§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

(a) Routine physical checkups such as:

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic examinations, prostate cancer screening tests, or glaucoma screening exams that meet the criteria specified in paragraphs (k)(6) through (k)(10) of this section.

(2) Examinations required by insurance companies, business establishments, government agencies, or other third parties.

(b) Eyeglasses or contact lenses, except for:

(1) Post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed (e.g., cataract surgery);

(2) Prosthetic lenses for patients who lack the lens of the eye because of congenital absence or surgical removal; and

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

(c) Eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive error only and procedures performed in the course of any eye examination to determine the refractive state of the eyes, without regard to the reason for the performance of the refractive procedures. Refractive procedures are excluded even when performed in connection with otherwise covered diagnosis or treatment of illness or injury.

(d) Hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids.

(e) Immunizations, except for—

(1) Vaccinations or inoculations directly related to the treatment of an injury or direct exposure such as antitoxin or booster vaccine, botulin antitoxin, antivenom sera, or immune globulin;

(2) Pneumococcal vaccinations that are reasonable and necessary for the prevention of illness;

(3) Hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals, as defined in §410.63(a) of this chapter, who are at high or intermediate risk of contracting hepatitis B; and

(4) Influenza vaccinations that are reasonable and necessary for the prevention of illness.

(f) Orthopedic shoes or other supportive devices for the feet, except when shoes are integral parts of leg braces.

(g) Custodial care, except as necessary for the palliation or management of terminal illness, as provided in part 418 of this chapter. (Custodial care is any care that does not meet the requirements for coverage as SNF care as set forth in §§409.31 through 409.35 of this chapter.)

(h) Cosmetic surgery and related services, except as required for the prompt repair of accidental injury or to improve the functioning of a malformed body member.

(i) Dental services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth, except for inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(1) The individual’s underlying medical condition and clinical status; or

(2) The severity of the dental procedures.1

(j) Personal comfort services, except as necessary for the palliation or management of terminal illness as provided in part 418 of this chapter. The use of a television set or a telephone are examples of personal comfort services.

(k) Any services that are not reasonable and necessary for one of the following purposes:

(1) For the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

1Before July 1981, inpatient hospital care in connection with dental procedures was covered only when required by the patient’s underlying medical condition and clinical status.
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(2) In the case of hospice services, for the palliation or management of terminal illness, as provided in part 418 of this chapter.

(3) In the case of pneumococcal vaccine for the prevention of illness.

(4) In the case of the patient outcome assessment program established under section 1875(c) of the Act, for carrying out the purpose of that section.

(5) In the case of hepatitis B vaccine, for the prevention of illness for those individuals at high or intermediate risk of contracting hepatitis B. (Section 410.63(a) of this chapter sets forth criteria for identifying those individuals.)

(6) In the case of screening mammography, for the purpose of early detection of breast cancer subject to the conditions and limitations specified in § 410.34 of this chapter.

(7) In the case of colorectal cancer screening tests, for the purpose of early detection of colorectal cancer subject to the conditions and limitations specified in § 410.37 of this chapter.

(8) In the case of screening pelvic examinations, for the purpose of early detection of cervical or vaginal cancer subject to the conditions and limitations specified in § 410.56 of this chapter.

(9) In the case of prostate cancer screening exams for glaucoma, for the purpose of early detection of glaucoma, subject to the conditions and limitations specified in § 410.23 of this chapter.

(1) Foot care. (1) Basic rule. Except as provided in paragraph (1)(ii) of this section, any services furnished in connection with the following:

(i) Routine foot care, such as the cutting or removal of corns, or calluses, the trimming of nails, routine hygienic care (preventive maintenance care ordinarily within the realm of self care), and any service performed in the absence of localized illness, injury, or symptoms involving the feet.

(ii) The evaluation or treatment of subluxations of the feet regardless of underlying pathology. (Subluxations are structural misalignments of the joints, other than fractures or complete dislocations, that require treatment only by nonsurgical methods.

(iii) The evaluation or treatment of flattened arches (including the prescription of supportive devices) regardless of the underlying pathology.

