Payment Policy | Automated Testing Devices

EFFECTIVE DATE:04|05|2011
POLICY LAST UPDATED: 03|19|2020

OVERVIEW
This policy outlines the payment when automated testing devices are used for diagnostic testing or screening.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Testing by automated devices are covered when the following guidelines are met:

1. All testing with automated devices must be medically necessary to be eligible for payment.

2. All testing must be a covered service and be performed by a provider who is eligible to be contracted/participating provider to be eligible for payment. Blue Cross & Blue Shield of Rhode Island (BCBSRI) reserves the right to determine the requisite qualifications for reporting providers.

3. Any testing that has a professional component (usually interpretation and report) and technical component (e.g. device supply, data generation, technical support) may only be reported by more than one provider if BCBSRI has given specific written permission for such reporting in correspondence or policy. In all cases for which this is allowed, participating providers are additionally obligated to refer a component only to another contracted/participating provider.

4. New technology automated, or semi-automated devices should not be presumed to be correctly reported using existing CPT/HCPCS codes. Coding guidance by the manufacturer specifically will not be accepted as supporting correct coding assertions and reporting providers will be fully responsible for correct coding. Incorrect coding will be considered misrepresentation of the service and/or fraud and may be a basis of termination or funds recovery. Coding guidance received in writing from AMA-CPT or coding, coverage and billing guidance received in writing from BCBSRI are acceptable bases for supporting coding. Unless specified otherwise by BCBSRI or the AMA, the presumption shall be that such testing is properly reported with an "unlisted procedure" code.

5. "Unlisted procedures" require that BCBSRI have a coverage and payment policy in order to be adjudicated. Provisional payments based upon an estimated allowance should not be construed as BCBSRI having created final coverage and payment policy. Before performing such services, participating providers shall request policy rulings from BCBSRI. Services that are correctly reported using an "unlisted procedure" shall be presumed to be not medically necessary unless otherwise determined and published by BCBSRI.

6. BCBSRI may determine that certain devices are not medically necessary, even if the device performs a test correctly reported with a covered service, medically necessary CPT/HCPCS code.

7. If BCBSRI determines the service to be medically necessary, providers shall not assume that payment will be the same as or similar to allowances for the "traditional equivalent" or that it will be based upon and compensate for the supply costs for such tests. In some cases, such testing may be considered an aid to physical diagnosis or for other reason be bundled into an existing reported service. Unless BCBSRI has otherwise provided in writing, the service shall be considered to have an allowance of $0.01, if paid separately.

8. Providers who report testing services must be fully qualified to perform the test (or use trained and qualified technical personnel) and to personally interpret the results. This includes being able to perform all necessary quality control functions to validate test quality. It is expected that this generally requires the reporting provider to:
    - Understand the appropriate clinical uses of such tests, including appropriate population/clinical conditions, sensitivity, specificity, comparative utility/validity to alternative tests,
    - Understand how to interpret the data elements used to generate a conclusion (whether or not such data elements were presented to the provider by the device), and
    - Understand how to recognize testing that has failed to meet device performance requirements and to
    - Understand device quality control processes.

9. FDA approval is insufficient for coverage.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable Test or Device coverage.

BACKGROUND

Technological innovations have resulted in increasing availability of fully or nearly fully automated devices used for diagnostic testing or screening. These devices often include automated report or results generation. The automation ostensibly replaces the need for skilled and trained technicians/professionals to perform the testing. It also may purport to replace the need for a professional to interpret data in order to generate a report. These devices may allow testing to be brought to additional settings for screening purposes, such as allowing screening for hearing loss in the workplace or school. These devices may not all have uniform characteristics. For example, in some cases all the data is presented for an interpretation and report, but a provisional report may also be generated. In other cases, the result is all that is generated, e.g. "normal" or "abnormal".

Automated devices typically are used to perform similar testing as described by existing CPT® codes for a similar or identical clinical purpose. Device manufacturers commonly indicate that existing codes describe the service that their device performs, but such advice is not consistently accurate. The American Medical Association Current Procedural Terminology (AMA-CPT) has created several Category I and Category III codes that differentiate "automated" services from "traditional" testing services or directed that automated testing be reported with an "unlisted procedure" code. These devices may have different sensitivity, specificity and appropriate clinical uses than the traditional tests and may require confirmatory testing using the traditional methods. The work, practice expense and supplies may be different than in the traditional tests. The published validity and utility of testing using the specific device may be different than similar literature support for traditional tests.

CODING

Coding is device/test specific.

RELATED POLICIES
Unlisted Procedures

PUBLISHED
Provider Update May 2020
Provider Update December 2018
Provider Update February 2018
Provider Update June 2013

REFERENCES:
Not applicable

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