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MEDICAL NECESSITY

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Medical Necessity

Medical necessity appeals indirectly shape the future of healthcare quality. Uncontested medical necessity denials result in a subtle shift in treatment availability to the next patient because insurance carriers aim to consistently apply medical necessity limitations. Effective medical necessity appeals, on the other hand, bring to the carrier's attention necessary variations in care, emerging efficacy issues, and situations that reveal flaws in the day-to-day clinical application of the carrier's written criteria. Appeals offer both parties—provider and carrier—the opportunity to discuss and ultimately improve the quality of care. Even when such appeals do not result in additional benefits, open discourse on denied claims improves both providers' and carriers' understanding of how medical necessity decisions are reached and provides an avenue for cooperative problem-solving.

Defining medical necessity

No universally accepted definition of **medical necessity** exists and the term takes on different meanings to those who encounter it. To carriers, assessing benefit availability on a "medically necessary" basis is a contractual obligation they must fulfill when a beneficiary seeks medical care. The term is necessarily flexible to give carriers decision-making room as claims are presented and medical treatment approaches evolve.

The ambiguity and importance of the term are reflected in the following statement made by Bernard Mansheim, MD, vice president and chief medical officer for Coventry Health Care, in a 2004 Corporate Address:

> "Our foremost challenge is to interpret the phrase 'medical necessity,' because how we define it dictates what we cover, or pay for. Though it has no useful literal meaning, it is a commonly used phrase that begs for definition. Once, but no longer, it may have meant 'anything a doctor wants to do.' Today, it means different things to different people. Since there is no universal definition, and in order to clarify our contractual responsibility, we must define what we mean."
>
> (Source: *www.meetinglink.org/omar/ct/slides/mansheim.pdf*)

The extent of this contractual obligation is often determined by the judges involved in healthcare insurance litigation. It is a common theme in such litigation that because the carriers draft the terms of

the insurance policy, they are also responsible and potentially legally liable for any ambiguities in insurance contract terms. State insurance mandates often include “readability” standards, which require policies to be written so that the average person can understand and interpret the terms of the contract.

A common requirement of health insurance contract law is that carriers must make treatment decisions consistently and be able to provide beneficiaries with an understanding of how those decisions are made. Therefore, most insurance policies will have a standard medical necessity definition roughly describing medically necessary care as being the most appropriate treatment, rendered in the most appropriate setting, and not provided for the convenience of the patient. To provide some structure to medical necessity decision-making, carriers use a number of means to limit the scope of the term, such as utilization review and case management procedures, written clinical guidelines, published evidence-based medicine, technology assessments, and expert or independent review panels. These supplemental resources, all of which change over time, shape how the term *medical necessity* is defined. Thus, once a claim is submitted, the carrier looks to the supplemental resources rather than to the broader medical necessity definition featured in the policy. As providers are well aware, such assessments restrict treatment by making certain procedures available for only specified diagnoses and have the impact of narrowing the concept of medical necessity.

Doctors and patients make joint decisions regarding treatment in a high-pressure, health-focused environment; therefore, they rely on the breadth and flexibility in the term *medical necessity*. Although medical literature and evidence-based medicine are regularly employed by treatment providers, doctors must give due consideration to each patient’s unique medical needs, lifestyle, abilities, limitations, and complicating treatment issues. As such, consistency in decision-making is not as important as providing high-quality care appropriate for that patient. As the malpractice insurance industry well knows, the courts weigh heavily against treatment providers who fail to provide quality medical care.

Given the dynamic nature of medical care and the various pressures related to treatment delivery, carriers and providers have much at stake in deciding what kinds of treatment fall under the coverage terms and what treatment should be denied. Because of these challenges, appeal and grievance procedures are highly important. Appeal and grievance procedures require the insurance carrier to specify which internal rules, guidelines, and protocols were relied upon in making the decision. The process gives the provider the opportunity to address the appropriateness of how this supplemental information was used and to explain the treatment provided. Once this discourse in underway, however,

the satisfaction level of the parties and whether quality care is ultimately provided depend on the quality of the review process itself.

