RULES
OF
TENNESSEE DEPARTMENT OF FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE

CHAPTER 1200-13-16
MEDICAL NECESSITY

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1200-13-16-.01 DEFINITIONS.

(1) ADEQUATE when applied to a medical item or service shall mean that the item or service, considered as part of a course of diagnosis or treatment, is sufficient, but not in excess of what is needed, for diagnosis or treatment of the particular medical condition. In order for a medical item or service to be determined adequate, such item or service must also satisfy the requirements at rule 1200-13-16-.05(5) regarding "safe and effective" and the requirements at rule 1200-13-16-.05(6) regarding "not experimental or investigational."

(2) BEHAVIORAL HEALTH ORGANIZATION shall mean a type of managed care contractor approved by the Tennessee Department of Finance and Administration to deliver mental health and substance abuse services to TennCare Medicaid and TennCare Standard enrollees under the TennCare Program.

(3) BENEFITS shall mean the defined package of health care services, including long term care services, for which an enrollee is eligible under the TennCare Program including applicable limits on such services.

(4) BUREAU OF TENNCARE shall mean the single State Medicaid agency which is responsible for the administration of the TennCare program.

(5) CASE-CONTROL STUDY shall mean a study in which the study and control groups are selected on the basis of whether they have the disease (cases) rather than whether they have been exposed to a risk factor or clinical intervention. The design is therefore observational (as opposed to experimental) and retrospective (as opposed to prospective), with the clinical outcome already known at the outset. Principal disadvantages of this study design are that important confounding variables may be difficult to identify and adjust for, clinical outcome is already known and may influence the measurement and interpretation of data (observer bias), and participants may have difficulty in accurately recalling past medical history and previous exposures (recall bias).

(6) CASE REPORT shall mean to an uncontrolled observational study (prospective or retrospective) involving an intervention and an outcome in a single patient.

(7) CASE SERIES shall mean an uncontrolled study (prospective or retrospective) of a succession of consecutive patients who receive a particular intervention and are followed to observe their outcomes.

(8) CLINICAL TRIAL shall mean a study that involves the administration of a test regimen to humans to evaluate its efficacy and safety.

(Rule 1200-13-16-.01, continued)

(9) CONTROL GROUP shall mean a group of patients that serves as the basis of comparison when assessing the effects of the intervention of interest that is given to the patients in the treatment group. Depending upon the circumstances of the trial, a control group may receive no treatment, a "usual" or "standard" treatment, or a placebo. To make the comparison valid, the composition of the control group should resemble that of the treatment group as closely as possible.

(10) CONTROLLED CLINICAL TRIAL shall mean a clinical trial in which a control group (which receives a standard intervention, which may be no treatment) is compared to a study group (which receives the intervention under study) in order to test a research hypothesis. A controlled clinical trial may or may not be randomized.

(11) CONTROLLED COHORT STUDY shall mean an observational study in which outcomes in a group of patients that received an intervention are compared with outcomes in a similar group i.e., the cohort, either contemporary or historical, of patients that did not receive the intervention. Cohort studies are more subject to systematic bias than randomized trials because treatments, risk factors, and other covariables may be chosen by patients or physicians on the basis of important (and often unrecognized) factors that are related to outcome. Therefore, investigators in controlled cohort studies may identify and correct for confounding variables, which are related factors that may be more directly responsible for clinical outcome than the intervention/exposure in question. For example, in an adjusted- (or matched-) cohort study, investigators identify (or make statistical adjustments to provide) a cohort group that has characteristics (e.g., age, gender, disease severity) that are as similar as possible to the group that experienced the intervention.

(12) CONVENIENCE shall mean the degree to which an item or service is designed or recommended for the personal comfort or ease of an enrollee, caregiver, or provider. Alleviation of pain is not considered a matter of convenience.

(13) COST EFFECTIVE when applied to a medical item or service shall mean that the benefits associated with item or service, considered as part of diagnosis or treatment, outweigh the costs associated with the item or service. When appropriate, such analysis may include assessment of aggregate, population-level data related to the costs or benefits of a medical item or service.

(14) COST-EFFECTIVE ALTERNATIVE SERVICE shall mean a service that is not a covered service but that is approved by TennCare and CMS and provided at an MCC's discretion. TennCare enrollees are not entitled to receive these services. Cost-effective alternative services may be provided because they are either (1) alternatives to covered Medicaid services that, in the MCC's judgment, are cost-effective or (2) preventative in nature and offered to avoid the development of conditions that, in the MCC's judgment, would require more costly treatment in the future. Cost-effective alternative services need not be determined medically necessary except to the extent that they are provided as an alternative to covered Medicaid services. Even if medically necessary, a cost effective alternative service is not a covered service and is provided only at an MCC's discretion.

