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The Department of Defense, Office of the Secretary, has authorized the following addition(s)/ revision(s) to 32 CFR Part 199, reissued April 2005.

CHANGE TITLE: TRICARE; COVERAGE OF CARE RELATED TO NON-COVERED INITIAL SURGERY OR TREATMENT

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(B) Cosmetic, reconstructive, or plastic surgery procedures performed primarily for psychological reasons or as a result of the aging process also are excluded.

(C) Procedures performed for elective correction of minor dermatological blemishes and marks or minor anatomical anomalies also are excluded.

(iii) Noncovered surgery, all related services and supplies excluded. When it is determined that a cosmetic, reconstructive, or plastic surgery procedure does not qualify for CHAMPUS benefits, all related services and supplies are excluded, including any institutional costs.

(iv) Example of noncovered cosmetic, reconstructive, or plastic surgery procedures. The following is a partial list of cosmetic, reconstructive, or plastic surgery procedures that do not qualify for benefits under CHAMPUS. This list is for example purposes only and is not to be construed as being all-inclusive.

(A) Any procedure performed for personal reasons to improve the appearance of an obvious feature or part of the body that would be considered by an average observer to be normal and acceptable for the patient's age or ethnic or racial background.

(B) Cosmetic, reconstructive, or plastic surgical procedures that are justified primarily on the basis of a psychological or psychiatric need.

(C) Augmentation mammoplasties. Augmentation mammoplasties, except for breast reconstruction following a covered mastectomy and those specifically authorized in paragraph (e)(8)(i) of this section.

(D) Face lifts and other procedures related to the aging process.

(E) Reduction mammoplasties. Reduction mammoplasties (unless there is medical documentation of intractable pain, not amenable to other forms of treatment, resulting from large, pendulous breasts or unless performed as an integral part of an authorized breast reconstruction procedure under paragraph (e)(8)(i) of this section, including reduction of the collateral breast for purposes of ensuring breast symmetry)

(F) Panniculectomy; body sculpture procedures.

(G) Repair of sagging eyelids (without demonstrated and medically documented significant impairment of vision).

(H) Rhinoplasties (without evidence of accidental injury occurring within the previous 6 months that resulted in significant obstruction of breathing).

(I) Chemical peeling for facial wrinkles.

(J) Dermabrasion of the face.

(K) Elective correction of minor dermatological blemishes and marks or minor anatomical anomalies.

(L) Revision of scars resulting from surgery or a disease process, except disfiguring and extensive scars resulting from neoplastic surgery.

(M) Removal of tattoos.

(N) Hair transplants.

(O) Electrolysis.

(P) Any procedures related to transsexualism or such other conditions as gender dysphoria except as provided in paragraph (e)(7) of this section.

(Q) Penile implant procedure for psychological impotency, transsexualism, or such other conditions as gender dysphoria.

(R) Insertion of prosthetic testicles for transsexualism, or such other conditions as gender dysphoria.

(9) Care related to non-covered initial surgery or treatment. (i) Benefits are available for otherwise covered services and supplies required in the treatment of complications resulting from a non-covered incident of treatment (such as nonadjunctive dental care or cosmetic surgery) but only if the later complication represents a separate medical condition such as a systemic infection, cardiac arrest, and acute drug reaction. Benefits may not be extended for any later care or a procedure related to the complication that essentially is similar to the initial non-covered care. Examples of complications similar to the initial episode of care (and thus not covered) would be repair of facial scarring resulting from dermabrasion for acne.

(ii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care resulting from a non-covered incident of treatment provided in an MTF, when the initial non-covered service has been authorized by the MTF Commander and the MTF is unable to provide the necessary treatment of the complications or required follow-on care, according to the guidelines adopted by the Director, DHA, or a designee.

(iii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care resulting from a non-covered incident of treatment provided in the private sector pursuant to a properly granted waiver under Sec. 199.16(f). The Director, DHA, or designee, shall issue guidelines for implementing this provision.

(10) Dental. TRICARE/CHAMPUS does not include a dental benefit. However, in connection with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under, only institutional and anesthesia services may be provided as a benefit.

(i) Adjunctive dental care: Limited. Adjunctive dental care is limited to those services and supplies provided under the following conditions:

(A) Dental care which is medically necessary in the treatment of an otherwise covered

medical (not dental) condition, is an integral part of the treatment of such medical condition and is essential to the control of the primary medical condition. The following is a list of conditions for which CHAMPUS benefits are payable under this provision:

- (1) Intraoral abscesses which extend beyond the dental alveolus.
- (2) Extraoral abscesses.
- (3) Cellulitis and osteitis which is clearly exacerbating and directly affecting a medical condition currently under treatment.
- (4) Removal of teeth and tooth fragments in order to treat and repair facial trauma resulting from an accidental injury.
- (5) Myofacial Pain Dysfunction Syndrome.
- (6) Total or complete ankyloglossia.
- (7) Adjunctive dental and orthodontic support for cleft palate.
- (8) The prosthetic replacement of either the maxilla or the mandible due to the reduction of body tissues associated with traumatic injury (e.g., impact, gun shot wound), in addition to services related to treating neoplasms or iatrogenic dental trauma.

NOTE: The test of whether dental trauma is covered is whether the trauma is solely dental trauma. Dental trauma, in order to be covered, must be related to, and an integral part of medical trauma; or a result of medically necessary treatment of an injury or disease.

(B) Dental care required in preparation for medical treatment of a disease or disorder or required as the result of dental trauma caused by the medically necessary treatment of an injury or disease (iatrogenic).

(1) Necessary dental care including prophylaxis and extractions when performed in preparation for or as a result of in-line radiation therapy for oral or facial cancer.

(2) Treatment of gingival hyperplasia, with or without periodontal disease, as a direct result of prolonged therapy with Dilantin (diphenylhydantoin) or related compounds.

(C) Dental care is limited to the above and similar conditions specifically prescribed by the Director, OCHAMPUS, as meeting the requirements for coverage under the provisions of this section.

(ii) General exclusions.(A) Dental care which is routine, preventative, restorative, prosthodontic, periodontic or emergency does not qualify as adjunctive dental care for the purposes of CHAMPUS except when performed in preparation for or as a result of dental trauma caused by medically necessary treatment of an injury or disease.

(B) The adding or modifying of bridgework and dentures.

(C) Orthodontia, except when directly related to and an integral part of the medical or

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surgical correction of a cleft palate or when required in preparation for, or as a result of, trauma to the teeth and supporting structures caused by medically necessary treatment of an injury or disease.

(iii) Preauthorization required. In order to be covered, adjunctive dental care requires preauthorization from the Director, TRICARE Management Activity, or a designee, in accordance with paragraph (a)(12) of this section. When adjunctive dental care involves a medical (not dental) emergency (such as facial injuries resulting from an accident), the requirement for preauthorization is waived. Such waiver, however, is limited to the essential adjunctive dental care related to the medical condition requiring the immediate emergency treatment. A complete explanation, with supporting medical documentation, must be submitted with claims for emergency adjunctive dental care.

(iv) Covered oral surgery. Notwithstanding the above limitations on dental care, there are certain oral surgical procedures that are performed by both physicians and dentists, and that are essentially medical rather than dental care. For the purposes of CHAMPUS, the following procedures, whether performed by a physician or dentist, are considered to be in this category and benefits may be extended for otherwise covered services and supplies without preauthorization:

- (A) Excision of tumors and cysts of the jaws, cheeks, lips, tongue, and roof and floor of the mouth, when such conditions require a pathological (histological) examination.
- (B) Surgical procedures required to correct accidental injuries of the jaws, cheeks, lips, tongue, and roof and floor of the mouth.
- (C) Treatment of oral or facial cancer.
- (D) Treatment of fractures of facial bones.
- (E) External (extra-oral) incision and drainage of cellulitis.
- (F) Surgery of accessory sinuses, salivary glands, or ducts.
- (G) Reduction of dislocations and the excision of the temporomandibular joints, when surgery is a necessary part of the reduction.
- (H) Any oral surgical procedure that falls within the cosmetic, reconstructive, or plastic surgery definition is subject to the limitations and requirements set forth in paragraph (e)(8) of this section.

NOTE: Extraction of unerupted or partially erupted, malposed or impacted teeth, with or without the attached follicular or development tissues, is not a covered oral surgery procedure except when the care is indicated in preparation for medical treatment of a disease or disorder or required as a result of dental trauma caused by the necessary medical treatment of an injury or illness. Surgical preparation of the mouth for dentures is not covered by CHAMPUS.

(v) Inpatient hospital stay in connection with non-adjunctive, noncovered dental care. Institutional benefits specified in paragraph (b) of this section may be extended for inpatient hospital stays related to noncovered, nonadjunctive dental care when such inpatient stay is medically necessary to safeguard the life of the patient from the effects of dentistry because of the existence of a specific and serious nondental organic impairment currently under active treatment. (Hemophilia is an example of a condition that could be considered a serious nondental impairment.) Preauthorization by the Director, OCHAMPUS, or a designee, is required for such inpatient stays to be covered in the same manner as required for adjunctive dental care described in paragraph (e)(10)(iii) of this section. Regardless of whether or not the preauthorization request for the hospital admission is approved and thus qualifies for institutional benefits, the professional service related to the nonadjunctive dental care is not covered.

(vi) Anesthesia and institutional costs for dental care for children and certain other patients. Institutional benefits specified in paragraph (b) of this section may be extended for hospital and in-out surgery settings related to noncovered, nonadjunctive dental care when such outpatient care or inpatient stay is in conjunction with dental treatment for patients with developmental, mental, or physical disabilities or for pediatric patients age 5 or under. For these patients, anesthesia services will be limited to the administration of general anesthesia only. Patients with developmental, mental, or physical disabilities are those patients with conditions that prohibit dental treatment in a safe and effective manner. Therefore, it is medically or psychologically necessary for these patients to require general anesthesia for dental treatment. Patients with physical disabilities include those patients having disabilities as defined in Sec. 199.2 as a serious physical disability. Preauthorization by the Director, TRICARE Management Activity, or a designee, is required for such outpatient care or inpatient stays to be covered in the same manner as required for adjunctive dental care described in paragraph (e)(10)(iii) of this section. Regardless of whether or not the preauthorization request for outpatient care or hospital admission is approved and thus qualifies for institutional benefits, the professional service related to the nonadjunctive dental care is not covered, with the exception of coverage for anesthesia services.

(11) Drug abuse. Under the Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to paragraph (d) of this section). However, TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means. Drugs, including the substitution of a therapeutic drug with addictive potential for a drug of addiction, prescribed to beneficiaries undergoing medically supervised treatment for a substance use disorder as authorized under paragraph (e)(4)(ii) of this section are not considered to be in support of, or to maintain, an existing or potential drug abuse situation and are allowed. The Director, TRICARE Management Activity, may prescribe appropriate policies to implement this prescription drug benefit for those undergoing medically supervised treatment for a substance use disorder.

