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BAYSTATE PATHOLOGY

April 18, 2022

Dear Colleague,

Baystate Reference Laboratories (BRL) maintains an active compliance program that reflects our commitment to conduct business in compliance with all federal, state and local laws. The Office of the Inspector General (OIG) and the Department of Health and Human Services recommends in its Model Laboratory Compliance Plan that laboratories send an annual notice to physicians advising them of the elements of the laboratory's compliance program (available at http://oig.hhs.gov/authorities/docs/cpglab.pdf). This annual notice provides the following information and education regarding laboratory compliance, billing and coding guidelines, current Medicare program requirements and BRL policies:

- Medicare Medical Necessity Requirements and Use of ABN
- Standard Requisitions and Ordering and Reporting Guidelines
- CPT Code Updates
- Supplies prohibited by Stark Law
- Pre-Authorization of Lab Orders
- Reflex Testing
- Organ /Disease Oriented Panels
- Clinical Consultants
- Medicare Fee Schedule

We hope that sharing this information will lead to a better understanding of the regulations that we must follow and their impact upon our practices and procedures. Thank you very much for your continued support of Baystate Reference Laboratories. If you have any questions regarding this document, please call 413-794-4550 or contact your BRL Account Manager at 413-322-4000 or 1-800-778-5599.

Sincerely,

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Medicare Medical Necessity

Physicians must establish the necessity of tests by providing diagnostic information to the laboratory by including appropriate ICD 10 code(s). Medicare will only pay for tests that they deem are reasonable and necessary for patient care. When ordering laboratory tests for Medicare patients, it is important to do the following:

- Physicians and other health care providers should only order those tests that they believe are medically necessary for the diagnosis, treatment and therapy of their patient.
- Organ and disease panels should be used only when all components are medically necessary.
- A numerical diagnosis code (ICD-10) -and not simply a narrative description- must be provided for each test ordered.
- The laboratory will not knowingly bill Medicare for tests that are not covered, reasonable or necessary.

If BRL receives an order without any diagnosis information or is unable to bill for testing performed because coding does not meet medical necessity requirements, BRL will attempt to contact your practice to obtain additional diagnosis codes that may appear in the patient charts but which were not provided with the original order. To prevent false claim submission, BRL will not assign diagnosis codes without documentation submitted by the provider.

Advanced Beneficiary Notices (ABN)

Medicare can deny reimbursement for tests based upon absence of medical necessity; tests specified for investigational use only; tests ordered for routine screening (including tests ordered only as pre-operative screening), and when preventative services are ordered more frequently that screening benefits cover.

If a non-covered diagnosis is used, the patient must be notified prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (ABN). The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity or frequency limitations. ABNs are used to advise Medicare beneficiaries (only), prior to items or services being rendered, when there is a likelihood that an ordered service may not be paid and may require the beneficiary to pay for services as an out-of-pocket expense. ABNs serve an important fraud and abuse compliance function that is the responsibility of the healthcare provider involved in ordering a test, procedure or item on behalf of a Medicare beneficiary. The signed, original ABN must accompany the original lab order prior to submission.

Per Medicare rules, blanket waivers for all tests ordered on a Medicare beneficiary are not allowed by Medicare and will not be accepted by the laboratory. Each ABN must be specific to each laboratory test ordered. The provider will be notified if a test ordered fails medical necessity. BRL Laboratory test requisitions are designed in support of these regulations and to emphasize physician choice. The Local Coverage Determinations(LCD) and National Coverage Determinations (NCD) can be found at http://www.cms.gov/mcd .

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Standard Requisitions and Required Information

Laboratory testing must be ordered by a licensed provider or other individuals authorized by law. A provider with a revoked or suspended license may not order or refer for laboratory testing.

We encourage the completion of the BRL Laboratory Requisition or complete order information submitted electronically via an interface. However, our laboratory will accept requisitions and orders that contain the following information, which is required by federal and/or state regulations and CLIA requirements:

- Name of physician or qualified healthcare professional ordering the test
- Address of physician or qualified healthcare professional
- Phone number of physician or qualified healthcare professional
- Patient first and last name; or unique patient identifier
- Patient gender, date of birth or age
- Date and time of specimen collection
- Tests to be performed
- Source of the specimen, when appropriate
- Diagnosis information (ICD-10 code)
- Patient's billing information (copy of both sides of patient's insurance card)
- Any additional information relevant and necessary for a specific test to ensure accurate, timely testing and reporting of results

Please note that specimen collection containers must be labeled with two pieces of identification: the patient's full name and the patient's date of birth. Various accrediting agencies strongly recommend this process and this is our standard practice within Baystate Medical Center/ Baystate Reference Laboratories.

Although the provider signature is not required on laboratory requisitions, if signed, the requisition will serve as acceptable documentation of a physician order for the testing. In the absence of a signed requisition, documentation of intent to order each laboratory test must be included in the patient's medical record. Documentation must accurately describe the individual tests ordered; it is not sufficient to state 'labs ordered'. The pre-printed test order requisition is the tool used to communicate the physician order to the laboratory, but is NOT considered the valid 'order' as defined by Medicare.

