Annual Notification to Physicians:
Laboratory Medicare Charge and Billing Requirements for 2019

As part of Clinical Laboratories' Compliance Plan for the Federal Office of Inspector General (OIG), we are required to notify all providers annually of the following policies, which are developed to reflect government guidance:

(1) Medical Necessity Requirement:
- Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary for the beneficiary, given his or her clinical condition. Documentation supporting the medical necessity of the service provided and billed by the laboratory should be available in the medical record.
- Medicare national and local medical review policies exist for certain lab tests. Specific information on NCDs (National Coverage Determination) and LCDs (Local Coverage Determination) can be found on the CMS website: (https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDs.html)
- Providers must provide ICD-10 codes or diagnoses with all outpatient laboratory requests to support medical necessity. Code the condition(s) to the highest degree of certainty for that encounter/visit.

(2) Review of Tests Combined into a Group/Profile:
- Providers should understand ordering testing customized into “profiles” or groups may result in the ordering of tests which are not covered, reasonable or necessary. Providers should order only testing which is medically necessary for the diagnosis or treatment of a patient related to the encounter in which the tests are ordered. For laboratories to bill Medicare, every test, including each component of a panel, must be medically necessary. Customized groups/profiles should only be utilized when all the tests included in the group are necessary. OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.
- AMA Approved “Panels”:
  - Basic Metabolic panel (BMP) - Calcium, (ionized), Carbon dioxide, Chloride, Creatinine, Glucose, Potassium, Sodium, Urea Nitrogen.
  - BMP with Calcium (total) – as above with total Calcium vs ionized.
  - Electrolyte Panel – Carbon dioxide, Chloride, Potassium, Sodium.
  - Comprehensive Metabolic Panel (CMP) – BMP, plus Albumin, Bilirubin, (total), Alkaline Phosphatase, Protein, (total), Alanine Amino Transferase (ALT), Aspartate Amino Transferase (AST).
  - Lipid Panel – Cholesterol, serum total, Lipoprotein, HDL (direct measurement), Triglycerides.
  - Renal Function Panel - Albumin, Calcium (total), Carbon dioxide (bicarbonate), Chloride, Creatinine, Glucose, Phosphate, Potassium, Sodium, Urea nitrogen.
  - Hepatic Function panel – Albumin, Bilirubin (total and direct), Alkaline Phosphatase, Protein total, Alanine Amino Transferase(ALT), Aspartate Amino Transferase (AST).
  - Acute Hepatitis Panel – Hepatitis A Antibody IgM, Hepatitis B Core Antibody IgM, Hepatitis B Surface Antigen, Hepatitis C Antibody.
General Health Panel – CBC with Differential, Comprehensive Metabolic Panel (CMP), Thyroid Stimulating Hormone (TSH).

(3) The 2019 Clinical Laboratory Fee Schedule is available at:
   - Note this fee is what Medicare is reimbursing, not what is being charged by the hospital.
   - The Medicaid reimbursement amount will be equal to or less than the Medicare reimbursement amount.
   - A list of changes to Pathology and Laboratory CPT codes for 2019 is available through the lab upon request.

(4) Reflex Testing:
   - Reflex testing and confirmatory testing may be medically indicated when the initial test results fall within certain parameters. The Clinical Laboratory uses Medical Board-approved testing algorithms whenever possible to avoid delays in patient care. A list of laboratory tests that may generate additional testing and the conditions under which they are performed is available through the lab upon request.

