

(b) *Definitions.* As used in this section—

Immediate relative means any of the following:

- (1) Husband or wife.
- (2) Natural or adoptive parent, child, or sibling.
- (3) Stepparent, stepchild, stepbrother, or stepsister.
- (4) Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law.
- (5) Grandparent or grandchild.
- (6) Spouse of grandparent or grandchild.

Member of the household means any person sharing a common abode as part of a single family unit, including domestic employees and others who live together as part of a family unit, but not including a mere roomer or boarder.

Professional corporation means a corporation that is completely owned by one or more physicians and is operated for the purpose of conducting the practice of medicine, osteopathy dentistry, podiatry, optometry, or chiropractic, or is owned by other health care professionals as authorized by State law.

(c) *Applicability of the exclusion.* The exclusion applies to the following charges in the specified circumstances:

(1) *Physicians' services.* (i) Charges for physicians' services furnished by an immediate relative of the beneficiary or member of the beneficiary's household, even if the bill or claim is submitted by another individual or by an entity such as a partnership or a professional corporation.

(ii) Charges for services furnished incident to a physician's professional services (for example by the physician's nurse or technician), only if the physician who ordered or supervised the services has an excluded relationship to the beneficiary.

(2) *Services other than physicians' services.* (i) Charges imposed by an individually owned provider or supplier if the owner has an excluded relationship to the beneficiary; and

(ii) Charges imposed by a partnership if any of the partners has an excluded relationship to the beneficiary.

(d) *Exception to the exclusion.* The exclusion does not apply to charges im-

posed by a corporation other than a professional corporation.

§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 exams, prostate cancer screening tests, glaucoma screening exams, ultrasound screening for abdominal aortic aneurysms (AAA), cardiovascular disease screening tests, diabetes screening tests, a screening electrocardiogram, initial preventive physical examinations that meet the criteria specified in paragraphs (k)(6) through (k)(15) of this section, additional preventive services that meet the criteria in §410.64 of this chapter, or annual wellness visits providing personalized prevention plan services.

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

(b) *Low vision aid exclusion.*—(1) *Scope.* The scope of the eyeglass exclusion encompasses all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision.

(2) *Exceptions.* (i) Post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed (for example, cataract surgery).

(ii) Prosthetic intraocular lenses and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(iii) Prosthetic lenses used by Medicare beneficiaries who are lacking the natural lens of the eye and who were not furnished with an intraocular lens.

(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 examinations for the purpose of prescribing, fitting, or changing hearing aids.

(1) *Scope.* The scope of the hearing aid exclusion encompasses all types of air conduction hearing aids that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound and bone conduction hearing aids that provide mechanical stimulation of the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

(2) *Devices not subject to the hearing aid exclusion.* Paragraph (d)(1) of this section shall not apply to the following devices that produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve:

(i) Osseointegrated implants in the skull bone that provide mechanical energy to the cochlea via a mechanical transducer, or

(ii) Cochlear implants and auditory brainstem implants that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.

(e) *Immunizations, except for—*

(1) Vaccinations or inoculations directly related to the treatment of an injury or direct exposure such as antirabies treatment, tetanus 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;

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

(5) COVID-19 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—(1) Basic rule.* Dental services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth.

(2) *Exception.* Except for inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(i) The individual's underlying medical condition and clinical status; or

(ii) The severity of the dental procedures.⁵⁷⁷

(3) *Inapplicability.* (i) Dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not excluded; payment may be made under Medicare Parts A and B for services furnished in the inpatient or outpatient setting. Such services include, but are not limited to:

(A) Dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: organ transplant, hematopoietic stem cell transplant, bone marrow transplant, cardiac valve replacement, valvuloplasty procedures,

⁵⁷⁷ Before 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.

chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, and administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

(B) The reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor.

(C) The stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints.

(D) The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.

(E) Dental or oral examination performed as part of a comprehensive workup prior to, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with, and medically necessary diagnostic and treatment services to address dental or oral complications after, treatment of head and neck cancer using radiation, chemotherapy, surgery, or any combination of these.

