



**CALIFORNIA**  
HEALTH BENEFITS REVIEW PROGRAM

April 20, 2009

The Honorable Dave Jones  
Chair, California Assembly Committee on Health  
State Capitol, Room 6005  
10<sup>th</sup> and L Streets  
Sacramento, CA 95814

The Honorable Elaine Alquist  
Chair, California Senate Committee on Health  
State Capitol, Room 2191  
10<sup>th</sup> and L Streets  
Sacramento, CA 95814

*Via e-mail only*

Dear Assembly Member Jones and Senator Alquist:

The California Health Benefits Review Program (CHBRP) submitted the *Analysis of Senate Bill 92 (Aanestad), Health Care Reform*, on April 13, 2009. Our report focused on four provisions that (1) would allow a carrier domiciled in another state to offer a health insurance product in California without holding a license issued by the California Department of Managed Health Care (DMHC) or a certificate of authority issued by the California Department of Insurance (CDI), and (2) would authorize carriers to offer individual health insurance policies that do not include all of the benefits mandated under state law to individuals with income below 350% of the federal poverty level. This report may be found online at [www.chbrp.org/documents/sb\\_92\\_rptfnl.pdf](http://www.chbrp.org/documents/sb_92_rptfnl.pdf).

After CHBRP received the request for analysis, SB 92 was subsequently amended to include the following provision to define the term “medical necessity”:

*Under the Sections amending Sections 1345 of the Health and Safety Code:*

*(s) A service is “medically necessary” or a “medical necessity” when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.*

*Under the Sections adding Sections 10123.136 of the Insurance Code:*

*For purposes of this code, with respect to a policy of health insurance, a service is “medically necessary” or a “medical necessity” when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.*

Staff of the Senate Committee on Health have requested that CHBRP provide input on what issues must be considered to determine how this definition of medical necessity may impact coverage of benefits. This letter is in response to that request.

This letter will provide:

- Context about the term “medical necessity” and how it has been used
- Examples of states that have incorporated definitions of medical necessity in statute
- Examples of medical necessity definitions in under publicly and privately insured plans’ contracts
- Examples of implementation questions that would have to be considered to assess the potential impacts of adapting this definition of medical necessity for health plans and policies in California

“Medical necessity” is a term that payers, such as private insurers and public health insurance programs, use to make coverage determinations. The term has been used to explain how benefits are covered and often defined in contractual documents such as member contracts and evidence of coverage booklets.

In the past decade, health services researchers have reviewed the ways in which health plans have defined medical necessity and the various ways it has been used to make coverage determinations. In 1999, the California HealthCare Foundation funded Stanford University’s Center for Health Policy to identify the variation in how coverage determinations are made based on various definitions of medical necessity in California.<sup>1</sup> Researchers found that:

- Most plans make coverage determinations after an initial review of the member’s benefits, eligibility, the plans’ coverage policies and guidelines, and the effectiveness and appropriateness of treatment.
- Lack of a standard, clear, and specific definition of medical necessity (and benefit coverage guidelines) has led to disputes among treating physicians and plans.
- The process in which a service or treatment is considered medically necessary and subsequently covered or denied is important to all stakeholders, including the plan, the treating provider, and the patient. Transparency in the process, opportunities for input, and clear communications are important components to ensure a functioning process.<sup>2</sup>
- There is variation among medical directors’ determinations regarding whether treatments are effective or appropriate and should be considered medically necessary.

Based on these findings, researchers developed Model Contractual Language for Medical Necessity through a consensus-building process, including input from plan and medical group directors, consumers, treating physicians, regulators, and other stakeholder groups (see *Attachment 1*). Researchers acknowledged that developing model language was a challenging process since the resulting language requires sufficient specificity to provide guidance regarding what must be covered, while providing enough flexibility to account for evolving standards of care and rare clinical situations. The principle on which the group agreed was that there should be a hierarchy of evidence, based on best available information. However, the locus of power in making determinations (i.e., among the plan, the treating provider, and the medical group) was a subject of debate and controversy.

