

(i) Must have a valid provisional certificate, or a valid certificate, that has been issued by FDA indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(ii) Has not been issued a written notification by FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.

(iii) Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).

(b) *Conditions for coverage of diagnostic mammography services.* Medicare Part B pays for diagnostic mammography services if they meet the following conditions:

(1) They are ordered by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(2) They are furnished by a supplier of diagnostic mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(c) *Conditions for coverage of screening mammography services.* Medicare Part B pays for screening mammography services if they are furnished by a supplier of screening mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(d) *Limitations on coverage of screening mammography services.* The following limitations apply to coverage of screening mammography services as described in paragraphs (c) and (d) of this section:

(1) The service must be, at a minimum a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of each breast.

(2) Payment may not be made for screening mammography performed on a woman under age 35.

(3) Payment may be made for only 1 screening mammography performed on a woman over age 34, but under age 40.

(4) For an asymptomatic woman over 39 years of age, payment may be made for a screening mammography performed after at least 11 months have passed following the month in which the last screening mammography was performed.

[59 FR 49833, Sept. 30, 1994, as amended at 60 FR 14224, Mar. 16, 1995; 60 FR 63176, Dec. 8, 1995; 62 FR 59100, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998]

§ 410.35 X-ray therapy and other radiation therapy services: Scope.

Medicare Part B pays for X-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

[51 FR 41339, Nov. 14, 1986. Redesignated at 55 FR 53522, Dec. 31, 1990]

§ 410.36 Medical supplies, appliances, and devices: Scope.

(a) Medicare Part B pays for the following medical supplies, appliances and devices:

(1) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(2) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including—

(i) Replacement of prosthetic devices; and

(ii) One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted.

(3) Leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the individual's physical condition.

(b) As a requirement for payment, CMS may determine through carrier instructions, or carriers may determine, that an item listed in paragraph (a) of this section requires a written