Seeking a quality medical necessity review from payers

When medical necessity decisions are not amicably reached, judges lacking clinical training often end up being the arbiters of what is and what is not medically necessary treatment. Faced with such complex decisions about challenging clinical questions, the legal system has come to depend on a close assessment of the carrier's medical necessity review performance as a very important indicator of whom to side with in the argument.

The article "Managed Care's Crimea" (*Duke Law Journal*, 53:593–666) closely examined medical necessity determinations that have reached court level. In a comprehensive review of these decisions, the author, William Sage, found that courts often acknowledged the potential conflicts of interest among medical necessity decision-makers and viewed the case information generated as "untrustworthy." In the absence of any clear consensus among the opposing medical opinions cited in such cases, courts relied upon what was referred to by the author as "hallmarks of procedural" fairness, such as clear explanations regarding denials, timely access to appeals, and external review. Such protections reassured the courts of the fairness of the carrier's decisions. When clinical opinions differed, a good decision-making process, involving the following components, was viewed as being a precursor to a good clinical decision:

- Flexibility to allow for patient-specific variables and appreciation for the complexities of medical care
- Consistency in treatment allowed for similar patients
- Highly qualified personnel
- Reliance on written criteria
- Transparency
- Information-seeking approach

On the reverse side, procedural fairness is not a given in the appeals and grievance process. The study "Medical Necessity in Private Health Plans," prepared for the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services, focused on medical necessity decision-making in mental health care treatment. An extensive review of insurance industry

medical necessity definitions and interviews with healthcare executives on the nature of such determinations revealed what the study identifies as "Common Procedural Problems in Medical Necessity Determination Processes Noted in Investigations, Litigation, and Case Law." The following shortcomings were identified:

Decision made in [an] arbitrary or capricious manner without consideration of individual patient needs
Decision made inconsistently (e.g., some patients' claims denied [and] others in equivalent circumstances approved)
Claims reviewers unqualified or not appropriately trained
Application of arbitrary and unreasonable caps on coverage and dollar limits
Insufficient information provided in claims denials:

- No disclosure of clinical rationale used in making decision
- No disclosure of qualifying credentials of reviewer
- No disclosure of evidence or documentation used in decision
- No description of the procedures, time frames, and consumer rights for grievance and appeal

Failure to consult with treating physician
Failure to consider medical evidence provided by patient
Failure to provide full and fair review to patient appealing claims denial
Lack of clarity and specificity in plan documents of excluded services (e.g., definitions of "experimental" and "convenience")
Conflict of interest of [managed care organization] decision-maker that biased impartial judgment
(Source: *http://mentalhealth.samhsa.gov/publications/allpubs/SMA03-3790/figure04.asp*)

Gaining access to procedural fairness in medical necessity appeals

One or even a combination of these procedural review problems may prevent the thorough assessment of any clinical information provided to justify treatment and, ultimately, compromise any appeal effort. The presentation and explanation of clinical information is not the only goal of a medical necessity appeal. One must also address how the clinical information should be reviewed and whether the review process provided includes the basic hallmarks of procedural fairness. It must often be emphasized that procedural fairness equates to a quality medical decision. Each medical necessity appeal should incorporate detailed information regarding the following three components:

- Patient-specific clinical information in the context of industry standards of care
- Assessment of carrier's claim review procedures affecting denial (disclosure of denial

detail, timeliness of utilization review and appeal responses, credentials of reviewers, use of independently developed care standards)

- Potentially applicable compliance/regulatory consumer protections

Medical necessity appeal component 1: Submission of medical records and inclusion of patient-specific clinical care citations

Medical records submission and letters of medical necessity outlining the need for treatment are the focus of most medical necessity appeals. The treating physician's opinion and supporting documentation are vastly important in any medical necessity appeal, but a successful medical necessity appeal should, if possible, include specialty-specific clinical care guidelines to affirm the appropriateness of treatment. Medical records should be reviewed and pertinent information highlighted and marked with a page marker to ensure that the appeal reviewer sees the specific indicators that support the treatment. A summary of the clinical justification for treatment should appear within the body of the letter, but carriers typically require the actual documentation from which the clinical information was taken.