(15) COVERED SERVICES shall mean medical items and services that are within an enrollee's scope of defined benefits, and not in excess of any applicable limits on such items or services. Covered services include long term care services for those enrollees eligible for long term care. With the exception of cost-effective alternative services and even in cases of emergency, only a covered service can be determined to be medically necessary for reimbursement purposes under the program.

(16) DIAGNOSIS shall mean the act or process of identifying or determining the nature and cause of a medical problem or condition through evaluation of patient history, examination, and review of laboratory data and other pertinent information. Diagnosis may include cost effective screening services provided in accordance with nationally accepted standards or guidelines developed or endorsed by respected medical organizations, such as the Centers for Disease Control and Prevention.

(17) EFFECTIVE describes the use of a medical item or service that produces the intended result and where the benefit of the medical item or service outweighs the adverse medical risks or consequences.

(Rule 1200-13-16-.01, continued)

(18) ELIGIBLE describes a person who has been determined to meet the eligibility criteria for the TennCare program.

(19) ENROLLEE shall mean an individual who is eligible for and enrolled in the TennCare program.

(20) EVIDENCE-BASED shall mean the ordered and explicit use of the best medical evidence available when making health care decisions.

(21) EXPERIMENTAL STUDY shall mean a randomized controlled clinical trial.

(22) HIERARCHY OF EVIDENCE shall mean a ranking of the weight given to medical evidence depending on objective indicators of its validity and reliability including the nature and source of the medical evidence, the empirical characteristics of the studies or trials upon which the medical evidence is based, and the consistency of the outcome with comparable studies. The hierarchy in descending order, with Type I given the greatest weight is:

(a) Type I: Meta-analysis done with multiple, well-designed controlled clinical trials;

(b) Type II: One or more well-designed experimental studies;

(c) Type III: Well-designed, quasi-experimental studies;

(d) Type IV: Well-designed, non-experimental studies; and

(e) Type V: Other medical evidence defined as evidence-based

1. Clinical guidelines, standards or recommendations from respected medical organizations or governmental health agencies;

2. Analyses from independent health technology assessment organizations; or

3. Policies of other health plans.

(23) HOME HEALTH SERVICES shall mean:

(a) Any of the following services ordered by a treating physician and provided by a licensed home health agency pursuant to a plan of care at an enrollee's place of residence:

1. Part-time or intermittent nursing services;

2. Home health aide services; or

3. Physical therapy, occupational therapy, or speech pathology and audiology services.

(b) Medical supplies, equipment, and appliances ordered by a treating physician and suitable for use at an enrollee's place of residence.

(c) Home health providers may only provide services that have been ordered by the treating physician and are pursuant to a plan of care and may not provide other services such as general child care services, cleaning services or preparation of meals. For this reason and to the extent that home services are provided to a person under 18 years of age, a responsible adult (other than the home healthcare provider) must be present at all times in the home during provision of home health services.

(Rule 1200-13-16-.01, continued)

(24) INSTITUTIONAL REVIEW BOARD shall mean a specifically constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

(25) LONG TERM CARE shall mean institutional services of a nursing facility, an intermediate care facility for the mentally retarded, or services provided through a Home and Community Based Services (HCBS) waiver program.

(26) MCC (MANAGED CARE CONTRACTOR) shall mean:

(a) A managed care organization, behavioral health organization, pharmacy benefits manager, and/or a dental benefits manager which has signed a TennCare Contract with the State and operates a provider network and provides covered health services to TennCare enrollees; or

(b) A pharmacy benefits manager, dental benefits manager, or behavioral health organization which subcontracts with a managed care organization or behavioral health organization to provide services; or

(c) A State government agency (i.e., Department of Children's Services and Division of Mental Retardation Services) that contracts with TennCare for the provision of services.

(27) MCO (MANAGED CARE ORGANIZATION) shall mean an appropriately licensed Health Maintenance Organization (HMO) contracted with the Bureau of TennCare to manage the delivery, provide for access, contain the cost, and ensure the quality of specified covered medical and/or behavioral benefits to TennCare enrollee-members through a network of qualified providers.

(28) MEDICAID shall mean the federal- and state-financed, state-run program of medical assistance pursuant to Title XIX of the Social Security Act.

(29) MEDICAL CONDITION shall mean a disorder or an abnormal condition of the body and/or mind.

(30) MEDICAL EVIDENCE shall mean Type I-IV analyses and studies and/or Type V evidence defined in rule 1200-13-16-.01(22).

(31) MEDICAL ITEM OR SERVICE shall mean an item or service that is provided, ordered, or prescribed by a licensed health care provider and is primarily intended for a medical and/or behavioral purpose and designed to achieve that medical and/or behavioral purpose.