(i) Limitations on who can prescribe drugs. CHAMPUS benefits are not available for any drugs prescribed by a member of the beneficiary's family or by a nonfamily member residing in the same household with the beneficiary or sponsor.

(ii) (Reserved).

- (iii) Kinds of prescription drugs that are monitored carefully by CHAMPUS for possible abuse situations--(A) Narcotics. Examples are Morphine and Demerol.
- (B) Nonnarcotic analgesics. Examples are Talwin and Darvon.
- (C) Tranquilizers. Examples are Valium, Librium, and Meprobamate.
- (D) Barbiturates. Examples are Seconal and Nembuttal.
- (E) Nonbarbituate hypnotics. Examples are Doriden and Chloral Hydrate.
- (F) Stimulants. Examples are amphetamines.
- (iv) CHAMPUS fiscal intermediary responsibilities. CHAMPUS fiscal intermediaries are responsible for implementing utilization control and quality assurance procedures designed to identify possible drug abuse situations. The CHAMPUS fiscal intermediary is directed to screen all drug claims for potential overutilization and irrational prescribing of drugs, and to subject any such cases to extensive review to establish the necessity for the drugs and their appropriateness on the basis of diagnosis or definitive symptoms.
- (A) When a possible drug abuse situation is identified, all claims for drugs for that specific beneficiary or provider will be suspended pending the results of a review.
- (B) If the review determines that a drug abuse situation does in fact exist, all drug claims held in suspense will be denied.
- (C) If the record indicates previously paid drug benefits, the prior claims for that beneficiary or provider will be reopened and the circumstances involved reviewed to determine whether or not drug abuse also existed at the time the earlier claims were adjudicated. If drug abuse is later ascertained, benefit payments made previously will be considered to have been extended in error and the amounts so paid recouped.
- (D) Inpatient stays primarily for the purpose of obtaining drugs and any other services and supplies related to drug abuse also are excluded.
- (v) Unethical or illegal provider practices related to drugs. Any such investigation into a possible drug abuse that uncovers unethical or illegal drug dispensing practices on the part of an institution, a pharmacy, or physician will be referred to the professional or investigative agency having jurisdiction. CHAMPUS fiscal intermediaries are directed to withhold payment of all CHAMPUS claims for services and supplies rendered by a provider under active investigation for possible unethical or illegal drug dispensing activities.
- (vi) Detoxification. The above monitoring and control of drug abuse situations shall in no way be construed to deny otherwise covered medical services and supplies related to drug detoxification (including newborn, addicted infants) when medical supervision is required.
- (12) (Reserved)

(13) Domiciliary care. The statute under which CHAMPUS operates also specifically excludes domiciliary care (refer to Sec. 199.2 of this part for the definition of "Domiciliary Care").

(i) Examples of domiciliary care situations. The following are examples of domiciliary care for which CHAMPUS benefits are not payable.

(A) Home care is not available. Institutionalization primarily because parents work, or extension of a hospital stay beyond what is medically necessary because the patient lives alone, are examples of domiciliary care provided because there is no other family member or other person available in the home.

(B) Home care is not suitable. Institutionalization of a child because a parent (or parents) is an alcoholic who is not responsible enough to care for the child, or because someone in the home has a contagious disease, are examples of domiciliary care being provided because the home setting is unsuitable.

(C) Family unwilling to care for a person in the home. A child who is difficult to manage may be placed in an institution, not because institutional care is medically necessary, but because the family does not want to handle him or her in the home. Such institutionalization would represent domiciliary care, that is, the family being unwilling to assume responsibility for the child.

(ii) Benefits available in connection with a domiciliary care case. Should the beneficiary receive otherwise covered medical services or supplies while also being in a domiciliary care situation, CHAMPUS benefits are payable for those medical services or supplies, or both, in the same manner as though the beneficiary resided in his or her own home. Such benefits would be cost-shared as though rendered to an outpatient.

(iii) General exclusion. Domiciliary care is institutionalization essentially to provide a substitute home--not because it is medically necessary for the beneficiary to be in the institution (although there may be conditions present that have contributed to the fact that domiciliary care is being rendered). CHAMPUS benefits are not payable for any costs or charges related to the provision of domiciliary care. While a substitute home or assistance may be necessary for the beneficiary, domiciliary care does not represent the kind of care for which CHAMPUS benefits can be provided.

(14) CT scanning--(i) Approved CT scan services. Benefits may be extended for medically necessary CT scans of the head or other anatomical regions of the body when all of the following conditions are met:

(A) The patient is referred for the diagnostic procedure by a physician.

(B) The CT scan procedure is consistent with the preliminary diagnosis or symptoms.

(C) Other noninvasive and less costly means of diagnosis have been attempted or are not appropriate.

(D) The CT scan equipment is licensed or registered by the appropriate state agency responsible for licensing or registering medical equipment that emits ionizing radiation.

- (E) The CT scan equipment is operated under the general supervision and direction of a physician.
- (F) The results of the CT scan diagnostic procedure are interpreted by a physician.
- (ii) Review guidelines and criteria. The Director, OCHAMPUS, or a designee, will issue specific guidelines and criteria for CHAMPUS coverage of medically necessary head and body part CT scans.

(15) Morbid obesity. The TRICARE morbid obesity benefit is limited to those bariatric surgical procedures for which the safety and efficacy has been proven comparable or superior to conventional therapies and is consistent with the generally accepted norms for medical practice in the United States medical community. (See the definition of reliable evidence in Sec. 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

(i) Conditions for coverage.

(A) Payment for bariatric surgical procedures is determined by the requirements specified in paragraph (g)(15) of this section, and as defined in Sec. 199.2(b) of this part.

(B) Covered bariatric surgical procedures are payable only when the patient has completed growth (18 years of age or documentation of completion of bone growth) and has met one of the following selection criteria:

(1) The patient has a BMI that is equal to or exceeds 40 kg/m² and has previously been unsuccessful with medical treatment for obesity.

(2) The patient has a BMI of 35 to 39.9 kg/m², has at least one high-risk co-morbid condition associated with morbid obesity, and has previously been unsuccessful with medical treatment for obesity.

NOTE: The Director, TMA, shall issue guidelines for review of the specific high-risk co-morbid conditions, exacerbated or caused by obesity based on the Reliable Evidence Standard as defined in Sec. 199.2 of this part.

(ii) Treatment of complications.

(A) Payment may be extended for repeat bariatric surgery when medically necessary to correct or treat complications from the initial covered bariatric surgery (a takedown). For instance, the surgeon in many cases will do a gastric bypass or gastroplasty to help the patient avoid regaining the weight that was lost. In this situation, payment is authorized even though the patient's condition technically may not meet the definition of morbid obesity because of the weight that was already lost following the initial surgery.

(B) Payment is authorized for otherwise covered medical services and supplies directly related to complications of obesity when such services and supplies are an integral and necessary part of the course of treatment that was aggravated by the obesity.

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(iii) Exclusions. CHAMPUS payment may not be extended for weight control services, weight control/loss programs, dietary regimens and supplements, appetite suppressants and other medications; food or food supplements, exercise and exercise programs, or other programs and equipment that are primarily intended to control weight or for the purpose of weight reduction, regardless of the existence of co-morbid conditions.

(16) Maternity care.(i) Benefit. The CHAMPUS Basic Program may share the cost of medically necessary services and supplies associated with maternity care which are not otherwise excluded by this part.

(ii) Cost-share. Maternity care cost-share shall be determined as follows:

(A) Inpatient cost-share formula applies to maternity care ending in childbirth in, or on the way to, a hospital inpatient childbirth unit, and for maternity care ending in a non-birth outcome not otherwise excluded by this part.

(B) Ambulatory surgery cost-share formula applies to maternity care ending in childbirth in, or on the way to, a birthing center to which the beneficiary is admitted and from which the beneficiary has received prenatal care, or a hospital-based outpatient birthing room.

(C) Outpatient cost-share formula applies to maternity care which terminates in a planned childbirth at home.

(D) Otherwise covered medical services and supplies directly related to "Complications of pregnancy," as defined in Sec. 199.2 of this part, will be cost-shared on the same basis as the related maternity care for a period not to exceed 42 days following termination of the pregnancy and thereafter cost-shared on the basis of the inpatient or outpatient status of the beneficiary when medically necessary services and supplies are received.

(17) Biofeedback Therapy. Biofeedback therapy is a technique by which a person is taught to exercise control over a physiologic process occurring within the body. By using modern biomedical instruments the patient learns how a specific physiologic system within his body operates and how to modify the performance of this particular system.

(i) Benefits Provided. CHAMPUS benefits are payable for services and supplies in connection with electrothermal, electromyograph and electrodermal biofeedback therapy when there is documentation that the patient has undergone an appropriate medical evaluation, that their present condition is not responding to or no longer responds to other forms of conventional treatment, and only when provided as treatment for the following conditions:

(A) Adjunctive treatment for Raynaud's Syndrome.

(B) Adjunctive treatment for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, or incapacitating muscle spasm or weakness.

(ii) Limitations. Payable benefits include initial intake evaluation. Treatment following the initial intake evaluation is limited to a maximum of 20 inpatient and outpatient biofeedback treatments per calendar year.

(iii) Exclusions. Benefits are excluded for biofeedback therapy for the treatment of ordinary muscle tension states or for psychosomatic conditions. Benefits are also excluded for the rental or purchase of biofeedback equipment.

(iv) Provider Requirements. A provider of biofeedback therapy must be a CHAMPUS-authorized provider. (Refer to Sec. 199.6, "Authorized Providers). If biofeedback treatment is provided by other than a physician, the patient must be referred by a physician.

(v) Implementation Guidelines. The Director of OCHAMPUS shall issue guidelines as are necessary to implement the provision of this paragraph.

(18) Cardiac rehabilitation. Cardiac rehabilitation is the process by which individuals are restored to their optimal physical, medical, and psychological status, after a cardiac event. Cardiac rehabilitation is often divided into three phases. Phase I begins during inpatient hospitalization and is managed by the patient's personal physician. Phase II is a medically supervised outpatient program which begins following discharge. Phase III is a lifetime maintenance program emphasizing continuation of physical fitness with periodic follow up. Each phase includes an exercise component, patient education, and risk factor modification. There may be considerable variation in program components, intensity, and duration.

(i) Benefits Provided. CHAMPUS benefits are available on an inpatient or outpatient basis for services and supplies provided in connection with a cardiac rehabilitation program when ordered by a physician and provided as treatment for patients who have experienced the following cardiac events within the preceding twelve (12) months:

- (A) Myocardial Infarction.
- (B) Coronary Artery Bypass Graft.
- (C) Coronary Angioplasty.
- (D) Percutaneous Transluminal Coronary Angioplasty
- (E) Chronic Stable Angina (see limitations below).
- (F) Heart valve surgery.
- (G) Heart or Heart-lung Transplantation.