Since the model language has been available, various states and plans have considered adopting some version of the language in statute or in contracts. Hawaii and Kansas have included variations of the model language in statute or regulation—Hawaii included it in the Patients’ Bill of Rights that was signed into law in 2000 and Kansas included it as part of the definition for their Medicaid program (See *Attachment 2*).<sup>3</sup>

Further research, funded by the Robert Wood Johnson Foundation and conducted by Stanford University’s Center for Health Policy in 2000 and 2001 on a national level among health plan medical directors and state

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<sup>1</sup> Singer S, Bergthold L, Vorhaus C, Olson S, Mutchnick I, Goh YY, Zimmeran S, Enthoven A. *Decreasing Variation in Medical Necessity Decision Making: Final Report to the California HealthCare Foundation*. August 1999. Available at [www.chcf.org/topics/view.cfm?itemID=12462](http://www.chcf.org/topics/view.cfm?itemID=12462). Accessed April 3, 2009.

<sup>2</sup> Singer S, Bergthold L. Prospects for Improved Decision Making about Medical Necessity. *Health Affairs*. 2001;20(1):200-206.

<sup>3</sup> Personal communication with Linda Bergthold, Independent Consultant and Researcher, April, 2009.



regulators, indicated a lack of consistent definition and application of the terms “medical necessity” and “coverage.” This resulted in variation from state to state in the manner in which coverage determinations were made and the way in which “medical necessity” was applied. The same research indicated that among health plan medical directors, there was a strong preference to rely on technology assessment reports, followed by randomized controlled clinical trials and guidelines from professional societies in determining whether a health care service is “medically necessary.” Medical directors preferred less to rely on expert opinion or prevailing community standards of care.<sup>4</sup>

By 2006, to deal with disputes related to coverage, 44 states and the District of Columbia had passed legislation to establish an independent medical review (IMR) process.<sup>5</sup> In general, an enrollee or physician that is disputing a health plan’s coverage determination may access the IMR process after they have exhausted grievances processes internal to the plan. The IMR process usually entails a review by a group of independent specialists with expertise in the condition or health care service in dispute.<sup>6</sup> In California, enrollees in health insurance products regulated by the DMHC or by the CDI may access the IMR process. In California, the IMR process is required to take medical necessity into account. To determine whether the service is medically necessary, reviewers are to use clinical considerations, specifically, any of the following:

- Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service
- Nationally recognized professional standards
- Expert opinion
- Generally accepted standards of medical practice
- Treatments likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious<sup>7</sup>

Evidence regarding the IMR process in California shows that it has afforded consumer protections because reviewers have overturned 30% to 40% of the cases in favor of the enrollee.

Examples of medical necessity definitions in plans’ contracts are provided in *Attachment 3*. These examples serve to illustrate the various definitions that are used by publicly insured health insurance products (since these definitions were available via publicly available sources). Health insurance products purchased by public programs typically refer to “appropriate and necessary” while excluding those services primarily for the convenience of the member or treating physician.

In order to assess the potential impacts of the provision in SB 92 related to medical necessity, one would have to consider a myriad of implementation questions. Some key examples follow:

1. The definition used in the amended version of SB 92 appears to be taken from Medi-Cal’s definition. Medi-Cal’s Manual of Criteria for Medi-Cal Authorization, which clarifies the coverage criteria that apply to some services provided under Medi-Cal, also states, “If the clinical condition of the patient meets the definition of medical necessity, the proposed treatment meets objective medical criteria and is not contraindicated, and such information is adequately documented on the TAR [Treatment Authorization Request], the consultant shall grant authorization if in his/her professional judgment the service request is both reasonable in cost and consistent with the medical needs of the patient.”<sup>8</sup> Medi-Cal’s regulations and the “Plan and Policy Letters” (for Medi-Cal Managed Care Plans) also provide further information

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<sup>4</sup> The Robert Wood Johnson’s Foundations Changes in Health Care Financing and Organization (HCFO) Initiative. Final Grant Report. Understanding Medical Necessity Decision-making GRANT # 039396. June 1, 2000-October 31, 2001.

<sup>5</sup> America’s Health Insurance Plans. January 2006. Update on State External Review Programs. Available at [www.ahipresearch.org/pdfs/External\\_ReviewJan06.pdf](http://www.ahipresearch.org/pdfs/External_ReviewJan06.pdf). Accessed on April 14, 2009.

<sup>6</sup> Chuang KH, Aubry WM, Dudley RA. Independent Medical Review of Health Plan Coverage Denials: Early Trends. *Health Affairs (Millwood)*. 2004;23(6): 163-169.