(5) Contact information for a clinical consultant:
   - CLIA Laboratory Medical Director – Mark A Lovell, MD 720-777-5468
   - Anatomical Pathology- Jennifer Black, MD 720-777-1852
   - Biochemical Genetics-Steven Goodman, MD 720-777-0506
   - Clinical Chemistry/Toxicology – Melkon DomBourian, MD 720-777-5421
   - Clinical Microbiology- Sam Domínguez, MD PhD 720-777-8883
   - Hematology/Flow Cytometry- Xiang Liang, MD 720-777-5421
   - Mitochondrial Testing- Johan Van Hove, MD, PhD 303-724-2365
   - Precision Diagnostics- Amanda (Amy) Treece, MD 720-777-4337
   - Transfusion Medicine- Kyle Annen, DO 720-777-2721

The laboratory needs providers to be aware of the national review policy for lab testing (referred to above) as well as institutional policies which are available at:
   - Children’s Hospital Colorado Medical Staff Policies and Procedures.
   - Organizational Charge Capture Policy.
   - Laboratory Charge Capture Policy.

This notification and the associated list of reflex testing was approved by the Medical Board of Children’s Hospital Colorado February 4, 2019.

Respectfully submitted,

Mark A. Lovell, MD
CLIA Laboratory Medical Director
Approval of Laboratory Reflex Testing 2019-2020

The laboratory performs additional testing or alters ordered testing when indicated for medical interpretation or as a screening step before, or in place of, the ordered laboratory test. These changes/additions to physician orders can be because of laboratory “standards of practice” or regulatory requirements. Testing will be charged for accordingly.

Blood Bank
1. **Newborn workup**: for patients less than 4 months of age, consisting of ABO, Rh, Antibody Screen, DAT and IAT to detect ABO incompatibility with the mother (if baby is non- Group O).
2. **Irradiation of all cellular blood products** for all Children's Hospital Colorado patients who have not attained their first birthday.
3. **Irradiation for all Directed Donation blood products**
4. Irradiation of all platelets prior to entering inventory. Only patients for whom irradiation of platelets is ordered will be charged for irradiation.
5. **Antibody identification** for any patient with a positive antibody screen, DAT, or other indication of unexpected antibodies.
6. **Confirmatory ABO** (no charge)

Biochemical Genetics
1. **Mucopolysaccharide screen**: if the spot screen is positive, it is reflexed to a TLC plate for identification of abnormal mucopolysaccharides present.

Chemistry
1. **HIV Testing**: HIV Screen that is reactive will be reflexed to an immunochromatographic assay HIV-1/HIV-2 differentiation and/or HIV-NAT testing for confirmation.
2. **Hepatitis B Antigen confirmation** performed on repeat positive screening test for Hepatitis B Antigen.
3. **Sweat Na** – performed when the Sweat Cl is ≥ 30 mmol/L

Hematology
1. **ANA screen** performed before ordered profile; if an ANA profile is ordered and it is not a Rheumatology patient, an ANA screen is performed first; if the screen is positive a profile is completed.
2. **Platelet Function Assay (PFA)**: initially perform a PFA-EPI if abnormal reflex to PFA-ADP.
3. **CSF Cell Count with cytology differential**: if fewer than 5 WBC no cytology performed.
4. **CSF Cell Count ordered without cytology** reflexes to include cytology if greater than 5 WBC
5. **Cytology on all Fluids** (other than CSF) regardless of cell count.
6. **PTT performed when PTT 1:1 correction ordered and correction performed only if abnormal.
7. **PT performed when PT 1:1 correction ordered and correction performed only if abnormal.

Microbiology/Virology
- **Group Tests**: one order that generates multiple billable tests.
- **Reflex Tests**: automatic tests generated from the result of a prior test.

