Defining Medical Necessity

Strategies for Promoting Access to Quality Care for Persons with Developmental Disabilities, Mental Retardation, and Other Special Health Care Needs

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MEDICAL NECESSITY

The Joseph P. Kennedy, Jr. Foundation has for many years dedicated its resources to improving the lives of persons with mental retardation and other disabilities. Promoting access to their health care of high quality is one of the Foundation’s most important goals.

Children and adults with mental retardation and other disabilities now are obtaining health services through managed care organizations. These institutions have the responsibility for identifying and supporting medically necessary health services. The definition of “medical necessity” serves an extraordinarily important purpose because it establishes the foundation for deciding what services each person will receive.

The Foundation wants to promote definitions of medical necessity that are sufficiently well formulated and comprehensive to meet the health needs of persons with mental retardation and other disabilities. As managed care organizations and insurers seek innovative ways to meet the needs of all enrolled groups, model criteria for definitions of medical necessity are absolutely essential.

This report provides an exceptionally strong rationale for a comprehensive approach to defining necessity, as well as practical language that can apply to diverse purposes.

I am delighted that the Joseph P. Kennedy, Jr. Foundation was able to assist in supporting this work, and I am confident that it will be useful to everyone who is working to promote high quality of health care for persons with mental retardation, other disabilities or special needs.

Eunice Kennedy Shriver

May 19, 1999
The content of this report has emerged from numerous discussions with colleagues and the deliberations of an exceptionally dedicated steering committee. This committee included Polly Arango, Julie Beckett, Shelly Gehshan, Ian Hill, and Mary Tierney. The report benefited from comments provided by members of an expert panel, convened to review an early draft of the report, who urged us to clarify the criteria for evaluating medical necessity definitions. The expert panel (see Appendix A) included legislators, legislative staff, physicians, family advocates, managed care administrators, lawyers, policy analysts, and other professionals concerned with persons with developmental disabilities and other special health care needs.

We imposed upon a large number of friends and colleagues by asking them to read an early draft. Many responded with uncommon thoughtfulness (see Appendix A). Colleen Sonosky, Richard Hegner, and members of the Association of Maternal and Child Health Programs deserve special mention for the many perceptive comments they gave us. To all our friends and colleagues, we owe many thanks for helping to make this a useful document. Their knowledge, experience, and careful scrutiny of early drafts were instrumental in shaping the report’s final conclusions and recommendations, but they are absolved of all technical errors and misjudgments on our part. The views expressed in this report are the authors’ and do not necessarily reflect those of any agency or foundation that supported this effort.

This project was supported by a grant from the Joseph P. Kennedy, Jr. Foundation to the National Policy Center for Children with Special Healthcare Needs in the Department of Population and Family Health Sciences, School of Hygiene and Public Health, The Johns Hopkins University. We are especially grateful for Eunice Shriver’s conviction that this issue deserved sustained and widespread attention. George Jesien and David Egnor provided a steady stream of encouragement from the Kennedy Foundation.

The policy center operates under a cooperative agreement (24MCP) from the Maternal and Child Health Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services, and is described on the inside back cover of this report. Janis Lambert Connallon, center coordinator, provided thoughtful responses and assistance throughout this project. Fran Keyser handled many of the administrative details with her usual thoroughness and good cheer.
Existing definitions of medical necessity may lead to the denial of services required by persons with special health care needs.
SECTION I

What Is the Problem?

Children, youth, and adults with developmental disabilities, mental retardation, serious emotional disorders, or other special health care needs require continuing access to a wide range of health services. Failure to obtain needed services may curtail the ability of these persons to communicate, attend school, join the work force, and participate actively in community life (Neff and Anderson, 1995). The distinctive needs of this population pose major challenges to the evolving managed health care systems in this country and give urgency to the broad social issue of how to allocate the nation’s health care resources in a fair and just manner (Rushton, 1996).

The concept of “medical necessity” has come to play a central role in determining the extent to which persons with disabling conditions receive appropriate services in managed care systems. How this concept is defined and applied operationally will influence the extent to which needed services will be accessible to vulnerable populations. For example, a sharply limited definition of medical necessity may prevent a young girl with cerebral palsy from obtaining the weekly, ongoing physical therapy services needed to keep her walking.

In the current health care environment, the term “medical necessity” refers to the legal authority of a managed care organization (MCO), a Medicaid agency, or other purchaser of health care to determine whether a specific service will be covered in a specific situation. Health insurance policies often define medical necessity differently from the way a physician uses the term in everyday practice (Braslow et al., 1998). Final responsibility for decisions on medical necessity usually rests with an MCO’s medical director, who may rely on standard protocols or administrative procedures (e.g., prior authorization) rather than on patient-specific information. Some decisions may conflict with a physician’s recommended course of care (Rosenbaum et al., 1999).

Our review of studies and reports on medical necessity decision-making underscores a primary problem: Existing definitions of medical necessity may lead to the denial of services required by children, youth, and adults with developmental disabilities, mental retardation,
genetic disorders, serious mental health problems, or other special health care needs. Most definitions lack critical components that will promote appropriate care for this population. Even the broad medical necessity criteria of many state Medicaid programs may not be carried over into Medicaid managed care plans.

For example, many current definitions of medical necessity require evidence that a service will significantly improve a person's health status. However, many children and adults with disabilities frequently need health or medical services that will maintain their functional capacity. Defining as medically necessary only services that improve their health status means that they will be denied many services vital to their day-to-day lives.