(2) Exceptions. (i) Treatment of warts is not excluded.

(ii) Treatment of mycotic toenails may be covered if it is furnished no more often than every 60 days or the billing physician documents the need for more frequent treatment.

(iii) The services listed in paragraph (1)(1) of this section are not excluded if they are furnished—

(A) As an incident to, at the same time as, or as a necessary integral part of a primary covered procedure performed on the foot; or

(B) As initial diagnostic services (regardless of the resulting diagnosis) in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.

(m) Services to hospital patients—(1) Basic rule. Except as provided in paragraph (m)(3) of this section, any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in § 410.2 of this chapter) during an encounter (as defined in § 410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital’s patients. As used in this paragraph (m)(1), the term “hospital” includes a CAH.

(2) Scope of exclusion. Services subject to exclusion from coverage under the provisions of this paragraph (m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment and supplies covered under the prosthetic device benefits; and services incident to a physician service.

(3) Exceptions. The following services are not excluded from coverage:

(i) Physicians’ services that meet the criteria of § 415.102(a) of this chapter for
payment on a reasonable charge or fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(vi) Services of an anesthetist, as defined in §410.69 of this chapter.

(n) Certain services of an assistant-at-surgery.

(1) Services of an assistant-at-surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate QIO or a carrier has approved the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition.

(2) Services on an assistant-at-surgery in a surgical procedure (or class of surgical procedures) for which assistants-at-surgery on average are used in fewer than 5 percent of such procedures nationally.

(o) Experimental or investigational devices, except for certain devices—

(1) Categorized by the FDA as a non-experimental/investigational (Category B) device defined in §405.201(b) of this chapter; and

(2) Furnished in accordance with the FDA-approved protocols governing clinical trials.

(p) Services furnished to SNF residents—(1) Basic rule. Except as provided in paragraph (p)(2) of this section, any service furnished to a resident of an SNF during a covered Part A stay by an entity other than the SNF, unless the SNF has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to the SNF’s residents. Services subject to exclusion under this paragraph include, but are not limited to—

(i) Any physical, occupational, or speech-language therapy services, regardless of whether the services are furnished by (or under the supervision of) a physician or other health care professional, and regardless of whether the resident who receives the services is in a covered Part A stay; and

(ii) Services furnished as an incident to the professional services of a physician or other health care professional specified in paragraph (p)(2) of this section.

(2) Exceptions. The following services are not excluded from coverage, provided that the claim for payment includes the SNF’s Medicare provider number in accordance with §424.32(a)(5) of this chapter:

(i) Physicians’ services that meet the criteria of §415.102(a) of this chapter for payment on a fee schedule basis.

(ii) Services performed under a physician’s supervision by a physician assistant who meets the applicable definition in section 1861(aa)(5) of the Act.

(iii) Services performed by a nurse practitioner or clinical nurse specialist who meets the applicable definition in section 1861(aa)(5) of the Act and is working in collaboration (as defined in section 1861(aa)(6) of the Act) with a physician.

(iv) Services performed by a certified nurse-midwife, as defined in section 1861(gg) of the Act.

(v) Services performed by a qualified psychologist, as defined in section 1861(ii) of the Act.

(vi) Services performed by a certified registered nurse anesthetist, as defined in section 1861(bb) of the Act.

(vii) Dialysis services and supplies, as defined in section 1861(s)(2)(F) of the Act, and those ambulance services that are furnished in conjunction with them.

(viii) Erythropoietin (EPO) for dialysis patients, as defined in section 1861(s)(2)(O) of the Act.

(ix) Hospice care, as defined in section 1861(dd) of the Act.

(x) An ambulance trip that initially conveys an individual to the SNF to be admitted as a resident, or that conveys an individual from the SNF in connection with one of the circumstances specified in paragraphs (p)(3)(i) through (p)(3)(iv) of this section as ending the individual’s status as an SNF resident.
§411.20 Basis and scope.

(a) Statutory basis. (1) Section 1862(b)(2)(A)(i) of the Act precludes Medicare payment for services to the extent that payment has been made or can reasonably be expected to be made under a group health plan with respect to—