(ii) Limitations. Payable benefits include separate allowance for the initial evaluation and testing. Outpatient treatment following the initial intake evaluation and testing is limited to a maximum of thirty-six (36) sessions per cardiac event, usually provided 3 sessions per week for twelve (12) weeks. Patients diagnosed with chronic stable angina are limited to one treatment episode (36 sessions) in a calendar year.

(iii) Exclusions. Phase III cardiac rehabilitation lifetime maintenance programs performed at home or in medically unsupervised settings are not covered.

(iv) Providers. A provider of cardiac rehabilitation services must be a TRICARE authorized hospital (see Sec. 199.6 (b)(4)(i)) or a freestanding cardiac rehabilitation facility that meets the

requirements of Sec. 199.6 (f). All cardiac rehabilitation services must be ordered by a physician.

(v) Payment. Payment for outpatient treatment will be based on an all inclusive allowable charge per session. Inpatient treatment will be paid based upon the reimbursement system in place for the hospital where the services are rendered.

(vi) Implementation Guidelines. The Director of OCHAMPUS shall issue guidelines as are necessary to implement the provisions of this paragraph.

(19) Hospice care. Hospice care is a program which provides an integrated set of services and supplies designed to care for the terminally ill. This type of care emphasizes palliative care and supportive services, such as pain control and home care, rather than cure-oriented services provided in institutions that are otherwise the primary focus under CHAMPUS. The benefit provides coverage for a humane and sensible approach to care during the last days of life for some terminally ill patients.

(i) Benefit coverage. CHAMPUS beneficiaries who are terminally ill (that is, a life expectancy of six months or less if the disease runs its normal course) will be eligible for the following services and supplies in lieu of most other CHAMPUS benefits:

(A) Physician services.

(B) Nursing care provided by or under the supervision of a registered professional nurse.

(C) Medical social services provided by a social worker who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education, and who is working under the direction of a physician. Medical social services include, but are not limited to the following:

(1) Assessment of social and emotional factors related to the beneficiary's illness, need for care, response to treatment, and adjustment to care.

(2) Assessment of the relationship of the beneficiary's medical and nursing requirements to the individual's home situation, financial resources, and availability of community resources.

(3) Appropriate action to obtain available community resources to assist in resolving the beneficiary's problem.

(4) Counseling services that are required by the beneficiary.

(D) Counseling services provided to the terminally ill individual and the family member or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other care-giver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death. Bereavement counseling, which consists of counseling services provided to the individual's family after the individual's death, is a required hospice service but it is not reimbursable.

(E) Home health aide services furnished by qualified aides and homemaker services. Home health aides may provide personal care services. Aides also may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient. Examples of such services are changing the bed or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in personal care, maintenance of a safe and healthy environment, and services to enable the individual to carry out the plan of care. Qualifications for home health aides can be found in 42 CFR 484.36.

(F) Medical appliances and supplies, including drugs and biologicals. Only drugs that are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment, as well as other self-help and personal comfort items related to the palliation or management of the patient's condition while he or she is under hospice care. Equipment is provided by the hospice for use in the beneficiary's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care. Medical appliances and supplies are included within the hospice all-inclusive rates.

(G) Physical therapy, occupational therapy and speech-language pathology services provided for purposes of symptom control or to enable the individual to maintain activities of daily living and basic functional skills.

(H) Short-term inpatient care provided in a Medicare participating hospice inpatient unit, or a Medicare participating hospital, skilled nursing facility (SNF) or, in the case of respite care, a Medicaid-certified nursing facility that additionally meets the special hospice standards regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management. Inpatient care may also be furnished to provide respite for the individual's family or other persons caring for the individual at home. Respite care is the only type of inpatient care that may be provided in a Medicaid-certified nursing facility. The limitations on custodial care and personal comfort items applicable to other CHAMPUS services are not applicable to hospice care.

(ii) Core services. The hospice must ensure that substantially all core services are routinely provided directly by hospice employees; i.e., physician services, nursing care, medical social services, and counseling for individuals and care givers. Refer to paragraphs (e)(19)(i)(A), (e)(19)(i)(B), (e)(19)(i)(C), and (e)(19)(i)(D) of this section.

(iii) Non-core services. While non-core services (i.e., home health aide services, medical appliances and supplies, drugs and biologicals, physical therapy, occupational therapy, speech-language pathology and short-term inpatient care) may be provided under arrangements with other agencies or organizations, the hospice must maintain professional management of the patient at all times and in all settings. Refer to paragraphs (e)(19)(i)(E), (e)(19)(i)(F), (e)(19)(i)(G), and (e)(19)(i)(H) of this section.

(iv) Availability of services. The hospice must make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis. All other covered services must be made available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of

the terminal illness and related condition. These services must be provided in a manner consistent with accepted standards of practice.

(v) Periods of care. Hospice care is divided into distinct periods of care. The periods of care that may be elected by the terminally ill CHAMPUS beneficiary shall be as the Director, TRICARE determines to be appropriate, but shall not be less than those offered under Medicare's Hospice Program.

(vi) Conditions for coverage. The CHAMPUS beneficiary must meet the following conditions/criteria in order to be eligible for the hospice benefits and services referenced in paragraph (e)(19)(i) of this section.

(A) There must be written certification in the medical record that the CHAMPUS beneficiary is terminally ill with a life expectancy of six months or less if the terminal illness runs its normal course.

(1) Timing of certification. The hospice must obtain written certification of terminal illness for each of the election periods described in paragraph (e)(19)(vi)(B) of this section, even if a single election continues in effect for two, three or four periods.

(i) Basic requirement. Except as provided in paragraph (e)(19)(vi)(A)(1)(ii) of this section the hospice must obtain the written certification no later than two calendar days after the period begins.

(ii) Exception. For the initial 90-day period, if the hospice cannot obtain the written certifications within two calendar days, it must obtain oral certifications within two calendar days, and written certifications no later than eight calendar days after the period begins.

(2) Sources of certification. Physician certification is required for both initial and subsequent election periods.

(i) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (e)(19)(vi)(A)(1)(ii) of this section) from:

(A) The individual's attending physician if the individual has an attending physician; and

(B) The medical director of the hospice or the physician member of the hospice interdisciplinary group.

(ii) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (e)(19)(vi)(A)(2)(i)(B) of this section.

(B) The terminally ill beneficiary must elect to receive hospice care for each specified period of time; i.e., the two 90-day periods, a subsequent 30-day period, and a final period of unlimited duration. If the individual is found to be mentally incompetent, his or her representative may file the election statement. Representative means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is found to be mentally incompetent.

- (1) The episodes of care must be used consecutively; i.e., the two 90-day periods first, then the 30-day period, followed by the final period. The periods of care may be elected separately at different times.
- (2) The initial election will continue through subsequent election periods without a break in care as long as the individual remains in the care of the hospice and does not revoke the election.
- (3) The effective date of the election may begin on the first day of hospice care or any subsequent day of care, but the effective date cannot be made prior to the date that the election was made.
- (4) The beneficiary or representative may revoke a hospice election at any time, but in doing so, the remaining days of that particular election period are forfeited and standard CHAMPUS coverage resumes. To revoke the hospice benefit, the beneficiary or representative must file a signed statement of revocation with the hospice. The statement must provide the date that the revocation is to be effective. An individual or representative may not designate an effective date earlier than the date that the revocation is made.
- (5) If an election of hospice benefits has been revoked, the individual, or his or her representative may at any time file a hospice election for any period of time still available to the individual, in accordance with Sec. 199.4(e)(19)(vi)(B).
- (6) A CHAMPUS beneficiary may change, once in each election period, the designation of the particular hospice from which he or she elects to receive hospice care. To change the designation of hospice programs the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:
 - (i) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.
 - (ii) The date the change is to be effective.
- (7) Each hospice will design and print its own election statement to include the following information:
 - (i) Identification of the particular hospice that will provide care to the individual.
 - (ii) The individual's or representative's acknowledgment that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.
 - (iii) The individual's or representative's acknowledgment that he or she understands that certain other CHAMPUS services are waived by the election.
 - (iv) The effective date of the election.
 - (v) The signature of the individual or representative, and the date signed.

(8) The hospice must notify the CHAMPUS contractor of the initiation, change or revocation of any election.

(C) The beneficiary must waive all rights to other CHAMPUS payments for the duration of the election period for:

(1) Care provided by any hospice program other than the elected hospice unless provided under arrangements made by the elected hospice; and

(2) Other CHAMPUS basic program services/benefits related to the treatment of the terminal illness for which hospice care was elected, or to a related condition, or that are equivalent to hospice care, except for services provided by:

(i) The designated hospice;

(ii) Another hospice under arrangement made by the designated hospice; or

(iii) An attending physician who is not employed by or under contract with the hospice program.

(3) Basic CHAMPUS coverage will be reinstated upon revocation of the hospice election.

(D) A written plan of care must be established by a member of the basic interdisciplinary group assessing the patient's needs. This group must have at least one physician, one registered professional nurse, one social worker, and one pastoral or other counselor.

(1) In establishing the initial plan of care the member of the basic interdisciplinary group who assesses the patient's needs must meet or call at least one other group member before writing the initial plan of care.

(2) At least one of the persons involved in developing the initial plan must be a nurse or physician.

(3) The plan must be established on the same day as the assessment if the day of assessment is to be a covered day of hospice care.

(4) The other two members of the basic interdisciplinary group--the attending physician and the medical director or physician designee--must review the initial plan of care and provide their input to the process of establishing the plan of care within two calendar days following the day of assessment. A meeting of group members is not required within this 2-day period. Input may be provided by telephone.

(5) Hospice services must be consistent with the plan of care for coverage to be extended.

(6) The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, medical director or physician designee and interdisciplinary group. These reviews must be documented in the medical records.

(7) The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

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(8) The plan must include an assessment of the individual's needs and identification of the services, including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

(E) Complete medical records and all supporting documentation must be submitted to the CHAMPUS contractor within 30 days of the date of its request. If records are not received within the designated time frame, authorization of the hospice benefit will be denied and any prior payments made will be recouped. A denial issued for this reason is not an initial determination under Sec. 199.10, and is not appealable.

(vii) Appeal rights under hospice benefit. A beneficiary or provider is entitled to appeal rights for cases involving a denial of benefits in accordance with the provisions of this part and Sec. 199.10.

(20) (Reserved)

(21) Home health services. Home health services are covered when furnished by, or under arrangement with, a home health agency (HHA) that participates in the TRICARE program, and provides care on a visiting basis in the beneficiary's home. Covered HHA services are the same as those provided under Medicare under section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) and 42 CFR part 409, subpart E.

