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MEDICAL NECESSITY, COVERAGE POLICY, AND EVIDENCE BASED MEDICINE

Institute of Medicine
Determination of Essential Health Benefits
January 13, 2011
Coverage and medical necessity

- Coverage: what insurance will pay for generally
- Medical necessity: what insurance will pay for in specific instances

*Categorical exclusions from coverage: not everything that is medically necessary is covered (e.g., drugs and preventive services were excluded from Medicare in the past)*

*Not everything that is covered is medically necessary*
Important distinctions

- Everything beneficial to health, *medically indicated for a patient*, and *medically necessary for coverage* are linked but not equivalent.
How *medical necessity* fits in...

- A **coverage decision** is a policy decision about categories of health interventions provided to a population as part of the statutory mandate.
- A **medical necessity** decision is about the appropriateness of a specific treatment for a specific patient.
- Not all covered services are *medically necessary*; not all **medically necessary** treatments are covered.
Unless the contrary is specified, the term “medical necessity” must refer to what is medically necessary *for a particular patient*, and hence entails an individual assessment rather than a general determination of what works in the ordinary case.

Medical necessity definition from settlements of *in re Managed Care*, 2003-2006
“Medically Necessary” or “Medical Necessity” shall mean health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: a) in accordance with generally accepted standards of medical practice; b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and c) not primarily for the convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “generally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.
A model definition

- The Stanford research project presented preliminary findings to a workshop of key stakeholders in California in 1999
- The workshop participants focused on developing a model definition of *medical necessity* for use in private contracts
- The Stanford language was adopted by State Medicaid programs and private plans
The Stanford definition: medical necessity based on five criteria

Decision-making authority
Purpose of the intervention
Scope of the intervention
Standards of evidence
Value (cost effectiveness)
The Stanford Preamble

- An intervention will be covered if it is an otherwise covered category of service, not specifically excluded, and *medically necessary*.
  - An intervention may be medically indicated yet not be a covered benefit or meet this contractual definition of *medical necessity*.
  - Medicaid may choose to cover interventions that do not meet this contractual definition of *medical necessity*.
Authority

- An intervention is *medically necessary* if, as recommended by the *treating physician* and determined by the Medicaid plan’s medical director or physician designee, it is (all of the following):
A health intervention for the purpose of treating a medical condition

A health intervention is an item or service delivered or undertaken primarily to treat (i.e., prevent, diagnose, detect, treat, or palliate) a medical condition (i.e., disease; illness; injury; genetic or congenital defect; pregnancy; or a biological or psychological condition that lies outside the range of normal, age-appropriate human variation) or to maintain or restore functional ability. For the contractual definition of medical necessity, a health intervention is defined not only by the intervention itself, but also by the medical condition and patient indications for which it is being applied.
Scope

- The most **appropriate** supply or level of service, considering potential benefits and harms to the patient
  - “**Appropriate**” (level or supply of service) means that generally accepted forms of treatment that are less invasive have been tried and found to be ineffective or otherwise unsuitable, and (for hospital stays), inpatient care is necessary due to the severity of the medical condition that dictates that safe and adequate care cannot be received in a less intensive setting.
Evidence

- Known to be **effective** in improving **health outcomes**.
  
  **Effective** means that the intervention can reasonably be expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.
  
  **Health outcomes** are outcomes that affect health status as measured by the length or quality (primarily as perceived by the patient) of a person’s life.

- For **new** interventions, effectiveness is determined by **scientific evidence**.
- For **existing** interventions, effectiveness is determined first by scientific evidence, then by professional standards, and then by expert opinion.
Evidence: **Scientific defined**

- **Scientific evidence** consists primarily of controlled clinical trials that either directly or indirectly demonstrate the effect of the intervention on health outcomes. If controlled clinical trials are not available, observational studies that demonstrate a causal relationship between the intervention and health outcomes can be used. Partially controlled observational studies and uncontrolled clinical series may be suggestive, but do not by themselves demonstrate a causal relationship unless the magnitude of the effect observed exceeds anything that could be explained either by the natural history of the medical condition or potential experimental biases.
Evidence: New and Existing Interventions

- **New interventions** for which clinical trials have not been conducted because of epidemiological reasons (i.e., rare or new diseases or orphan populations) shall be evaluated on the basis of professional standards of care or expert opinion.

- For **existing interventions**, the scientific evidence should be considered first, and to the greatest extent possible, should be the basis for determinations of medical necessity. If no scientific evidence is available, professional standards of care should be considered. If professional standards of care do not exist, or are outdated or contradictory, decisions about existing interventions should be based on expert opinion. Giving priority to scientific evidence does not mean that coverage of existing interventions should be denied in the absence of conclusive scientific evidence. Existing interventions can meet the contractual definition of medical necessity in the absence of scientific evidence if there is a strong conviction of effectiveness and benefit expressed through up-to-date and consistent professional standards of care, or in the absence of such standards, convincing expert opinion.
Value

- Cost effective for this condition compared to alternative interventions, including no intervention.
  - “Cost-effective” does not necessarily mean lowest price.
  - An intervention is considered cost effective if the benefits and harms relative to costs represents an economically efficient use of resources for patients with this condition. In the application of this criterion to an individual case, the characteristics of the individual patient shall be determinative.
The role of cost in medical necessity
## EXHIBIT 1
How Health Plans Take Cost Into Consideration When Evaluating New Interventions

<table>
<thead>
<tr>
<th></th>
<th>Formal CE analysis (%)</th>
<th>Selectively apply preauthorization (%)</th>
<th>Establish explicit coverage policies (%)</th>
<th>Require less costly interventions first (%)</th>
<th>Consider cost in any of these ways (%)</th>
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</table>

**SOURCE:** Adapted from L.A. Bergthold et al., “Using Evidence and Cost in Managed Care Decision-Making” (Stanford, Calif.: Center for Health Policy/Center for Primary Care and Outcomes Research, Stanford University, 2002), available as a supplemental document online at content.healthaffairs.org/cgi/content/full/hlthaff.w4.284v1/DC2.

**NOTE:** CE is cost-effectiveness.
### EXHIBIT 2
Likelihood That Plan Will Cover A New Intervention Compared With A Standard Intervention

<table>
<thead>
<tr>
<th></th>
<th>Equal effectiveness for equal cost (%)</th>
<th>Equal effectiveness for greater cost (%)</th>
<th>Less effectiveness for equal cost (%)</th>
<th>Less effectiveness for less cost (%)</th>
<th>Greater effectiveness for equal cost (%)</th>
<th>Greater effectiveness for greater cost (%)</th>
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HCFA’s Proposed Rule for Medicare Coverage Decisions

Announced in May 16, 2000 Federal Register

Intended to clarify coverage decision making process and to formalize role of Medicare Coverage Advisory Committee

Medicare will cover a service if it fits in one of four categories
4. **Added value (c)**

Will the item or service result in equivalent or lower total costs for the Medicare population than the Medicare-covered alternative? If yes, it is covered, if no, it is not covered.
Post-ACA: will medical necessity still matter?

Key payment innovations give providers greater responsibility for costs of care
- bundled payments
- ACOs and shared savings
- disease management
Key issues

- Fair processes – public involvement
- The more expansive the definition of medical necessity, the greater the cost
- Accommodating individual variation in ability to benefit