<sup>7</sup> Health and Safety Code Section 1374.30-1374.36 and Insurance Code Section 10169 to 10169.5

<sup>8</sup> *Manual of Criteria for Medi-Cal Authorization*, Department of Health Care Services, Last Revision: April, 2004. Available at: [http://www.dhcs.ca.gov/services/medi-cal/Documents/ManCriteria\\_03\\_Intro.htm](http://www.dhcs.ca.gov/services/medi-cal/Documents/ManCriteria_03_Intro.htm). Accessed April 9, 2009.



as to what is considered covered and the criteria to determine coverage determinations. Would an analogous or similar level of effort, in terms of regulation and guidance, be required by the DMHC and the CDI to clarify the definition of medical necessity if it is codified in statute?

2. The current language includes services that “prevent significant illness or disability” as medically necessary. However, how would diagnostic services (e.g., a service or test used to identify the cause of abnormal physical signs or symptoms) be considered under this definition since they would not be preventive?
3. The same phrase raises additional questions regarding the definition of “significant illness or significant disability.” Would physical therapy be considered medically necessary under this definition since, in some instances, a patient may get better eventually without the therapy? Would gym memberships or over-the-counter nicotine replacement therapy be considered medically necessary since lack of exercise or continued smoking may lead to “significant illness”?
4. Would diagnostic and treatment services that are not related to severe pain or are not considered life-threatening be considered medically necessary?
5. Would the condition of pregnancy be considered an “illness” or “disability”?
6. What would be considered “significant” illness or disability and what is the threshold for “significant”? The term “significant” may be interpreted by plans or insurers, regulators, and providers differently and may ultimately be clarified or decided by the courts. An analogous example is one related to the Americans with Disabilities Act. The ADA specifies protections for individuals who have “substantial” limitations. Cases were brought to the Supreme Court, who then served as the arbiter on the interpretation of the term “substantial.”<sup>9</sup>
7. Who would determine whether the “pain” that is being experienced is “severe” enough to warrant medically necessary treatment?
8. Would services such as physical, occupational, or speech therapy be considered necessary if they are provided to maintain the patient’s health status or to return the patient back to their original function prior to impairment?
9. Would prevailing standards of care or clinical guidelines developed by professional societies be permitted to be incorporated into the consideration of medical necessity?
10. How would the diagnosis and treatment of mental health care services be considered under this definition of medical necessity?
11. What are the implications for the DMHC’s and the CDI’s current IMR processes?

We hope this information provides some context for the various ways in which “medical necessity” is used and the potential complexity in interpreting corresponding definitions. An important consideration in implementing any definition of medical necessity is whether the language is clear or subject to varying interpretations. My colleagues and I are available to answer any further questions.

Sincerely,



Susan Philip, MPP  
Director, CHBRP  
Division of Health Sciences and Services  
University of California, Office of the President

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<sup>9</sup> Examples include: *Murphy v. United Parcel Service, Inc.*, 527 U.S. 516, 119 S. Ct. 2133 (1999); *Sutton v. United Airlines*, 527 U.S. 471, 119 S. Ct. 2139 (1999); *Toyota Motor Mfg. v. Williams*, 534 U.S. 184, 122 S. Ct. 681 (2002).



cc: Senator Sam Aanestad, Author of SB 92  
Assembly Member Karen Bass, Speaker of the Assembly  
Senator Darrell Steinberg, President Pro Tem of the Senate  
Assembly Member Nathan Fletcher, Vice Chair, Assembly Committee on Health  
Assembly Member Kevin de Leon, Chair, Assembly Committee on Appropriations  
Assembly Member Jim Nielsen, Vice Chair, Assembly Committee on Appropriations  
Senator Tony Strickland, Vice Chair, Senate Committee on Health  
Senator Christine Kehoe, Chair, Senate Committee on Appropriations  
Senator Dave Cox, Vice-Chair, Senate Committee on Appropriations  
Senator Ron Calderon, Chair, Senate Committee on Banking, Finance, and Insurance  
Senator George Runner, Vice Chair, Senate Committee on Banking, Finance, and Insurance  
Linda Halderman, M.D., Senior Policy Advisor for Senator Aanestad; Office of Senator Aanestad  
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Shawn Martin, Director, Health Services, Legislative Analyst's Office  
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David Link, Deputy Commissioner, CDI  
Cindy Ehnes, Director, California Department of Managed Health Care (DMHC)  
Sherrie Lowenstein, Senior Supervising Counsel/Legislative Coordinator, California DMHC  
Mark Yudof, President, University of California, Office of the President (UCOP)  
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Angela Gilliard, Legislative Director, State Governmental Relations, UCOP  
John Stobo, Senior Vice President, Health Sciences and Services, UCOP  
Cathryn Nation, Associate Vice President, Health Sciences and Services, UCOP  
Lauren LeRoy, President and CEO, Grantmakers In Health and CHBRP  
National Advisory Council Chair

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# ATTACHMENTS

## Attachment 1: Model Contractual Language for Medical Necessity

Taken from: *Appendix B in Decreasing variation in medical necessity decision-making: Final report to the California HealthCare Foundation.*<sup>10</sup>

For contractual purposes, 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*.