When reviewing medical records for pertinent information, the history and physical are also a good source of information on provider concurrence regarding care, the history of failed treatment, and the patient's compliance record with less aggressive treatment attempts. This information may also be highlighted and a recommendation included in the appeal letters to obtain all potentially pertinent records, including information regarding failed treatments, before rendering an adverse determination.

Medical necessity appeals should also discuss the carrier's use of clinical guidelines in making a treatment decision. Insurance carriers routinely cite evidence-based clinical guidelines when denying treatment authorization. Thousands of clinical guidelines have been developed within the past decade, and as one might expect, there is a great deal of contradictory information as well as limitations in using these guidelines. One of the most frequently mentioned limitations of clinical guidelines is that they are not developed from a diverse group of patients, and thus, minorities, pediatrics, and geriatrics are underrepresented. A number of insurance industry resources confirm that medical insurance decision-makers must consider the patient's unique medical condition and should deviate from the clinical guidelines when appropriate.

Requesting deviation from the guidelines will typically require an appeal focusing on the patient's unique medical needs and an explanation of why application of the guidelines is not appropriate. Some of the specific factors to address in such an appeal include the following:

- Patient's previous treatments and discussion of failed treatment attempts and unwanted side effects
- Patient's secondary diagnosis which potentially complicates treatment
- Any anatomical anomalies or age-related factors (prenatal or geriatric challenges)
- Ongoing diagnostic assessment for unexplained symptoms/atypical disease/disorder presentation

The guidelines can be called into question if they do not appear to adhere to current industry quality care standards or to incorporate the latest treatment options. Some of the specific questions useful for assessing the quality of the guidelines include the following:

- How frequently are the guidelines updated to incorporate recent medical developments?
- Which patient demographic was used to develop standards; that is, did the development of the guidelines include studies involving a diverse patient population inclusive of prenatal patients, geriatrics, and minorities, to ensure appropriate application across a diverse population?

A study of medical necessity decisions made by private health plans discusses the widespread adoption of clinical guidelines for use in medical necessity decision-making. According to this study, "Medical Necessity in Private Health Plans: Implications for Behavioral Health Care," several insurer medical directors acknowledged that clinical guidelines are simply a decision-making tool and should allow for

flexible implementation. As stated in the study:

> "Interviewees stated that guidelines are not mandates or absolute protocols; rather, they are considered 'guideposts' to be informed by, and adapted to, individual circumstances and psychosocial needs of patients. Ongoing audits, performance measurement of in-house care managers and contracted providers, and member and provider satisfaction surveys are used to monitor the appropriate use of treatment guidelines in medical necessity decisions and to build in quality improvements at all levels of decision making."

The study is available online at *http://download.ncadi.samhsa.gov/ken/pdf/SMA03-3790/SMA03-3790.PDF.*

Submission of peer-reviewed literature with appeals: My evidence-based guideline versus your evidence-based guideline

Submission of peer-reviewed literature can strengthen medical necessity and experimental/investigational appeals. Insurance companies have a duty to review information submitted during an appeal. Furthermore, an insurance company's failure to properly review clinical information can jeopardize its ability to legally defend its denial decision. In litigation involving a Prudential medical necessity denial, an attorney submitted 25 peer-reviewed articles supporting physical therapy for the treatment of multiple sclerosis. The court noted that the information was not specifically responded to and that no one attempted to contact the ordering physician to review the matter.

"Our odyssey through this record makes clear Prudential never evaluated Ms. McGraw's individual case but rubber stamped the nature of her condition and denied each subsequent claim arising from her MS," the court finding states. Read the decision at *www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=150591*.

In *Hughes v. Blue Cross of Northern California*, 263 Cal. Rptr. 850, the patient was admitted for inpatient treatment of a mental disorder after several attempts at outpatient treatment had failed to produce desired results. The insurer denied the coverage for the treatment and indicated that care should have continued at a lower level. The insurer's denial, however, did not outline specific medical

reasons to support the decision.

