

§ 414.522

42 CFR Ch. IV (10–1–20 Edition)

date of service of the test must be the date the test was performed only if—

(A) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

(B) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(D) The results of the test do not guide treatment provided during the hospital stay; and

(E) The test was reasonable and medically necessary for the treatment of an illness.

(ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of service of the test must be the date the specimen was obtained from storage.

(3) In the case of a chemotherapy sensitivity test performed on live tissue, the date of service of the test must be the date the test was performed only if—

(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(iv) The results of the test do not guide treatment provided during the hospital stay; and,

(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, “chemotherapy sensitivity test” means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

(5) In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, or a test designated by CMS as an ADLT

under paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, the date of service of the test must be the date the test was performed only if—

(i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department;

(ii) The specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2 of this chapter);

(iii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

(iv) The results of the test do not guide treatment provided during the hospital outpatient encounter; and

(v) The test was reasonable and medically necessary for the treatment of an illness.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66402, Nov. 27, 2007; 82 FR 52636, Nov. 13, 2017; 82 FR 59496, Dec. 14, 2017; 84 FR 61490, Nov. 12, 2019]

§ 414.522 Payment for new advanced diagnostic laboratory tests.

(a) The payment rate for a new ADLT—

(1) During the new ADLT initial period, is equal to its actual list charge.

(2) Prior to the new ADLT initial period, is determined by the Medicare Administrative Contractor based on information provided by the laboratory seeking new ADLT status for its laboratory test.

(b) After the new ADLT initial period, the payment rate for a new ADLT is equal to the weighted median established under the payment methodology described in § 414.507(b).

(c) If, after the new ADLT initial period, the actual list charge of a new ADLT is greater than 130 percent of the weighted median established under the payment methodology described in § 414.507, CMS will recoup the difference between the ADLT actual list charge and 130 percent of the weighted median.

(d) If CMS does not receive any applicable information for a new ADLT by the last day of the second quarter of the new ADLT initial period, the payment rate for the test is determined either by the gapfilling or crosswalking

method as described in § 414.508(b)(1) and (2).

[81 FR 41100, June 23, 2016]

Subpart H—Fee Schedule for Ambulance Services

SOURCE: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

§ 414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule. Section 1834(l)(17) of the Act requires the development of a data collection system to collect cost, revenue, utilization, and other information determined appropriate from providers of services and suppliers of ground ambulance services.

[67 FR 9132, Feb. 27, 2002, as amended at 84 FR 63193, Nov. 15, 2019]

§ 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as “ground”) ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel.

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary sup-

plies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures:

- (1) Manual defibrillation/cardioversion.
- (2) Endotracheal intubation.
- (3) Central venous line.
- (4) Cardiac pacing.
- (5) Chest decompression.
- (6) Surgical airway.
- (7) Intraosseous line.

Advanced life support (ALS) personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications. The EMT-Paramedic is defined as possessing the qualifications of the EMT-Intermediate and also, in accordance with State and local laws, as having enhanced skills that include being able to administer additional interventions and medications.

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished. Also, at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the State or local authority where the services are furnished and be legally authorized