

National Health Law Program

June 24, 2004

To: Health Advocates

From: National Health Law Program

Contacts: Jane Perkins (NC office) or Mara Youdelman (DC office)

Re: Defining “medical necessity” in state Medicaid programs¹

Question: Our office has been contacted by Ms. G., a 32-year-old Medicaid recipient. She tells us that the state Medicaid agency is seeking to implement a definition of “medical necessity” that, when applied to her condition, will cause her physical therapy services to be terminated. What is the Medicaid Act definition of “medical necessity” and are there elements of the state’s definition that we should be concerned about?

Brief Answer: The Medicaid Act does not define the term “medical necessity.” Over the years, recipients have relied on regulatory and decisional principles to define the scope of coverage. However, a number of states are now reviewing medical necessity and defining it restrictively for Medicaid purposes. You must monitor the situation in your state closely and, if necessary, conduct education on the topic and submit written comments.

The Basic Rules of Coverage²

From the early days of the Medicaid program, federal rules, federal and state court opinions, and administrative fair hearing decisions prescribed the following standards for deciding when a service should be covered by Medicaid:

1. The Medicaid Act lists the mandatory and optional benefits that are available to recipients. *E.g.*, 42 U.S.C. §§ 1396a(a)(10), 1396d(a).
2. States must establish reasonable coverage standards that are comparable for eligibility groups. Services must be covered in sufficient amount, duration and scope to reasonably achieve their purpose, and states cannot deny a mandatory

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² The coverage rules for adults and children have been explained, in depth, in previous publications. *See, e.g.*, Sarah Somers, *Medicaid’s Amount, Duration and Scope Requirement: Challenging Cuts to Services for Adults* (NAPAS Fact Sheet: Apr. 2004); Jane Perkins & Sarah Somers, *Toward a Healthy Future: Medicaid Early and Periodic Screening Diagnostic and Treatment Services for Poor Children and Youth* (Apr. 2003).

service solely because of the diagnosis, type of illness, or condition. *E.g.*, 42 U.S.C. §§ 1396a(a)(10)(B), 1396a(a)(17); 42 C.F.R. § 440.230.

3. States must make all mandatory and optional Medicaid services available to children under age 21 and cover these services when needed to “correct or ameliorate” a mental or physical condition of the child. *E.g.*, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), 1396d(r).

Noticeably, these criteria do not refer to “medical necessity.” This gap has not affected most Medicaid recipients, however, because the vast majority of decisions regarding services and treatment have been made by health care providers in the clinical setting. Medical necessity has been defined in legal terms only in the uncommon situation where the recipient has contested the state’s denial of a service in an administrative or judicial appeal.

Defining Medicaid Necessity

The Medicaid Act does not use the term “medical necessity.” Medicaid regulations allow states to place appropriate limits on a service, based on criteria such as “medical necessity,” 42 C.F.R. § 440.230(d), but do not define the term.

In *Beal v. Doe*, 432 U.S. 438, 444 (1977), the Supreme Court stated that Medicaid “confers broad discretion on the states to adopt standards for determining the extent of medical assistance” that will be provided through the Medicaid programs. Until relatively recently, the decision of whether a particular covered treatment was medically necessary rested with the individual’s treating physician. This is consistent with Congressional intent:

The Committee’s bill provides that the physician is to be the key figure in determining utilization of health services—and provides that it is a physician who is to decide upon admission to a hospital, order tests, drugs, and treatments, and determine the length of stay.

S. Rep. No. 404, 89th Cong., 1st Sess., *reprinted in* 1965 U.S.C.C.A.N. 1943, 1986. *See also*, *e.g.*, *Pinneke v. Preisser*, 623 F.2d 546, 550 (8th Cir. 1980) (recognizing that “the decision of whether or not certain treatment or a particular type of treatment is ‘medically necessary’ rests with the individual recipient’s physician and not with clerical personnel or government officials”); *Hope Med. Group for Women v. Edwards*, 860 F. Supp. 1149, 1151 (E.D. La. 1994) (holding that “[e]ach state’s Medicaid plan must cover those mandatory covered services which an individual patient’s physician certifies as ‘medically necessary.’”); *Preterm v. Dukakis*, 591 F.2d 121 (1st Cir. 1979) (describing two levels of judgment as to medical necessity: macro-decisions of the legislature that only certain services are covered and micro-decisions of a physician that a patient needs a covered service).³

Recently, a number of states have moved to curb Medicaid spending by defining the term medical necessity restrictively in regulations or contracts, most often as an element of Medicaid

³ For extensive citation, *see* Jane Perkins and Sarah Somers, National Health Law Program, *An Advocate’s Guide to the Medicaid Program* at 4.6-4.7 (June 2003).

utilization review or managed care. For example, some states are introducing limitations that shift deference from the treating provider to standards of medical practice and that require there to be no equally effective, less costly alternative treatment.