The purpose of this brief is to outline a strategy for defining medical necessity in a fashion that will promote high-quality care for children, youth, and adults with developmental disabilities, mental retardation, genetic disorders, and other special health care needs. The brief also includes a draft definition that can be incorporated into legislation, regulation, or contractual language. The material in this report can be used to craft a process for defining medical necessity that will be administratively feasible, avoid undue risk for key stakeholders, and protect this vulnerable group of children and adults.

**Project Context and Background**

Published studies and discussions with legal experts, policymakers, plan administrators, providers, and consumers indicate that definitions of medical necessity are frequently problematic for children, youth, and adults with developmental disabilities, mental retardation, and other special health care needs. Definitions used by state Medicaid programs are stronger because under federal law covered services that promote children's growth and development must be considered medically necessary, even when services are needed on a long-term basis. But implementation of Medicaid law varies widely at the state level. Overall, federal and state statutes, regulations, judicial decisions, and managed care contracts have yielded a confusing array of medical necessity definitions (Bergthold, 1995; Braslow et al., 1998; Eddy, 1996; Hein, 1997; Jacobson et al., 1997; National Institute for Healthcare Management, 1999).
Managed care systems have the conflicting task of achieving the greatest good for the greatest number while maintaining respect for the individual.

This confusion reflects, in part, an underlying ethical problem of deciding how to distribute fairly the nation’s health care resources (Buchanan, 1981; Veatch, 1976). On the one hand, the utilitarian or practical side of our society suggests that we should allocate resources to achieve the greatest good for the greatest number of persons. This position leads to the argument that limited resources are better spent on ensuring a decent level of medical care for everyone, rather than spending a great deal on a small group of individuals. On the other hand, our society values respect and fairness for the individual, as indicated by such laws as the Individuals with Disabilities Education Act and other legislation that ensures that resources are available for persons to develop and sustain their functional capacity.

Health insurers, including MCOs, are caught in the middle of this debate (Braslow et al., 1998). Our society has delegated to managed care systems the conflicting tasks of distributing resources in an equitable and efficient manner (the greatest good for the greatest number) while also ensuring that individuals are not denied appropriate health services (respect for the individual). Moreover, the health care industry has yet to determine appropriate capitation rates that pertain to populations of children and adults with disabilities (Kronick et al., 1996; Neff and Anderson, 1995). Even the most compelling definition of medical necessity will not compensate for the current financial incentives that discourage insurers from serving this population.

In this brief, we seek to provide a foundation for a decision process that must necessarily balance competing needs. MCOs have an obligation to constrain costs by discouraging the delivery of ineffectual services. Providers and consumers will argue that a particular service is needed to achieve a particular medical or developmental outcome for a particular patient. No definition of medical necessity will avoid all difficult judgments about appropriate care in individual situations.

Defining the Population and Its Service Needs

For the purposes of this report, children and adults with disabilities are defined in broad terms to include persons with developmental disabilities, mental retardation, genetic disorders, serious emotional disorders, ongoing orthopedic disorders, or any of the diverse chronic illnesses that affect our population. Specific definitions and operational strategies for estimating prevalence have been developed for both children (Newacheck et al., 1998) and adults (Jones, 1991).
Taken altogether, disabilities affect less than 20 percent of the nation’s population. As a result, persons with disabilities will always be a minority of enrollees in most health plans. Having an appropriate definition of medical necessity will help ensure their access to services, which might otherwise be inappropriately restricted in an effort to serve the needs of most plan members and to limit overall expenditures.

Because of their diverse health needs, children and adults in this population require access to a wide range of services and hence a broad benefit package. The following are a few examples:

• A child with phenylketonuria (PKU) requires a low phenylalanine diet. Without appropriate diet, sufficient dietary education, and follow-up, the child’s developmental and health status will deteriorate seriously, with corresponding increases in medical costs.

• Many children and adults with cerebral palsy will require ongoing physical therapy to prevent health problems that would otherwise require extensive outpatient services or hospitalization.

• The outcomes of even the most technically brilliant surgery for a brain malformation can be compromised by inadequate postoperative care at home.

In general, the range of services that may be needed for good health outcomes for this population may be quite specialized and extends beyond narrowly defined medical services.

Moreover, most chronic conditions are known to vary broadly in the way they are expressed and experienced. This natural variation in disease expression requires commensurate variation in medical treatments. For example, although persons with cerebral palsy have certain characteristics in common, the functional severity and expression of the condition will vary a great deal. As a result, different persons with the same condition will require a somewhat different set of services at varying rates of...
frequency and duration. This fact leads to the need for a more individualized package of benefits than is appropriate for the general population. Some organizations (e.g., the Federal Interagency Coordinating Council, 1999) have developed specific lists of services for inclusion in benefit packages that cover persons with disabilities.

Creating a general definition of medical necessity that pertains to all members enrolled in a health plan but also responds to the needs of persons with developmental disabilities, mental retardation, or other special health care needs has been the focus of this report. This decision reflects the recognition that (1) the special health care needs of children with these disabilities do not disappear as children grow into adulthood, (2) multiple definitions of medical necessity for different subgroups can create administrative problems, and (3) limiting the definition to specific diagnoses could preclude coverage of needed care for other, coexisting conditions.
Financial support for research has been lacking because of the population’s relatively small size.
Three major reasons underscore the need for a careful process of decision-making on whether a service is medically necessary:

1. Knowledge regarding health care changes over time; new treatments emerge continually, especially for persons with disabilities, genetic disorders, chronic illnesses, serious mental health disorders, and other special health care needs. Moreover, certain services and their duration may be appropriate for some persons but not for others, depending on how the condition is actually expressed. As a result, decisions about what is appropriate for all persons in all situations can never be specified completely in a “rule-book” format.

