
42 C.F.R. § 414.502

Definitions.

For purposes of this subpart—

Actual list charge means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Advanced diagnostic laboratory test (ADLT) means a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of that laboratory, and meets one of the following criteria:

(1) The test—

- (i) Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;
- (ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies);
- (iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
- (iv) May include other assays.

(2) The test is cleared or approved by the Food and Drug Administration.

Applicable information, with respect to each CDLT for a data collection period:

(1) Means—

- (i) Each private payor rate for which final payment has been made during the data collection period;
- (ii) The associated volume of tests performed corresponding to each private payor rate; and
- (iii) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

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