The lower court ruled that the insurer breached its covenant of good faith and fair dealing by employing a standard of medical necessity significantly at variance with community standards, and by failing to properly investigate all records pertinent to the insured's claim. The court stated:

> "By not identifying the records on which the consultant's recommendation was based, the letters tended to assure that the staff's earlier failure to secure all relevant records would go undetected. And by omitting any explanation of the medical grounds for the intended denial of coverage, the letters placed an undue burden of inquiry on the insured's physician. The Blue Cross witnesses, in fact, defended the letters on the grounds that the physician was free to write or call the medical review department to gain more information. The covenant of good faith and fair dealing, however, placed the burden on the insurer to seek information relevant to the claim. This requires that the necessary letter to a treating physician be drafted in a manner to elicit an informed response."

Medical necessity appeal component 2: Assessment of carrier's claim review procedures affecting denial

A medical necessity appeal is not complete until the carrier's utilization review and claim processing performance has been scrutinized for any weaknesses in its response. The utilization review tracking tools are not meant simply to serve as follow-up tools to remind carriers of impending deadlines, but also should give the provider documentation to cite in appeals. Further, the utilization review appeal letters specifically demand that the carrier provide the credentials of the peer reviewer(s) involved in any decision and the clinical review criteria utilized. If such requests have gone unanswered, this failure should be detailed with copies of the request letters.

Disclosure of denial detail

Appeal letters should always seek full disclosure of the claim denial detail. Providers cannot effectively appeal if they do not know the basis of the denial. Securing this information is the starting point for assessing the quality of the review. The following demand paragraph can be incorporated as is or customized to more specifically request required information:

If benefits remain denied, please provide the following information in addition to the specific information requested above:

- Name of the board-certified (specialty) reviewer who reviewed this claim and a description of any applicable advanced training or experience this reviewer has related to this type of care
- Board-certified (specialty) reviewer's recommendation regarding alternative care for treatment-resistant patients
- A copy of applicable internal clinical guidelines, if such exist, and the date of development
- An outline of the specific records reviewed and a description of any records which would be necessary in order to justify coverage of this treatment
- Copies of any peer-reviewed literature, technical assessments, or expert medical opinions reviewed by your company in regard to treatment of this nature and its efficacy

If coverage and/or denial disclosure demands were made in a Pretreatment Request, during utilization review, or in earlier appeals or correspondence, you should state that this is a *second request* for denial disclosure, and either attach the previous request or outline the details, including date mailed and specific information requested.

To have such requests ignored not only is frustrating, but also delays subsequent appeals. However, providers should obstinately maintain their rights to full disclosure of complete information related to the denial. It may also be necessary to reference the carrier's legal obligation related to release of that information. General wording such as the following may be incorporated into disclosure requests:

> In order to fully respond to your denial of care, we have previously requested the following information. It is our position that disclosure of this information may likely be required under both state and federal disclosure laws. Further, proper disclosure of this information allows all interested parties to assess the basis of the decision and address the appropriateness of the decision.

If this general wording is not effective, it may be necessary to determine what type of coverage is involved in order to assess whether Employee Retirement Income Security Act of 1974 (ERISA), Medicare/Medicaid, or state disclosure laws could be cited to obtain the information. See Chapters 10 and 11 for more detailed information on ERISA and Medicare disclosure protections and how to cite such protections to obtain more detailed information.

Once complete disclosure is made, higher-level appeals should focus on any questionable review practices revealed in the disclosed information. For example, one of the most frequent challenges is ensuring that specialty care treatment is reviewed by a qualified professional familiar with the diagnoses, related challenges, and most current medical standards related to the care of that disease or injury. See Sample Appeal Letter H, *Unsatisfactory Reviewer ID/Qualifications Appeal*, for situations in which it does not appear that a medical review was undertaken by an appropriately credentialed medical professional.

Timeliness of utilization review and appeal responses

Even if previous utilization review and appeal responses were negative, note the carrier's compliance with the applicable industry or regulatory standards. Point out any effect of the carrier's noncompliance. For example, emphasize that the patient's safety required immediate response or that appropriate transfer/discharge arrangements could not be made due to the delay in carrier response.