2. Children, youth, and adults with disabilities (such as mental retardation, developmental disabilities, genetic disorders, chronic illnesses, or serious mental health disorders) often encounter physicians and others who are not familiar with the outcomes of new treatments. For example, many new interventions for this population are aimed at problems that have resulted from rare combinations of chronic conditions or that have not yielded to conventional therapies. Financial support for developing a foundation of relevant research has been lacking for this population, in part because of its heterogeneity and its relatively small size. Thus, evidence on outcomes of new treatments may be known only to a few specialists. When no such data exist, standards for best practice, treatment guidelines, and person-specific evaluations must be used together for decision-making purposes.

3. Developmental considerations must be integrated into medical necessity determinations. For example, some persons, such as those who have certain types of cerebral palsy, need treatments to maintain their ability to function and to prevent the deterioration of their health; these treatments may be needed frequently or for extended periods, or both. Reasonable limits on the frequency, duration, or scope of services for children or adults in general may be inappropriate for persons with special needs. Moreover, some services may be needed for...
habilitative purposes (e.g., promoting overall functioning), even when full rehabilitation or cure is not possible.

The Current Organizational Context of Medical Necessity Determinations

Understanding the context in which organizations determine medical necessity can illuminate why comprehensive definitions of medical necessity are important for persons with developmental disabilities, mental retardation, and other special health care needs. Figure 1 illustrates where medical necessity determinations typically occur in an insurer’s decision-making process and how that process determines whether and to what extent a person may receive services:

- Insurers apply medical necessity criteria after they have determined whether or not a service is included in a benefit package. For example, if speech therapy is not a covered benefit in the insurance policy for a particular child, then (from the insurer’s point of view) decisions about the medical necessity of speech therapy will be irrelevant. Distinguishing what is a covered service for a particular person is separate from deciding whether or not the covered service is medically necessary in a particular situation.

- After insurers determine that a service is to be covered, they may impose limitations on the amount, duration, and scope of that service. For example, speech therapy may be a covered benefit, but a person’s policy may specify that speech therapy can be provided only for certain conditions, for a limited period, or until certain milestones are reached. These milestones may be functional (e.g., the acquisition of near-normal speech) or financial (e.g., the expenditure of a specified number of dollars). The point here is that determining whether a service is medically necessary is separate from determining how and how long the service will be provided.

- Insurers must decide whether or not the treatment or service is experimental. The definition of experimental, which is itself the subject of much controversy (Braslow et al., 1998; Newcomer, 1990; National Institute for Health Care Management, 1999), is not addressed in this paper. It is important to note that medical necessity determinations are separate from decisions about whether a service, item, or procedure is experimental.

This illustration of how decisions are made within an organization also indicates that several procedural components are important beyond an adequate definition of medical necessity:

- The types of covered services in a health plan must be broad enough to respond to the breadth of needs of persons with developmental disabilities, mental retardation, and other special health care needs.

- Financing must be adequate to support the delivery of these services.

- Appropriate service providers must be available.

- The organization and coordination of services must assist the person and his or her family in actually obtaining care.

In addition, insurers must be required to communicate their decisions about services and the
Figure 1. Medical Necessity Determinations: Their Place in Many Current Service Systems
rationale for denials to the individual and her or his family. Although communicating this information is not technically part of the determination process itself, this issue requires attention in the consumer rights portion of legislation, contracts, or regulations (Sofaer, 1995). For example, insurers should promptly notify the individual or family and the relevant providers. The notice should include information on how decisions could be appealed and whether or not the service will be provided during the appeal process.

Rationing vs. Medical Necessity Determinations

Another purpose for clearly defining medical necessity is to distinguish it from rationing. By definition, rationing means “to distribute equitably.” It implies the withholding of treatment on the basis of both cost and outcome. For example, surgical intervention on an infant with widespread congenital malformations may be withheld because of treatment costs and the likelihood of poor outcomes. Rationing is a deliberate, if uncomfortable, decision to protect resources for the group as a whole at the expense of the individual.

Decisions about rationing must balance individual and group needs in light of expected costs. The key question is, Should this intervention be forgone to protect resources for other purposes? In contrast, decisions about medical necessity should be based on a person’s medical, health, and family situation, and not on cost. Here, the key question is, Does this person need this intervention to maintain or promote health?

The process of rationing should be kept distinct from medical necessity. However, this is often not the case in “real-world” settings of insurance programs, where issues of cost often enter into medical necessity decision-making (Bergthold, 1995; Jacobson et al., 1997; National Institute for Health Care Management, 1999). The extent and nature of the role of cost constraints in determining medical necessity is poorly understood.

Definitions of medical necessity should not be used in the service of rationing.
However, the mixing of these two issues contributes to much of the current concern about medical necessity determinations.

Considerations of cost should be carefully weighed in deciding which services to cover and to what extent. Resources for society as a whole must be balanced against the needs of small populations. However, linking these issues to definitions of medical necessity disguises society’s difficulties in making the hard choices that rationing demands. Definitions of medical necessity should not be used in the service of rationing.
The first step in decision-making must be a review of what is known about the person, the condition, and the person’s family.
Many approaches to defining medical necessity are now available and Medicaid contracts illustrate the enormous range in current definitions (see Appendix B). To what extent does each definition promote high-quality care for persons with developmental disabilities, mental retardation, chronic illnesses, and other special health care needs? In considering this question, the following five criteria were examined and are discussed below:

(1) The definition should incorporate appropriate outcomes within a developmental framework.

