

Medical Necessity Experimental and Investigational

In General

The application of these concepts to the administration of health care plans has been the most difficult and the one most given to litigation.

Two types of health care plans must be considered:

Type 1. Determines the application of these concepts in general terms.

Type 2. Defines with great specificity what is and what is not covered with clear direction in making the adjudications when the Plan is yet unclear.

Determining The Application In General Terms

The complexity of the definition gives a good explanation of why there has been so much litigation in this area. New technologies, legal and social pressures, etc., all make such adjudication a nearly impossible task for the Plan Supervisor.

Determining The Application By Plan Document

This approach has the Plan Document, including the Guide to Questionable or Not Covered Items, specify clearly what is and what is not covered with absolute clarity in the huge majority of instances. Where yet not clear, the Plan Supervisor may (a) rely on a written statement of medical necessity from the Patient's attending physician or (b) obtain a written opinion of medical necessity from an independent board- certified physician, at plan expense.

Determination Process

Medical Necessity

Medical necessity is the grounds on which many benefits are denied. Yet the phrase can be difficult to define and a physician is the person who should decide what medical necessity is in any specific claims situation.

To be considered medically necessary, the service or supply:

- Must be ordered by a doctor for diagnosis or treatment.

- Must be commonly and customarily recognized by the medical profession as appropriate in the treatment or diagnosis of the diagnosed condition.
- Must not be educational or experimental in nature.
- Must not be provided primarily for medical or other research.
- Must not represent unnecessarily repeated tests.
- Must not primarily for the convenience of the patient or provider.

Basically, *medical necessity or medically necessary* means that a given setting in which treatment is administered is *needed to actually treat* the condition of the patient. In the last several years, health care providers have been criticized for using the inpatient setting when outpatient or admission daycare could be safely substituted. Unnecessary overnight stays cost money, which adds up year after year, patient after patient. Eventually, we all bear the brunt of that expense, because those unnecessary charges, along with the costs of larger support staffs and expanded health care facilities, spread across the cost of care to the entire community. Thus, it becomes imperative that we work to prevent the costs of those medically unnecessary services from getting into the health care system.

When it comes to hospitalization and medical treatment, unnecessary and inappropriate costs can be disallowed through hindsight, although the appropriate terminology is retrospective utilization review.

There are six essential areas of concern that a comprehensive after-the-fact review program must address:

- Necessity of inpatient admission
- Customary treatment for the diagnosis
- Appropriate length of inpatient stay
- Accuracy of hospital charges
- Applicability of charges to insurance coverage
- Whether an alternative treatment setting was appropriate.

Experimental Investigational

Thirteen questions help in this determination:

1. Is there appropriate logic for the treatment?
2. Is there hard evidence that the treatment is effective?
3. Is it harmful?
4. Has it been deemed experimental by FDA, AMA, etc.?
5. Is it needful to save or prolong life?
6. Is there ongoing research or investigation?
7. Is it used in foreign countries?
8. What is the practice of other payers?
9. Is it legal?
10. Are there controlled medical tests?
11. Is it for a rare or a common ailment?
12. What are the population subgroups suitable for the treatment?
13. Are there alternatives?

Alternatively these are criteria which also may be used to help decide the issue.

1. Treatment must be approved by AMA, FDA, etc.
2. Well-designed and scientifically-accepted tests must be available and endorse the treatment.
3. Net health outcome must be improved-quality of life is a factor.
4. Treatment must measure up favorably with any of the alternatives.
5. Improvement will not be expected except with the treatment.

Experimental Drug or Medical Device Criteria. For many reasons, the determination of what is experimental is fairly straightforward for drug and medical devices. Reason: the Food and Drug Administration has an objective and clear cut classification as to what is and what is not experimental. Even so, one court, in deliberating on the subject, set forth rational criteria using five questions.