(32) MEDICAL NECESSITY shall mean the quality of being "medically necessary" as defined by Tennessee Code Annotated, Section 71-5-144, and applies to TennCare enrollees. Implementation of the term "medical necessity" is provided for in these regulations, consistent with the statutory provisions, which control in case of ambiguity.

(33) MEDICAL NECESSITY DETERMINATION a decision made by the Chief Medical Officer of the Bureau of TennCare or his or her clinical designee or by the Medical Director of one of its Managed Care Contractors or his or her clinical designee regarding whether a requested medical item or service satisfies the definition of medical necessity contained in Tennessee Code Annotated, Section 71-5-144 and these regulations as defined herein. Items or services that are not determined medically necessary shall not be paid for by TennCare.

(34) MEDICAL NECESSITY GUIDELINES shall mean evidence-based guidelines approved by the Chief Medical Officer of the Bureau of TennCare for the purpose of guiding medical necessity determinations for particular courses of diagnosis or treatment.

(35) MEDICALLY NECESSARY is defined by Tennessee Code Annotated, Section 71-5-144, and shall describe a medical item or service that meets the criteria set forth in that statute. The term "medically

(Rule 1200-13-16-.01, continued)

necessary," as defined by Tennessee Code Annotated, Section 71-5-144, applies to TennCare enrollees. Implementation of the term "medically necessary" is provided for in these regulations, consistent with the statutory provisions, which control in case of ambiguity. No enrollee shall be entitled to receive and TennCare shall not be required to pay for any items or services that fail fully to satisfy all criteria of "medically necessary" items or services, as defined either in the statute or in these regulations.

(36) MEDICAL RECORD shall mean all medical histories; records, reports and summaries; diagnoses; prognoses; records of treatment and medication ordered and given; x-ray and radiology interpretations; physical therapy charts and notes; lab reports; other individualized medical documentation in written or electronic format; and analyses of such information.

(37) META-ANALYSIS shall mean systematic methods that use statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion that can be provided by any individual study.

(38) NON-CONTROLLED COHORT STUDY shall mean a longitudinal study in which a group of people who share a common characteristic or experience are tracked over time with observation of outcomes within the group.

(39) NON-COVERED SERVICE shall mean items and services that are not within the scope of defined benefits for which a beneficiary is eligible under TennCare, including cost-effective alternative services and medical items and services that are in excess of any applicable limits on such items or services that might otherwise be covered. With the exception of cost-effective alternative services, non-covered services under TennCare, including medical items and services in excess of benefit limits, are never to be paid for by TennCare, even if they otherwise would qualify as "medically necessary," regardless of the medical circumstances involved.

(40) NON- EXPERIMENTAL STUDY shall mean a study that is not randomized or controlled. Examples of non-experimental studies include non-controlled cohort studies, case series or case reports.

(41) NON-RANDOMIZED CONTROLLED CLINICAL TRIAL shall mean a controlled clinical trial that assigns patients to intervention and control groups using a method that does not involve randomization, e.g., at the convenience of the investigators or some other technique such as alternate assignment. Controlled trials that are not randomized are subject to a variety of biases, including selection bias, in which persons who volunteer or are assigned by investigators to study groups may differ in characteristics other than the intervention itself.

(42) OFF-LABEL USE shall mean the use of a drug or biological product that has been approved for marketing by the United States Food and Drug Administration (FDA) but is proposed to be used for other than the FDA-approved purpose.

(43) PHYSICIAN shall mean a person licensed pursuant to Chapter 6 or 9 of Title 63 of the Tennessee Code Annotated.

(44) QUASI-EXPERIMENTAL STUDY shall mean a study in which the investigator lacks full control over randomization of subjects (lacks full control over the allocation and/or timing of intervention) but nonetheless conducts the study as if it were an experiment, allocating subjects to groups. Examples of quasi-experimental studies include non-randomized controlled clinical trials, controlled cohort studies, or case-control studies.

(45) RANDOMIZED CONTROLLED CLINICAL TRIAL shall mean a clinical trial in which participants are assigned in a randomized fashion to a study group (which receives the intervention) or a control group (which receives a standard treatment, which may be no intervention or a placebo). Randomization enhances the comparability of the groups and provides a more valid basis for

(Rule 1200-13-16-.01, continued)

measuring statistical uncertainty. In this manner, differences in outcomes can be attributed to the intervention rather than to differences between the groups. Randomized controlled trials may or may not be blinded. In a blinded trial, the investigators, the subjects, or both (double-blinded study) are not told to which group they have been assigned, so that this knowledge will not influence their assessment of outcome.

(46) SCREEN shall mean to test for or examine for the presence of a medical problem or condition in the absence of signs and symptoms of disease.

(47) STUDY shall mean a careful examination or analysis applying scientific methodology and published in a peer-reviewed scientific journal or periodical.