(i) Benefit coverage. Coverage will be extended for the following home health services subject to the conditions of coverage prescribed in paragraph (e)(21)(ii) of this section:

(A) Part-time or intermittent skilled nursing care furnished by a registered nurse or a licensed practical (vocational) nurse under the supervision of a registered nurse;

(B) Physical therapy, speech-language pathology, and occupational therapy;

(C) Medical social services under the direction of a physician;

(D) Part-time or intermittent services of a home health aide who has successfully completed a state-established or other training program that meets the requirements of 42 CFR Part 484;

(E) Medical supplies, a covered osteoporosis drug (as defined in the Social Security Act 1861(kk), but excluding other drugs and biologicals) and durable medical equipment;

(F) Medical services provided by an interim or resident-in-training of a hospital, under an approved teaching program of the hospital in the case of an HHA that is affiliated or under common control of a hospital; and

(G) Services at hospitals, SNFs or rehabilitation centers when they involve equipment too cumbersome to bring to the home but not including transportation of the individual in connection with any such item or service.

(ii) Conditions for Coverage. The following conditions/criteria must be met in order to be eligible for the HHA benefits and services referenced in paragraph (e)(21)(i) of this section:

- (A) The person for whom the services are provided is an eligible TRICARE beneficiary.
- (B) The HHA that is providing the services to the beneficiary has in effect a valid agreement to participate in the TRICARE program.
- (C) Physician certifies the need for home health services because the beneficiary is homebound.
- (D) The services are provided under a plan of care established and approved by a physician.
- (1) The plan of care must contain all pertinent diagnoses, including the patient's mental status, the types of services, supplies, and equipment required, the frequency of visits to be made, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, all medications and treatments, safety measures to protect against injury, instructions for timely discharge or referral, and any additional items the HHA or physician chooses to include.
- (2) The orders on the plan of care must specify the type of services to be provided to the beneficiary, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services.
- (E) The beneficiary must need skilled nursing care on an intermittent basis or physical therapy or speech-language pathology services, or have continued need for occupational therapy after the need for skilled nursing care, physical therapy, or speech-language pathology services has ceased.
- (F) The beneficiary must receive, and an HHA must provide, a patient-specific, comprehensive assessment that:
- (1) Accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes;
- (2) Identifies the beneficiary's continuing need for home care and meets the beneficiary's medical, nursing, rehabilitative, social, and discharge planning needs.
- (3) Incorporates the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Director, TRICARE Management Activity.
- (G) TRICARE is the appropriate payer.
- (H) The services for which payment is claimed are not otherwise excluded from payment.
- (I) Any other conditions of coverage/participation that may be required under Medicare's HHA benefit; i.e., coverage guidelines as prescribed under Sections 1861(o) and 1891 of the Social Security Act (42 U.S.C. 1395x(o) and 1395bbb), 42 CFR Part 409, Subpart E and 42 CFR Part 484.

(22) Pulmonary rehabilitation. TRICARE benefits are payable for beneficiaries whose conditions are considered appropriate for pulmonary rehabilitation according to guidelines adopted by the Executive Director, TMA, or a designee.

(23) A speech generating device (SGD) as defined in Sec. 199.2 of this part is covered as a voice prosthesis. The prosthesis provisions found in paragraph (d)(3)(vii) of this section apply.

(24) A hearing aid, but only for a dependent of a member of the uniformed services on active duty and only if the dependent has a profound hearing loss as defined in Sec. 199.2 of this part. Medically necessary and appropriate services and supplies, including hearing examinations, required in connection with this hearing aid benefit are covered.

(25) Rehabilitation therapy as defined in Sec. 199.2 of this part to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient when prescribed by a physician. The rehabilitation therapy must be medically necessary and appropriate medical care, rendered by an authorized provider, necessary to the establishment of a safe and effective maintenance program in connection with a specific medical condition, and must not be custodial care or otherwise excluded from coverage.

(26) National Institutes of Health clinical trials. By law, the general prohibition against CHAMPUS cost-sharing of unproven drugs, devices, and medical treatments or procedures may be waived in connection with clinical trials sponsored or approved by the National Institutes of Health National Cancer Institute if it is determined that such a waiver will promote access by covered beneficiaries to promising new treatments and contribute to the development of such treatments. A waiver shall only be exercised as authorized under this paragraph.

(i) Demonstration waiver. A waiver may be granted through a demonstration project established in accordance with Sec. 199.1(o) of this part.

(ii) Continuous waiver.(A) General. As a result of a demonstration project under which a waiver has been granted in connection with a National Institutes of Health National Cancer Institute clinical trial, a determination may be made that it is in the best interest of the government and CHAMPUS beneficiaries to end the demonstration and continue to provide a waiver for CHAMPUS cost-sharing of the specific clinical trial. Only those specified clinical trials identified under paragraph (e)(26)(ii) of this section have been authorized a continuous waiver under CHAMPUS.

(B) National Cancer Institute (NCI) sponsored cancer prevention, screening, and early detection clinical trials. A continuous waiver under paragraph (e)(26) of this regulation has been granted for CHAMPUS cost-sharing for those CHAMPUS-eligible patients selected to participate in NCI sponsored Phase II and Phase III studies for the prevention and treatment of cancer. Additionally, Phase I studies may be approved on a case by case basis when the requirements below are met.

(1) TRICARE will cost-share all medical care and testing required to determine eligibility for an NCI-sponsored trial, including the evaluation for eligibility at the institution conducting the NCI-sponsored study. TRICARE will cost-share all medical care required as a result of participation in NCI-sponsored studies. This includes purchasing and administering

all approved chemotherapy agents (except for NCI-funded investigational drugs), all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program if the following conditions are met:

(i) The provider seeking treatment for a CHAMPUS-eligible patient in an NCI approved protocol has obtained pre-authorization for the proposed treatment before initial evaluation; and,

(ii) Such treatments are NCI sponsored Phase I, Phase II or Phase III protocols; and

(iii) The patient continues to meet entry criteria for said protocol; and,

(iv) The institutional and individual providers are CHAMPUS authorized providers; and,

(v) The requirements for Phase I protocols in paragraph (e)(26)(ii)(B)(2) of this section are met:

(2) Requirements for Phase I protocols are:

(i) Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative; and,

(ii) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative; and,

(iii) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and,

(iv) The referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of paragraphs (e)(26)(ii)(B)(2)(i) through (iii) of this section.

(3) TRICARE will not provide reimbursement for care rendered in the National Institutes of Health Clinical Center or costs associated with non-treatment research activities associated with the clinical trials.

(4) Cost-shares and deductibles applicable to CHAMPUS will also apply under the NCI-sponsored clinical trials.

(5) The Director, TRICARE (or designee), shall issue procedures and guidelines establishing NCI-sponsorship of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under NCI-sponsored cancer clinical trials.

(27) TRICARE will cost share forensic examinations following a sexual assault or domestic violence. The forensic examination includes a history of the event and a complete physical and collection of forensic evidence, and medical and psychological follow-up care. The examination for sexual assault also includes, but is not limited to, a test kit to retrieve forensic evidence, testing for pregnancy, testing for sexually transmitted disease and HIV, and medical services and supplies for prevention of sexually transmitted diseases, HIV,

pregnancy, and counseling services.

(28) Preventive care. The following preventive services are covered:

(i) Cervical, breast, colon and prostate cancer screenings according to standards issued by the Director, TRICARE Management Activity, based on guidelines from the U.S. Department of Health and Human Services. The standards may establish a specific schedule that includes frequency, age specifications, and gender of the beneficiary, as appropriate.

(ii) Immunizations as recommended by the Centers for Disease Control and Prevention (CDC).

(iii) Well-child visits for children under 6 years of age as described in paragraph (c)(3)(xi) of this section.

(iv) Health promotion and disease prevention visits (which may include all of the services provided pursuant to Sec. 199.18(b)(2)) for beneficiaries 6 years of age or older may be provided in connection with immunizations and cancer screening examinations authorized by paragraphs (e)(28)(i) and (ii) of this section.

(29) Physical examinations. In addition to the health promotion and disease prevention visits authorized in paragraph (e)(28)(iv) of this section, the following physical examinations are specifically authorized:

(i) Physical examinations for dependents of Active Duty military personnel who are traveling outside the United States. The examination must be required because of an Active Duty member's assignment and the travel is being performed under orders issued by a Uniformed Service. Any immunizations required for a dependent of an Active Duty member to travel outside of the United States is covered as a preventive service under paragraph (e)(28) of this section.

(ii) Physical examinations for beneficiaries ages 5-11 that are required for school enrollment and that are provided on or after October 30, 2000.

(iii) Other types of physical examinations not listed above are excluded including routine, annual, or employment-requested physical examinations and routine screening procedures that are not part of medically necessary care or treatment or otherwise specifically authorized by statute.

(30) Smoking cessation program. The TRICARE smoking cessation program is a behavioral modification program to assist eligible beneficiaries who desire to quit smoking. The program consists of a pharmaceutical benefit; smoking cessation counseling; access to a toll-free quit line for non-medical assistance; and, access to print and internet web-based tobacco cessation materials.

(i) Availability. The TRICARE smoking cessation program is available to all TRICARE beneficiaries who reside in one of the 50 United States or the District of Columbia who are not eligible for Medicare benefits authorized under Title XVIII of the Social Security Act. In addition, pursuant to Sec. 199.17, if authorized by the Assistant Secretary of Defense (Health Affairs), the TRICARE smoking cessation program may be implemented in whole or in part

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in areas outside the 50 states and the District of Columbia for active duty members and their dependents who are enrolled in TRICARE Prime (overseas Prime beneficiaries). In such cases, the Assistant Secretary of Defense (Health Affairs) may also authorize modifications to the TRICARE smoking cessation program rules and procedures as may be appropriate to the overseas area involved. Notice of the use of this authority, not otherwise mentioned in this paragraph (e)(30), shall be published in the **Federal Register**.

(ii) Benefits. There is no requirement for an eligible beneficiary to be diagnosed with a smoking related illness to access benefits under this program. The specific benefits available under the TRICARE smoking cessation program are:

(A) Pharmaceutical agents. Products available under this program are identified through the DoD Pharmacy and Therapeutics Committee, consistent with the DoD Uniform Formulary in Sec. 199.21. Smoking cessation pharmaceutical agents, including FDA-approved over-the-counter (OTC) pharmaceutical agents, are available through the TRICARE Mail Order Pharmacy (TMOP) or the MTF at no cost to the beneficiary. Smoking cessation pharmaceuticals through the TRICARE program will not be available at any retail pharmacies. A prescription from a TRICARE-authorized provider is required to obtain any pharmaceutical agent used for smoking cessation, including OTC agents. For overseas Prime beneficiaries, pharmaceutical agents may be provided either in the MTF or through the TMOP where such facility or service is available.

(B) Face-to-face smoking cessation counseling. Both individual and group smoking cessation counseling are covered. The number and mix of face-to-face counseling sessions covered under this program shall be determined by the Director, TMA; however, shall not exceed the limits established in paragraph (e)(30)(iii) of this section. A TRICARE-authorized provider listed in Sec. 199.6 must render all counseling sessions.

