

**ASSURING HIGH QUALITY OF CARE FOR PERSONS WITH
DEVELOPMENTAL DISABILITIES AND OTHER SPECIAL HEALTH CARE NEEDS:
SPECIFICATIONS FOR A DEFINITION OF MEDICAL NECESSITY**

A Report Prepared by

Henry T. Ireys, PhD, Associate Professor
Department of Population and Family Health Sciences
School of Hygiene and Public Health
The Johns Hopkins University

Elizabeth Wehr, JD, Research Scientist
Center for Health Services Research and Policy
The School of Public Health and Health Services
George Washington University Medical Center

and

Robert E. Cooke, MD, Emeritus Professor
Department of Pediatrics
State University of New York, Buffalo
Former Pediatrician and Chief
Johns Hopkins Hospital

June, 1999

Acknowledgments

The content of this report has emerged from numerous discussions with colleagues and deliberations of an exceptionally dedicated steering committee. This committee included Polly Arango, Julie Beckett, Shelly Gehshan, Ian Hill, and Mary Tierney. 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 report benefitted 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 this population. 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). Ms. Colleen Sonosky, Mr. Richard Hegner, and members of Association of Maternal and Child Health Programs (AMCHP) deserve special mention for the many perceptive comments they gave to us. To all of our friends and colleagues we owe many thanks for helping to make this a useful document.

This project was supported by a grant from the Joseph P. Kennedy, Jr. Foundation to the National Policy Center for Children with Special Health Care Needs in the Department of Population and Family Health Science, School of Hygiene and Public Health, the Johns Hopkins University. We are especially grateful for Ms. Eunice Shriver's conviction that this issue deserved sustained and widespread attention. The Center operates under a cooperative agreement from the Maternal and Child Health Bureau, HRSA, DHHS, and is described on the back cover of this report. Ms. Janis Lambert, Center Coordinator, provided thoughtful responses and assistance throughout this project. Ms. Fran Keyser handled many of the administrative details with her usual thoroughness and good cheer.

Intended Audience

Our intended audience includes health policy makers, purchasers of managed care services, families, advocates, health care providers, and the managed care industry. State legislators especially can make a major difference in the lives of these citizens by adopting standards for defining medical necessity for Medicaid contracts and other health plans that are not under ERISA.

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SECTION I

INTRODUCTION: WHAT IS THE PROBLEM?

Children, youth, and adults with developmental disabilities, mental retardation, birth defects, 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 & 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 individuals with disabling conditions receive appropriate services in managed care systems. How this concept is defined and applied operationally has major implications for whether 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 denial of services required by children, youth, and adults with developmental disabilities, mental retardation, birth defects, 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. Many children and adults with disabilities, however, 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 of care for children, youth, and adults with developmental disabilities, mental retardation, birth defects, 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, policy makers, 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; NIHCM, 1999).

This confusion reflects, in part, an underlying ethical problem of deciding how to distribute fairly the nation's health care resources (Buchanan, 1981; Veatch & Branson, 1976). On the one hand, the utilitarian or practical side of our American 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 assuring 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 assures resources are available for persons to develop and sustain their functional capacity.

Health insurers, including managed care organizations, 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 assuring 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 & Anderson, 1995); even the most compelling definition of medical necessity will not compensate for current financial incentives that discourage insurers from serving this population.

In this brief, we seek to provide a foundation for a decisional process that must necessarily balance competing needs. MCOs have an obligation to constrain costs by discouraging 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 judgements concerning appropriate care in individual situations.

Defining the Population and Their Service Needs

For the purposes of this report, we are defining children and adults with disability in broad terms to include persons with developmental disabilities, mental retardation, birth defects, 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).

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. For example, a child with 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 post-operative 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 have broad variation in the way they are expressed and experienced. For example, although the group of individuals 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 have developed specific lists of services for inclusion in benefit packages that cover persons with disabilities (e.g., Federal Interagency Coordinating Council, 1999).

