



The National Association of Community Health Centers, Inc.

Emerging Issues in Medicaid and SCHIP #1:

Tennessee's New Definition of "Medically Necessary" and Its Implications for Medicaid and Health Centers

May 2005

Summary

In May 2004, Tennessee enacted legislation¹ to change the definition of "medically necessary" for its Medicaid program, TennCare. Draft rules to implement the new definition were recently released and can be viewed at <http://www.nachc.com/advocacy/Files/state-policy/MNRules6-14Draft.pdf>. Under the new definition, TennCare will determine medical necessity based on whether the service is "least costly" and has adequate "empirically-based objective clinical scientific evidence" for its use, among other criteria. These increased restrictions accompanied several additional program modifications intended to reduce Medicaid spending. This new law raises the following four concerns: (1) medical decisions may no longer be made by clinicians based on standards of care, (2) providers may not receive reimbursement for services that were previously covered, (3) there is no clear appeals process, and (4) certain Medicaid populations may have limited services available to them.

Background

There is no federal statutory or regulatory definition of "medically necessary" in the Medicaid program, thereby allowing states to use their own interpretations. The exception is children under age 21, who are statutorily entitled to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services. Previously Tennessee defined "medically necessary" as services provided by an institution, physician, or other provider that are "required to treat a TennCare enrollee's illness or injury." TennCare stipulated that these services be "the most appropriate supply or level of services which can safely be provided to the enrollee. When applied to the care of an inpatient, it further means that services for the enrollee's medical symptoms or condition cannot be safely provided to the enrollee as an outpatient."² (See Appendix A)

TennCare covers 22.3% of the state's population, more than any other state.³ In an attempt to maintain this high level of enrollment in the face of growth in program costs, Tennessee developed a proposal to amend the program. A key aspect of this reform is restricting payment for medical services through a narrower definition of "medically necessary." Tennessee has stated to the federal government in its proposed amendment to its current Section 1115 waiver that it is "within the state's authority to define what constitutes a medically necessary Medicaid service" and "the state does not need and is not requesting any waivers" from the Centers for Medicare and Medicaid Services (CMS).⁴ However, the state requests "confirmation from CMS that the state does not need CMS approval prior to the implementation" of the new definition.

Major changes under the new definition are that the service must be the "least costly alternative... that is adequate for the medical condition of the enrollee" and must not be

experimental or investigational. (See Appendices B and D) The legislative definition is more restrictive than the definition currently used by Tennessee and the standard relied on by other state Medicaid agencies, Medicare, Federal Employee Health Benefits contractors, and private sector plans. (See Appendix C)

Issues

The state law removes criteria with the following effect:

- A service no longer has to be consistent with the symptoms, diagnosis, or treatment of the condition.
- A service no longer has to be appropriate based on standards of good medical practice.
- EPSDT services are not expressly stated as covered under the new medical necessity definition. However, the TennCare Bureau is authorized to “make special limited provisions” to comply with federal law.

The state law introduces a new criterion

There must be adequate “empirically-based objective clinical scientific evidence” of the “safety and effectiveness” of the service. The legislation does not expand on specific characteristics that would meet these requirements, and explicitly states that “this standard is not satisfied by a provider’s subjective clinical judgment on the safety and effectiveness of a medical item or service.”

Cost effective vs. “least costly”

Cost effectiveness is the standard by which other public and private programs operate, meaning that precedence is given to the least costly form of care that is equally effective as alternative treatments. The new definition of “medically necessary” uses cost alone to determine what is covered, apart from safety or efficacy. “Standards of good medical practice,” which was the basis of the previous TennCare definition would no longer be the standard; instead the new language states that services only need to be “adequate to address” the medical condition, including, “where appropriate, no treatment at all.”⁵

TennCare Bureau vs. medical providers

The legislation states that “it is the responsibility of the bureau of TennCare ultimately to determine what medical items and services are medically necessary,” and goes on to say that “the fact that a provider has prescribed, recommended or approved a medical item or service does not, in itself, make such item or service medically necessary.” Healthcare decisions would no longer be made primarily by the providers of care.

