§ 410.29 Limitations on drugs and biologicals.

Medicare part B does not pay for the following:

(a) Except as provided in § 410.28(a) for outpatient diagnostic services and § 410.63(b) for blood clotting factors, and except for EPO, any drug or biological that can be self-administered.

(b) Any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is subject to a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program, that there is a compelling justification of the drug product’s medical need. (21 CFR 310.6 contains an explanation of the efficacy review program.)

(c) Any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (b) of this section.

§ 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.

§ 410.31 Bone mass measurement: Conditions for coverage and frequency standards.

(a) Definition. As used in this section unless specified otherwise, the following definition applies:

Bone mass measurement means a radiologic, radioisotopic, or other procedure that meets the following conditions:

(1) Is performed for the purpose of identifying bone mass, detecting bone loss, or determining bone quality.

(2) Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or with a bone sonometer system that has been cleared for marketing for this use by the FDA under 21 CFR part 807, or approved for marketing by the FDA for this use under 21 CFR part 814.

(3) Includes a physician’s interpretation of the results of the procedure.

(b) Conditions for coverage. (1) Medicare covers a medically necessary bone mass measurement if the following conditions are met:

(i) Following an evaluation of the beneficiary’s need for the measurement, including a determination as to whether the appropriate procedure to be used for the beneficiary, it is ordered by the physician or a qualified nonphysician practitioner (as these terms are defined in §410.32(a)) treating the beneficiary.

(ii) It is performed under the appropriate level of supervision of a physician (as set forth in §410.32(b)).

(iii) It is reasonable and necessary for diagnosing and treating the Condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(2) Medicare covers a medically necessary bone mass measurement for an individual defined under paragraph (d)(5) of this section if the conditions under paragraph (b)(1) of this section are met and the monitoring is performed by the use of a dual energy x-ray absorptiometry system (axial skeleton).

(3) Medicare covers a medically necessary confirmatory baseline bone mass measurement for an individual defined under paragraph (d) of this section, if the conditions under paragraph (b)(1) of this section are met and the confirmatory baseline bone mass measurement is performed by a dual energy x-ray absorptiometry system (axial skeleton) and the initial measurement was not performed by a dual energy x-ray absorptiometry system (axial skeleton).

(c) Standards on frequency of coverage—(1) General rule. Except as allowed under paragraph (c)(2) of this section, Medicare may cover a bone mass measurement for a beneficiary if at least 23 months have passed since the month the last bone mass measurement was performed.