MEDICARE COVERAGE OF LABORATORY TESTING

Please remember when ordering laboratory tests that are billed to Medicare/Medicaid or other federally funded programs, the following requirements apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests except for certain specifically approved procedures and may not pay for non-FDA approved tests or those tests considered experimental.
2. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should then sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
3. The ordering physician must provide an ICD-10 diagnosis code or narrative description, if required by the fiscal intermediary or carrier.
4. Organ- or disease-related panels should be billed only when all components of the panel are medically necessary.
5. Both ARUP- and client-customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
6. Medicare National Limitation Amounts for CPT codes are available through the Centers for Medicare & Medicaid Services (CMS) or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

The CPT Code(s) for test(s) profiled in this bulletin are for informational purposes only. The codes reflect our interpretation of CPT coding requirements, based upon AMA guidelines published annually. CPT codes are provided only as guidance to assist you in billing. ARUP strongly recommends that clients reconfirm CPT code information with their local intermediary or carrier. CPT coding is the sole responsibility of the billing party.

The regulations described above are only guidelines. Additional procedures may be required by your fiscal intermediary or carrier.

0091533 Acetaminophen and Oxycodone Quantitative, Serum or Plasma PERCOC SP

Specimen Required: Specimen Preparation: Transfer 3 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.1 mL)

2006230 Alagille Syndrome (*JAG1*) Sequencing and Deletion/Duplication JAG1 FGA

Specimen Required: Storage/Transport Temperature: Refrigerated. Protect from extreme temperatures.
Stability (collection to initiation of testing): Ambient: 24 hours; Refrigerated: 1 week; Frozen: Unacceptable

CPT Code(s): 81479

Delete **2008794 *Babesia duncani* (WA1) Antibody, IgG by IFA WA1 IGG**

HOT LINE NOTE: Delete this test.

New Test **2013284** **PD-L1 22C3 pharmDx by Immunohistochemistry with Interpretation, pembrolizumab (KEYTRUDA)** **22C3 IP**

*This test performed at ARUP Laboratories.
FDA-approved test to identify patients with NSCLC who may qualify for treatment with pembrolizumab (KEYTRUDA).

Available February 1, 2016

Methodology: Immunohistochemistry
Performed: Mon-Fri
Reported: 1-5 days

Specimen Required: Collect: Tumor tissue.
Specimen Preparation: Formalin fix (10 percent neutral buffered formalin) and paraffin embed specimen. Protect paraffin block and/or slides from excessive heat. Transport tissue block or 5 unstained (3- to 5-micron thick sections), positively charged slides in a tissue transport kit (ARUP supply #47808 recommended but not required), available online through eSupply using ARUP Connect™ or contact ARUP Client Services at (800) 522-2787. (Min: 3 slides) If sending precut slides, do not oven bake.
Storage/Transport Temperature: Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Remarks: Include surgical pathology report and indicate tissue site with the test order. For additional technical details, please contact ARUP Client Services at (800) 522-2787.
Unacceptable Conditions: Paraffin block with no tumor tissue remaining; specimens fixed in any fixative other than 10 percent neutral buffered formalin.
Stability (collection to initiation of testing): Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Interpretive Data: Refer to report.

Note: This test code includes pathologist interpretation.

CPT Code(s): 88342

New York DOH approval pending. Call for status update.

HOT LINE NOTE: Refer to the Test Mix Addendum for interface build information.

0091568 **Sulfhemoglobin Quantitative, Whole Blood** **SULFHEMOGL**

Specimen Required: Patient Prep: Collect at end of work shift.
Specimen Preparation: Transport 1 mL whole blood. (Min: 0.3 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature.
Stability (collection to initiation of testing): Ambient: 3 months; Refrigerated: 3 months; Frozen: Unacceptable