(C) Toll-free quit line. Access to a non-medical toll-free quit line 7 days a week, 24 hours a day will be available. The quit line will be staffed with smoking cessation counselors trained to assess a beneficiary's readiness to quit, identify barriers to quitting, and provide specific suggested actions and motivational counseling to enhance the chances of a successful quit attempt. When appropriate, quit line counselors will refer beneficiaries to a TRICARE-authorized provider for medical intervention. The quit line may, at the discretion of the Director, TMA, include the opportunity for the beneficiary to request individual follow-up contact initiated by quit line personnel; however, the beneficiary is not required to participate in the quit line initiated follow-up. Printed educational materials on the effects of tobacco use will be provided to the beneficiary upon request. This benefit may be made available to overseas Prime beneficiaries should the ASD(HA) exercise his authority to do so and provide appropriate notice in the **Federal Register**.

(D) Web-based resources. Downloadable educational materials on the effects of tobacco use will be available through the internet or other electronic media. This service may be made available to overseas Prime beneficiaries in all locations where web based resources are available. There shall be no requirement to create web based resources in any geographic area in order to make this service available.

(iii) Limitations of smoking cessation program. Eligible beneficiaries are entitled to two quit attempts per year (consecutive 12 month period). A third quit attempt may be covered per year with physician justification and pre-authorization. A quit attempt is defined as up to

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eighteen face-to-face counseling sessions over a 120 consecutive day period and/or 120 days of pharmacologic intervention for the purpose of smoking cessation. Counseling and pharmacological treatment periods that overlap by at least 60-days are considered a single quit attempt.

(f) Beneficiary or sponsor liability--(1) General. As stated in the introductory paragraph to this section, the Basic Program is essentially a supplemental program to the Uniformed Services direct medical care system. To encourage use of the Uniformed Services direct medical care system wherever its facilities are available and appropriate, the Basic Program benefits are designed so that it is to the financial advantage of a CHAMPUS beneficiary or sponsor to use the direct medical care system. When medical care is received from civilian sources, a CHAMPUS beneficiary is responsible for payment of certain deductible and cost-sharing amounts in connection with otherwise covered services and supplies. By statute, this joint financial responsibility between the beneficiary or sponsor and CHAMPUS is more favorable for dependents of members than for other classes of beneficiaries.

(2) Dependents of members of the Uniformed Services. CHAMPUS beneficiary or sponsor liability set forth for dependents of members is as follows:

(i) Annual fiscal year deductible for outpatient services and supplies.

(A) For care rendered all eligible beneficiaries prior to April 1, 1991, or when the active duty sponsor's pay grade is E-4 or below, regardless of the date of care:

(1) Individual Deductible: Each beneficiary is liable for the first fifty dollars (\$50.00) of the CHAMPUS-determined allowable amount on claims for care provided in the same fiscal year.

(2) Family Deductible: The total deductible amount for all members of a family with the same sponsor during one fiscal year shall not exceed one hundred dollars (\$100.00).

(B) For care rendered on or after April 1, 1991, for all CHAMPUS beneficiaries except dependents of active duty sponsors in pay grades E-4 or below.

(1) Individual Deductible: Each beneficiary is liable for the first one hundred and fifty dollars (\$150.00) of the CHAMPUS-determined allowable amount on claims for care provided in the same fiscal year.

(2) Family Deductible: The total deductible amount for all members of a family with the same sponsor during one fiscal year shall not exceed three hundred dollars (\$300.00).

(C) CHAMPUS-approved Ambulatory Surgical Centers or Birthing Centers. No deductible shall be applied to allowable amounts for services or items rendered to active duty for authorized NATO dependents.

(D) Allowable Amount does not exceed Deductible Amount. If fiscal year allowable amounts for two or more beneficiary members of a family total less than \$100.00 (\$300.00 if paragraph (f) (2)(i)(B)(2) of this section applies), but more of the beneficiary members submit a claim for over \$50.00 (\$150.00 if paragraph (f)(2)(i)(B)(1) of this section applies), neither the

family nor the individual deductible will have been met and no CHAMPUS benefits are payable.

(E) For any family the outpatient deductible amounts will be applied sequentially as the CHAMPUS claims are processed.

(F) If the fiscal year outpatient deductible under either paragraphs (f)(2)(i)(A) or (f)(2)(i)(B) of this section has been met by a beneficiary or a family through the submission of a claim or claims to a CHAMPUS fiscal intermediary in another geographic location from the location where a current claim is being submitted, the beneficiary or sponsor must obtain a deductible certificate from the CHAMPUS fiscal intermediary where the applicable beneficiary or family fiscal year deductible was met. Such deductible certificate must be attached to the current claim being submitted for benefits. Failure to obtain a deductible certificate under such circumstances will result in a second beneficiary or family fiscal year deductible being applied. However, this second deductible may be reimbursed once appropriate documentation, as described in paragraph (f)(2)(i)(F) of this section, is supplied to the CHAMPUS fiscal intermediary applying the second deductible.

(G) Notwithstanding the dates specified in paragraphs (f)(2)(i)(A) and (f)(2)(i)(B) of this section in the case of dependents of active duty members of rank E-5 or above with Persian Gulf Conflict service, dependents of service members who were killed in the Gulf, or who died subsequent to Gulf service, and of members who retired prior to October 1, 1991, after having served in the Gulf War, the deductible shall be the amount specified in paragraph (f)(2)(i)(A) of this section for care rendered prior to October 1, 1991, and the amount specified in paragraph (f)(2)(i)(B) of this section for care rendered on or after October 1, 1991.

(H) The Director, TRICARE Management Activity, may waive the annual individual or family fiscal year deductible for dependents of a Reserve Component member who is called or ordered to active duty for a period of more than 30 days or a National Guard member who is called or ordered to fulltime federal National Guard duty for a period of more than 30 days in support of a contingency operation (as defined in 10 U.S.C. 101(a)(13)). For purposes of this paragraph, a dependent is a lawful husband or wife of the member and a child is defined in paragraphs (b)(2)(ii)(A) through (F) and (b)(2)(ii)(H)(1), (2), and (4) of Sec 199.3.

(ii) Inpatient cost-sharing. Dependents of members of the Uniformed Services are responsible for the payment of the first \$25 of the allowable institutional costs incurred with each covered inpatient admission to a hospital or other authorized institutional provider (refer to Sec. 199.6 of the part), or the amount the beneficiary or sponsor would have been charged had the inpatient care been provided in a Uniformed Service hospital, whichever is greater.

NOTE: The Secretary of Defense (after consulting with the Secretary of Health and Human Services and the Secretary of Transportation) prescribes the fair charges for inpatient hospital care provided through Uniformed Services medical facilities. This determination is made each fiscal year.

(A) Inpatient cost-sharing payable with each separate inpatient admission. A separate cost-sharing amount (as described in paragraph (f)(2) of this section) is payable for each inpatient admission to a hospital or other authorized institution, regardless of the purpose of the admission (such as medical or surgical), regardless of the number of times the

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beneficiary is admitted, and regardless of whether or not the inpatient admissions are for the same or related conditions; except that successive inpatient admissions shall be deemed one inpatient confinement for the purpose of computing the inpatient cost-share payable, provided not more than 60 days have elapsed between the successive admissions. However, notwithstanding this provision, all admissions related to a single maternity episode shall be considered one confinement, regardless of the number of days between admissions (refer to paragraph (b) of this section).

(B) Multiple family inpatient admissions. A separate cost-sharing amount is payable for each inpatient admission, regardless of whether or not two or more beneficiary members of a family are admitted at the same time or from the same cause (such as an accident). A separate beneficiary inpatient cost-sharing amount must be applied for each separate admission on each beneficiary member of the family.

(C) Newborn patient in his or her own right. When a newborn infant remains as an inpatient in his or her own right (usually after the mother is discharged), the newborn child becomes the beneficiary and patient and the extended inpatient stay becomes a separate inpatient admission. In such a situation, a new, separate inpatient cost-sharing amount is applied. If a multiple birth is involved (such as twins or triplets) and two or more newborn infants become patients in their own right, a separate inpatient cost-sharing amount must be applied to the inpatient stay for each newborn child who has remained as an inpatient in his or her own right.

(D) Inpatient cost-sharing for mental health services. For care provided on or after October 1, 1995, the inpatient cost-sharing for mental health services is \$20 per day for each day of the inpatient admission. This \$20 per day cost sharing amount applies to admissions to any hospital for mental health services, any residential treatment facility, any substance abuse rehabilitation facility, and any partial hospitalization program providing mental health or substance use disorder rehabilitation services.

(iii) Outpatient cost-sharing. Dependents of members of the Uniformed Services are responsible for payment of 20 percent of the CHAMPUS-determined allowable cost or charge beyond the annual fiscal year deductible amount (as described in paragraph (f)(2)(i) of this section) for otherwise covered services or supplies provided on an outpatient basis by authorized providers.

(iv) Ambulatory surgery. Notwithstanding the above provisions pertaining to outpatient cost-sharing, dependents of members of the Uniformed Services are responsible for payment of \$25 for surgical care that is authorized and received while in an outpatient status and that has been designated in guidelines issued by the Director, OCHAMPUS, or a designee.

(v) Psychiatric partial hospitalization services. Institutional and professional services provided under the psychiatric partial hospitalization program authorized by paragraph (b)(10) of this section shall be cost shared as inpatient services.

(vi) Transitional Assistance Management Program (TAMP). Members of the Armed Forces (and their family members) who are eligible for TAMP under paragraph 199.3(e) of this Part are subject to the same beneficiary or sponsor liability as family members of members of the uniformed services described in this paragraph (f)(2).

(3) Former members and dependents of former members. CHAMPUS beneficiary liability set forth for former members and dependents of former members is as follows:

(i) Annual fiscal year deductible for outpatient services or supplies. The annual fiscal year deductible for otherwise covered outpatient services or supplies provided former members and dependents of former members is the same as the annual fiscal year outpatient deductible applicable to dependents of active duty members of rank E-5 or above (refer to paragraph (f)(2)(i)(A) or (B) of this section).

(ii) Inpatient cost-sharing. Cost-sharing amounts for inpatient services shall be as follows:

(A) Services subject to the CHAMPUS DRG-based payment system. The cost-share shall be the lesser of: an amount calculated by multiplying a per diem amount by the total number of days in the hospital stay except the day of discharge; or 25 percent of the hospital's billed charges. The per diem amount shall be calculated so that, in the aggregate, the total cost-sharing amounts for these beneficiaries is equivalent to 25 percent of the CHAMPUS-determined allowable costs for covered services or supplies provided on an inpatient basis by authorized providers. The per diem amount shall be published annually by OCHAMPUS.