(ii) Ancillary services and supplies furnished incident to covered dental services are not excluded, and Medicare payment may be made under Part A or Part B, as applicable, whether the service is performed in the inpatient or outpatient setting, including, but not limited to the administration of anesthesia, diagnostic x-rays, use of operating room, and other related procedures.

(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.

(2) In the case of hospice services, for the palliation or management of ter-

минаl 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 tests, for the purpose of early detection of prostate cancer, subject to the conditions and limitations specified in §410.39 of this chapter.

(10) In the case of 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.

(11) In the case of initial preventive physical examinations, with the goal of health promotion and disease prevention, subject to the conditions and limitations specified in §410.16 of this chapter.

(12) In the case of ultrasound screening for abdominal aortic aneurysms, with the goal of early detection of abdominal aortic aneurysms, subject to the conditions and limitation specified in §410.19 of this chapter.

(13) In the case of cardiovascular disease screening tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for that disease, subject to the

conditions specified in § 410.17 of this chapter.

(14) In the case of diabetes screening tests furnished to an individual at risk for diabetes for the purpose of the early detection of that disease, subject to the conditions specified in § 410.18 of this chapter.

(15) In the case of additional preventive services not otherwise described in this title, subject to the conditions and limitation specified in § 410.64 of this chapter.

(16) In the case of an annual wellness visit providing a personalized prevention plan, subject to the conditions and limitations specified in § 410.15 of this subpart.

(1) *Foot care*—(1) *Basic rule.* Except as provided in paragraph (1)(2) 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 con-

dition 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 Category B (Nonexperimental/investigational) device as defined in §405.201(b) of the chapter; and

(2) Furnished in accordance with the coverage requirements in §405.211(b).

(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 marriage and family therapist, as defined in section 1861(lll)(2) of the Act.

(vii) Services performed by a mental health counselor, as defined in section 1861(lll)(4) of the Act.

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

(ix) 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.

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

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

(xii) 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.

(xiii) The transportation costs of electrocardiogram equipment (HCPCS code R0076), but only with respect to those electrocardiogram test services furnished during 1998.

(xiv) Services described in paragraphs (p)(2)(i) through (viii) of this section when furnished via telehealth under section 1834(m)(4)(C)(ii)(VII) of the Act.

(xv) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020, J9040–J9151, J9170–J9185, J9200–J9201, J9206–J9208, J9211, J9230–J9245, and J9265–J9600, and as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534 (as subsequently modified by CMS), and any additional chemotherapy items identified by CMS.

(xvi) Those chemotherapy administration services identified, as of July 1,

§ 411.15

42 CFR Ch. IV (10–1–24 Edition)

1999, by HCPCS codes 36260–36262, 36489, 36530–36535, 36640, 36823, and 96405–96542 (as subsequently modified by CMS), and any additional chemotherapy administration services identified by CMS.

(xvii) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440 (as subsequently modified by CMS), and any additional radioisotope services identified by CMS.

(xviii) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340, L5500–L5611, L5613–L5986, L5988, L6050–L6370, L6400–6880, L6920–L7274, and L7362–L7366 (as subsequently modified by CMS) and any additional customized prosthetic devices identified by CMS, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(xix) Those blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211 (as subsequently modified by CMS) and items and services related to the furnishing of such factors, and any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors.

(xx) Those RHC and FQHC services that are described in § 405.2411(b)(2) of this chapter.

