

January, 2023

Dear Physician:

St. Louis Children's Hospital Department of Laboratories is committed to possessing the reliability, honesty, trustworthiness and high degree of business integrity expected of a participant in federally funded healthcare programs. As part of this commitment, our policy concerning profiles and panels is to provide physicians with the flexibility to choose appropriate tests to assure that the convenience of ordering profiles and panels does not distance physicians from making deliberate decisions regarding which tests are truly medically necessary.

To demonstrate our commitment, we provide an annual notice to each of our physician clients advising them that if they order tests for Medicare or Medicaid beneficiaries, they should only order those tests that are medically necessary for each patient. The United States Department of Health and Human Services, Office of Inspector General, takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties. Any clinical laboratory that conforms its conduct to meet the Model Compliance Plan for clinical laboratories established by the Office of the Inspector General as we do, must provide this type of annual notice to its clients.

Explanation of Attachments

As part of this commitment to the government and to you, attached to this letter are lists of the standard organ or disease panels, reflex tests, confirmation tests and profiles available at by St. Louis Children's Hospital Department of Laboratories. The attachment is structured as follows:

1. Attachment 1 lists the American Medical Association's (AMA) organ or disease panels effective January 1, 2023

The panels are broken out to show the individual test components by name and by CPT code. For your information and convenience, please visit these payers' websites to obtain their current fee schedules:

- Medicare (http://www.cms.hhs.gov/ClinicalLabFeeSched/02_clinlab.asp#TopOfPage)
- Illinois Medicaid (https://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/Practitioner.aspx)
- Missouri Medicaid or MO Health Net (<u>https://dss.mo.gov/mhd/providers/fee-for-service-providers.htm</u>).
- Local and National Coverage Determinations applicable for Barnes-Jewish Hospital can be accessed on the WPS Medicare website under topic center policies: <u>https://www.wpsgha.com/wps/portal/mac/site/home/!ut/p/z1/04_Sj9CPykssy0xPLMnMz0vMAfljo8ziAz</u> w8zDwMLQx8_I18DQwcfd3CjF0tfLzMTUz1wwkpiAJKG-A

The implementation of PAMA required Medicare to pay the weighted median of private payer rates for each separate HCPCS code. Organ or Disease Oriented panels are panels that consist of groups of specified tests. Laboratories shall report the panel tests where appropriate and not report separately the tests that make up that panel. All Medicare coverage rules apply.

The Medicare standard systems must calculate the correct payment amount. The only acceptable Medicare definition for the component tests included in the CPT codes for organ or disease oriented panels is the American Medical Association (AMA) definition of component tests. CMS will not pay for the panel code unless all of the tests in the definition are performed and are medically necessary.

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- 2. Attachment 2 lists our standard tests and profiles that contain a confirmation or a reflex test(s). The list shows the initial test name, the CPT code, the criteria for performing the confirmation or reflex test(s), and the name and CPT code for the confirmation or reflex test(s).
- Attachments 3 and 4 list certain standard profiles in which every test component is essential to providing a medically valid result. The profiles are broken out to show the individual test components by name and by CPT code.

CPT Coding

St. Louis Children's Hospital Department of Laboratories bills its test procedures to third party payers, such as Medicare, Medicaid and private insurance, at the same fee it bills patients and in accordance with any specific CPT coding required by the payer. The CPT codes listed in this letter are from the 2023 edition of the Physicians' Current Procedural Terminology, a publication of the AMA. CPT codes are provided for the information of our clients; however, correct coding often varies from one payer to another. Therefore, these codes should not be used without confirming with the appropriate payer that their use is appropriate in each case.

MO HealthNet

St. Louis Children's Hospital as a MO HealthNet enrolled hospital may bill for outpatient laboratory services if the services are performed:

- in their hospital's laboratory
- by an independent laboratory enrolled as a MO HealthNet provider under an arrangement which documents that the hospital is responsible for billing the services provided by the independent laboratory.
- by an independent laboratory not enrolled as a MO HealthNet provider under an arrangement which documents that the hospital is responsible for billing the services provided by the independent laboratory.

Providers need to keep a copy of this documentation as well as the appropriate CLIA certification on file and be able to provide upon request.

Additionally, MO HealthNet enrolled independent laboratories also have the choice to bill for outpatient laboratory services. However, laboratory services that are billed by the hospital cannot be billed by the independent laboratory and vice versa. This is considered duplicate billing and claims are subject to recoupment. (https://dss.mo.gov/mhd/providers/pdf/bulletin39-53_2017may17.pdf)

Illinois Public Aid

St. Louis Children's Hospital may not charge Illinois Public Aid for outpatient laboratory testing that is forwarded to an independent referral laboratory for analysis and not performed by St. Louis Children's Hospital Department of Laboratories unless St. Louis Children's Hospital has a financial agreement with the independent referral laboratory (<u>https://www.illinois.gov/hfs/SiteCollectionDocuments/LabPolicyTopicL21012Rev060118.pdf</u>)

If the independent referral laboratory is not an enrolled provider of Illinois Public Aid and/or there is no financial agreement, only the performing laboratory may submit claims for payment. To achieve compliance with this regulation, it is the responsibility of the physician or the submitting institution to provide the patient's complete insurance information to be forwarded to the performing laboratory for billing to the appropriate state department.

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For organizations not doing business in Missouri or Illinois it is the responsibility of the submitting institution to validate the laws governing their state to ensure they comply with billing requirements in regard to referral testing.

Laboratory Date of Service Policy

by St. Louis Children's Hospital Department of Laboratories follows the rules outlined in the CMS Laboratory Date of Service Policy. The policy can be found at <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy</u>

Specifically, under 42 CFR 414.510(b)(5), in the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in 42 CFR 414.502, a test that is a cancer-related protein-based MAAA, or the test described by CPT code 81490,, the date of service of the test must be the date the test was performed. If all of the requirements are met, the DOS of the test must be the date the test was performed, which effectively unbundles the laboratory test from the hospital outpatient encounter. As a result, the test is not considered a hospital outpatient service for which the hospital must bill Medicare and for which the performing laboratory must seek payment from the hospital, but rather a laboratory test under the Clinical Laboratory Fee Schedule for which the performing laboratory must bill Medicare directly.

Please review carefully the panels listed in the Attachments. If you have any questions or would like to discuss this matter with us, please contact Customer Service at the address and phone number listed below. Barnes-Jewish Hospital Laboratory clinical consultant can be contacted as follows: St. Louis Children's Hospital Laboratory clinical Director can be contacted as follows: Gregory Storch, MD, or Dennis Dietzen, PhD (314-454-4525).

Thank you for your attention to this matter. St. Louis Children's Hospital Department of Laboratories One Children's Place St. Louis, MO 63110 (314) 454-4161 (314) 454-4108 (fax)

Attachment(s)

Attachment 1 - AMA Organ or Disease Panels Attachment 2 - Standard Reflex/Confirmation Tests Attachments 3 and 4 - Standard Profiles