Taken altogether, disabilities affect less than twenty 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 to assure access to services, which might otherwise be inappropriately restricted in an effort to serve the needs of the majority of plan members and to limit overall expenditures.

We focused on creating a general definition of medical necessity that pertains to all members enrolled in a health plan but is also responsive to the needs of individuals with developmental disabilities, mental retardation, or other special health care needs. This decision reflects our 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, co-existing conditions.

SECTION II

WHY ARE MEDICAL NECESSITY DETERMINATIONS IMPORTANT?

Three major reasons underscore the continuing need for a careful process of decision-making on whether a service is medically necessary:

First, 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 others, depending on how the condition is actually expressed. As a result, decisions regarding what is appropriate for all persons in all situations can never be specified completely in a “rule-book” format.

Second, children, youth, and adults with disabilities, such as mental retardation, developmental disabilities, genetic disorders, chronic illnesses, or serious mental health disorders often encounter situations where outcomes of proposed treatments are unfamiliar to many physicians. For example, many new interventions for this population are aimed at problems that have *not* yielded to conventional therapies or that result from rare combinations of chronic conditions. Financial support for developing a foundation of relevant research has been lacking for this population -- in part because of 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 decisional purposes.

Third, developmental considerations must be integrated into medical necessity determinations. For example, some persons (e.g., individuals with certain types of cerebral palsy) need treatments to maintain function and prevent deterioration of their health status; these treatments may be needed frequently or for extended periods of time, or both. Reasonable limits on 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.

Current Organizational Context of Medical Necessity Determinations

Understanding the organizational context of medical necessity determinations can help in understanding why comprehensive definitions of medical necessity are important for persons with developmental disabilities, mental retardation, and other special health care needs. The figure on page 6 illustrates where medical necessity determinations typically occur in an insurer’s overall decision making process. It underscores that several factors will determine whether and to what extent an individual may receive services.

First, medical necessity criteria are applied after the service is determined to be 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 regarding its medical necessity will be irrelevant. Distinguishing what is a covered services is separate from the decision about whether a covered service is medically necessary for a particular person in a particular situation.

Second, the figure illustrates that after a service is determined to be covered, limitations may be imposed on amount, duration, and scope of treatment. Speech therapy may be a covered benefit, for example, but an individual's policy may specify that it can be provided only for certain conditions, for a limited period of time, or until certain milestones are reached. These milestones may be functional (e.g., acquisition of near-normal speech) or financial (e.g., after a specified number of dollars have been spent). 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.

Third, a decision has to be made on whether the treatment or service is "experimental." The definition of "experimental" is itself the subject of much controversy (Braslow et al., 1998; Newcomer, 1990; NIHCM, 1999), which we do not address here. It is important to note that medical necessity determinations are separate from decisions about whether a service, item, or procedure is experimental.

This picture of how decisions occur in an organizational framework illustrates that several elements are necessary beyond an adequate definition of medical necessity: the types of covered services must be broad enough to respond to the breadth of needs in this population; financing must be adequate to support the delivery of these services; appropriate providers must be available; and the organization and coordination of services must assist the individual and family in actually obtaining care.

Another task involves communicating medical necessity determinations and the rationale for denials to the individual and her or his family. Although 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 the service continues through the appeal process.

