consultants**

Gundersen Health System Laboratory makes the following consultants available to Gundersen Boscobel Area Hospital and Clinics providers to discuss appropriate testing, test ordering, and test interpretation:

**(608) 782-7300 or (800) 362-9567**

Daniel Schraith MD, Extension 52701

Wayne Bottner MD, Extension 52208

Sean Agger PhD, Extension 50410

Christopher Cogbill MD, Extension 54612

Stefan Brettfeld MD, Extension 52820

Stephen Bloechl MD, Extension 59645

Grzegorz Gurda MD, Extension 52107

Arick Sabin MD, Extension 52817

Richard Wittchow MD, Extension 52709

Gordon Zeng MD, Extension 52262

Sarah Hughes MD, Extension 52640

Lacey Schrader MD, Extension 56477

Rasleen Saluja MD, Extension 50381

Sarah Pedley MD, Extension 52640