Bacteriology, Mycology and Mycobacteriology
1. **Aspirate/Fluid Workup**: includes aerobic bacterial culture, gram stain with broth culture on non-permissive sterile sites.
2. **BAL Culture Group**: includes quantitative culture and cytopsin gram stain.
3. **CSF Culture Group**: (LP or shunt) includes aerobic culture with cytopsin gram stain.
4. **Cystic Fibrosis Pathogen Group**: includes quantitative culture with gram stain and fungal culture with calcofluor stain, susceptibilities performed automatically on inpatients.
5. **Methicillin-resistant S. aureus and S. aureus PCR**: includes culture backup confirmation and susceptibility testing if MRSA is detected. For nasal swabs only.
6. **Respiratory Bacterial Group**: includes aerobic bacterial culture with gram stain for tracheal aspirates.
7. **Strep A Reflex Group**: Strep A Only Culture performed when Rapid Strep test is negative.
8. **Tissue Bacterial Group**: includes tissue grinding, aerobic culture with anaerobic culture and gram stain with broth culture non-permissive sterile sites.
9. **Urine Catheter Bacterial Group**: includes gram stain, quantitative urine culture with presumptive identification of organisms as needed. Aerobic identification and antimicrobial susceptibility as defined in Microbiology Urine Culture Procedure.

10. **Urine Bacterial Group – Clean Catch**: includes quantitative urine culture with presumptive identification of organisms as needed. Aerobic identification and antimicrobial susceptibility as defined in Microbiology Urine Culture Procedure.

11. **Vaginal Pathogen Screen**: includes Immunoassay for *Trichomonas vaginalis*, the BV Blue Immunoassay for detection of Bacterial Vaginosis and gram stain looking for yeast and WBCs.

12. **Fungal Culture Group**: fungal culture with direct calcofluor stain for selected sources.

13. **Mycobacterial Culture Group**: includes mycobacterial culture with direct stain. All first positive mycobacterial cultures will reflex to identification and susceptibility testing.

14. **Bacterial Identifications and Susceptibilities**: Identification and susceptibility testing are reflex ordered on appropriate, recognized pathogens. The first two isolates on blood, tissue or CSF cultures will have full identification and susceptibility testing. A repeat identification and susceptibility will be repeated 4 days after the initial culture. Positive blood cultures will be tested with a rapid molecular assay that allows for early identification of pathogens.

15. **Fungal Susceptibilities**: Yeast susceptibilities will be performed automatically on all yeast isolated from blood cultures and sterile body fluid aspirates on the first positive culture. Antifungal susceptibilities included: Amphotericin, Micafungin, Fluconazole and Voriconazole. Other fungal susceptibilities must be requested individually after a fungus has been isolated.

16. **Blood culture**: first positive blood culture on any patient will include a BCID (Blood Culture Identification) PCR panel, which detects 8 gram positive bacteria, 12 gram negative bacteria, 5 fungi, and 3 antimicrobial resistance mechanisms.

17. **Broth Culture**: blood culture bottles are automatically inoculated with tissues and aspirates from non-permissive sites (called a broth culture). First positive broth cultures will be tested using the BCID (Blood Culture Identification) PCR panel, which detects 8 gram positive bacteria, 12 gram negative bacteria, 5 fungi, and 3 antimicrobial resistance mechanisms.

**Virology**


2. **GI Pathogen PCR**: Detects 22 pathogens including campylobacter, toxigenic *Clostridium difficile*, *Plesiomonas*, *Salmonella*, Vibrio, *Yersinia*, 4 *E. coli* types (including shiga-toxin producing *E. coli* 0157, *Shigella*, *Cryptosporidium*, * Cyclospora*, *Entamoeba*, *Giardia*, *Adenovirus* 40, *Astrovirus*, *Norovirus*, *Rotavirus* A, and *Sapovirus*. A wet prep for RBCs and WBCs will be performed on fresh stool. If *Salmonella* or *Shigella* are detected, culture is performed to obtain the isolate for antimicrobial susceptibility testing.

3. **Bordetella pertussis/B. parapertussis PCR Group**: Includes PCR for *B. pertussis* and *B. parapertussis*. PCR for *B. parapertussis* can be de-selected.

4. **MEP (Meningoencephalitis Panel)**: When conditional MEP is ordered for a CSF specimen, an MEP will be performed when the white blood count is 5 cells/mm(3) or greater.

**Serology Reflex Groups**

1. **RPR Reflex Group**: when RPR is reactive, RPR Titer and FTA are reflex ordered.