Medical necessity length-of-stay denials are often complicated by the carrier's untimely response or availability for concurrent care review. Further, carriers have developed length-of-stay guidelines on a diagnosis- or procedure-code basis and claims may be rejected without so much as a request for medical records related to these length-of-stay denials. It is important to remind carriers of your attempts to stay within industry standards regarding length of stay and what unique factors affect the timing of transfers and discharges. For example, elderly-patient discharge is often complicated by a number of factors, which may not be well represented by the carrier's guidelines. Length-of-stay denials should be appealed with detailed information such as the following:

Efficiency-based guidelines such as those utilized by your review staff are generally

regarded as optimal efficiency standards applicable to middle-aged populations. Our hospital has initiated a number of protections to ensure that the length of stay is appropriate for the treatment and safety of the patient. However, a number of unavoidable factors can affect a hospital's ability to provide care within these parameters. We have identified the following issues which appear to specifically affect the discharge of geriatric patients (choose the following applicable factors or substitute a more appropriate explanation):

- Age-related comorbidities complicating patient self-care
- Extended observation due to the lack of adequate family or other support at home
- Extended observation due to inability of patient to adequately detect and report pertinent medical information
- Need to discuss patient care, pharmacopoeia management with caregiver
- Patient preferences related to heightened anxiety over recent medical episodes
- Patient education

Sample Appeal Letter I, "Level II Appeals – Unsatisfactory Use of Written Criteria Appeal/Geriatric Patients," highlights the preceding information in a letter that is useful for seeking more appropriate clinical decisions for geriatric patients.

Negotiating medical necessity contractual protections

Managed care contracts should specifically address clinical care guidelines that will be used in both utilization review and medical necessity decision-making. In addition, care should be taken to insert language stating that the clinical care guidelines will be waived when they conflict with the medical necessity definitions or situations in which a patient presents a unique combination of illnesses or suffers from treatment-resistant illnesses.

According to a 2003 study conducted by the Utilization Review Accreditation Commission, most insurers use an externally developed medical review guideline, with the most widely used standard being Milliman & Robertson. One Kansas hospital successfully explained in court that Milliman & Robertson guidelines reflect "optimal efficiencies" not attainable in rural hospitals. The Milliman Web site states that its guidelines will soon affect the care of 100 million Americans; however, the Kansas

hospital just referenced was able to negotiate terms prohibiting the use of these guidelines for its own claims.

An interview between the Kansas Department of Insurance and a hospital negotiator discusses the hospital's successful efforts to specify that its managed care organization contract uses InterQual instead of Milliman & Robertson because the Milliman & Robertson guidelines are based on "optimal efficiencies," which some rural hospitals cannot reach. You can read the interview at *www.ksinsurance.org/about/archive/bcbs/public_testimony/intervenors/kms/statement_Fairbank.pdf*.

You can appeal applications of the clinical guidelines that do not seem appropriate for the patient's condition on a case-by-case basis, but these appeals may be more effectively argued if certain protections are negotiated into the contract.

Prior to negotiating terms, it is helpful to review your medical necessity denials with that carrier to determine whether the carrier is using a clinical guideline that is frequently at odds with your own quality care guidelines. If there is a more generous or widely followed industry standard at odds with the carrier's clinical guideline, bring that information to the table to demonstrate the problem and explain how it affects your organization.

If such managed care review protections are agreed to in the contract, these protections should be cited in medical necessity and prior authorization appeals to ensure compliance. If the exact guidelines cannot be agreed upon between parties, the following protections at least give you more ammunition for overturning medical necessity denials on a case-by-case basis.

Defining medical necessity broadly to allow the physician decision-making authority

As discussed, the policy/plan definition of medical necessity is typically very broad and may even reference medical necessity to be care and treatment recognized by the *carrier* as most appropriate for the patient.

The American Medical Association Model Managed Care Contract medical necessity definition, a more provider-friendly definition, reads:

> "Carrier agrees to provide payment for medically necessary treatment. For both utilization review and claim processing, medical necessity is defined as follows: Health care services or procedures that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease or its symptoms in a manner that is (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician or other health care provider."

