§ 410.28

42 CFR Ch. IV (10–1–10 Edition)

Hospital or CAH diagnostic services furnished to outpatients: Conditions.

(a) Medicare Part B pays for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

(1) They are furnished by or under arrangements made by a participating hospital or participating CAH, except in the case of an SNF resident as provided in § 411.15(p) of this chapter.

(2) They are ordinarily furnished by, or under arrangements made by, the hospital or CAH to its outpatients for the purpose of diagnostic study.

(3) They would be covered as inpatient hospital services if furnished to an inpatient.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.168.

(c) Diagnoses by nonphysician practitioners are subject to the limitations specified in § 410.42(a).

(d) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in § 410.168.

(e) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

(f) Services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § 410.42(a).

(g) For purposes of this section, “in the hospital or CAH” means areas in the main building(s) of the hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital or CAH; and for which the hospital or CAH bills the services furnished under the hospital’s or CAH’s CMS Certification Number.


§ 410.29

medicine or osteopathy, as specified in §§ 410.47 and 410.49, respectively.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.168.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in § 410.168.

(d) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

(e) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(f) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished by or under arrangements made by the participating hospital, only when the diagnostic services are furnished under the appropriate level of physician supervision specified by CMS in accordance with the definitions in §§ 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility. In addition—

(1) For services furnished directly or under arrangement in the hospital or in an on-campus outpatient department of the hospital, as defined in § 413.65 of this subchapter, “direct supervision” means that the physician must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. For this purpose, the definition of “in the hospital” is as specified in § 410.27(g).

(2) For services furnished directly or under arrangement in an off-campus outpatient department of the hospital, as defined in § 413.65 of this subchapter, “direct supervision” means the physician must be present in the off-campus
provider-based department of the hospital and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

(3) For services furnished under arrangement in nonhospital locations, “direct supervision” means the definition specified in §410.32(b)(3)(ii).

(f) The rules for clinical diagnostic laboratory tests set forth in §§410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.


§ 410.30 Prescription drugs used in immunosuppressive therapy.

(a) Scope. Payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the FDA and that meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a carrier (in accordance with part 421, subpart C of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient’s transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient’s transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(b) Eligibility. For drugs furnished on or after December 21, 2000, coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, provided the individual is eligible to receive Medicare Part B benefits.

(c) Coverage. Drugs are covered under this provision irrespective of whether they can be self-administered.