(B) Services subject to the CHAMPUS mental health per diem payment system. The cost-share is dependent upon whether the hospital is paid a hospital-specific per diem or a regional per diem under the provisions of Sec. 199.14(a)(2). With respect to care paid for on the basis of a hospital specific per diem, the cost-share shall be 25% of the hospital-specific per diem amount. For care paid for on the basis of a regional per diem, the cost share shall be the lower of a fixed daily amount or 25% of the hospital's billed charges. The fixed daily amount shall be 25 percent of the per diem adjusted so that total beneficiary cost shares will equal 25 percent of total payments under the mental health per diem payment system. These fixed daily amount shall be updated annually and published in the Federal Register along with the per diems published pursuant to Sec. 199.14(a)(2)(iv)(B).

(C) Other services. For services exempt from the CHAMPUS DRG-based payment system and the CHAMPUS mental health per diem payment system and services provided by institutions other than hospitals, the cost-share shall be 25% of the CHAMPUS-determined allowable charges.

(iii) Outpatient cost-sharing. Former members and dependents of former members are responsible for payment of 25 percent of the CHAMPUS-determined allowable costs or charges beyond the annual fiscal year deductible amount (as described in paragraph (f)(2)(i) of this section) for otherwise covered services or supplies provided on an outpatient basis by authorized providers.

(iv) Psychiatric partial hospitalization services. Institutional and professional services provided under the psychiatric partial hospitalization program authorized by paragraph (b)(10) of this section shall be cost shared as inpatient services.

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(4) Former spouses. CHAMPUS beneficiary liability for former spouses eligible under the provisions set forth in Sec. 199.3 of this part is as follows:

(i) Annual fiscal year deductible for outpatient services or supplies. An eligible former spouse is responsible for the payment of the first \$150.00 of the CHAMPUS-determined reasonable costs or charges for otherwise covered outpatient services or supplies provided in any one fiscal year. (Except for services received prior to April 1, 1991, the deductible amount is \$50.00). The former spouse cannot contribute to, nor benefit from, any family deductible of the member or former member to whom the former spouse was married or of any CHAMPUS-eligible children.

(ii) Inpatient cost-sharing. Eligible former spouses are responsible for payment of cost-sharing amounts the same as those required for former members and dependents of former members.

(iii) Outpatient cost-sharing. Eligible former spouses are responsible for payment of 25 percent of the CHAMPUS-determined reasonable costs or charges beyond the annual fiscal year deductible amount for otherwise covered services or supplies provided on an outpatient basis by authorized providers.

(5) Cost-Sharing under the Military-Civilian Health Services Partnership Program. Cost-sharing is dependent upon the type of partnership program entered into, whether external or internal. (See paragraph (p) of Sec. 199.1, for general requirements of the Military-Civilian Health Services Partnership Program.)

(i) External Partnership Agreement. Authorized costs associated with the use of the civilian facility will be financed through CHAMPUS under the normal cost-sharing and reimbursement procedures applicable under CHAMPUS.

(ii) Internal Partnership Agreement. Beneficiary cost-sharing under internal agreements will be the same as charges prescribed for care in military treatment facilities.

(6)-(7) [Reserved]

(8) Cost-sharing for services provided under special discount arrangements--
 (i) General rule. With respect to services determined by the Director, OCHAMPUS (or designee) to be covered by Sec. 199.14(e), the Director, OCHAMPUS (or designee) has authority to establish, as an exception to the cost-sharing amount normally required pursuant to this section, a different cost-share amount that appropriately reflects the application of the statutory cost-share to the discount arrangement.

(ii) Specific applications. The following are examples of applications of the general rule; they are not all inclusive.

(A) In the case of services provided by individual health care professionals and other noninstitutional providers, the cost-share shall be the usual percentage of the CHAMPUS allowable charge determined under Sec. 199.14(e).

(B) In the case of services provided by institutional providers normally paid on the basis of a pre-set amount (such as DRG-based amount under Sec. 199.14(a)(1) or per-diem amount

under Sec. 199.14(a)(2)), if the discount rate is lower than the pre-set rate, the cost-share amount that would apply for a beneficiary other than an active duty dependent pursuant to the normal pre-set rate would be reduced by the same percentage by which the pre-set rate was reduced in setting the discount rate.

(9) Waiver of deductible amounts or cost-sharing not allowed--(i) General rule. Because deductible amounts and cost sharing are statutorily mandated, except when specifically authorized by law (as determined by the Director, OCHAMPUS), a provider may not waive or forgive beneficiary liability for annual deductible amounts or inpatient or outpatient cost sharing, as set forth in this section.

(ii) Exception for bad debts. This general rule is not violated in cases in which a provider has made all reasonable attempts to effect collection, without success, and determines in accordance with generally accepted fiscal management standards that the beneficiary liability in a particular case is an uncollectible bad debt.

(iii) Remedies for noncompliance. Potential remedies for noncompliance with this requirement include:

(A) A claim for services regarding which the provider has waived the beneficiary's liability may be disallowed in full, or, alternatively, the amount payable for such a claim may be reduced by the amount of the beneficiary liability waived.

(B) Repeated noncompliance with this requirement is a basis for exclusion of a provider.

(10) Catastrophic loss protection for basic program benefits. Fiscal year limits, or catastrophic caps, on the amounts beneficiaries are required to pay are established as follows:

(i) Dependents of active duty members. The maximum family liability is \$1,000 for deductibles and cost-shares based on allowable charges for Basic Program services and supplies received in a fiscal year.

(ii) All other beneficiaries. For all other categories of beneficiary families (including those eligible under CHAMPVA) the fiscal year cap is \$3,000.

(iii) Payment after cap is met. After a family has paid the maximum cost-share and deductible amounts (dependents of active duty members \$1,000 and all others \$3,000), for a fiscal year, CHAMPUS will pay allowable amounts for remaining covered services through the end of that fiscal year.

Note to paragraph (f)(10): Under the Defense Authorization Act for Fiscal Year 2001, the cap for beneficiaries other than dependents of active duty members was reduced from \$7,500 to \$3,000 effective October 30, 2000. Prior to this, the Defense Authorization Act for Fiscal Year 1993 reduced this cap from \$10,000 to \$7,500 on October 1, 1992. The cap remains at \$1,000 for dependents of active duty members.

(11) Beneficiary or sponsor liability under the Pharmacy Benefits Program. Beneficiary or sponsor liability under the Pharmacy Benefits Program is addressed in Sec. 199.21.

(12) Elimination of cost-sharing for certain preventive services.(i) (i) Effective for dates of service on or after October 14, 2008, beneficiaries, subject to the limitation in paragraph (f)(12)(iii) of this section, shall not pay any cost-share for preventive services listed in paragraph (e)(28)(i) through (iv) of this section. The beneficiary shall not be required to pay any portion of the cost of these preventive services even if the beneficiary has not satisfied the deductible for that year.

(ii) Beneficiaries who paid a cost-share for preventive services listed in paragraph (e)(28)(i) through (iv) of this section on or after October 14, 2008, may request reimbursement until January 28, 2013 according to procedures established by the Director, TRICARE Management Activity.

(iii) This elimination of cost-sharing for preventive services does not apply to any beneficiary who is a Medicare-eligible beneficiary. For purposes of this section, the term "Medicare-eligible" beneficiary is defined in 10 U.S.C. 1111(b) and refers to a person eligible for Medicare Part A.

(iv) Appropriate copayments and deductibles will apply for all services not listed in paragraph (e)(28) of this section, whether considered preventive in nature or not.

(g) Exclusions and limitations. In addition to any definitions, requirements, conditions, or limitations enumerated and described in other sections of this part, the following specifically are excluded from the Basic Program:

(1) Not medically or psychologically necessary. Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness (including mental disorder) or injury, for the diagnosis and treatment of pregnancy or well-baby care except as provided in the following paragraph.

(2) Unnecessary diagnostic tests. X-ray, laboratory, and pathological services and machine diagnostic tests not related to a specific illness or injury or a definitive set of symptoms except for cancer screening mammography and cancer screening papanicolaou (PAP) tests provided under the terms and conditions contained in the guidelines adopted by the Director, OCHAMPUS.

(3) Institutional level of care. Services and supplies related to inpatient stays in hospitals or other authorized institutions above the appropriate level required to provide necessary medical care.

(4) Diagnostic admission. Services and supplies related to an inpatient admission primarily to perform diagnostic tests, examinations, and procedures that could have been and are performed routinely on an outpatient basis.

NOTE: If it is determined that the diagnostic x-ray, laboratory, and pathological services and machine tests performed during such admission were medically necessary and would have been covered if performed on an outpatient basis, CHAMPUS benefits may be extended for such diagnostic procedures only, but cost-sharing will be computed as if performed on an outpatient basis.

(5) Unnecessary postpartum inpatient stay, mother or newborn. Postpartum inpatient stay of a mother for purposes of staying with the newborn infant (usually primarily for the purpose of breast feeding the infant) when the infant (but not the mother) requires the extended stay; or continued inpatient stay of a newborn infant primarily for purposes of remaining with the mother when the mother (but not the newborn infant) requires extended postpartum inpatient stay.

(6) Therapeutic absences. Therapeutic absences from an inpatient facility, except when such absences are specifically included in a treatment plan approved by the Director, OCHAMPUS, or a designee. For cost-sharing provisions refer to Sec. 199.14, paragraph (f)(3).

(7) Custodial care. Custodial care as defined in Sec. 199.2.

(8) Domiciliary care. Domiciliary care as defined in Sec. 199.2.

(9) Rest or rest cures. Inpatient stays primarily for rest or rest cures.

(10) Amounts above allowable costs or charges. Costs of services and supplies to the extent amounts billed are over the CHAMPUS determined allowable cost or charge, as provided for in Sec. 199.14.

(11) No legal obligation to pay, no charge would be made. Services or supplies for which the beneficiary or sponsor has no legal obligation to pay; or for which no charge would be made if the beneficiary or sponsor was not eligible under CHAMPUS; or whenever CHAMPUS is a secondary payer for claims subject to the CHAMPUS DRG-based payment system, amounts, when combined with the primary payment, which would be in excess of charges (or the amount the provider is obligated to accept as payment in full, if it is less than the charges).

(12) Furnished without charge. Services or supplies furnished without charge.

(13) Furnished by local, state, or Federal Government. Services and supplies paid for, or eligible for payment, directly or indirectly by a local, state, or Federal Government, except as provided under CHAMPUS, or by government hospitals serving the general public, or medical care provided by a Uniformed Service medical care facility, or benefits provided under title XIX of the Social Security Act (Medicaid) (refer to Sec. 199.8 of this part).

(14) Study, grant, or research programs. Services and supplies provided as a part of or under a scientific or medical study, grant, or research program.

(15) Unproven drugs, devices, and medical treatments or procedures. By law, CHAMPUS can only cost-share medically necessary supplies and services. Any drug, device, or medical treatment or procedure, the safety and efficacy of which have not been established, as described in this paragraph (g)(15), is unproved and cannot be cost-shared by CHAMPUS except as authorized under paragraph 199.4(e)(26) of this part.