A health plan may choose to cover interventions that do not meet this contractual definition of *medical necessity*.

Authority	Purpose	Scope	Evidence	Value
An intervention is <i>medically necessary</i> if, as recommended by the treating physician <sup>11</sup> and determined by the health plan's medical director or physician designee, <sup>12</sup> it is (all of the following):	A health intervention <sup>13</sup> for the purpose of treating a medical condition;	the most appropriate supply or level of service, considering potential benefits and harms to the patient;	known to be effective <sup>14</sup> in improving health outcomes <sup>15</sup> (For new interventions, <sup>16</sup> effectiveness is determined by scientific evidence. <sup>17,18</sup> For existing interventions, effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion. <sup>19</sup> ); and	cost effective for this condition compared to alternative interventions, including no intervention. <sup>20</sup> "Cost effective" does not necessarily mean lowest price.

<sup>10</sup> Singer S, Berghold L, Vorhaus C, Olson S, Mutchnick I, Goh YY, Zimmeran S, Enthoven A. *Decreasing Variation in Medical Necessity Decision Making: Final Report to the California HealthCare Foundation: Appendices*. August 1999. This draft was developed at the "Decreasing Variation in Medical Necessity Decision Making" Decision Maker Workshop in Sacramento, March 11-13, 1999. This contractual definition represents a work in progress; not all terms have been defined.

<sup>11</sup> *Treating physician* means a physician who has personally evaluated the patient.

<sup>12</sup> *Physician designee* means a physician designated to assist in the decision-making process.

<sup>13</sup> 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.

<sup>14</sup> *Effective* means that the intervention can reasonably be expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.

<sup>15</sup> *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.

<sup>16</sup> An *intervention* is considered to be *new* if it is not yet in widespread use for the medical condition and patient indications being considered.

<sup>17</sup> *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.

<sup>18</sup> *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 (as described in footnote 9).

<sup>19</sup> 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.

<sup>20</sup> An intervention is considered *cost effective* if the benefits and harms relative to costs represent 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.



## Attachment 2: Examples of States' Statutes

### Chapter 432E-A Section 2. Hawaii Revised Statutes.

**[§432E-1.4] Medical necessity.** (a) For contractual purposes, a health intervention shall be covered if it is an otherwise covered category of service, not specifically excluded, recommended by the treating licensed health care provider, and determined by the health plan's medical director to be medically necessary as defined in subsection (b). A health intervention may be medically indicated and not qualify as a covered benefit or meet the definition of medical necessity. A managed care plan may choose to cover health interventions that do not meet the definition of medical necessity.

(b) A health intervention is medically necessary if it is recommended by the treating physician or treating licensed health care provider, is approved by the health plan's medical director or physician designee, and is:

- (1) For the purpose of treating a medical condition;
- (2) The most appropriate delivery or level of service, considering potential benefits and harms to the patient;
- (3) Known to be effective in improving health outcomes; provided that:
  - (A) Effectiveness is determined first by scientific evidence;
  - (B) If no scientific evidence exists, then by professional standards of care; and
  - (C) If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion; and
- (4) Cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention. For purposes of this paragraph, cost-effective shall not necessarily mean the lowest price.

(c) When the treating licensed health care provider and the health plan's medical director or physician designee do not agree on whether a health intervention is medically necessary, a reviewing body, whether internal to the plan or external, shall give consideration to, but shall not be bound by, the recommendations of the treating licensed health care provider and the health plan's medical director or physician designee.

(d) For the purposes of this section:

“Cost-effective” means a health intervention where the benefits and harms relative to the costs represent an economically efficient use of resources for patients with the medical condition being treated through the health intervention; provided that the characteristics of the individual patient shall be determinative when applying this criterion to an individual case.

“Effective” means a health intervention that may reasonably be expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.