(48) TENNCARE shall mean the TennCare waiver demonstration program(s) and/or Tennessee's traditional Medicaid program.

(49) TREATING PHYSICIAN OR OTHER TREATING HEALTH CARE PROVIDER shall mean a licensed physician practicing within the scope of his or her license or other licensed health care provider practicing within the scope of his or her license who has personally examined a particular TennCare enrollee and who has provided diagnostic or treatment services for that particular enrollee (whether or not those services were covered by TennCare) for purposes of treating or supporting the treatment of a known or suspected medical condition of that particular enrollee. The term excludes all other providers, including those who have evaluated a particular enrollee's medical condition primarily or exclusively for the purposes of supporting or participating in a decision regarding TennCare coverage.

(50) TREATMENT shall mean the provision of medical items or services based on the recommendation of a treating physician or other treating health care provider practicing within the scope of his or her license.

Authority: *T.C.A. §§4-5-209, 71-5-105, 71-5-109, Executive Order No. 23.* ***Administrative History:*** *Public necessity rule filed December 1, 2006; expires May 15, 2007.*

1200-13-16-.02 INTRODUCTION.

The medical necessity standard set forth in the TennCare reform statute and in these regulations shall govern the delivery of all medical items and services to all enrollees or classes of beneficiaries in the TennCare program. The definition of medical necessity will be implemented consistent with federal law, including Early Periodic Screening Diagnosis and Treatment (EPSDT) requirements, and within the state's authority to define what constitutes a medically necessary Medicaid service. The state recognizes that current EPSDT requirements include coverage of "necessary health care, diagnostic services, treatment and other measures to correct or ameliorate defects and physical and mental illness and conditions discovered by screening services, whether or not such services are covered under the state plan".

Authority: *T.C.A. §§4-5-209, 71-5-105, 71-5-109, Executive Order No. 23.* ***Administrative History:*** *Public necessity rule filed December 1, 2006; expires May 15, 2007.*

1200-13-16-.03 THE SCOPE OF TENNCARE'S PAYMENT OBLIGATION.

(1) Tennessee has an obligation to provide payment on behalf of TennCare enrollees for and only for (a) covered services (b) that are medically necessary.

(2) No TennCare enrollee is entitled to receive (a) non-covered services including cost effective alternative services or (b) covered services that are not medically necessary.

(3) In the context of prior authorization or concurrent review:

(Rule 1200-13-16-.03, continued)

(a) When a covered service has been designated by the Bureau of TennCare or a managed care contractor as requiring prior approval, no TennCare enrollee is entitled to receive covered services until the favorable conclusion of the prior approval process.

(b) When a covered service has been designated by the Bureau of TennCare or a managed care contractor as requiring concurrent review, the enrollee may receive covered services until the expiration of any existing authorization for treatment or until a determination that such service is no longer medically necessary. No TennCare enrollee is entitled to receive covered services subject to concurrent review beyond the expiration of any existing authorization for treatment unless such authorization has been extended through the concurrent review process. For TennCare enrollees under 21, upon receipt of a timely filed request to continue authorization of a service originally prescribed on an ongoing basis, such authorization is automatically extended pending completion of concurrent review. A request to continue authorization shall be timely if received by the MCC prior to the expiration of the current authorization.

Authority: *T.C.A. §§4-5-209, 71-5-105, 71-5-109, Executive Order No. 23.* ***Administrative History:*** *Public necessity rule filed December 1, 2006; expires May 15, 2007.*

1200-13-16-.04 PRIOR AUTHORIZATION AND CONCURRENT UTILIZATION REVIEW.

(1) The Bureau of TennCare may identify certain items or services that, for purposes of determining medical necessity, shall require prior authorization and/or concurrent review.

(a) Managed care contractors and/or a state agency performing the function of a managed care contractor shall implement prior authorization and/or concurrent review procedures for all items or services specified by the Bureau of TennCare and, at their individual discretion, may require prior authorization and/or concurrent review for additional non-emergency medical items or services not specified by the Bureau of TennCare.

(b) Managed care contractors and/or a state agency performing the function of a managed care contractor will inform their enrollees and their participating providers which medical items or services require prior authorization and/or concurrent review. Such notice need not be individualized in nature. Thus, failure to provide individualized prior authorization notices does not invalidate the requirement for prior authorization and/or concurrent review. Notice to providers shall be in writing and such notice requirement may be satisfied by publishing notice on the internet.

Authority: *T.C.A. §§4-5-209, 71-5-105, 71-5-109, Executive Order No. 23.* ***Administrative History:*** *Public necessity rule filed December 1, 2006; expires May 15, 2007.*

1200-13-16-.05 MEDICAL NECESSITY CRITERIA.

