IMMEDIATE CHANGE HOT LINE: Effective December 7, 2015

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-9 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.

Delete **2010740** **Allergen, Drug, Sulfamethoxazole IgE** **SULFA IGE**

HOT LINE NOTE: Delete this test.

Delete **0097639** **Allergen, Food, Eel IgE** **EEL IGE**

HOT LINE NOTE: Delete this test.

0097911 **Allergen, Food, Sugar Cane IgG4** **SUGAR IGG4**

Specimen Required: Collect: Plain red or serum separator tube.
Specimen Preparation: Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.5 mL/allergen)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Hemolyzed, icteric, or lipemic specimens.
Stability (collection to initiation of testing): Ambient: 2 weeks; Refrigerated: 3 weeks; Frozen: Indefinitely

2001503 Antimicrobial Susceptibility - Carbapenemase Production MA KPC

*This test performed at ARUP Laboratories.
Breakpoints updated requiring new interpretive comments.

Performed: Sun-Sat
Reported: 2-4 days

Specimen Required: Collect: Actively growing *Enterobacteriaceae* species or *Pseudomonas aeruginosa* in pure culture.
Specimen Preparation: Transport sealed container with pure culture on agar slant or in bacterial transport media. Place each specimen in an individually sealed bag.
Storage/Transport Temperature: Room temperature.
Remarks: Isolate identification and specimen source required.
Unacceptable Conditions: Mixed cultures or non-viable organisms.
Stability (collection to initiation of testing): Ambient: 1 week; Refrigerated: 48 hours; Frozen: Unacceptable

Interpretive Data: Carbapenemase production is a common mechanism of carbapenem resistance. For guidance on treatment of carbapenemase producers, consultation with an Infectious Disease physician is recommended.

CPT Code(s): CPT codes vary based on method

0091570 Aspirin and Oxycodone Quantitative, Serum or Plasma PERCODAN S

Specimen Required: Collect: Plain red, lavender (EDTA) or pink (K_2EDTA).
Specimen Preparation: Transfer 2 mL serum or plasma to ARUP Standard Transport Tubes. (Min: 0.92 mL)
Storage/Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.
Unacceptable Conditions: Separator tubes.
Stability (collection to initiation of testing): Ambient: 1 month; Refrigerated: 1 month; Frozen: 1 month

2010481 Phenytoin, Free DIL FR

Reference Interval: **Effective December 7, 2015**

Therapeutic:	1.0-2.0 µg/mL
Toxic:	Greater than 2.0 µg/mL

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0092066 Thiopurine Methyltransferase, RBC TPMT RBC

*This test performed at ARUP Laboratories.
Assay improvement revised reference ranges. Current ranges misidentify patient enzyme activity and could negatively impact dosing.

Reference Interval: Normal TPMT activity: 24.0-44.0 U/mL - Individuals are predicted to be at low risk of bone marrow toxicity (myelosuppression) as a consequence of standard thiopurine therapy; no dose adjustment is recommended.

Intermediate TPMT activity: 17.0-23.9 U/mL – Individuals are predicted to be at intermediate risk of bone marrow toxicity (myelosuppression), as a consequence of standard thiopurine therapy; a dose reduction and therapeutic drug management is recommended.

Low TPMT activity: < 17.0 U/mL - Individuals are predicted to be at high risk of bone marrow toxicity (myelosuppression) as a consequence of standard thiopurine dosing. It is recommended to avoid the use of thiopurine drugs.

High TPMT activity: > 44.0 U/mL - Individuals are not predicted to be at risk for bone marrow toxicity (myelosuppression) as a consequence of standard thiopurine dosing, but may be at risk for therapeutic failure due to excessive inactivation of thiopurine drugs. Individuals may require higher than the normal standard dose. Therapeutic drug management is recommended.

Interpretive Data: The TPMT, RBC assay is used as a screen to detect individuals with low and intermediate TPMT activity who may be at risk for myelosuppression when exposed to standard doses of thiopurines, including azathioprine (Imuran) and 6-mercaptopurine (Purinethol). TPMT is the primary metabolic route for inactivation of thiopurine drugs in the bone marrow. When TPMT activity is low, it is predicted that proportionately more 6-mercaptopurine can be converted into the cytotoxic 6-thioguanine nucleotides that accumulate in the bone marrow causing excessive toxicity. The activity of TPMT is measured by the nanomoles of 6-methylmercaptopurine (inactive metabolite) produced per 1 mL of packed red blood cells, (U/mL).

TPMT phenotype testing does not replace the need for clinical monitoring of patients treated with thiopurine drugs. Genotype for TPMT cannot be inferred from TPMT activity (phenotype). Phenotype testing should not be requested for patients currently treated with thiopurine drugs. Current TPMT phenotype may not reflect future TPMT phenotype, particularly in patients who received blood transfusion within 30-60 days of testing. TPMT enzyme activity can be inhibited by several drugs such as: naproxen (Aleve), ibuprofen (Advil, Motrin), ketoprofen (Orudis), furosemide (Lasix), sulfasalazine (Azulfidine), mesalamine (Asacol), olsalazine (Dipentum), mefenamic acid (Ponstel), thiazide diuretics, and benzoic acid inhibitors. TPMT inhibitors may contribute to falsely low results; patients should abstain from these drugs for at least 48 hours prior to TPMT testing. Falsely low results may also occur as a result of inappropriate specimen handling and hemolysis.

See Compliance Statement B: www.aruplab.com/CS