(3) *SNF resident defined.* For purposes of this paragraph, a beneficiary who is admitted to a Medicare-participating SNF is considered to be a resident of the SNF for the duration of the beneficiary's covered Part A stay. In addition, for purposes of the services described in paragraph (p)(1)(i) of this section, a beneficiary who is admitted to a Medicare-participating SNF is considered to be a resident of the SNF regardless of whether the beneficiary is in a covered Part A stay. Whenever the beneficiary leaves the facility, the beneficiary's status as an SNF resident for purposes of this paragraph (along with the SNF's responsibility to furnish or make arrangements for the

services described in paragraph (p)(1) of this section) ends when one of the following events occurs—

(i) The beneficiary is admitted as an inpatient to a Medicare-participating hospital or CAH, or as a resident to another SNF;

(ii) The beneficiary receives services from a Medicare-participating home health agency under a plan of care;

(iii) The beneficiary receives outpatient services from a Medicare-participating hospital or CAH (but only for those services that CMS designates as being beyond the general scope of SNF comprehensive care plans, as required under § 483.21(b) of this chapter); or

(iv) The beneficiary is formally discharged (or otherwise departs) from the SNF, unless the beneficiary is readmitted (or returns) to that or another SNF before the following midnight.

(q) *Assisted suicide.* Any health care service used for the purpose of causing, or assisting to cause, the death of any individual. This does not pertain to the withholding or withdrawing of medical treatment or care, nutrition or hydration or to the provision of a service for the purpose of alleviating pain or discomfort, even if the use may increase the risk of death, so long as the service is not furnished for the specific purpose of causing death.

(r) A home health service (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) as defined in section 1861(m) of the Act furnished to an individual who is under a plan of care of an HHA, unless that HHA has submitted a claim for payment for such services.

(s) Unless § 414.404(d) or § 414.408(e)(2) of this subchapter applies, Medicare does not make payment if an item or service that is included in a competitive bidding program (as described in part 414, subpart F of this subchapter) is furnished by a supplier other than a contract supplier (as defined in § 414.402 of this subchapter).

[54 FR 41734, Oct. 11, 1989; 55 FR 1820, Jan. 19, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 411.15, see the List of CFR

Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

Subpart B—Insurance Coverage That Limits Medicare Payment: General Provisions

§ 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—

(i) A beneficiary entitled to Medicare on the basis of ESRD during the first 18 months of that entitlement;

(ii) A beneficiary who is age 65 or over, entitled to Medicare on the basis of age, and covered under the plan by virtue of his or her current employment status or the current employment status of a spouse of any age; or

(iii) A beneficiary who is under age 65, entitled to Medicare on the basis of disability, and covered under the plan by virtue of his or her current employment status or the current employment status of a family member.

(2) Section 1862(b)(2)(A)(ii) 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 any of the following:

- (i) Workers' compensation.
- (ii) Liability insurance.
- (iii) No-fault insurance.

(b) *Scope.* This subpart sets forth general rules that apply to the types of insurance specified in paragraph (a) of this section. Other general rules that apply to group health plans are set forth in subpart E of this part.

[60 FR 45361, Aug. 31, 1995, as amended at 71 FR 9470, Feb. 24, 2006]

§ 411.21 Definitions.

In this subpart B and in subparts C through H of this part, unless the context indicates otherwise—

Conditional payment means a Medicare payment for services for which another payer is responsible, made either on the bases set forth in subparts C through H of this part, or because the

intermediary or carrier did not know that the other coverage existed.

Coverage or covered services, when used in connection with primary payments, means services for which a primary payer would pay if a proper claim were filed.

Monthly capitation payment means a comprehensive monthly payment that covers all physician services associated with the continuing medical management of a maintenance dialysis patient who dialyses at home or as an outpatient in an approved ESRD facility.

Plan means any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness.

Primary payer means, when used in the context in which Medicare is the secondary payer, any entity that is or was required or responsible to make payment with respect to an item or service (or any portion thereof) under a primary plan. These entities include, but are not limited to, insurers or self-insurers, third party administrators, and all employers that sponsor or contribute to group health plans or large group health plans.

Primary payment means, when used in the context in which Medicare is the secondary payer, payment by a primary payer for services that are also covered under Medicare.

Primary plan means, when used in the context in which Medicare is the secondary payer, a group health plan or large group health plan, a workers' compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or no-fault insurance.

Prompt or promptly, when used in connection with primary payments, except as provided in §411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim.

Proper claim means a claim that is filed timely and meets all other claim filing requirements specified by the plan, program, or insurer.

Secondary, when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be