(1) To be medically necessary, a medical item or service must satisfy each of the following criteria:

(a) It must be recommended by a licensed physician who is treating the enrollee or other licensed healthcare provider practicing within the scope of his or her license who is treating the enrollee;

(b) It must be required in order to diagnose or treat an enrollee’s medical condition;

(c) It must be safe and effective;

(d) It must not be experimental or investigational; and

(e) It must be the least costly alternative course of diagnosis or treatment that is adequate for the enrollee’s medical condition.

(Rule 1200-13-16-.05, continued)

(2) The convenience of an enrollee, the enrollee's family, the enrollee's caregiver, or a provider, shall not be a factor or justification in determining that a medical item or service is medically necessary.

(3) Services required to diagnose an enrollee's medical condition.

(a) Provided that all the other medical necessity criteria are satisfied, services required to diagnose an enrollee's medical condition may include screening services, as appropriate.

(b) Screening services are "appropriate" if they meet one of the following three categories:

1. Services required to achieve compliance with federal statutory or regulatory mandates under the EPSDT program.

2. Newborn testing for metabolic/genetic defects as set forth in Tennessee Code Annotated, Section 68-5-401; or

3. Pap smears, mammograms, prostate cancer screenings, colorectal cancer screenings, and screening for tuberculosis and sexually transmitted diseases, including HIV, in accordance with nationally accepted clinical guidelines adopted by the Bureau of TennCare.

(c) Unless specifically provided for herein, other screening services are "appropriate" only if they satisfy each of the following criteria:

1. The Bureau of TennCare, a managed care contractor, or a state agency performing the functions of a managed care contractor determines that the screening services are cost effective;

2. The screening must have a significant probability of detecting the disease;

3. The disease for which the screening is conducted must have a significant detrimental effect on the health status of the affected person;

4. Tests must be available at a reasonable cost;

5. Evidence-based methods of treatment must be available for treating the disease at the disease stage which the screening is designed to detect; and

6. Treatment in the asymptomatic phase must yield a therapeutic result.

(d) Services required to diagnose an enrollee's medical condition include diagnostic services mandated by EPSDT requirements.

(4) Services required to treat an enrollee's medical condition. Provided that all other elements of medical necessity are satisfied, treatment of an enrollee's medical condition may only include:

(a) Medical care that is essential in order to treat a diagnosed medical condition, the symptoms of a diagnosed medical condition, or the effects of a diagnosed medical condition and which, if not provided, would have a significant and demonstrable adverse impact on quality or length of life;

(b) Medical care that is essential in order to treat the significant side effects of another medically necessary treatment (e.g., nausea medications for side effects of chemotherapy);

(c) Medical care that is essential, based on an individualized determination of a particular patient's medical condition, to avoid the onset of significant health problems or significant complications

(Rule 1200-13-16-.05, continued)

that, with reasonable medical probability, will arise from that medical condition in the absence of such care;

(d) Home health services

1. Home health aide services are necessary to treat an enrollee's medical condition only if such services;

(i) Are of a type that the enrollee cannot perform for himself or herself;

(ii) Are of a type for which there is no caregiver able to provide the services; and

(iii) Consist of hands-on care of the enrollee.

2. All other home health services are necessary to treat an enrollee's medical condition only if they are ordered by the treating physician, are pursuant to a plan of care, and meet the requirements described at subparagraph (a), (b), or (c) immediately above or (f) immediately below. Services that do not meet these requirements, such as general child care services, cleaning services or preparation of meals, are not required to treat an enrollee's medical condition and will not be provided. For this reason, to the extent that home health services or private duty nursing services are provided to a person under 18 years of age, a responsible adult (other than the home healthcare provider) must be present at all times in the home during provision of home health services.

3. Private Duty Nursing services are separate services from home health services. When private duty nurses are authorized by the MCC to provide home health aide services pursuant to rule 1200-13-13-.04(14)(c) or 1200-13-14-.04(14)(c), these services must meet the requirements described at part 1. immediately above.

4. Home health services may not be denied on any of the following grounds:

(i) Because such services are medically necessary on a long term basis or are required for the treatment of a chronic condition;

(ii) Because such services are deemed to be custodial care;

(iii) Because the enrollee is not homebound;

(iv) Because private insurance utilization guidelines, including but not limited to those published by Milliman & Robertson or developed in-house by TennCare managed care contractors, do not authorize such health care as referenced above;

(v) Because the enrollee does not meet coverage criteria for Medicare or some other health insurance program, other than TennCare;

(vi) Because the home health care that is needed does not require or involve a skilled nursing service;

(vii) Because the care that is required involves assistance with activities of daily living;

(viii) Because the home health services that is needed involves home health aide services;

(ix) Because of a numerical limit unrelated to medical necessity;

(Rule 1200-13-16-.05, continued)

(x) Because the enrollee meets the criteria for receiving Medicaid nursing facility services; or

(xi) On the grounds that such medically necessary home health care is not a covered service.