Ordering and Reporting Guidelines

A. Standing Orders

Standing orders direct the laboratory to perform a particular test(s) at specified intervals for a defined time period without having to submit a new requisition form each time. Standing orders must be renewed in writing every twelve months, must state a start and stop date as well as the frequency of the order, and must have a diagnosis (ICD-10 code) for each standing order test.

B. Verbal Test Orders
Medicare regulations require that all orders for laboratory tests be in writing. If a physician or his/her authorized representative orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. In these cases, BRL will send a confirmation of the verbal order request to the ordering physician, requesting it to be signed and sent back to the laboratory for our records. Testing will not be performed until the signed confirmation or a properly completed BRL requisition form is received by the laboratory.

CPT Code Updates
CPT code updates are communicated via the BRL Test Dictionary Update. CPT codes and other test information is also available in the BRL online Laboratory Services Guide available on the Baystate Health website. Baystatehealth.org →For Healthcare Professionals→Baystate Reference Laboratories-→ Our Services (see our test catalog).
https://www.baystatehealth.org/health-care-professionals/baystate-reference-laboratories

Supplies Prohibited by Stark Law
Per CMS Regulations and Stark Law, BRL can only provide supplies that are used **solely** to collect, transport, process, or store specimens referred to our laboratory. BRL monitors supply usage to comply with this regulation.

Pre-Authorization of Lab Orders
Pre-authorization of certain lab testing (i.e. Genetics, Cytogenetics, etc.) may be required, as defined by the patient's insurance provider. Any preauthorization paperwork must be completed by the ordering provider and submitted for approval prior to submission of any lab orders. Please include the preauthorization number on the lab order along with any related documentation.

Reflex Testing
Some tests may trigger additional reflex testing and additional charges, based on laboratory policy that reflects standard of care or by the request of the ordering provider. All procedures that contain a reflexive pathway are identified in the online BRL Laboratory Services Guide, including criteria that will lead to these charges and the specific CPT code(s) used.

Organ/Disease Oriented Panels
Review the components of all laboratory test panels, whether AMA approved or laboratory developed, and only order the panel when ALL the individual components are medically necessary as determined by the specific ICD-10 code(s) and documented in the patient medical record. If any component is not medically necessary, order only those individual tests that are. Refer to the BRL online Laboratory Services Guide at Baystatehealth.org →For Healthcare Professionals→Baystate Reference Laboratories-→ Our Services (see our test catalog)
https://www.baystatehealth.org/health-care-professionals/baystate-reference-laboratories

AMA-Defined Organ or Disease Oriented Panels

Panel Name	Individual Components	Panel CPT Code
Acute Hepatitis Panel	Hepatitis A Antibody, IgM Hepatitis B Core Antibody, IgM Hepatitis B Surface Antigen Hepatitis C Antibody	**80074**
Basic Metabolic Panel (Calcium Ionized)	Calcium, Ionized Carbon Dioxide Chloride Creatinine Glucose Potassium Sodium Urea Nitrogen	**80047**
Basic Metabolic Panel (Calcium, Total	Calcium, Total Carbon Dioxide Chloride Creatinine Glucose Potassium Sodium Urea Nitrogen	**80048**
Comprehensive Metabolic Panel	Albumin Alkaline Phosphatase Bilirubin, Total Calcium, Total Carbon Dioxide Chloride Creatinine Glucose Potassium Protein, Total Sodium SGPT (ALT) SGOT (AST) Urea Nitrogen	**80053**
Electrolyte Panel	Carbon Dioxide Chloride Potassium Sodium	**80051**
Hepatic Function Panel	Albumin Alkaline Phosphatase Bilirubin, Direct Bilirubin, Total Protein, Total SGPT (ALT) SGOT (AST)	**80076**
Lipid Panel	Cholesterol HDL Cholesterol LDL (calculated) Triglycerides	**80061**
Renal Function Panel	Albumin Calcium, Total Carbon Dioxide Chloride Creatinine Glucose Phosphorus (inorganic) Potassium Sodium Urea Nitrogen	**80069**

Clinical Consultants
BRL offers clinical consulting by our physician Laboratory Directors. Discussions related to appropriate testing and test ordering as well as questions regarding reports may be scheduled by calling 413-794-4550 or contacting your BRL Account Manager at 413-322-4000 or 1-800-778-5599.

Medicare Lab Fee Schedule
Lastly, the Model Compliance Plan also suggests that we provide you with a copy of the Medicare laboratory fee schedule and advise you that the Medicaid reimbursement amount may be equal to or less than the amount of Medicare reimbursement. The Medicare fee schedule may be found on the CMS webpage at http://www.cms.hhs.gov/ClinicalLabFeeSched .