(2) The definition should explicitly address the information needed in the decision-making process.

(3) The definition should identify who will participate in the decision-making process.

(4) The definition should refer to specific standards.

(5) The definition should support flexibility in the sites of service delivery.

1. Incorporating Appropriate Outcomes Within a Developmental Framework

Any approach to defining medical necessity has to consider whether the service in question will promote positive outcomes. Positive outcomes can include the following:

• Anticipating future health problems
• Reducing disease progression or the rate of functional deterioration
• Preventing or ameliorating the effects of a condition or illness
• Assisting in maintaining or facilitating functional capacity
• Promoting physical, intellectual, and psychological development

The service also must be appropriate to the age and health status of the individual. For children, this criterion rests on the critical need for pediatric standards in all health insurance contracts, an issue that has been discussed elsewhere (Berman, 1997; Wehr and Jameson, 1994). A lifespan developmental approach can...
also be usefully applied to adults (Janicki and Selzer, 1991).

2. Defining a Decision-Making Process: What Information Should Be Used?

In instances where outcomes of a treatment are generally known and the pertinent research foundation is strong, standard protocols are appropriate and should be used for efficiency. In instances where a person has a rare or particularly complex condition, questions about treatment effects may arise and research data may be sparse. Standard protocols should not be substituted for carefully reasoned judgments based on discussions with the individual, family members, and physicians or other clinicians with demonstrated experience. The same disability or chronic illness may take different pathways for different individuals. As a result, individually tailored treatment strategies are often required. The first goal in the decision-making process must be a comprehensive review of what is known about the person, the condition, and the person’s family.

Two levels of knowledge are generally required to meet this goal:

(1) General information about the condition and the population. This includes

- Normal variation in disease expression within populations of children, youth, and adults with specific conditions
- Research on new treatment procedures and outcomes for populations with rare conditions

(2) Specific information about the individual.

Because of the complexity and low prevalence of many chronic disabling conditions, information from a wide range of resources is needed to ensure that decisions will be made in light of how a particular person’s situation differs from the typical. For example, many children and young adults with disabilities have had multiple developmental and medical evaluations from diverse agencies and institutions, including educational and social service agencies, early intervention programs, and multidisciplinary teams supported by Title V monies. School evaluations pertaining to the development of individualized educational plans usually contain important information about functional limitations and educational goals; in some states, services included in these plans are linked specifically to medical necessity determinations (Center for Health Policy Research, 1998). In many instances, persons with developmental disabilities or mental retardation have been evaluated at specialty clinics because of coexisting medical problems. Moreover, parents and family members, as well as the individuals themselves, will have opinions about which services are needed, including inexpensive accommodations that can prevent the need for more costly treatments.
3. Identifying Who Makes the Decision

Medical directors of MCOs usually have the final responsibility for making decisions about medical necessity. As a result, they also have the obligation to ensure that the knowledge they possess or obtain is sufficient to accomplish this task effectively. To develop this knowledge, most medical directors, who typically have backgrounds in family practice, internal medicine, or pediatrics, will need to consult with subspecialty providers, family members, the person's own primary care physician, and, where needed and available, multidisciplinary centers (Jacobson et al., 1997; Quinn, 1997). Integrating expert judgment and a consumer perspective is especially important for persons with conditions that are outside the scope of problems seen in the general population and that will require significant involvement of family members (Arno et al., 1999).

4. Referencing Appropriate Standards

Underlying most medical necessity determinations is the question of which standards will be used to judge whether a service is effective or appropriate. It is useful to have strong scientific evidence documenting that a particular treatment has a particular outcome in a particular group; in these situations, medical necessity determinations are easy. For many medical treatments, however, a strong scientific base is unavailable—even for widely used interventions. In these instances, practice guidelines and consensus statements from expert panels are used as the standard. Consequently, professional guidelines and standards should be used as the standard reference in determining medical necessity for persons with developmental disabilities, mental retardation, and special health care needs. Some specific guidelines are available through the American Academy of Pediatrics and other medical organizations, disease-focused subspecialty organizations, consumer groups, and other pertinent organizations. These guidelines can be used as a starting point in the determination process.

5. Ensuring Flexibility in Sites for Service Provision

For many persons with developmental disabilities, chronic illnesses, and serious emotional disorders, many medical and health-related treatments may be best provided in the home and in other community settings, such as schools. For example, a teen with mental retardation and cerebral palsy in a family in which both parents work may need to have physical therapy provided in either the school, the after-school program, the home, or some combination of these settings, depending on the circumstances of the family and community. Medical necessity determinations must account for this reality and should specifically acknowledge that effective and appropriate services can be delivered in many different sites, assuming that reasonable safeguards, monitoring, and follow-up services are available, and that family capacity and circumstances are acknowledged directly in the decision-making process.
These specifications can serve as a starting point for drafting legislative or contractual language.
For the purposes of this report, specifications for defining medical necessity were developed by the steering committee with much guidance from the expert panel and other colleagues. The specifications were designed to meet the five criteria outlined in Section III and to promote a high quality of care for persons with developmental disabilities, mental retardation, serious emotional disorders, and other special health care needs.