(e) Personal Care Services

1. Personal care services are necessary to treat an enrollee's medical condition only if such services are ordered by the treating physician pursuant to a plan of care to address a medical condition identified as a result of an EPSDT screening. Personal care services must be supervised by a registered nurse and delivered by a home health aide. In addition the services must:

(i) Be of a type that the enrollee cannot perform for himself or herself;

(ii) Be of a type for which there is no caregiver able to provide the services; and

(iii) Consist of hands-on care of the enrollee.

2. Services that do not meet these requirements, such as general child care services, cleaning services or preparation of meals, are not required to treat an enrollee's medical condition and will not be provided. For this reason, to the extent that personal care services are provided to a person under 18 years of age, a responsible adult (other than the home health aide) must be present at all times during provision of personal care services.

(f) The following preventive services:

1. Prenatal and maternity care delivered in accordance with standards endorsed by the American College of Obstetrics and Gynecology;

2. Family planning services;

3. Age-appropriate childhood immunizations delivered according to guidelines developed by the Advisory Committee on Immunization Practices;

4. Health education services for TennCare-eligible children under age 21 in accordance with 42 U.S.C. Section 1396d;

5. Other preventive services that are required to achieve compliance with federal statutory or regulatory mandates under the EPSDT program; or

6. Other preventive services that have been endorsed by the Bureau of TennCare or a particular managed care contractor as representing a cost effective approach to meeting the medically necessary health care needs of an individual enrollee or group of enrollees.

(5) Safe and effective.

(a) To qualify as being safe and effective, the type, scope, frequency, intensity, and duration of a medical item or service must be consistent with the symptoms or confirmed diagnosis and treatment of the particular medical condition. The type, scope, frequency, intensity, and duration of a medical item or service must not be in excess of the enrollee's needs.

(b) The reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on:

1. The enrollee's condition; and

2. The weight of medical evidence as ranked in the hierarchy of evidence in rule 1200-13-16-.01(22) and as applied in rule 1200-13-16-.06(6) and (7).

(6) Not experimental or investigational.

(a) A medical item or service is experimental or investigational if there is inadequate empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question. This standard is not satisfied by a provider's subjective clinical judgment on the safety and effectiveness of a medical item or service or by a reasonable medical or clinical hypothesis based on an extrapolation from use in diagnosing or treating another condition. However, extrapolation from one population group to another (e.g. from adults to children) may be appropriate. For example, extrapolation may be appropriate when the item or service has been proven effective, but not yet tested in the population group in question. This standard may only be satisfied if the weight of medical evidence supports the safety and efficacy of the medical item or service in question as ranked in the hierarchy of evidence in rule 1200-13-16-.01(22) and as applied in rule 1200-13-16-.06(6) and (7).

(b) Subject to the provisions set forth in subparagraph (c) immediately below, use of a drug or biological product that has not been approved for marketing under a new drug application or abbreviated new drug application by the United States Food and Drug Administration (FDA) is deemed experimental.

(c) Use of a drug or biological product that has been approved for marketing by the FDA but is proposed to be used for other than the FDA-approved purpose (i.e., off-label use) is experimental and not medically necessary unless the off-label use is shown to be widespread and all other medical necessity criteria as set forth in rule 1200-13-16-.05(1)((a), (b), (c), and (e)) are satisfied.

(d) Items or services provided or performed for research purposes are experimental and not medically necessary. Evidence of such research purposes may include written protocols in which evaluation of the safety and efficacy of the service is a stated objective or when the ability to perform the service is contingent upon approval from an Institutional Review Board, or a similar body.

(e) Unless a proposed diagnosis or treatment independently satisfies the criteria for “not experimental or investigational”, and satisfies all other medical necessity criteria, the fact that an experimental/investigational treatment is the only available treatment for a particular medical condition or that the patient has tried other more conventional therapies without success does not qualify the service for coverage.

(7) The least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee.

(a) Where there are less costly alternative courses of diagnosis or treatment that are adequate for the medical condition of the enrollee, more costly alternative courses of diagnosis or treatment are not medically necessary, even if the less costly alternative is a non-covered service under TennCare.

(b) Where there are less costly alternative settings in which a course of diagnosis or treatment can be provided that is adequate for the medical condition of the enrollee, the provision of services in a setting more costly to TennCare is not medically necessary.

(Rule 1200-13-16-.05, continued)

(c) If a medical item or service can be safely provided to a person in an outpatient setting for the same or lesser cost than providing the same item or service in an inpatient setting, the provision of such medical item or service in an inpatient setting is not medically necessary and TennCare shall not provide payment for that inpatient service.