Clearly, the legal concept of “medical necessity” will play an increasing role in deciding the extent to which individuals with chronic and disabling conditions receive appropriate services through Medicaid. Careful monitoring and informed advocacy must assure that any legal definition of medical necessity used by the state Medicaid program promotes high-quality care for individuals with disabilities.

Much research has focused on articulating appropriate definitions of medical necessity. These definitions have evolved into a multidimensional evaluation that includes consideration of: whether the treatment accords with professional standards of practice, whether it will be delivered in the safest and least intrusive manner, whether the treatment is medical in nature (as opposed to social or otherwise non-medical), and whether the treatment is cost effective.⁴ For example, the American Medical Association suggests that medical necessity be defined as:

health care services or products that a prudent physician would provide to a patient for the purposes of preventing, diagnosing, or treating an illness, injury, disease, or its symptoms in a manner that is (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the convenience of the patient, physician, or other health care provider.⁵

Furthermore, when cost is considered, the assessment should occur within the context of comparing equally efficacious treatments. For example, in the health services research community, a seminal article developed a consensus definition of medical necessity which states that an intervention should be “cost-effective for this condition compared to alternative interventions, including no intervention. ‘Cost-effective’ does not necessarily mean lowest price.”⁶

In sum, any attempt to impose a medical necessity requirement beyond that inherent in a doctor having prescribed the particular treatment should meet the following five criteria. It should:

1. incorporate appropriate outcomes within a developmental framework, including preventing or ameliorating the effects of a condition, assisting in maintaining or facilitating functional capacity, and promoting physical, intellectual and psychological development.

⁴ See, e.g., Sara Rosenbaum et al., *Medical Necessity in Private Health Plans: Implications for Behavioral Health Care* (Center for Mental Health Services, Substance Abuse and Mental Health Services Administration: 2003) (DHHS Pub. No. (SMA) 03-3790).

⁵ From the American Medical Association’s Model Managed Care Contract project, available at <http://www.ama-assn.org/ama1/pub/upload/mm/368/supplement1.pdf>.

⁶ S.J. Singer et al., *Decreasing variation in medical necessity decision-making* (Palo Alto, CA: 1999).

2. explicitly address the information that will be needed in the decision making process, emphasizing individually tailored treatment strategies.
3. identify who will participate in the decision making process.
4. refer to specific standards as a starting point—scientific evidence where it is available and, otherwise where available, practice guidelines and consensus statements from expert panels.
5. support flexibility in the sites of service delivery.⁷

Pending Threats—the Tennessee Example

Unfortunately, a number of states are considering medical necessity definitions that will neither promote high-quality health care for people with disabilities nor meet the prevailing standards for defining the term. Tennessee illustrates this situation. That state has recently developed a definition of medical necessity that is to be submitted to the Centers for Medicare & Medicaid Services as part of a section 1115 waiver request to restructure its Medicaid program, called “TennCare.” The definition works an unprecedented reconceptualization of the notions of medical necessity.⁸ To obtain a service, even if included within the scope of benefits, the service must meet a four part definition, which is quoted (in bold) and then analyzed below. The burden of demonstrating that any given service meets the test rests solely with the patient and/or her provider.

Part 1 – A medical item or service must be required in order to diagnose or treat an enrollee’s [Medicaid patient’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.

Analysis

Diagnose or treat. The requirement that a service be required to “diagnose or treat” a medical condition eliminates much of the preventive care authorized, and in some cases mandated, by Medicaid. It would eliminate immunizations, newborn hearing screens, children’s developmental screens, lead blood tests, diabetes and colorectal screenings, pap smears, and mammograms. Any service provided to monitor, but not treat, a patient’s condition would presumably be excluded, for example, glucose monitoring of a diabetic patient. The definition would exclude a number of services, which TennCare now covers, that maintain functional capacity and/or improve the quality of life but do not actually treat or diagnose. These include home health care for ventilator dependent children and adults; personal care and home health aid

⁷ Henry T. Ireys et al., *Defining Medical Necessity: Strategies for Promoting Access to Quality Care for Persons with Developmental Disabilities, Mental Retardation, and Other Special Health Care Needs* (Sept. 1999) (published by the Health Resources and Services Administration, Maternal and Child Health Bureau).

⁸ See Tennessee H.B. 3513 § 22 (on file at NHeLP).

services for elderly patients with Alzheimer’s disease; and physical and occupational therapy services that prevent regression for children with cerebral palsy. Other services that would likely be precluded by this definition include genetic testing and many services for individuals with mental illness.

Medical condition. The definition further requires that an item or service will only be provided if used to diagnose or treat an enrollee’s “medical” condition. On its face, the definition excludes many services that Medicaid currently covers for non-medical conditions. For example, children with developmental disabilities may not have a “medical” condition *per se* but receive Medicaid services essential to assist in day-to-day functioning. It is not clear whether dental services, prosthetic devices, and durable medical equipment would be covered under this definition. Since pain medications are almost always used for treatment of a symptom rather than a medical condition, this definition would seem to exclude coverage of them.

