

Medicare Clinical Laboratory Fee Schedule

Revised Laboratory Date of Service (DOS) Policy

Effective January 1, 2018

Laboratory Tests For Which the DOS is the Date the Test is Performed

(Subject to the Conditions Specified in 42 CFR 414.510(b)(5))*

Notes

*In the case of a molecular pathology test, a test designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, a test identified as a cancer-related protein-based MAAA, or the test described by CPT code 81490, the DOS must be the date the test was performed only if: (1) The test was performed following a hospital outpatient's discharge from the hospital outpatient department; (2) The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2); (3) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) The results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) The test was reasonable and medically necessary for the treatment of an illness. In the CY 2020 Hospital Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule published on November 12, 2019, CMS finalized a revision to the laboratory DOS exception at 42 CFR 414.510(b)(5) to exclude molecular pathology tests when performed by laboratories that are blood banks or centers. CMS also adopted a definition of "blood bank or center" and clarified that this policy change categorically excludes molecular pathology testing performed by laboratories that are blood banks or blood centers from the laboratory DOS exception at 42 CFR 414.510(b)(5).

**Tests granted ADLT status by CMS under Criterion (A), molecular pathology tests, tests identified as cancer-related protein-based MAAAs, and the test described by CPT code 81490 are assigned OPPS payment status indicator A. Status indicator "A" is defined as: "Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS."

Payment for ADLTs and molecular pathology tests excluded from OPPS packaging policy (Status A) are paid at the CLFS rate outside of the OPPS.