“Rationing” vs Medical Necessity Determinations

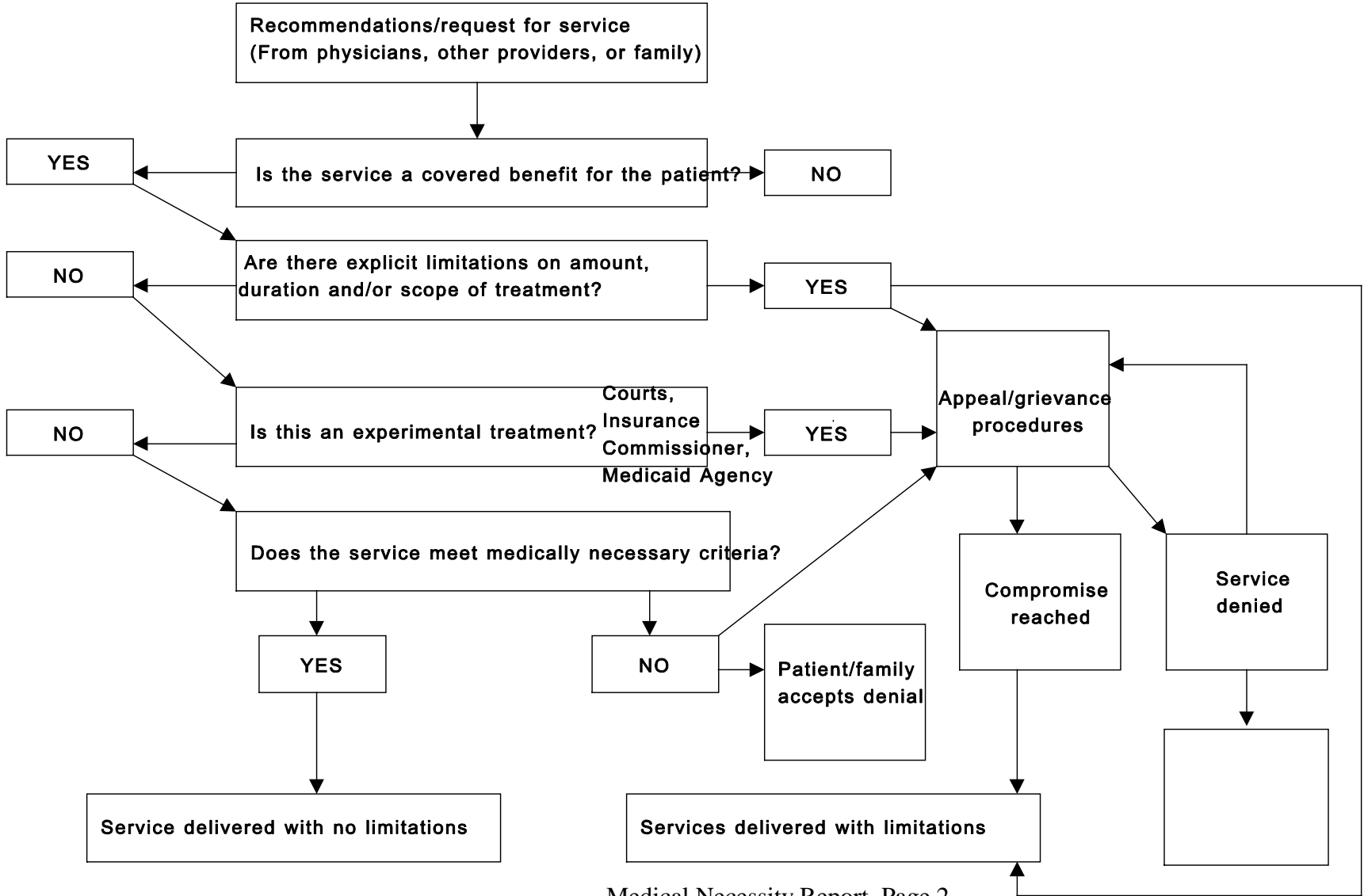
Another purpose of having a clear definition of medical necessity is to distinguish it from “rationing.” By definition, rationing means “to distribute equitably.” It implies the withholding of treatment on the basis of both cost and outcome considerations. For example, surgical intervention on an infant 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 individual needs.

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

In our view, the process of rationing should be kept distinct from medical necessity. 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; NIHCM, 1999). The extent and nature of the role of cost constraints in determining medical necessity is poorly understood. The mixing of these two issues, however, contributes to much of the current concern about medical necessity determinations.

Considerations of cost should be carefully weighed in deciding what services to cover and to what extent; and resources for society as a whole must be balanced against the needs of small populations. But linking these issues to definitions of medical necessity serves to disguise society’s difficulties in making the hard choices that rationing demands. We believe that medical necessity should not be used in the service of rationing.