(i) A drug, device, or medical treatment or procedure is unproven:

(A) If the drug or device cannot be lawfully marketed without the approval or clearance of the United States Food and Drug Administration (FDA) and approval or clearance for

marketing has not been given at the time the drug or device is furnished to the patient.

NOTE: Although the use of drugs and medicines not approved by the FDA for commercial marketing, that is for use by humans, (even though permitted for testing on humans) is excluded from coverage as unproven, drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered by CHAMPUS as if FDA approved.

Certain cancer drugs, designated as Group C drugs (approved and distributed by the National Cancer Institute) and Treatment Investigational New Drugs (INDs), are not covered under CHAMPUS because they are not approved for commercial marketing by the FDA. However, medical care related to the use of Group C drugs and Treatment INDs can be cost-shared under CHAMPUS when the patient's medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice.

CHAMPUS will consider coverage of off-label uses of drugs and devices that meet the definition of Off-Label Use of a Drug or Device in Sec. 199.2(b). Approval for reimbursement of off-label uses requires review for medical necessity and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use of the drug or device is safe, effective, and in accordance with nationally accepted standards of practice in the medical community.

(B) If a medical device (as defined by 21 U.S.C. 321(h)) with an Investigational Device Exemption (IDE) approved by the Food and Drug Administration is categorized by the FDA as experimental/investigational (FDA Category A).

NOTE: CHAMPUS will consider for coverage a device with an FDA-approved IDE categorized by the FDA as non-experimental/investigational (FDA Category B) for CHAMPUS beneficiaries participating in FDA approved clinical trials. Coverage of any such Category B device is dependent on its meeting all other requirements of the laws and rules governing CHAMPUS and upon the beneficiary involved meeting the FDA-approved IDE study protocols.

(C) Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis. (See the definition of *reliable evidence* in Sec. 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)

(D) If reliable evidence shows that the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated doses, its toxicity, its safety, or its effectiveness as compared with the standard means of treatment or diagnosis (see the definition of reliable evidence in Sec. 199.2 for the procedures used in determining if a medical treatment or procedure is unproven).

(ii) CHAMPUS benefits for rare diseases are reviewed on a case-by-case basis by the Director, Office of CHAMPUS, or a designee. In reviewing the case, the Director, or a designee, may consult with any or all of the following sources to determine if the proposed therapy is considered safe and effective:

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- (A) Trials published in refereed medical literature.
- (B) Formal technology assessments.
- (C) National medical policy organization positions.
- (D) National professional associations.
- (E) National expert opinion organizations.
- (iii) Care excluded. This exclusion from benefits includes all services directly related to the unproven drug, device, or medical treatment or procedure. However, CHAMPUS may cover services or supplies when there is no logical or causal relationship between the unproven drug, device or medical treatment or procedure and the treatment at issue or where such a logical or causal relationship cannot be established with a sufficient degree of certainty. This CHAMPUS coverage is authorized in the following circumstances:
- (A) Treatment that is not related to the unproven drug, device or medical treatment or procedure; e.g., medically necessary in the absence of the unproven treatment.
- (B) Treatment which is necessary follow-up to the unproven drug, device or medical treatment or procedure but which might have been necessary in the absence of the unproven treatment.
- (16) Immediate family, household. Services or supplies provided or prescribed by a member of the beneficiary's immediate family, or a person living in the beneficiary's or sponsor's household.
- (17) Double coverage. Services and supplies that are (or are eligible to be) payable under another medical insurance or program, either private or governmental, such as coverage through employment or Medicare (refer to Sec. 199.8 of this part).
- (18) Nonavailability Statement required. Services and supplies provided under circumstances or in geographic locations requiring a Nonavailability Statement (DD Form 1251), when such a statement was not obtained.
- (19) Preauthorization required. Services or supplies which require preauthorization if preauthorization was not obtained. Services and supplies which were not provided according to the terms of the preauthorization. The Director, OCHAMPUS, or a designee, may grant an exception to the requirement for preauthorization if the services otherwise would be payable except for the failure to obtain preauthorization.
- (20) Psychoanalysis or psychotherapy, part of education. Psychoanalysis or psychotherapy provided to a beneficiary or any member of the immediate family that is credited towards earning a degree or furtherance of the education or training of a beneficiary or sponsor, regardless of diagnosis or symptoms that may be present.
- (21) Runaways. Inpatient stays primarily to control or detain a runaway child, whether or not admission is to an authorized institution.

(22) Services or supplies ordered by a court or other government agency. Services or supplies, including inpatient stays, directed or agreed to by a court or other governmental agency. However, those services and supplies (including inpatient stays) that otherwise are medically or psychologically necessary for the diagnosis or treatment of a covered condition and that otherwise meet all CHAMPUS requirements for coverage are not excluded.

(23) Work-related (occupational) disease or injury. Services and supplies required as a result of occupational disease or injury for which any benefits are payable under a worker's compensation or similar law, whether or not such benefits have been applied for or paid; except if benefits provided under such laws are exhausted.

(24) Cosmetic, reconstructive, or plastic surgery. Services and supplies in connection with cosmetic, reconstructive, or plastic surgery except as specifically provided in paragraph (e)(8) of this section.

(25) Surgery, psychological reasons. Surgery performed primarily for psychological reasons (such as psychogenic).

(26) Electrolysis.

(27) Dental care. Dental care or oral surgery, except as specifically provided in paragraph (e)(10) of this section.

(28) Obesity, weight reduction. Service and supplies related "solely" to obesity or weight reduction or weight control whether surgical or nonsurgical; wiring of the jaw or any procedure of similar purpose, regardless of the circumstances under which performed (except as provided in paragraph (e)(15) of this section).

(29) Transsexualism or such other conditions as gender dysphoria. Services and supplies related to transsexualism or such other conditions as gender dysphoria (including, but not limited, to intersex surgery, psychotherapy, and prescription drugs), except as specifically provided in paragraph (e)(7) of this section.

(30) Therapy or counseling for sexual dysfunctions or sexual inadequacies. Sex therapy, sexual advice, sexual counseling, sex behavior modification, psychotherapy for mental disorders involving sexual deviations (i.e., transvestic fetishism), or other similar services, and any supplies provided in connection with therapy for sexual dysfunctions or inadequacies.

(31) Corns, calluses, and toenails. Removal of corns or calluses or trimming of toenails and other routine podiatry services, except those required as a result of a diagnosed systemic medical disease affecting the lower limbs, such as severe diabetes.

(32) Dyslexia.

(33) Surgical sterilization, reversal. Surgery to reverse surgical sterilization procedures.

(34) Noncoital reproductive procedures including artificial insemination, in-vitro fertilization, gamete intrafallopian transfer and all other such reproductive technologies. Services and supplies related to artificial insemination (including semen donors and semen banks), in-vitro fertilization, gamete intrafallopian transfer and all other noncoital reproductive technologies.

(35) Nonprescription contraceptives.

(36) Tests to determine paternity or sex of a child. Diagnostic tests to establish paternity of a child; or tests to determine sex of an unborn child.

(37) Preventive care. Except as stated in paragraph (e)(28) of this section, preventive care, such as routine, annual, or employment-requested physical examinations and routine screening procedures.

(38) Chiropractors and naturopaths. Services of chiropractors and naturopaths whether or not such services would be eligible for benefits if rendered by an authorized provider.

(39) Counseling. Educational, vocational, and nutritional counseling and counseling for socioeconomic purposes, stress management, and/or lifestyle modification purposes, except that the following are not excluded:

(i) Services provided by a certified marriage and family therapist, pastoral or mental health counselor in the treatment of a mental disorder as specifically provided in paragraph (c)(3)(ix) of this section and in Sec. 199.6.

(ii) Diabetes self-management training (DSMT) as specifically provided in paragraph (d)(3)(ix) of this section.

(iii) Smoking cessation counseling and education as specifically provided in paragraph (e)(30) of this section.

(iv) Services provided by alcoholism rehabilitation counselors only when rendered in a CHAMPUS-authorized treatment setting and only when the cost of those services is included in the facility's CHAMPUS-determined allowable cost rate.

(40) Acupuncture. Acupuncture, whether used as a therapeutic agent or as an anesthetic.

(41) Hair transplants, wigs/hair pieces/cranial prosthesis.

NOTE: In accordance with section 744 of the DoD Appropriation Act for 1981 (Pub. L. 96-527), CHAMPUS coverage for wigs or hairpieces is permitted effective December 15, 1980, under the conditions listed below. Continued availability of benefits will depend on the language of the annual DoD Appropriation Acts.

(i) Benefits provided. Benefits may be extended, in accordance with the CHAMPUS-determined allowable charge, for one wig or hairpiece per beneficiary (lifetime maximum) when the attending physician certifies that alopecia has resulted from treatment of a malignant disease and the beneficiary certifies that a wig or hairpiece has not been obtained previously through the U.S. Government (including the Veterans Administration).

- (ii) Exclusions. The wig or hairpiece benefit does not include coverage for the following:
 - (A) Alopecia resulting from conditions other than treatment of malignant disease.
 - (B) Maintenance, wig or hairpiece supplies, or replacement of the wig or hairpiece.
 - (C) Hair transplants or any other surgical procedure involving the attachment of hair or a wig or hairpiece to the scalp.
 - (D) Any diagnostic or therapeutic method or supply intended to encourage hair regrowth.
- (42) Education or training. Self-help, academic education or vocational training services and supplies, unless the provisions of Sec. 199.4, paragraph (b)(1)(v) relating to general or special education, apply.
- (43) Exercise/relaxation/comfort devices. Exercise equipment, spas, whirlpools, hot tubs, swimming pools, health club membership or other such charges or items.
- (44) Exercise. General exercise programs, even if recommended by a physician and regardless of whether or not rendered by an authorized provider. In addition, passive exercises and range of motion exercises also are excluded, except when prescribed by a physician and rendered by a physical therapist concurrent to, and as an integral part of, a comprehensive program of physical therapy.
- (45) (Reserved).
- (46) Vision care. Eye exercises or visual training (orthoptics).
- (47) Eye and hearing examinations. Eye and hearing examinations except as specifically provided in paragraphs (c)(2)(xvi), (c)(3)(xi), and (e)(24) of this section, or except when rendered in connection with medical or surgical treatment of a covered illness or injury.
- (48) Prosthetic devices. Prostheses other than those determined by the Director, OCHAMPUS to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. All dental prostheses are excluded, except for those specifically required in connection with otherwise covered orthodontia directly related to the surgical correction of a cleft palate anomaly.
- (49) Orthopedic shoes. Orthopedic shoes, arch supports, shoe inserts, and other supportive devices for the feet, including special-ordered, custom-made built-up shoes, or regular shoes later built up.
- (50) Eyeglasses. Eyeglasses, spectacles, contact lenses, or other optical devices, except as specifically provided under paragraph (e)(6) of this section.
- (51) Hearing aids. Hearing aids or other auditory sensory enhancing devices, except those allowed in paragraph (e)(24) of this section.
- (52) Telephone services. Services or advice rendered by telephone are excluded, except that a diagnostic or monitoring procedure which incorporates electronic transmission of data

or remote detection and measurement of a condition, activity, or function (biotelemetry) is not excluded when:

(i) The procedure without electronic transmission of data or biotelemetry is otherwise an explicit or derived benefit of this section; and

(ii) The addition of electronic transmission of data or biotelemetry to the procedure is found by the Director, CHAMPUS, or designee, to be medically necessary and appropriate medical care which usually improves the efficiency of the management of a clinical condition in defined circumstances; and

(iii) That each data transmission or biotelemetry device incorporated into a procedure that is otherwise an explicit or derived benefit of this section, has been classified by the U.S. Food and Drug Administration, either separately or as a part of a system, for use consistent with the defined circumstances in paragraph (g)(52)(ii) of this section.