The specifications are described in the following section; they meet the five criteria outlined in Section III by

• Incorporating references to developmental outcomes (Paragraphs 1 and 3)
• Defining explicitly what information should be included (Paragraph 2)
• Defining who should be involved in the decision (Paragraph 4)
• Referencing appropriate standards (Paragraph 3)
• Addressing flexibility in sites for service provision (Paragraph 5)

This approach is likely to serve as a starting point for actually drafting medical necessity definitions to fit into differing legislative, regulatory, or contractual structures. Ensuring inclusion of critical concepts is more important than specific wording.

These specifications were developed after reviewing reports on medical necessity and analyzing current definitions in light of the criteria outlined in Section III. Current definitions vary widely. At one end of the spectrum, some definitions clearly recognized that certain medical or health services might be necessary to preserve a person’s functional capacity. At the other end of the spectrum, definitions narrowly defined services as interventions for “illness and injury” or as interventions that would improve an enrollee’s health status. All of the existing definitions failed to meet at least one of the criteria. Appendix C includes examples of the analysis. As the review was completed, the argument for developing a new, comprehensive approach was strengthened.

In developing specifications, we reviewed definitions of medical necessity that were included...
in a variety of state Medicaid programs, such as managed care contracts, and in other sources (see Appendix B). These definitions cover most of the pertinent elements; many of these elements were incorporated into the recommended approach. We did not systematically review managed care contracts in the private sector because those contracts are proprietary information and their contents are not generally available.
Specifications for Defining Medical Necessity

1. A covered service or item is medically necessary if it will do, or is reasonably expected to do, one or more of the following:
   • Arrive at a correct medical diagnosis\(^1\)
   • Prevent the onset of an illness, condition, injury, or disability (in the individual or in covered relatives, as appropriate)\(^2\)
   • Reduce, correct, or ameliorate the physical, mental, developmental, or behavioral effects of an illness, condition, injury, or disability
   • Assist the individual to achieve or maintain sufficient functional capacity to perform age-appropriate or developmentally appropriate daily activities

2. The MCO or insurer must determine medical necessity on the basis of health information provided by the following persons: the individual (as appropriate to his or her age and communicative abilities), the individual’s family, the primary care physician, and consultants with appropriate specialty training, as well as other providers, programs, multidisciplinary teams, educational institutions, or agencies that have evaluated the individual.

3. The determination of medical necessity must be made on an individual basis and must consider
   • The functional capacity of the person and those capacities that are appropriate for persons of the same age or developmental level
   • Available research findings, health care practice guidelines, and standards issued by professionally recognized organizations or government agencies

4. Final determinations will be made by a physician in concert with the following persons: the individual’s primary care physician; a consultant with experience appropriate to the individual’s age, disability, or chronic condition; and the individual and/or family.

5. Medically necessary services must be delivered in a setting (e.g., an individual’s home, school, child care center, workplace, or community-based agency) that is appropriate to the specific health needs of the individual.

\(^1\)Unspecified or undiagnosed conditions are common in this population; hence, additional or special diagnostic procedures or tests are frequently needed to reach a diagnosis that will assist in determining an appropriate care plan.

\(^2\)Knowledge about the role of genetics in chronic disease and disability is growing rapidly. For example, diagnosis of fragile X syndrome in a child requires pedigree analysis and laboratory studies not only to permit accurate diagnoses, but also to ensure that genetic counseling is provided to help individuals and families make informed choices on reproductive issues.
Research is needed on treatment effects, costs associated with different definitions, and team approaches to medical necessity determinations.
A comprehensive approach to determinations of medical necessity for persons with developmental disabilities, mental retardation, and other special health care needs will have management and fiscal implications. Depending on how it is implemented, a comprehensive approach may require the following:

- Procedures for determining the scope of medical and related information that will be needed to determine whether a service is medically necessary; installation of data-tracking methods that will assist in this effort
- Procedures for determining when standard protocols can be used and when they are not appropriate
- Assurance that medical necessity determinations will address whether the service in question will help accomplish the person’s overall health and functional goals and whether evidence is available on the intervention’s treatment effects
- Assurance that medical necessity determinations for this vulnerable population of children and adults will be made and monitored routinely by appropriate personnel
- Demonstrations that comprehensive structural procedures are in place to ensure that services needed by a vulnerable population are available and that consumer and provider perspectives are incorporated in a consistent, organized manner
- An ongoing quality assessment process that is separate from an appeal or grievance process

In the final analysis, purchasers and plans will have to consider whether the costs of implementing a comprehensive process of determining medical necessity for vulnerable populations is worth the cost of not doing so (Glassman et al., 1997). In the latter instance, these costs may include (1) increased medical expenditures if denial of services ultimately increases a patient’s morbidity and subsequent use of covered services; (2) the administrative burden of frequent appeals; and (3) the financial costs of court settlements of cases in which medical necessity determinations were not made on the
basis of comprehensive information (Hall and Anderson, 1992; Sage, 1995).

Currently, little information is available to assess the varying costs of different definitions of medical necessity, to measure "necessity" (Kahan et al., 1994), or even to understand how cost considerations influence medical necessity determinations. A carefully conceptualized program of research is needed that will directly address these issues as they affect children, youth, and adults with developmental disabilities, mental retardation, serious emotional disorders, chronic illnesses, and other special health care needs. In particular, research is needed on treatment effects pertaining to this population, on how medical necessity decisions are actually made in different types of financing systems, and on the implications of a team approach in medical necessity determinations.