1. Is the drug or device approved by the food and Drug Administration and marketed for the particular indication or application in question?
2. Is there sufficient information in the peer-review medical and scientific literature to enable the payer to make conclusions about the safety and efficacy of the drug, device or procedure?
3. Does the available scientific evidence demonstrate a net beneficial effect on health outcomes?
4. Is the drug, device or procedure as safe and efficacious as existing diagnostic or therapeutic alternatives?
5. Might the drug, device or procedure reasonably be expected to satisfy questions three and four when applied outside the research setting?

Criteria to be followed by Medicare in determining what drugs or medical devices are experimental are these: lack of Food and Drug Administration approval; explicit research purposes; and inadequate evidence regarding safety and effectiveness as indices of *experimental and investigational status*.

Relative Court Decisions

The hospitalization was for diagnostic purposes; this did not constitute a reason for denial because of medical necessity wondering was not specific. Had the plan document been specific in providing that diagnostic-only care was covered, such claim could have been denied.

Tooth restoration due to an accident was not to be denied just because it was dental-related.

Medical necessity includes palliative-only care. Inhalation therapy was held to be not medically necessary. Surgery to control exogenous obesity was held to be medically necessary.

Court hold, unless stated otherwise in the plan document, that a biobtic examination would include a sputum test.

Where the plan states only that an RN is covered, using an LPN because an RN was not available does not make the claim payable. Courts recognize sharp distinction between RN and LPN.

Prescription drugs, obtained without a prescription, were deemed deniable.

Fully-equipped van for a paraplegic was not medically necessary.

Group therapy sessions was held to be medically necessary care.

Plan properly paid for the removal of the left breast for cancer but denied the removal of the right on the grounds of cosmetic and therefore not medically necessary.

Care in hospital was not deniable, even though for custodial, diagnostic, palliative only reasons, because there was no one else to care for the patient; only by hospitalization could care have been provided.

Repair of fallopian tubes or vasectomy reversal were both held to be *not* medically necessary.

Speech therapy was held to be a subclass of physical therapy.

Home care was held medically necessary because of danger of seizures and the need to monitor anti-convulsive medication.

Chiropractic care usually has been held to be medically necessary.

Unless specifically excluded, off-shore cancer clinic care will be held to be medically necessary; similar logic was applied to a controversial allergy clinic; also similar logic was applied to laetrile treatment, even though such was illegal.

Private aircraft, as an ambulance, will not be excludable as not medically necessary, if plan does not limit ambulance to *local hospitals* only.

Care must always be taken with the medical necessity issue due to danger of courts holding the plan supervisor guilty of bad faith.

Obesity stapling in a perfectly well patient was not medically necessary; where obesity is morbid, it is medically necessary.

Herbal drugs, even if prescribed (or recommended by the physician) are not medically necessary.

Plan imprudently had provision that a physician's statement was conclusive proof of coverage (i.e., medical necessity).

A commonly-applied test of medical necessity must be community medical standards.

Holistic care involving testing of mercury levels and food allergies was held to be medically necessary.

To define medical necessity as one determined by either one of (a) AMA, (b) U.S. Department of Public Health, (c) National Institutes of Health or (d) U.S. Surgeon General was held to be too ambiguous.

Massage therapy was held to be not medically necessary. However, a full cranial prosthesis (wig) for hair loss was held to be medically necessary in one instance and not so in another.

Claims for home health aides was held not medically necessary. Round-the-clock home care was held medically necessary for systemic myloidosis. Home health care was medically necessary where chest percussion or a gastronomy tube is involved.

Liver transplant surgery for an adult with cirrhosis was held to be medically necessary and in conformity with community medical standards.

Being in a nursing home where provided care involved (a) constant nursing attention, (b) monitoring of tubes, feeding, pressure sores, etc and (c) physical restraining does not constitute *principally custodial* care.

Because of poor document drafting, chiropractic manipulations were deemed to be physical therapy.

Surgery for *peace of mind* (potential or likelihood of the condition developing into cancer) was held to have been medically necessary.

Care to correct reproductive problems are generally held to be medically necessary.

Sterilizations were held to be covered if such were deemed to be medically necessary. Contrary decisions are usually found with *in vitro* fertilizations where medical necessity is not an issue.