Implications

The new TennCare “medically necessary” definition could have implications not only for Tennessee, but also for other states and other insurance standards, such as Medicare and FEHBP, that may decide to adopt similar strategies.

Medicaid Beneficiaries

Because the new definition of “medically necessary” is much more restrictive, beneficiaries may experience limited access to services. This in turn could contribute to greater health disparities and poorer health outcomes. In addition, the standard states that the service

should not be for “the convenience of an enrollee, the enrollee’s family, or the provider,” raising questions of whether services provided to frail elderly and children with disabilities to enable them to stay in the home would be covered. Overall, because of these restrictions, there may be poorer health outcomes, increased emergency room use, and consequently increased costs over time.

Health Centers

Health centers primarily serve uninsured and Medicaid populations. Medicaid payments are critical to financing health centers since it covers 36% of health center patients and provides 36% of health centers’ total operating revenues.⁶ State Medicaid reductions, such as the new TennCare restrictions, could mean fewer revenues for health centers. FQHCs may have to use grant funds to subsidize Medicaid patients – funds that were intended for care of the uninsured.

Because the new definition stipulates that a service “must be required in order to diagnose or treat an enrollee’s medical *condition*,” certain preventive and health maintenance services currently offered by FQHCs may no longer be reimbursed. FQHCs may find that they are not compensated for some services, or that they are forced to limit the services they provide. However, per the requirements of their Section 330 PHS grants, FQHCs are required to provide prenatal and perinatal services; screening for breast and cervical cancer; well-child services; immunizations against vaccine-preventable diseases; screenings for elevated blood lead levels, communicable diseases, and cholesterol; pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care; voluntary family planning services; and preventive dental services. So any refusal on the part of TennCare to pay for these, due to a determination that some of these services do not meet all four criteria of the medical necessity definition, would mean a loss of Medicaid compensation.

Further, some preventive and enabling services provided by health centers may not be evidence-based, another requirement for coverage under the new “medically necessary” definition. According to the new definition, for a service to be deemed evidence-based it would require “empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question”. In addition, enabling services, such as transportation to and from the health center for disabled persons, may no longer be covered under the “required in order to diagnose or treat” clause.

Coverage of EPSDT services may also be an issue. TennCare’s current definition of “medically necessary” states expressly that “when applied to enrollees under 21 years of age, services shall be provided in accordance with EPSDT requirements.”² The new legislative definition does not explicitly mention this. Although Tennessee has stated in a supplement to the proposed amendment that the definition “will be implemented consistent with current federal law, including EPSDT requirements,” the state asserts that it has the ability to waive EPSDT benefits for children in the demonstration population and is seeking reaffirmation of this from CMS. A reduction in children’s benefits would have significant implications for health centers, since 40% of health center patients are under the age of 19.⁷

Health centers have also had an impact on reducing racial and ethnic disparities as measured by infant mortality rates, tuberculosis case rates, death rates, and lack of access to prenatal care.⁸ The possibility of inadequate financing through Medicaid in Tennessee may counteract the strides health centers have made in decreasing health disparities for these populations.

Other Healthcare Providers

Providers may not be reimbursed for certain services if the TennCare Bureau decides that they are not “medically necessary,” leaving physicians responsible for anticipating whether the services they prescribe fall under the definition.⁵ The new definition lacks objective standards that can be used to appeal a denial, so patients cannot effectively challenge a denial of coverage and providers cannot effectively appeal a denial of reimbursement.⁶ The increased uncertainty of what is medically necessary and therefore reimbursable may cause some providers to stop serving Medicaid patients, adding to the pressure on health centers and the safety net. Finally, **clinicians would no longer be the mainstay of the medical decision-making process.**

Recommendations

As states struggle to balance budgets, many are looking for ways to control Medicaid costs. In this environment, other states may look to Tennessee as an example and consider making similar changes to their definition of “medically necessary”. As this occurs, the following should be considered:

- Preventive and health maintenance services should be explicitly protected under “medically necessary.” These services cost less than major medical procedures and may save the state money by addressing minor health problems before they develop into serious ones.
- The same language of “generally accepted by the professional medical community as an effective and proven treatment” that Tennessee has adopted for prescription drugs should be used for medical services.
- Any change should include a clearly outlined appeals process to allow providers and patients to pursue further treatment as necessary.
- Existing evidence-based medicine guidelines, such as those of the Agency for Health Care Research and Quality and the Centers for Disease Control, should be used when implementing such a change, rather than creating entirely new guidelines.