The role of scientific evidence in shaping the financing and delivery of health care will continue to grow. Unfortunately, recent efforts to define new policies on medical necessity and the breadth of benefits fail to address specific issues about vulnerable populations. The research community (both investigators and funding sources) must focus attention on these populations in order to develop the knowledge base needed for reasoned equity in the allocation of our nation's health resources.

Finally, it is no secret that U.S. health care systems are changing rapidly. Issues pertaining to medical necessity are likely to shift substantially as MCOs develop new products with differing benefit packages, service coordination models, co-payment structures, and strategies for managing provider networks. Families, physicians, other health care providers, and legislative staff will need to monitor these changes closely to ensure that children and adults with disabilities, mental retardation, and chronic illnesses receive the services they need.
References


APPENDIX A

Contributors

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Most of the following definitions come from state Medicaid managed care contracts and can be found in Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts (Rosenbaum et al., 1998).

State Definitions

Arizona: Medically necessary services are those covered services provided by a physician or other licensed practitioner of the healing arts within the scope of their practice under state law to (a) prevent death, treat/cure disease, and ameliorate disabilities or other adverse health conditions, and/or (b) prolong life.

Colorado: Medically Necessary shall mean any health care service required to preserve the Covered Person's health and which, as determined by the Contractor's designated medical representative or Medical Director, is

- Consistent with accepted standards for the prevention of disease and disability and for treatment of symptoms
- Appropriate with regard to standards of good medical practice
- Not solely for the convenience of the Covered Person, his or her Physician(s), Hospital, or other providers

When specifically applied to an inpatient, it further means that the covered person's medical symptoms or condition requires that the diagnosis or treatment cannot be safely provided to the Covered Person in any other setting, i.e., home, outpatient, Nursing Facility.

Georgia: Those services which are reasonable and necessary in establishing a diagnosis and providing palliative, curative, or restorative treatment for physical and/or mental health conditions in accordance with the standards of medical practice generally accepted at the time the services are rendered. The services provided, as well as the type of provider and setting, must be appropriate to the specific medical needs of the Member.

Kansas: Those services and medical supplies which are required for prevention, diagnosis, or treatment for sickness or injury which are

- Consistent with the symptoms of a medical condition or treatment of a medical condition
- Appropriate with regard to standards of good medical practice and generally recognized by the medical scientific community as effective

APPENDIX B

Medical Necessity Definitions
• Not solely for the convenience of an HMO member or provider of the service or medical supplies

• The most effective of the alternative levels of service or medical supplies which can safely be provided

**Minnesota:** Pursuant to Minnesota Rules, Part 9505.0175, Subpart 25, “medically necessary” or “medical necessity” means a health service that is consistent with the enrollee's diagnosis or condition and

• Is recognized as the prevailing standard or current practice by the provider's peer group; and

• Is rendered in response to a life threatening condition or pain; or to treat an injury, illness, or infection; or to treat a condition that could result in physical or mental disability; or to care for the mother and child through the maternity period; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; or

• Is a preventive health service defined under Minnesota Rules, Part 9505.0355.

**Montana:** A service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions in a patient which endanger life, cause suffering or pain, result in illness or infirmity, threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. A service or item is medically necessary only if there is no other equally effective, more conservative, or substantially less costly course of treatment medically appropriate for the recipient requesting the service or, when appropriate, no treatment at all. Experimental services or service generally regarded by the medical profession as unacceptable treatment are not medically necessary.

**Nebraska:** The term “medical necessity” and “medically necessary” with reference to a covered service means health care services and supplies which are medically appropriate to meet the basic health needs of the client; rendered in the most cost effective manner and type of setting appropriate for the delivery of the covered services; consistent in type, frequency, and duration of treatment with scientifically based guidelines of national medical research or health care organizations or government agencies; consistent with the diagnosis of the condition; required for reasons other than the convenience of the client or of his or her physician; no more intrusive or restrictive than necessary to provide a proposed balance of safety, effectiveness, and efficiency; of demonstrated value; and a no more intensive level of service than can be safely provided. The fact that the physician has performed or prescribed a procedure or treatment or the fact that it may be the only treatment for a particular injury, sickness, or mental illness does not mean that it is medically necessary.

**New Jersey:** Services or supplies necessary to prevent, diagnose, correct, prevent the worsening of, alleviate, ameliorate, or cure a physical or mental illness or condition; to maintain health; to prevent the onset of an illness, condition, or disability; to prevent or treat a condition that endangers life or causes suffering or pain or results in illness or infirmity; to prevent the deterioration of a condition; to promote the development or maintenance of maximal functioning capacity in performing daily activities, taking into account both the functional
capacity of the individual and those functional capacities that are appropriate for individuals of the same age; to prevent or treat a condition that threatens to cause or aggravate a handicap or cause physical deformity or malfunction, and there is no other equally effective, more conservative, or substantially less costly course of treatment available or suitable for the enrollee.

The service provided, as well as the type of provider and setting, must be reflective of the level of services that can be safely provided, must be consistent with the diagnosis of the condition and appropriate to the specific medical needs of the enrollee and not solely for the convenience of the enrollee or provider of service and in accordance with standards of good medical practice and generally recognized by the medical scientific community as effective. Course of treatment may include mere observation or, where appropriate, no treatment at all. Experimental services or service generally regarded by the medical profession as unacceptable treatment are not medically necessary for the purposes of this contract.