(d) An alternative course of diagnosis or treatment may include observation, lifestyle, or behavioral changes or, where appropriate, no treatment at all when such alternative is adequate for the medical condition of the enrollee.

(e) The following is a non-exhaustive illustrative set of circumstances that could fit within the provisions of rule 1200-13-16-.05(7)(d). These examples may or may not be appropriate, depending on an individualized medical assessment of a patient's unique circumstances:

1. Rest, fluids and over-the-counter medication for symptomatic relief might be recommended for a viral respiratory infection, as opposed to a prescription for an antibiotic;

2. Rest, ice packs and/or heat for acute, uncomplicated, mechanical low back pain along with over-the-counter pain medicine, as opposed to x-rays and a prescription for analgesics;

3. Clear liquids and advance diet as tolerated for uncomplicated, acute gastroenteritis, as opposed to prescription antidiarrheals.

(8) The Bureau of TennCare may make limited special exceptions to the medical necessity requirements described at rule 1200-13-16-.05(1) for particular items or services, such as long term care, or such as may be required for compliance with federal law.

(9) Transportation services that meet the requirements described at rule 1200-13-13-.04 and 1200-13-14-.04 shall be deemed to be medically necessary if provided in connection with medically necessary items or services.

Authority: *T.C.A. §§4-5-209, 71-5-105, 71-5-109, Executive Order No. 23.* ***Administrative History:*** *Public necessity rule filed December 1, 2006; expires May 15, 2007.*

1200-13-16-.06 DETERMINATION OF MEDICAL NECESSITY.

(1) The Bureau of TennCare is ultimately responsible for determining whether specific medical items and/or services under TennCare (a) are covered services and (b) are medically necessary. In the vast majority of cases, medical necessity determinations will be made as part of a prior authorization or concurrent review process. However, less frequently such determinations may be made retrospectively in the course of the investigation of unusual billing or practice patterns. The Bureau of TennCare may delegate covered services and/or medical necessity decisions to managed care contractors. All medical necessity decisions must be made by licensed medical staff with appropriate clinical expertise. The Bureau may review such decisions as a part of routine monitoring or as a result of an enrollee appeal or provider complaint and may overturn such decisions if not made in accordance with these rules.

(2) Non-covered services, including medical items and services in excess of benefit limits, are never to be paid for by TennCare, even if they otherwise would qualify as "medically necessary," regardless of the medical circumstances involved, unless an MCC, in its discretion, provides a cost effective alternative service.

(3) If, after an enrollee is provided the opportunity by the State or managed care contractor to consult with a physician, a medical item or service has not been recommended, ordered or prescribed by a treating physician or other treating health care provider practicing within the scope of his or her license, it is not medically necessary and is not covered under TennCare.

(Rule 1200-13-16-.06, continued)

(4) In making a medical necessity determination, TennCare or its designee will consider a recommendation, order, or prescription for a covered medical item or service from a treating physician or other treating health care provider.

(a) A recommendation, order or prescription from a treating physician or other treating health care professional shall be based on a thorough, up-to-date assessment of the enrollee's medical condition, with careful consideration of all required medical necessity criteria as defined by statute and by these regulations.

(b) The managed care contractor will evaluate the information provided by the treating provider in support of a recommendation, order or prescription for a covered service. If the information or opinion of the treating provider deviates significantly from that of the MCC, the MCC will request further explanation from the treating provider. Upon request from the enrollee's MCC or the Bureau of TennCare for purposes of making an individualized medical necessity determination, the treating physician or other treating health care provider shall provide information and/or documentation supporting the need for the recommended medical item or service in order to diagnose or treat the enrollee's medical condition.

(c) In addition, when requested, the treating physician or other treating health care provider will provide a written explanation as to why a proposed less costly alternative is not believed to be adequate to address the enrollee's medical condition.

(d) Information/documentation requested by the managed care contractor or the Bureau of TennCare for purposes of making a medical necessity determination will be provided free of charge.

(e) Providers who fail to provide information/documentation requested by the managed care contractor or the Bureau of TennCare for purposes of making a medical necessity determination shall not be entitled to payment for provision of the applicable medical item or service. In such instances, providers may not seek payment from patients or third parties for items or services denied payment.

(5) The treating physician's conclusory statements, without more, are not binding on the State.

(6) In evaluating the request/recommendation of the treating physician or other treating health care provider, a managed care contractor and/or the Bureau of TennCare shall use the hierarchy of evidence to determine if the requested item or service is safe and effective, as referenced at rule1200-13-16-.05(5) and (6)(a), for the enrollee by classifying the item or service as having an A, B, C or D level of supporting evidence. In classifying the item or service as having A, B, C or D level of supporting evidence, extrapolation from one population group to another (e.g. from adults to children) may be appropriate. For example, extrapolation may be appropriate when the item or service has been proven effective, but not yet tested in the population group in question.

