ABSTRACT. The term “medical necessity” is used by Medicare and Medicaid and in insurance contracts to refer to medical services that are generally recognized as appropriate for the diagnosis, prevention, or treatment of disease and injury. There is no consensus on how to define and apply the term and the accompanying rules and regulations, and as a result there has been substantial variation in medical-necessity definitions and interpretations. With this policy statement, the American Academy of Pediatrics hopes to encourage insurers to adopt more consistent medical-necessity definitions that take into account the needs of children. Pediatrics 2005; 116:261–262; medical necessity, medically necessary, managed care, contract.

INTRODUCTION

The definition of “medical necessity” in this statement articulates model language that takes into account the unique needs of infants, children, adolescents, and young adults through 21 years of age. To the extent possible, this definition draws on model language developed by Stanford University.1 For contractual purposes, an intervention will be covered if it is an otherwise covered category of service, not specifically excluded, and medically necessary.

DEFINITION

Health insurers should define medical necessity as health interventions for children that take into account all of the following criteria.

Scope of Health Problems

Medically necessary health interventions are intended to promote normal growth and development and prevent, diagnose, detect, treat, ameliorate, or palliate the effects of a physical, mental, behavioral, genetic, or congenital condition, injury, or disability. They should:

* take into account the setting that is appropriate to the specific needs of the child and family; and
* reflect current bioethical standards.

Evidence of Effectiveness

Medically necessary interventions must be reasonably expected to produce the intended results for children and to have expected benefits that outweigh potential harmful effects.

* For new interventions, for which clinical trials have not been conducted, effectiveness should be determined on the basis of clinical judgment after assessing the professional standards of care for children or consensus pediatric expert medical opinion.
* For existing interventions, effectiveness for children should be determined first on the basis of scientific evidence.* If insufficient scientific evidence for children is available, professional standards of care for children must be considered. If professional standards of care for children do not exist or are outdated or contradictory, decisions about existing interventions must be made on the basis of consensus pediatric 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.

Value

Medically necessary interventions must consider value for children on the basis of effectiveness. Cost-effective does not necessarily mean lowest price.

Process for Determining Medical Necessity

The American Academy of Pediatrics recommends that health plans describe the processes by which physicians and other health care professionals pro-

* Scientific evidence consists primarily of randomized, controlled clinical trials that either directly or indirectly demonstrate the effect of the intervention on health outcomes. If randomized, 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 by either natural history of the medical condition or potential experimental biases.
vide justification for the medical necessity of health interventions that they prescribe or order. Descriptions of these processes should include:

- how to provide clinical evidence supporting coverage of interventions that meet the needs of the individual child;
- how to incorporate appropriate pediatric medical or surgical subspecialty or expert opinion or testimony supporting coverage of interventions;
- how to assist families or physicians who wish to appeal medical-necessity denials; and
- how and when coverage decisions will be made.

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