

**FREQUENTLY ASKED QUESTIONS REGARDING MEDICARE COVERAGE OF
TECHNOLOGICALLY ADVANCED CLINICAL LABORATORY TESTING**

1. What are the criteria Medicare uses to determine coverage for lab tests?

Medicare covers laboratory testing, which satisfies its medical necessity criteria, *i.e.*, the testing is consistent with generally accepted medical standards, and therefore is not experimental or investigational. HCFA and its carriers use information from a variety of sources (scientific advisors, industry experts, *etc.*) to make coverage determinations for particular tests and to determine an appropriate reimbursement value for each Current Procedural Terminology (CPT) code.

2. Does Medicare reimburse non-FDA-cleared tests?

In most instances, yes, although the rules can be confusing. Where the FDA requires clearance of a drug or device, the Medicare rules require FDA clearance to be obtained before coverage is provided. However, in some cases, FDA clearance is not required for laboratory tests because, as discussed in more detail in the following question regarding analyte-specific reagents ("home brew testing"), the FDA generally does not regulate laboratory tests or services, but instead limits itself to regulating the manufacturer of medical devices (including equipment, test kits and certain reagents) which are marketed for use in laboratory testing.

3. What are analyte-specific reagents or "home brew" tests and how does Medicare treat them for reimbursement purposes?

Analyte-specific reagents (ASR) or "home brews" are test systems intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens (abbreviated FDA definition). An ASR may be purchased from a manufacturer or prepared by a laboratory for testing purposes in its own facility. Under CLIA regulations, the laboratory must satisfy all applicable method performance specifications (validation of assay characteristics, quality control, *etc.*) Once the requirements of the CLIA regulations have been met, such ASR tests are eligible for Medicare reimbursement, assuming that there is an applicable CPT code established. Methodology based CPT codes are typically used.

4. If there is an existing FDA-cleared kit on the market along with ASR methods tests, does Medicare only reimburse for the FDA-cleared tests?

No. Both FDA-cleared and ASR-based assays are reimbursable. In the case of the former, the laboratory need only verify manufacturers' performance claims, while it must establish method performance validation data under the latter category.

5. Under what circumstances does lack of FDA clearance affect Medicare reimbursement?

If a laboratory uses a manufacturer's non-FDA-cleared test materials without independently validating them as ASR, then the lack of FDA clearance would cause the test not to be covered under Medicare.

6. What is the relationship of test-specific CPT codes and methodology-based CPT codes for billing Medicare?

In most cases, the American Medical Association (AMA) has designated test-specific CPT codes in order to identify a description and reimbursement as precisely as possible. In a large number of cases however, rather than designate test-specific codes, the AMA has established a class of CPT codes which covers a number of assays performed using the same methodology. In all cases, the most specific CPT code that is applicable should be used for billing purposes.