Part 2 – A medical item or service 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.

Analysis

Safe and effective. “Safe and effective” are terms of art that are used during the rigorous clinical trials for new drugs and devices. It is unclear how these terms could be adapted to determine the medical necessity of services such as physician visits. The definition would appear to foreclose coverage of services according to existing standards of practice that reflect the consensus of the professional community regarding a particular disease or treatment but that are not developed from determinations of safety and efficacy. This limitation is particularly significant for children and pregnant women, who, for ethical and legal reasons, are seldom included in clinical trials. Moreover, by restricting the definition to scientifically supported evidence, Tennessee constrains the ability of health care providers to apply new research to Medicaid recipients before a scientific study has been completed.

Part 3 – A medical item or service 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.

Analysis

Adequate alternative. This section limits coverage to the lowest price alternative that is adequate. However, “adequate” is not a medical term, and it implies treatment of a lesser standard than “most appropriate” or even “most cost effective,” the terms generally used in medical necessity definitions. As applied, the definition could have significant implications across the range of populations covered by Medicaid—for example, allowing only observation of a child with post traumatic stress disorder and a history of violence, rather than providing short-term crisis and family intervention and/or medication and medication monitoring; allowing only observation of a young child exhibiting signs of autism, rather than conducting diagnostic testing; allowing only diet and exercise for an elderly diabetic man, rather than providing glucose monitoring and insulin. As stated above, existing definitions of medical necessity contemplate that cost-effectiveness is an element of determining medical necessity, but only when comparing equally efficacious treatments.

Part 4 – A medical item or service 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 the 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.

Analysis

Experimental or investigational v. clinical scientific evidence of safety and effectiveness. On its face, this part of the Tennessee definition forecloses a wide array of medical services since most medical care in the United States is formulated pursuant to tradition and collective experience of proven efficacy. The undefined word “inadequate,” as applied to clinical scientific evidence, could cause usual treatment to be denied. It could, for example, result in denial of a treatment needed by a child with a rare disease, if only a few physicians specialize in that treatment, because the determination might well rest on the number of enrollees with a disease or physicians treating it rather than examining the actual benefits of the procedure.

Even for services or items that are not based on clinical judgment, the definition constrains medical necessity by prohibiting extrapolation from another setting. The definition implicitly recognizes that this provision will eliminate much care that is regarded by the medical community as necessary and appropriate, for it makes an exception that permits off-label use of drugs. Such use is permitted if it is shown to be “widespread [and] generally accepted by the professional medical community as an effective and proven treatment in the setting and condition for which it is used.” However, under this paragraph many treatments, other than medications, which are also “widespread and generally accepted by the professional medical community as an effective and proven treatment” will nonetheless be deemed “experimental and investigational” and therefore be excluded. Indeed, even off-label uses of some medications may be disallowed if there are relatively few people with the particular disease that the medicine is used to treat.

Conclusion

A number of states are considering medical necessity definitions and may seek to define the term restrictively for Medicaid purposes. You must monitor developments in your state and work to assure that medical necessity is defined in a way that assures high quality care for children, youth, and adults with disabilities. You can:

- ▶ Monitor notices of denials of Medicaid services. Make sure that the state Medicaid agency and its agents (for example, managed care plans) are applying the precedents for medical necessity that govern your state. If more restrictive definitions are being introduced in these notices of denial, complain.
- ▶ Monitor the application of medical necessity in administrative hearings. Counter state arguments and hearing officer questioning that appear to adopt an improper standard of medical necessity. Consider submitting pre- and/or post-hearing briefing.
- ▶ Monitor proposed legislation and regulations not only for definitions of medical necessity that may harm your clients but also for the introduction of processes that will hide the decision making process from public scrutiny—for example, by authorizing medical necessity decisions within the sole discretion of the Medicaid director.
- ▶ Monitor your state’s interest in obtaining a “waiver” from the U.S. Department of Health and Human Services to “reform” Medicaid. States, including Tennessee, New Hampshire, Florida, Connecticut, and California, are seeking unprecedented authority to operate their Medicaid programs without complying with provisions of the Medicaid Act. In the name of “flexibility,” these proposals may include dramatic revisions to the concepts of medical necessity that have traditionally applied in your state.
- ▶ Monitor the introduction and revision of utilization review and managed care programs, particularly as states contract with private entities to conduct these functions. Obtain a copy of the appropriate requests for proposals and/or model contrasts. Measure the definition of medical necessity against the principles outlined above and helpful precedents in your state.
- ▶ Educate the provider community about medical necessity as a legal concept. The new medical necessity definitions, such as that introduced in Tennessee, place health care providers in a wholly untenable position. Physicians who attempt to treat patients are bound by an ethical and legal duty to meet prevailing community standards of care. However, under revised definitions, providers may no longer be guaranteed reimbursement for care they are ethically required to prescribe.