¹ Tennessee Public Acts of 2004, Chapter 673

² Chapter-1200-13-12. Bureau of TennCare.

³ “TennCare At-A-Glance.” Office of the Governor, Tennessee.

Kaiser statehealthfacts.org, U.S. Census Bureau.

⁴ “Supplement to September 24, 2004 Proposed Amendment to the TennCare Demonstration Project.” Office of the Governor, State of Tennessee. January 19, 2005.

⁵ “The TennCare Waiver: More (Radical) Than Meets the Eye.” National Health Law Program.

⁶ Rosenbaum, S and Shin, P. “Health Centers as Safety Net Providers,” *Issue Paper* (Washington, DC: Kaiser Commission on Medicaid and the Uninsured, May 2003).

⁷ NACHC, 2004. <http://www.nachc.com/research/Files/USfactsheet.pdf>. Based on Bureau of Primary Health Care, HRSA, DHHS, 2003 Uniform Data System.

⁸ Shin P, Jones KC, and Rosenbaum S. *Reducing Racial and Ethnic Health Disparities: Estimating the Impact of Community Health Centers on Low-income Communities* (Washington, DC: National Association of Community Health Centers, 2003).

This publication was supported by Grant/Cooperative Agreement Number U30CS00209 from the Health Resources and Services Administration, Bureau of Primary Health Care (HRSA/BPHC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of HRSA/BPHC.

Written by: Shakti Nayar, Intern

Contact: Dawn McKinney, Assistant Director, State Affairs, National Association of Community Health Centers, Inc., Department of Federal, State and Public Affairs Office, 2001 L Street, NW Suite 300, Washington, DC 20036, dmckinney@nachc.com, 202/296.3410 voice ~ 202/296.3526 fax

Appendix A
Original TennCare "Medically Necessary" Standard

Rules of Tennessee Department of Finance and Administration
Bureau of TennCare
CHAPTER-1200-13-12
(Rule 1200-13-12-.01)

MEDICALLY NECESSARY shall mean services or supplies provided by an institution, physician, or other provider that are required to identify or treat a TennCare enrollee's illness or injury and which are:

- (a) Consistent with the symptoms or diagnosis and treatment of the enrollee's condition, disease, ailment or injury; and
- (b) Appropriate with regard to standards of good medical practice; and
- (c) Not solely for the convenience of an enrollee, physician, institution or other provider; and
- (d) The most appropriate supply or level of services which can safely be provided to the enrollee. When applied to the care of an inpatient, it further means that services for the enrollee's medical symptoms or condition require that the services cannot be safely provided to the enrollee as an outpatient; and
- (e) When applied to enrollees under 21 years of age, services shall be provided in accordance with EPSDT requirements including federal regulations as described in 42 CFR Part 441, Subpart B, and the Omnibus Budget Reconciliation Act of 1989.

Appendix B
New TennCare "Medically Necessary" Standard

Tennessee Public Acts of 2004
Chapter 673, Section 22

SECTION 22. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following language as a new appropriately designated section:

Section _____. (a) Enrollees under the TennCare program are eligible to receive, and TennCare shall provide payment for, only those medical items and services that are:

(1) within the scope of defined benefits for which the enrollee is eligible under the TennCare program; and

(2) determined by the TennCare program to be medically necessary.