Medical Necessity Determinations: Organizational Place in Many Current Service Systems



SECTION III

DEFINITIONS OF MEDICAL NECESSITY: KEY CRITERIA

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, five criteria were examined which are discussed below:

1. Whether the definition incorporates appropriate outcomes within a developmental framework,
2. How explicitly the definition addresses the information needed in the process of decision-making,
3. Whether the definition identifies who should participate in the decision,
4. Whether specific standards are referenced, and
5. The extent to which the definition supports flexibility in sites of service delivery.

1. Incorporating Appropriate Outcomes in 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:

- anticipating future health problems,
- reducing disease progression or rate of functional deterioration,
- preventing or ameliorating the effects of a person's condition or illness,
- assisting in maintaining or facilitating a person's functional capacity, or
- 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 which has been discussed elsewhere (Berman, 1997; Wehr & Jameson, 1994). A lifespan developmental approach can also be usefully applied to adults (Janicki & 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 purposes of efficiency. In instances where an individual has a rare or particularly complex condition -- when questions about treatment effects are likely to arise and available research is sparse -- standard protocols should not be substituted for carefully-reasoned judgements 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. The first involves general information about the condition and the population, including information on:

- "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, and
- potential care coordination problems related to conditions that require complex sequences of medical, ancillary, and follow-up services.

The second level of information involves the person. Because of the complexity and low prevalence of many chronic disabling conditions, information from a wide range of resources is needed to assure 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 multi-disciplinary teams supported by Title V monies. School evaluations pertaining to the development of Individual Educational Plans usually contain important information regarding 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, individuals with developmental disabilities or mental retardation have been evaluated at specialty clinics. Moreover, parents and family members, as well as the individuals themselves, will have opinions about what services are needed, including inexpensive accommodations that can prevent need for more costly treatments.

3. Identifying Who Makes the Decision

Medical directors of managed care organizations usually have the final responsibility for medical necessity decisions. As a result, they also have the obligation to assure that they have or obtain sufficient knowledge 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). The value of expert judgement and consumer perspective is especially important for individuals with conditions that are outside the scope of problems seen in the general population and that will require significant family involvement (Arno, Levine, & Memott, 1999).

4. Referencing Appropriate Standards

Underlying most medical necessity determinations is the question of what 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 of individuals; in these situations, medical necessity determinations are easy. For many medical treatments, however, a strong scientific base is lacking -- 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 this group of individuals. 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. Assuring Flexibility in Sites for Service Provision

For many individuals with developmental disabilities, chronic illnesses, and serious emotional disorders, many medical and health-related treatments may best be provided in the home and other community settings, such as schools. A teen with mental retardation and cerebral palsy who lives in a family where both parents work, for example, may need to have physical therapy provided in either the school, after-school program, home, or some combination depending on the circumstances of the family and community. Medical necessity determinations must account for this reality and 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.

SECTION IV

RECOMMENDED APPROACH TO DEFINING MEDICAL NECESSITY

For the purposes of the report, specifications for defining medical necessity were developed by the steering committee with much guidance from the expert panel and other colleagues. It was designed specifically to meet our five criteria and to promote a high quality of care for individuals with developmental disabilities, mental retardation, and other special health care needs.

Our specifications are described on the following page; they meet the five criteria outlined above by:

Incorporating reference 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), and

Addressing flexibility in sites for service provision (Paragraph 5).

We recognize that 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. Assuring inclusion of critical concepts is more important than specific wording.

Our decision to fashion these specifications was made after reviewing reports on medical necessity and analyzing current definitions in light of the criteria outlined in the previous section. We were struck by the wide variation in the definitions. At one end of the spectrum, some definitions clearly recognized that certain medical or health services might be necessary in order to preserve an individual's functional capacity. At the other end of the spectrum were definitions that defined services narrowly 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 our criteria. Appendix C includes examples of our analysis. As we completed our review, the argument for developing a new, comprehensive approach was strengthened.