(a) "A" level evidence: Shows the requested medical item or service is a proven benefit to the enrollee's condition as demonstrated by strong scientific literature and well-designed clinical trials such as a Type I evidence or multiple Type II evidence or combinations of Type II, III, or IV evidence with consistent results. An "A" rating cannot be based on Type III, Type IV, or Type V evidence alone.

(b) "B" level evidence: Shows the requested medical item or service has some proven benefit to the enrollee's condition as demonstrated by:

1. Multiple Type II or III evidence or combinations of Type II, III, or IV evidence with generally consistent findings of effectiveness and safety. A "B" rating cannot be based on Type IV or V evidence alone; or

(Rule 1200-13-16-.06, continued)

2. Singular Type II, III, IV, or V evidence when consistent with a Bureau of TennCare endorsed or established evidence-based clinical guidelines.

(c) "C" level evidence: Shows only weak and inconclusive evidence regarding safety and/or efficacy for the enrollee's condition such as:

1. Type II, III, or IV evidence with inconsistent findings; or

2. Only Type V evidence is available.

(d) "D" level evidence: Is not supported by any evidence regarding safety and efficacy for the enrollee's condition.

(7) Application of the Hierarchy of Evidence. After classifying the available evidence, the Bureau of TennCare or a managed care contractor will approve items or services in the following manner:

(a) Medical items or services with supporting "A" and "B" rated evidence will be considered safe and effective if the item or service does not place the enrollee at a greater risk of morbidity and mortality than an equally effective alternative treatment.

(b) Medical items or services with "C" rated evidence or a physician's clinical judgment that is not supported by objective evidence, will be considered safe and effective only if the provider shows that the requested service is the optimal intervention for meeting the enrollee's specific condition or treatment needs, and:

1. Does not place the enrollee at greater risk of morbidity or mortality than an equally effective alternative treatment; and

2. Is the next reasonable step for the enrollee in light of the enrollee's past medical treatment.

(c) Medical items or services with "D" rated evidence will not be considered safe and effective and; therefore, will not be determined medically necessary.

(8) The Bureau of TennCare or the managed care contractor's classification of available medical evidence as described at rule 1200-13-16-.01(22) and any resulting approval of items or services as described at rule 1200-13-16-.06(6) and (7) shall be binding on TennCare enrollees and providers.

(9) The managed care contractor or the Bureau of TennCare will rely upon all relevant information in making a medical necessity determination. Such determinations must be individualized and made in the context of medical /behavioral history information included in the enrollee's medical record.

(10) The fact that a particular medical item or service has been covered in one instance does not make such item or service medically necessary in any other case, even if such case is similar in certain respects to the situation in which the item or service was determined to be medically necessary.

(11) Items or services that are not determined medically necessary, as defined by the statute or by these regulations, shall not be paid for by TennCare.

Authority: *T.C.A. §§4-5-209, 71-5-105, 71-5-109, Executive Order No. 23.* ***Administrative History:*** *Public necessity rule filed December 1, 2006; expires May 15, 2007.*

1200-13-16-.07 DEVELOPMENT OF EVIDENCE-BASED MEDICAL NECESSITY GUIDELINES.

(1) In recognition of the ever-evolving nature of the study and practice of medicine, the growing body of evidence-based medical practice guidelines, the opportunity to achieve cost-containment objectives consistent with quality care, and the existence of practice variability among health care practitioners, the Bureau of TennCare may, on occasion, endorse or establish medical necessity guidelines that shall guide determinations of medical necessity for specific items or services across all managed care contractors and State agencies performing the function of managed care contractors.

(2) Such guidelines shall be established with input from managed care contractors, practicing physicians and other health care providers, shall be based on Type I or II evidence and shall take into consideration all criteria of the statutory definition of medical necessity.

(3) The Bureau of TennCare will disseminate approved evidence-based medical necessity guidelines to its contractors and the provider community.

(4) The Bureau of TennCare will implement a continuous medical review process to ensure that approved evidence-based medical necessity guidelines are responsive to advances in medical knowledge and technology.

Authority: *T.C.A. §§4-5-209, 71-5-105, 71-5-109, Executive Order No. 23.* ***Administrative History:*** *Public necessity rule filed December 1, 2006; expires May 15, 2007.*

1200-13-16-.08 RIGHT TO APPEAL A MEDICAL NECESSITY DETERMINATION.

An enrollee may appeal a determination that a medical item or service that is within the enrollee's scope of covered benefits is not medically necessary. In all such appeals, the burden of proof will rest with the enrollee at all stages.

Authority: *T.C.A. §§4-5-209, 71-5-105, 71-5-109, Executive Order No. 23.* ***Administrative History:*** *Public necessity rule filed December 1, 2006; expires May 15, 2007.*