In the case of pediatric enrollees, the definition shall apply with the additional criteria that the services, including those found to be needed by a child as a result of a comprehensive screening visit or an inter-periodic encounter whether or not they are ordinarily covered services for all other Medicaid enrollees, are appropriate for the age and health status of the individual and that the service will aid the overall physical and mental growth and development of the individual and the service will assist in achieving or maintaining functional capacity.

Oregon: “Medically Necessary Services and Items” are defined in the Department’s General Rules as those services and items that are required for diagnosis or treatment of illness, or injury, and which, in the judgment of the Medical Assistance Program, are

- Consistent with the diagnosis and treatment of the patient’s condition, and
- Appropriate with regard to standards of good medical practice, and
- Not primarily for the convenience of the patient or a provider of services and supplies, and
- The least costly of the alternative supplies or levels of service which can be safely provided to the patient, and
- Will significantly improve the basic health status of the client.

The fact that a licensed practitioner or other professional or provider prescribes, orders, or recommends, or approves a service or item does not, in itself, make the service or item medically necessary.

Pennsylvania: Determination of medical necessity for covered care and services, whether made on a prior authorization, concurrent, or post-utilization basis, shall be in writing, be compensable under medical assistance, and be based on the following standards. The plan shall base its determination on medical information provided by the individual’s family and the primary care practitioner, as well as any other providers, programs or agencies that have evaluated the individual. Medical necessity determinations must be made by qualified and trained providers. Satisfaction of any one of the following standards will result in authorization of the service:
• The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability.

• The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of illness, condition, injury, or disability.

• The service or benefit will assist the individual to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age.

**Tennessee:** “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

  • Consistent with the symptoms or diagnosis and treatment of the enrollee’s condition, disease, ailment or injury; and

  • Appropriate with regard to standards of good medical practice; and

  • Not solely for the convenience of an enrollee, physician, institution or other provider; and

  • 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 symptom or condition require that the services cannot be safely provided to the enrollee as an outpatient.

**Texas:** Medically necessary services shall be defined as services which are reasonable and necessary to prevent illness or medical conditions and provide early screening, intervention and treatments for conditions that cause suffering or pain, cause physical deformity or limitations in function, threaten to cause or worsen a handicap, cause illness or infirmity of a member, or endanger life; provided at appropriate facilities (which may include the beneficiary’s home) and at the appropriate level of care for the treatment of a member’s medical conditions; consistent with the health care practice guidelines and standards that are issued by professionally recognized health care organizations or governmental agencies; consistent with the diagnoses of the conditions; and no more intrusive or restrictive than necessary to provide a proposed balance of safety, effectiveness, and efficiency.

**Virginia:** Only supplies, equipment, and appliances that are considered medically necessary are covered. All of the following must be met to be considered medically necessary. The supplies and equipment or appliances must be

  • A reasonable and necessary part of the recipient’s treatment plan;

  • Consistent with the symptoms, diagnosis, or medical condition of the illness or injury under treatment;

  • Not furnished for the convenience of the recipient, the family, the attending practitioner, or other practitioner or supplier; and

  • Necessary and consistent with generally accepted professional medical standards (i.e., not experimental or investigational).
Washington: Medically necessary services are services which are reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions that endanger life, cause suffering or pain, result in illness or infirmity, threaten to cause or aggravate a handicap or cause physical deformity or malfunction, and there is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the member requesting the service. For the purpose of this contract, “course of treatment” may include mere observation or, where appropriate, no treatment at all. Medically necessary services shall include, but not be limited to, diagnostic, therapeutic, and preventive services which are generally and customarily provided in the service area, and performed, prescribed, or directed by the PCP and approved by the Contractor’s Medical Director, except where expressly limited or excluded by this contract.

Other Definitions

The Institute of Medicine: Medical necessity is the need for a specific medical service based on clinical expectations that the health benefits of the service will outweigh the health risks.

The American Academy of Pediatrics: The following criteria should be used to decide medical necessity and approval of services: Is the service appropriate for the age and health status of the individual; will the service prevent or ameliorate the effects of a condition, illness, injury, or disorder; will the service aid the overall physical and mental growth and development of the individual; and will the service assist in achieving or maintaining functional capacity? (Berman, 1997).

Medicaid’s Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Under the Medicaid EPSDT benefit, children enrolled in Medicaid are entitled to comprehensive health assessments at regular intervals and any follow up diagnostic and treatment services that are “necessary to correct or ameliorate defects and physical and mental illnesses and conditions” (42 U.S.C. 1396d). In addition, covered services must be sufficient to “reasonably achieve” the broadly preventive purpose of EPSDT, which has been interpreted to include early and continuing health care interventions to prevent or mitigate primary or secondary disability (42 C.F.R. 440.230) (See also Zimmerman et al., 1996).

Commercial Insurers: A typical benefits contract may define a medically necessary service as a service that is (1) necessary to meet the basic health needs of the covered person; (2) rendered in the most cost-efficient manner and type of setting appropriate for the delivery of the health service; (3) consistent in type, frequency, and duration of treatment with scientifically based guidelines of national medical, research, or healthcare coverage organizations or governmental agencies; (4) consistent with the diagnosis of the condition; (5) required for reasons other than the convenience of the covered person or his or her physician; and (6) demonstrated through prevailing peer-reviewed medical literature to be safe and effective for treating or diagnosing the condition or sickness for which the use of the service is proposed (Braslow et al., 1998, p. SP142–SP143).
With much assistance from the steering committee, the authors of this report analyzed a series of definitions of medical necessity in light of the criteria described in Section III. Three examples are presented briefly for the purposes of illustrating this exercise. Additional information on this process can be obtained from the authors.