In developing our specifications, we reviewed definitions of medical necessity included in a variety of state Medicaid programs, including managed care contracts, and in other sources (see Appendix B). These definitions include many elements that concern services for persons with developmental disabilities, mental retardation, and chronic illnesses. We incorporated many elements of these existing definitions into our recommended approach. We did not review specific private sector managed care contracts because they 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 or is reasonably expected to:
 - A. Arrive at a correct medical diagnosis;¹ or
 - B. Prevent the onset of an illness, condition, injury, or disability; or in the covered relatives of that individual as appropriate;² or
 - C. Reduce, correct, or ameliorate the physical, mental, developmental, or behavioral effects of an illness, condition, injury, or disability; or
 - D. Assist the individual to achieve or maintain optimum functional capacity in performing age-appropriate or developmentally-appropriate daily activities.
2. The MCO or insurer must base its determination of medical necessity on health information provided by the individual (as appropriate to his/her age and communicative abilities), the individual's family, the primary care physician, and consultants with appropriate speciality 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 take into account the:
 - A. Functional capacity of the individual and those capacities that are appropriate for individuals of the same age or developmental level; and
 - B. Available research findings, health care practice guidelines, and standards issued by professionally recognized organizations or governmental agencies.
4. Final determinations will be made by a physician in concert with 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 (which can include an individual's home, school, day care center, or community-based agency) that is appropriate to the specific health needs of the individual.

Note 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.

Note 2: There is a rapidly growing foundation of knowledge regarding the role of genetics in chronic disease and disability. For example, diagnosis of fragile X syndrome in a child requires pedigree analysis and laboratory studies to permit not only appropriate diagnostic conclusions but also to assure that genetic counseling is provided to assist individuals and families to make informed choices on reproductive issues.

SECTION V

IMPLICATIONS

Implementing a comprehensive approach to medical necessity determinations will have management and fiscal implications. For example, depending on how it is implemented, it may require plans to:

Implement procedures for determining the scope of medical and related information needed to complete medical necessity determinations for this population, and the related data tracking methods;

Develop procedures for determining when standard protocols can be used and when they are not appropriate;

Assure that medical determinations address whether the service in question will contribute to accomplishing the overall health and functional goals for the individual as well as evidence on the intervention's treatment effects;

Assure that medical necessity determinations for this vulnerable population of children and adults are made and monitored routinely by appropriate personnel;

Demonstrate that comprehensive structural procedures are in place to assure that services needed by a vulnerable population are available and that consumer and provider perspectives are incorporated in a consistent, organized manner;

Develop 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 denied services ultimately increase 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 in cases when medical necessity determinations were not based on a sufficiently comprehensive information (Hall & Anderson, 1992; Sage, 1995).

At the present time, little information is available to assess the varying costs of different definitions of medical necessity, or 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 address directly 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 breadth of benefits fail to address issues related specifically to vulnerable populations. The research community (both investigators and funders) 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 American health care systems are changing rapidly. Issues pertaining to medical necessity are likely to shift substantially as managed care organizations develop new products with differing benefit packages, co-pay structures, and strategies for managing provider networks. Families, physicians, other health care providers, and legislative staff will need to monitor these changes closely to assure that children and adults with disabilities, mental retardation, and chronic illnesses receive the services they need.

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APPENDIX A

CONTRIBUTORS

Steering Committee

Polly Arango
Julie Beckett
Robert Cooke
Shelly Gehshan

Ian Hill
Henry Ireys
Mary Tierney
Elizabeth Wehr

Expert Panel

Linda Attarian
Susan Burke
Karen Edwards
Marilyn Goldwater
Paula Colodny Hollinger
Vivian Jackson
Lawrence C. Kleinman
Merle McPherson
Sheila J. Mosee
Melvin Neufeld
Fred Palmer
John Reiss
Maxwell Schleifer
Colleen Sonosky
Nadine Thomas

Stephen Berman
Garnette Coleman
Harriette B. Fox
Catherine A. Hess
Janice Hutchinson
Rene Jenkins
Barbara Lardy
Mindy Morrell
Richard P. Nelson
Ed Neuschler
David Parella
Alina Salganicoff
Vern Smith
Bonnie Strickland
Peter Van Dyck

