GUNDERSEN
MOUNDVIEW
HOSPITAL AND CLINICS

**Laboratory Annual Notice**

**Date:** January 2, 2026

**To:** Gundersen Moundview Hospital and Clinics Medical Staff, Gundersen Moundview Hospital and Clinics Associate Staff

**From:** Sean Agger, PhD, Medical Director of Laboratories; Dr. Daniel Schraith, MD, Moundview Laboratory Medical Director; Keith Frye, Administrative Director, Gundersen Health System Laboratory; Rebecca Craig, Laboratory Manager, Gundersen Moundview Hospital and Clinics Laboratory

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

To comply with the Office of Inspector General Compliance Guidance for Laboratories and Medicare requirements, Gundersen Moundview 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 are reimbursed 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/symptoms 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

Physicians 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)**

Advanced 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 of 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 only be 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. To meet these requirements; ABN/NDMC forms print upon ordering then after the patient signs the ABN or has been provided a NDMC, a copy is given to the patient, and the original is scanned back into the computer system as a document.

**Panels/Profiles**

Gundersen Moundview Hospital and Clinics Laboratory offers a small number of disease orientated test groups, often referred to as profiles or panels that are found in the Current Procedural Terminology coding manual. It should be noted, the 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.

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

***Comprehensive Metabolic Panel CPT 800531:***

| | |
|---|---|
| Sodium | Albumin |
| Potassium | Total Protein |
| Chloride | Total Bilirubin |
| Carbon Dioxide | AST |
| BUN | ALT |
| Creatinine | Alkaline Phosphatase |
| Glucose | |
| Calcium | |

***Basic Metabolic Panel CPT 80048:***

| | |
|---|---|
| Sodium | BUN |
| Potassium | Creatinine |
| Chloride | Glucose |
| Carbon Dioxide | Calcium |

***4Plex CPT 0241U***
Covid 19
Influenza A,B
RSV

***Enteric Bacterial Panel CPT 87505:***

| | |
|---|---|
| Salmonella sp. | Shigella sp./EIEC |
| Campylobacter sp. | Shiga Toxin Producing Organisms (STEC, Shigella dysenteria) |

***Respiratory Infection, Multiplex (BioFire Film Array) CPT 0202U***

*Virus:*

| | | |
|---|---|---|
| Adenovirus | Coronavirus 229E | Coronavirus HKUI |
| Severe Acute Respiratory Syndrome Coronavirus | Coronavirus OC43 | Middle East Respiratory Syndrome Coronavirus |
| Coronavirus NL63 | Human Metapneumovirus | Human Rhinovirus/Enterovirus |
| Influenza A H1-2009 | Influenza A H3 | Influenza B |
| Parainfluenza Virus 1 | Paramfhmeza Virus 2 | Parainfluenza Vims 3 |
| Parainfluenza Vims 4 | Respiratory Syncytial Virus | |

Bacteria:

| | |
|---|---|
| *Bordetella parapertussis (IS 1001)* | *Bordetella pertussis (ptxP)* |
| *Chlamydia pneumoniae* | *Mycoplasma pneumoniae* |

***INRSV CPT 87631***

Influenza A,B

RSV

***Blood Culture Identification Panel CPT 87150 (per organism)***

Gram Positive Bacteria:

| | | |
|---|---|---|
| *Enterococcus faecalis* | *Staphylococcus spp.* | *Streptococcus spp.* |
| *Enterococcus faecium* | *S. aureus* | *S. agalactiae (Group B)* |
| *Listeria monocytogenes* | *S. epidermidis* | *S. pneumoniae* |
| | *S. lugdenensis* | *S. pyogenes (Group A)* |

Gram Negative Bacteria:

| | |
|---|---|
| *Acinetobacter calcoaceticus-baumannii complex* | *Enterobacteriaceae* |
| *Bacteroides fragilis group* | *E. cloacea complex* |
| *Haemophilus influenzae* | *E. coli* |
| *Neisseria meningitidis* | *K. aerogenes* |
| *Psuedomonas aeruginosa* | *K. oxytoca* |
| *Stenotrohpomonas maltophilia* | *K. pneumoniae group* |
| | *Proteus spp.* |
| | *Salmonella spp.* |
| | *S. marcescens* |

Yeast:

| | | |
|---|---|---|
| *Candida albicans* | *Candida krusei* | *Cryptococcus neoformans/gattii* |
| *Candida auris* | *Candida parapsilosis* | |
| *Candida glabrata* | *Candida tropicalis* | |