You can expand on this definition by addressing disclosure and industry standards with the following text:

> "Upon request, the carrier shall provide the clinical rationale used to make an adverse determination, both utilization review and benefit determination, in writing to the provider or facility rendering the service. The clinical rationale used by the carrier should conform to industry standards for quality healthcare such as (insert favorable care standards, such as InterQual, American Cardiology Care Guidelines, American College of Physician Guidelines, etc.)."

Medical necessity appeal component 3: Potentially applicable compliance/regulatory consumer protections

About half of the states include a definition of medical necessity as part of their insurance or public health statutes. Most of these definitions restrict the way a carrier can define *medical necessity*. A few, however, actually confirm the carrier's ability to define the term. Iowa's Health Care Service and Treatment Act, Code 514J.5, which established Iowa's external review program, states that medical necessity is defined by the policy or plan definition developed by the insurer.

External/independent review

Denial letters are often required to contain notification of the provider or patient's right to proceed to an external/independent review process. According to a Kaiser Family Foundation report, consumers use state-mandated external/independent review processes infrequently, and of those who do, roughly 50% experience a reversal of the original decision. The report (located at *www.kff.org/insurance/externalreviewpart2rev.pdf*) identifies how each state's review features vary and

provides detailed information on state variations such as decisions favorable to the requesting party. It states, "The rate at which external reviewers overturn health plan denials ranged from a low of 21 percent in Arizona and Minnesota to a high of 72 percent in Connecticut, and averaged 45 percent across all states. In addition, in about half of the states, reviewers have the option of partially overturning health plan denials, which they did, on average another 6 percent of the time."

Even if you do not plan to pursue external/independent review, your medical necessity appeals can cite specifics of the external/independent review protections. For example, external review processes require use of qualified medical reviewers. If you believe a carrier routinely uses para-professional staff for medical decision-making, your appeal should point out that this is a basic protection and is recognized in the state external review mandate.

Network adequacy/access to specialists

Network adequacy/access to specialist standards are designed to make sure that health plans have an adequate network of providers within a specific geographic area and sufficient specialty care providers to provide quality care. These regulations often specify the types and number of primary care and specialty providers necessary, the distance enrollees have to travel to see their providers, and the hours of operation and processes for requesting out-of-network care if the care is not readily available.

Although these protections affect the design of the network, they can also be cited in situations in which it appears that care was rendered out-of-network due to the unavailability of network care. Such protections may be valuable in situations in which a carrier provides a hospital precertification but does not include ancillary or specialty care services within that precertification.

ERISA expert review

The U.S. Department of Labor has stipulated that an appeal of an adverse benefit determination, based in whole or in part on a medical judgment, must involve a consultation with an appropriate healthcare professional. Please see Question D-8 at *www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html*, which states the following regarding medical expert review:

> "This requirement of consultation is intended to ensure that the fiduciary deciding a claim

> involving medical issues is adequately informed as to those issues. The consultation requirement, however, is not intended to constrain the fiduciary from consulting any other experts the fiduciary considers appropriate under the circumstances . . . In all cases, a fiduciary must take appropriate steps to resolve the appeal in a prudent manner, including acquiring necessary information and advice, weighing the advice and information so obtained, and making an independent decision on the appeal. The regulation's provision for consultation with a health care professional is not intended to alter the fiduciary standards that apply to claims adjudication."

Sample Appeal Letter J, "Request for Expert Review – ERISA," cites the expert review requirements. Chapter 10, on ERISA appeals, provides more extensive information on how this protection should be used in appeals.

Annual updates to clinical guidelines

A few states recognize the importance of requiring carriers to use the most up-to-date clinical information available. Under Vermont Rule 10, Vermont's Quality Assurance Standards and Consumer Protections for managed care plans, certain carriers are required to annually adopt new clinical practice guidelines as well as review clinical guidelines currently in use. In compliance with this law, Blue Cross Blue Shield of Vermont posts links to the guidelines used by that company at *www.bcbsvt.com/pages/forms/ClinicalPracticeGuidelines.htm*.

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