Other Colleagues

Rebecca Adelman
Treeby Brown
Charles Carter
Maxine Hayes
Richard Hegner
Walter Orchinko
Eileen Peterson
Clifford Sells
Karen VanLandeghem
Nora Wells

Lauren Agoratus
Gil Buchanan
Karen Doran
Al Healy
Douglas McCarthy
Andrew Penziner
Michael Piskai
Elizabeth Shenkman
Conni Wells
Josie Woll

APPENDIX B

MEDICAL NECESSITY DEFINITIONS

Most of these 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:

- a.) Consistent with accepted standards for the prevention of disease and disability and for treatment of symptoms;
- b.) Appropriate with regard to standards of good medical practice
- c.) Not solely for the convenience of the Covered Person, his or her Physician (s), Hospital, or other providers; and
- d.) The most appropriate supply or level of service which can be safely provided to the Covered Person.

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.

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.

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

- a.) Consistent with the symptoms of a medical condition or treatment of a medical condition;
- b.) Appropriate with regard to standards of good medical practice and generally recognized by the medical scientific community as effective;
- c.) Not solely for the convenience of an HMO member or provider of the service or medical supplies; and
- d.) 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” mean a health service that is consistent with the enrollee’s diagnosis or condition and:

- a.) Is recognized as the prevailing standard or current practice by the provider’s peer group; and
- b.) 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
- c.) Is a preventive health service defined under Minnesota Rules, Part 9505.0355.

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 service 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:

- a.) Consistent with the diagnosis and treatment of the patient’s condition, and
- b.) Appropriate with regard to standards of good medical practice, and
- c.) Not primarily for the convenience of the patient or a provider of services and supplies, and
- d.) The least costly of the alternative supplies or levels of service which can be safely provided to the patient, and
- e.) 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:

- a.) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability.
- b.) 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.
- c.) 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:

- 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 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: reasonably 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.

Utah: "Medically Necessary" means any mental health service that is necessary to diagnose, correct or ameliorate a mental condition, or prevent deterioration of that condition or development of additional health problems and there is not other equally effective course of

treatment available or suitable that is more conservative or substantially less costly.

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.) A reasonable and necessary part of the recipient's treatment plan;
- b.) Consistent with the symptoms, diagnosis, or medical condition of the illness or injury under treatment;
- c.) Not furnished for the convenience of the recipient, the family, the attending practitioner, or other practitioner or supplier; and,
- d.) 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 defines medical necessity as 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** recommends using the following criteria 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 and Diagnostic Testing: 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 CFR 440.230) (See also Zimmerman et al, 1996).

Commercial Insurer: 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).

APPENDIX C

ANALYSIS OF SELECTED DEFINITIONS OF MEDICAL NECESSITY

With much assistance from the Steering Committee, we 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 define an outcomes-based approach to defining medical necessity in the context of a developmental framework. They also emphasize the need to consider the service in light of the needs of the individual patient. Both attributes are especially important 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.

National Institute for Health Care Management (NIHCM)

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

1. The intervention must be used for a medical condition.
2. There is sufficient evidence to draw conclusions about the intervention's effects on

health outcomes.

3. The evidence demonstrates that the intervention can be expected to produce its intended effects on health outcomes.
4. The intervention's beneficial effects on health outcomes outweigh its expected harmful effects.
5. 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 in respect to this definition involves the basic level of research on treatment interventions for individuals with developmental disabilities and other special needs, including children with these conditions. This population, in part because of its small size and medical heterogeneity, 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, this definitional 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 enrolled.

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."

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. It does not mention issues of development, however, nor does it specify the type and source of information that would be included in reaching a decision on medical necessity.

Source: State of New Jersey, Department of Human Services, Division of Medical Assistance & Health Services. New Jersey Care 2000; HMO Request for Information Released for Public Comment (March, 1998).

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