The American Academy of Pediatrics

The American Academy of Pediatrics has developed an approach to defining medical necessity by stipulating that decisions must rest on answers to the following questions (Berman, 1997):

- Is the service appropriate for the age and health status of the individual?
- Will the service prevent or ameliorate the effects of a condition, illness, injury, or disorder?
- Will the service aid the overall physical and mental growth and development of the individual?
- Will the service assist in achieving or maintaining functional capacity?

These questions reflect an outcomes-based approach to defining medical necessity in the context of a developmental framework. They also emphasize the importance of considering the service in light of the needs of the individual patient. Both attributes are especially critical to the individual provider in the context of a provider-patient relationship. This approach, however, does not address explicitly what information will be used to answer these questions, or who will be involved in the discussion that leads to the final determination. It also does not explicitly mention the issue of where services may be delivered.

The National Institute for Health Care Management

In 1994, the National Institute for Health Care Management sponsored an effort, led by Dr. David Eddy, to establish model medical necessity language (Agency for Health Care Policy Research, 1995; Eddy, 1996; National Institute for Health Care Management, 1995). This approach is consistent with the rationalist tradition that emphasizes the use of scientific evidence in decision-making. Health plans would be expected to cover interventions if the interventions met the following criteria:

- The intervention must be used for a medical condition.
• There is sufficient evidence to draw conclusions about the intervention's effects on health outcomes.

• The evidence demonstrates that the intervention can be expected to produce its intended effects on health outcomes.

• The intervention's beneficial effects on health outcomes outweigh its expected harmful effects.

• The health intervention is the most cost-effective method available to address the medical condition.

Additional material that describes this approach notes also that “When applied to individual cases, these criteria should be interpreted with references to the specific circumstances of each case.”

Admirable in its appeal for basing decisions on evidence related to intervention outcomes, this approach is fairly explicit in identifying what standards should be used in deciding limits on coverage. Nonetheless, it ignores several important criteria outlined in Section III. First, it does not address developmental considerations. Second, it does not explicitly acknowledge the role of information provided by physicians, evaluation teams, the family, or the individual. Third, it does not address the need for flexibility in where services can be provided.

A final concern about this definition involves the basic level of research on treatment interventions for persons with developmental disabilities and other special needs, including children with these conditions. In part because of its small size and medical heterogeneity, this population has not received the level of research attention accorded to populations with more common conditions (e.g., adults with diabetes, cancer, or cardiac problems). Thus, NIHCM’s approach may inadvertently penalize children, youth, and adults with developmental disabilities, mental retardation, and other special needs because of its assumption that pertinent evidence is or will be available, when in fact it may not be.

**Department of Human Services, State of New Jersey**

In its March 1998 materials on New Jersey Care 2000, the Division of Medical Assistance and Health Service of New Jersey’s Department of Human Services defined medically necessary services as services or supplies necessary to

• Prevent, diagnose, correct, prevent the worsening of, alleviate, ameliorate, or cure a physical or mental illness or condition

• Maintain health

• Prevent the onset of an illness, condition, or disability

• Prevent or treat a condition that endangers life or causes suffering or pain or results in illness or infirmity

• Prevent the deterioration of a condition

• Promote the development or maintenance of maximal functioning capacity in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age

• Prevent or treat a condition that threatens to cause or aggravate a handicap or cause
physical deformity or malfunction and there is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the enrollee.

The material also notes: “Services provided, as well as the type of provider and setting, must be reflective of the level of services that can be safely provided, must be consistent with the diagnosis of the condition and appropriate to the specific medical needs of the enrollee and not solely for the convenience of the enrollee or provider of service and in accordance with standards of good medical practice and generally recognized by the medical scientific community as effective. Course of treatment may include mere observation or where appropriate, no treatment at all” (State of New Jersey, 1998).

In our view this definition (similar to many definitions found in state Medicaid regulations or contracts) covers most of the critical issues outlined in Section III. It is particularly detailed in specifying outcomes for the intervention. However, it does not mention issues of development, nor does it specify the type and source of information that would be included in reaching a decision on medical necessity.
The National Policy Center for Children with Special Health Care Needs aims to promote comprehensive, family-centered systems of care for children with special health care needs and their families. To accomplish this mission, the Center:

- Gathers and disseminates information that assists families, managed care organizations, state health departments, and policymakers to collaborate on improving systems of care for these children and their families.
- Conducts policy research related to cost and financing of services for children with special health care needs.
- Develops methods for evaluating integrated systems of care at the community level.
- Provides support and information to family advocacy efforts.
- Provides monitoring and system-design tools to managed care organizations and state agencies concerned with this population.

The Center is committed to producing information that is relevant to the operational needs of managed care organizations and state agencies; practical and easily used by professionals, families, and program administrators; comprehensive, in its ability to diagnose complex problems, frame alternative strategic solutions, and consider their strengths and weaknesses; and responsive to the concerns of multiple audiences, including federal and state officials, managed care organizations, and families.

The Center is a collaboration among:

- Department of Population and Family Health Sciences
  Johns Hopkins School of Hygiene and Public Health
  Baltimore, MD
- Health Systems Research, Inc.
  Washington, DC
- Family Voices
  Algodones, NM

A Center Advisory Board and issue-focused work groups support and extend the activities of the Center. The Center has been established through a cooperative agreement (24M CP) with the Maternal and Child Health Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services.

For more information about Center activities, contact any of the following:

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