Antimicrobial Resistance Genes:

| | | | | |
|---|---|---|---|---|
| CTX-M | KPC | mecA/C, MREJ | NDM | van A/B |
| IMP | Mcr-1 | OXA-48-like | VIM | |

***Joint Infection (JL) Panel CPT 87999:***

The following organisms are identified using the BIOFIRE JI Panel:

| GRAM POSITIVE BACTERIA | | |
|---|---|---|
| *Anaerococcus prevotii/vaginalis* | *Finegoldia magna* | *Streptococcus* spp. |
| *Clostridium perfringens* | *Parvimonas micra* | *Streptococcus agalactiae* |
| *Cutibacterium avidum/granulosum* | *Peptoniphilus* | *Streptococcus pneumoniae* |
| *Enterococcus faecalis* | *Peptostreptococcus anaerobius* | *Streptococcus pyogenes* |
| *Enterococcus faecium* | *Staphylococcus aureus* | |
| | *Staphylococcus lugdunensis* | |
| **GRAM NEGATIVE BACTERIA** | | |
| *Bacteroides fragilis* | *Kingella kingae* | *Proteus* spp. |
| *Citrobacter* | *Klebsiella aerogenes* | *Pseudomonas aeruginosa* |
| *Enterobacter cloacae* complex | *Klebsiella pneumoniae* group | *Salmonella* spp. |
| *Escherichia coli* | *Morganella morganii* | *Serratia marcescens* |
| *Haemophilus influenzae* | *Neisseria gonorrhoeae* | |
| **YEAST** | | |
| *Candida* | | |
| *Candida albicans* | | |

| ANTIMICROBIAL RESISTANCE GENES | | | |
|---|---|---|---|
| CTX-M | KPC | NDM | *vanA/B* |
| IMP | *mecA/C* and MREJ (MRSA) | OXA-48-like | VIM |

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

Critical Access Hospitals are reimbursed for laboratory services by a cost percentage. At Gundersen Moundview 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**

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

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

**Reflex Testing Protocols**

In a limited number of predefined circumstances and based on initial 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. Further testing will be sent to Versiti, Immunohematology 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 absorption.

*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 culture will be reflexed on a urinalysis test if the microscopic results meet any of the following conditions:

- For children <4 years old: a urine culture will always be reflexed if a microscopic is reflexed.
- For children aged 4-14: if the white blood cells are greater than 5/hpf AND if the squamous epithelial cells are not classified as "Many" (greater than 10/hpf).
- For those age 15 and older: if the white blood cells are greater than 10/hpf AND if the squamous epithelial cells are not classified as "Many" (greater than 10/hpf).

*Hematology:*

A manual peripheral blood differential is reflexed when parameter thresholds or instrument flagging criteria are exceeded.

A body fluid or CSF Cell Count and Diff with large mononuclear cells present reflexes to a pathologist review.

*Immunology:*

When Hepatitis A Total is positive, the Hepatitis A IgM will be performed.
When ANA is positive, a reflex to ANA titer will be performed.

*Microbiology:*

The following positive cultures will reflex antibody susceptibility testing:
Wound and fluid cultures growing small to large number of pathogens, a CSF culture with any growth, positive blood culture, urine culture with pathogenic growth, and respiratory cultures growing large numbers of pathogens.

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

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

C. difficile antigen positive / C. difficile toxin negative test results will reflex to a C. difficile 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.

Any positive HPV reflexes HPV 16 18/45 Genotype Assay.

*Specimens Submitted for Pathology Review:*

Surgical and cytology specimens for pathology review will be processed and evaluated with the use of routine macroscopic and microscopic techniques. 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 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 pathological 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 Moundview 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

Sean Agger PhD, Extension 50410

Christopher Cogbill MD, Extension 54612

Grzegorz Gurda MD, Extension 52107

Richard Wittchow MD, Extension 52709

Gordon Zeng MD, PhD Extension 52262

Sarah Pendley MD, Extension 52640

Stefan Brettfeld DO, Extension 52820

Arick Sabin DO, Extension 52817

Stephen Bloechl MD, Extension 59645

Lacey Schrader MD, Extension 56477

Rasleen Suluja MD, Extension 50381

Janet Torkelson RN NP, Extension 52139

Nadarra Stokes MD, Extension 56188