(b) To be determined to be medically necessary, a medical item or service must be recommended by a 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 and must satisfy each of the following criteria:

(1) It must be required in order to diagnose or treat an enrollee's medical condition. The convenience of an enrollee, the enrollee's family, or a provider, shall not be a factor or justification in determining that a medical item or service is medically necessary;

(2) It must be safe and effective. To qualify as safe and effective, the type and level of medical item or service must be consistent with the symptoms or diagnosis and treatment of the particular medical condition, and the reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on the enrollee's condition and scientifically supported evidence;

(3) It must be the least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee. When applied to medical items or services delivered in an inpatient setting, it further means that the medical item or service cannot be safely provided for the same or lesser cost to the person in an outpatient setting. Where there are less costly alternative courses of diagnosis or treatment, including less costly alternative settings, that are adequate for the medical condition of the enrollee, more costly alternative courses of diagnosis or treatment are not medically necessary. An alternative course of diagnosis or treatment may include observation, lifestyle or behavioral changes or, where appropriate, no treatment at all; and

(4) It must not be experimental or investigational. 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 another setting or from use in diagnosing or treating another condition.

(A) Use of a drug or biological product that has not been approved under a new drug application for marketing by the United States Food and Drug Administration (FDA) is deemed experimental.

(B) 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 will not be deemed medically necessary unless the use can be shown to be widespread, to be generally accepted by the professional medical community as an effective and proven treatment in the setting and for the condition for which it is used, and to satisfy the requirements of (b)(1)-(3).

(c) It is the responsibility of the bureau of TennCare ultimately to determine what medical items and services are medically necessary for the TennCare program. The fact that a provider has prescribed, recommended or approved a medical item or service does not, in itself, make such item or service medically necessary.

(d) The medical necessity standard set forth in this section shall govern the delivery of all services and items to all enrollees or classes of beneficiaries in the TennCare program. The bureau of TennCare is authorized to make limited special provisions for particular items or services, such as long-term care, or such as may be required for compliance with federal law.

(e) Medical protocols developed using evidence-based medicine that are authorized by the bureau of TennCare pursuant to Section 2 of this act shall satisfy the standard of medical necessity. Such protocols shall be appropriately published to all TennCare providers and managed care organizations.

(f) The bureau of TennCare is authorized to promulgate such rules and regulations as may be necessary to implement the provisions of this section.

New TennCare “Medically Necessary” Standard Compared to Public and Private Standards

<i>To have payment made, a covered item or service must satisfy each of the following criteria</i>					
Criterion Type	New TennCare Standard (May 2004)	Medicare Standard	FEHBP Blue Cross/Blue Shield National Plan Standard	Hawaii Commercial Health Insurance Standard	
Purpose	Must be required to “diagnose or treat” an enrollee’s “medical condition”	Must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”	Must be “appropriate to prevent, diagnose, or treat [an enrollee’s] condition, illness, or injury”	Must be “for the purpose of treating a medical condition”	
Benefit/Risk Analysis	“The reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on the enrollee’s condition and scientifically supported evidence”	No comparable requirement	Must be “consistent with standards of good medical practice in the United States”	Must be “the most appropriate delivery of level of service, considering potential benefits and harms to the patient”	
Cost	Must be the “least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee”	No comparable requirement	No comparable requirement	Must be “cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention....cost-effective shall not necessarily mean lowest price.”	
Evidence	Must have “adequate empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question”	No comparable requirement	No comparable requirement	Must be “known to be effective in improving health outcomes; provided that (A) Effectiveness is determined first by scientific evidence; (B) If no scientific evidence exists, then by professional standards of care; and (C) If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion”	

**Appendix D
Comparison of Original and New "Medically Necessary" Standards**

Prior and New TennCare "Medically Necessary" Standards

<i>To have payment made, a covered item or service must satisfy each of the following criteria</i>	
Prior Standard	New Standard
Must be required to "identify or treat"	Must be required to "diagnose or treat"
Must be "consistent with the symptoms or diagnosis or treatment"	No comparable criterion
Must be "appropriate with regards to standards of good medical practice"	No comparable criterion
Must be "most appropriate supply or level of services which can safely be provided to the enrollee"	Must be "least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee"
No comparable provision	Must have "adequate empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question"
In the case of services to children under 21, must be "provided in accordance with EPSDT requirements"	No comparable requirement (TennCare Bureau authorized to make "special limited provisions...as may be required for compliance with federal law.")

Schneider, Andy. "Tennessee's New 'Medically Necessary' Standard: Uncovering the Insured?" Policy Brief (Washington, DC: Kaiser Commission on Medicaid and the Uninsured, July 2004).