**Molecular Genetics**

1. **Fragile X**: when positive, sent to Baylor for Southern Blot.

**Molecular Diagnostics**

1. **BCR/ABL1** Major & minor analysis will be performed on all first time CML and ALL diagnostic specimens according to laboratory testing protocol.

**Molecular Oncology**

1. T&8 cell gene rearrangement MRD analysis cannot be performed unless previous diagnostic specimen has been performed by NGS methodology.
Common Referral Laboratory Reflex Testing (not all inclusive, refer to reference laboratory webpage for additional information.)

<table>
<thead>
<tr>
<th>MAYO TEST NAME</th>
<th>REFLEXED TEST NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEMOGLOBIN ELECTROPHORESIS CASCADE, BLOOD</td>
<td>HGB ELECTROPHORESIS, MOLECULAR</td>
</tr>
<tr>
<td></td>
<td>HGB S, SCREEN</td>
</tr>
<tr>
<td></td>
<td>HGB, UNSTABLE</td>
</tr>
<tr>
<td></td>
<td>HGB F, RED CELL DIST</td>
</tr>
<tr>
<td></td>
<td>HB VARIANT BY MASS SPEC</td>
</tr>
<tr>
<td></td>
<td>IEF CONFIRMS</td>
</tr>
<tr>
<td>RBC ENZYME EVAL</td>
<td>REFLEXED RBC ENZYMES</td>
</tr>
<tr>
<td></td>
<td>GLUTATHIONE</td>
</tr>
<tr>
<td>HSV AB SCRN, IGM, BY EIA, S</td>
<td>HSV AB, IGM, S BY IFA</td>
</tr>
<tr>
<td>FUNGAL AB SURVEY, S</td>
<td>HISTOPLASMA AB</td>
</tr>
<tr>
<td></td>
<td>CRYPTOCOCCUS AG</td>
</tr>
<tr>
<td>PORPHYRINS EVAL, WASHED ERYTHROCYTES</td>
<td>PROTOPORPHYRINS, FRACT</td>
</tr>
<tr>
<td></td>
<td>PORPHYRINS, FRACTION</td>
</tr>
<tr>
<td>BRUCELLA AB SCRN, IGG, IGM</td>
<td>BRUCELLA AB, AGGLUTIN</td>
</tr>
<tr>
<td>PARANEOPLASTIC AUTOAB EVAL</td>
<td>GAD65 AB ASSAY</td>
</tr>
<tr>
<td></td>
<td>PARANEOPLASTIC AUTOAB WB</td>
</tr>
<tr>
<td></td>
<td>CRMP-5-IGG WB</td>
</tr>
<tr>
<td></td>
<td>ACH RECEPTOR(MUS) MOD AB</td>
</tr>
<tr>
<td></td>
<td>NEUROMYELITIS OPTICA AUTOAB IGG</td>
</tr>
<tr>
<td></td>
<td>AMPHIPHYSIN WESTERN BLOT</td>
</tr>
<tr>
<td>DRUGS OF ABUSE SCRN, MECON 5</td>
<td>COCAINE AND METAB, CONF</td>
</tr>
<tr>
<td></td>
<td>CARBOXY-THC CONF</td>
</tr>
<tr>
<td></td>
<td>OPIATE CONF</td>
</tr>
<tr>
<td></td>
<td>AMPHETAMINES CONF</td>
</tr>
<tr>
<td></td>
<td>PCP CONF</td>
</tr>
<tr>
<td>ADAMTS13 ACTIVITY AND INHIBITOR PROFILE (NO KNOWN EVAL)</td>
<td>ADAMTS13 INHIBITOR SCREEN</td>
</tr>
<tr>
<td></td>
<td>ADAMTS13 INHIBITOR BETHESDA TITER</td>
</tr>
<tr>
<td>LYME DISEASE SEROLOGY</td>
<td>LYME DISEASE AB, CONF WITH WESTERN BLOT</td>
</tr>
</tbody>
</table>