(53) Air conditioners, humidifiers, dehumidifiers, and purifiers.

(54) Elevators or chair lifts.

(55) Alterations. Alterations to living spaces or permanent features attached thereto, even when necessary to accommodate installation of covered durable medical equipment or to facilitate entrance or exit.

(56) Clothing. Items of clothing or shoes, even if required by virtue of an allergy (such as cotton fabric as against synthetic fabric and vegetable-dyed shoes).

(57) Food, food substitutes. Food, food substitutes, vitamins, or other nutritional supplements, including those related to prenatal care.

(58) Enuretic. Enuretic conditioning programs, but enuretic alarms may be cost-shared when determined to be medically necessary in the treatment of enuresis.

(59) Duplicate equipment. As defined in Sec. 199.2, duplicate equipment is excluded.

(60) Autopsy and postmortem.

(61) Camping. All camping even though organized for a specific therapeutic purpose (such as diabetic camp or a camp for emotionally disturbed children), and even though offered as a part of an otherwise covered treatment plan or offered through a CHAMPUS-approved facility.

(62) Housekeeper, companion. Housekeeping, homemaker, or attendant services; sitter or companion.

(63) Noncovered condition/treatment, unauthorized provider. All services and supplies (including inpatient institutional costs) related to a non-covered condition or treatment, including any necessary follow-on care or the treatment of complications, are excluded from coverage except as provided under paragraph (e)(9) of this section. In addition, all services and supplies provided by an unauthorized provider are excluded.

(64) Comfort or convenience. Personal, comfort, or convenience items such as beauty and barber services, radio, television, and telephone.

(65) (Reserved)

(66) Megavitamin psychiatric therapy, orthomolecular psychiatric therapy.

(67) Transportation. All transportation except by ambulance, as specifically provided under paragraph (d), and except as authorized in paragraph (e)(5) of this section.

(68) Travel. All travel even though prescribed by a physician and even if its purpose is to obtain medical care, except as specified in paragraph (a)(6) of this section in connection with a CHAMPUS-required physical examination and as specified in Sec. 199.17(n)(2)(vi).

(69) Institutions. Services and supplies provided by other than a hospital, unless the institution has been approved specifically by OCHAMPUS. Nursing homes, intermediate care facilities, halfway houses, homes for the aged, or institutions of similar purpose are excluded from consideration as approved facilities under the Basic Program.

NOTE: In order to be approved under CHAMPUS, an institution must, in addition to meeting CHAMPUS standards, provide a level of care for which CHAMPUS benefits are payable.

(70) (Reserved)

(71) (Reserved)

(72) Inpatient mental health services. Effective for care received on or after October 1, 1991, services in excess of 30 days in any fiscal year (or in an admission), in the case of a patient nineteen years of age or older, 45 days in any fiscal year (or in an admission) in the case of a patient under 19 years of age, or 150 days in any fiscal year (or in an admission) in the case of inpatient mental health services provided as residential treatment care, unless coverage for such services is granted by a waiver by the Director, OCHAMPUS, or a designee. In cases involving the day limitations, waivers shall be handled in accordance with paragraphs (b)(8) or (b)(9) of this section. For services prior to October 1, 1991, services in excess of 60 days in any calendar year unless additional coverage is granted by the Director, OCHAMPUS, or a designee.

(73) Economic interest in connection with mental health admissions. Inpatient mental health services (including both acute care and RTC services) are excluded for care received when a patient is referred to a provider of such services by a physician (or other health care professional with authority to admit) who has an economic interest in the facility to which the patient is referred, unless a waiver is granted. Requests for waiver shall be considered under the same procedure and based on the same criteria as used for obtaining preadmission authorization (or continued stay authorization for emergency admissions), with the only additional requirement being that the economic interest be disclosed as part of the request. The same reconsideration and appeals procedures that apply to day limit waivers shall also apply to decisions regarding requested waivers of the economic interest exclusion. However, a provider may appeal a reconsidered determination that an economic relationship constitutes an economic interest within the scope of the exclusion to the same extent that a

provider may appeal determination under Sec. 199.15(i)(3). This exclusion does not apply to services under the Extended Care Health Option (ECHO) in Sec. 199.5 or provided as partial hospital care. If a situation arises where a decision is made to exclude CHAMPUS payment solely on the basis of the provider's economic interest, the normal CHAMPUS appeals process will be available.

(74) Not specifically listed. Services and supplies not specifically listed as a benefit in this part. This exclusion is not intended to preclude extending benefits for those services or supplies specifically determined to be covered within the intent of this part by the Director, OCHAMPUS, or a designee, even though not otherwise listed.

NOTE: The fact that a physician may prescribe, order, recommend, or approve a service or supply does not, of itself, make it medically necessary or make the charge an allowable expense, even though it is not listed specifically as an exclusion.

(h) Payment and liability for certain potentially excludable services under the Peer Review Organization program--

(1) Applicability. This subsection provides special rules that apply only to services retrospectively determined under the Peer Review organization (PRO) program (operated pursuant to Sec. 199.15) to be potentially excludable (in whole or in part) from the basic program under paragraph (g) of this section. Services may be excluded by reason of being not medically necessary (paragraph (g)(1) of this section), at an inappropriate level (paragraph (g)(3) of this section), custodial care (paragraph (g)(7) of this section) or other reason relative to reasonableness, necessity or appropriateness (which services shall throughout the remainder of this subsection, be referred to as "not medically necessary"). (Also throughout the remainder of the subsection, "services" includes items and "provider" includes supplier). This paragraph does not apply to coverage determinations made by OCHAMPUS or the fiscal intermediaries which are not based on medical necessity determinations made under the PRO program.

(2) Payment for certain potentially excludable expenses. Services determined under the PRO program to be potentially excludable by reason of the exclusions in paragraph (g) of this section for not medically necessary services will not be determined to be excludable if neither the beneficiary to whom the services were provided nor the provider (institutional or individual) who furnished the services knew, or could reasonably have been expected to know, that the services were subject to those exclusions. Payment may be made for such services as if the exclusions did not apply.

(3) Liability for certain excludable services. In any case in which items or services are determined excludable by the PRO program by reason of being not medically necessary and payment may not be made under paragraph (h)(2) of this section because the requirements of paragraph (h)(2) of this section are not met, the beneficiary may not be held liable (and shall be entitled to a full refund from the provider of the amount excluded and any cost share amount already paid) if:

(i) The beneficiary did not know and could not reasonably have been expected to know that the services were excludable by reason of being not medically necessary; and

(ii) The provider knew or could reasonably have been expected to know that the items or services were excludable by reason of being not medically necessary.

(4) Criteria for determining that beneficiary knew or could reasonably have been expected to have known that services were excludable. A beneficiary who receives services excludable by reason of being not medically necessary will be found to have known that the services were excludable if the beneficiary has been given written notice that the services were excludable or that similar or comparable services provided on a previous occasion were excludable and that notice was given by the OCHAMPUS, CHAMPUS PRO or fiscal intermediary, a group or committee responsible for utilization review for the provider, or the provider who provided the services.

(5) Criteria for determining that provider knew or could reasonably have been expected to have known that services were excludable. An institutional or individual provider will be found to have known or been reasonably expected to have known that services were excludable under this subsection under any one of the following circumstances:

(i) The PRO or fiscal intermediary had informed the provider that the services provided were excludable or that similar or reasonably comparable services were excludable.

(ii) The utilization review group or committee for an institutional provider or the beneficiary's attending physician had informed the provider that the services provided were excludable.

(iii) The provider had informed the beneficiary that the services were excludable.

(iv) The provider had received written materials, including notices, manual issuances, bulletins, guides, directives or other materials, providing notification of PRO screening criteria specific to the condition of the beneficiary. Attending physicians who are members of the medical staff of an institutional provider will be found to have also received written materials provided to the institutional provider.

(v) The services that are at issue are the subject of what are generally considered acceptable standards of practice by the local medical community.

(vi) Preadmission authorization was available but not requested, or concurrent review requirements were not followed.

[51 FR 24008, Jul 1, 1986; 67 FR 15725, Apr 3, 2002; 67 FR 18826, Apr 17, 2002; 67 FR 40602, Jun 13, 2002; 67 FR 42720, Jun 25, 2002; 67 FR 45311, Jul 9, 2002; 68 FR 44880, Jul 31, 2003; 68 FR 44883, Jul 31, 2003; 68 FR 65173, Nov 19, 2003; 69 FR 29229, May 21, 2004; 69 FR 44947, Jul 28, 2004; 69 FR 51564, Aug 20, 2004; 69 FR 55359, Sep 14, 2004; 69 FR 60554, Oct 12, 2004; 70 FR 12802, Mar 16, 2005; 70 FR 61377, Oct 24, 2005; 71 FR 31944, Jun 2, 2006; 71 FR 35390, Jun 20, 2006; 72 FR 54353, Sep 25, 2007; 73 FR 46809, Aug 12, 2008; 73 FR 74965, Dec 10, 2008; 74 FR 34696, Jul 17, 2009; 75 FR 47459, Aug 6, 2010; 75 FR 47461, Aug 6, 2010; 75 FR 50882, Aug 18, 2010; 75 FR 2253, Jan 13, 2011; 76 FR 8297, Feb 14, 2011; 76 FR 57642, Sep 16, 2011; 76 FR 80743, Dec 27, 2011; 76 FR 81370, Dec 28, 2011; 77 FR 38175, Jun 27, 2012; 77 FR 38178, Jun 27, 2012; 78 FR 12952, Feb 26, 2013; 78 FR 13240, Feb 27, 2013; 78 FR 62430, Oct 22, 2013; 79 FR 41641, Jul 17, 2014; 79 FR 78707, Dec 31, 2014]

EDITORIAL NOTE: For Federal Register citations affecting Sec. 199.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

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