“Health intervention” means an item or service delivered or undertaken primarily to treat a medical condition or to maintain or restore functional ability. 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. New interventions for which clinical trials have not been conducted and effectiveness has not been scientifically established shall be evaluated on the basis of professional standards of care or expert opinion. For existing interventions, scientific evidence shall be considered first and to the greatest extent possible, shall be the basis for determinations of medical necessity. If no scientific evidence is available, professional standards of care shall be considered. If professional standards of care do not exist or are outdated or contradictory, decisions about existing interventions shall be based on expert opinion. Giving priority to scientific evidence shall not mean that coverage of existing interventions shall be denied in the absence of conclusive scientific evidence. Existing interventions may meet the 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.

“Health outcomes” mean outcomes that affect health status as measured by the length or quality of a patient's life, primarily as perceived by the patient.

“Medical condition” means a 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.



“Physician designee” means a physician or other health care practitioner designated to assist in the decisionmaking process who has training and credentials at least equal to the treating licensed health care provider.

“Scientific evidence” means 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 the health outcomes may 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. Scientific evidence may be found in the following and similar sources:

- (1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;
- (2) Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National [Institutes] of Health’s National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS database Health Services Technology Assessment Research (HSTAR);
- (3) Medical journals recognized by the Secretary of Health and Human Services under section 1861(t)(2) of the Social Security Act, as amended;
- (4) Standard reference compendia including the American Hospital Formulary Service-Drug Information, American Medical Association Drug Evaluation, American Dental Association Accepted Dental Therapeutics, and United States Pharmacopoeia-Drug Information;
- (5) Findings, studies, or research conducted by or under the auspices of federal agencies and nationally recognized federal research institutes including but not limited to the Federal Agency for Health Care Policy and Research, National Institutes [of] Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services; and
- (6) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

“Treat” means to prevent, diagnose, detect, provide medical care, or palliate.

“Treating licensed health care provider” means a licensed health care provider who has personally evaluated the patient. [L 2000, c 250, §8]

#### Kansas Administrative Regulation 30-5-58

(ooo) (1) “Medical necessity” means that a health intervention is an otherwise covered category of service, is not specifically excluded from coverage, and is medically necessary, according to all of the following criteria:

- (A) “Authority.” The health intervention is recommended by the treating physician and is determined to be necessary by the secretary or the secretary’s designee.
- (B) “Purpose.” The health intervention has the purpose of treating a medical condition.
- (C) “Scope.” The health intervention provides the most appropriate supply or level of service, considering potential benefits and harms to the patient.
- (D) “Evidence.” The health intervention is known to be effective in improving health outcomes. For new interventions, effectiveness shall be determined by scientific evidence as provided in paragraph (ooo)(3). For existing interventions, effectiveness shall be determined as provided in paragraph (ooo)(4).
- (E) “Value.” The health intervention is cost-effective for this condition compared to alternative interventions, including no intervention. “Cost-effective” shall not necessarily be construed to mean lowest price. An intervention may be medically indicated and yet not be a covered benefit or meet this regulation’s definition of medical necessity. Interventions that do not meet this regulation’s definition of medical necessity may be covered at the choice of the secretary or the secretary’s designee. An intervention shall be considered cost effective if the benefits and harms relative to costs represent 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.



(2) The following definitions shall apply to these terms only as they are used in this subsection (ooo);

(A) “Effective” means that the intervention can be reasonably expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.

(B) “Health intervention” means an item or service delivered or undertaken primarily to treat a medical condition or to maintain or restore functional ability. For this regulation’s definition of medical necessity, a health intervention shall be determined not only by the intervention itself, but also by the medical condition and patient indications for which it is being applied.

(C) “Health outcomes” means treatment results that affect health status as measured by the length or quality of a person’s life.

(D) “Medical condition” means a 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.

(E) “New intervention” means an intervention that is not yet in widespread use for the medical condition and patient indications under consideration.

(F) “Scientific evidence” means controlled clinical trials that either directly or indirectly demonstrate the effect of the intervention on health outcomes. However, if controlled clinical trials are not available, observational studies that demonstrate a causal relationship between the intervention and health outcomes may be used. Partially controlled observational studies and uncontrolled clinical series may be considered to be suggestive, but shall not by themselves be considered to 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.

(G) “Secretary’s designee” means a person or persons designated by the secretary to assist in the medical necessity decision-making process.

(H) “Treat” means to prevent, diagnose, detect, or palliate a medical condition.

(I) “Treating physician” means a physician who has personally evaluated the patient.

(3) Each new intervention for which clinical trials have not been conducted because of epidemiological reasons, including rare or new diseases or orphan populations, shall be evaluated on the basis of professional standards of care or expert opinion as described below in paragraph (ooo)(4).

(4) The scientific evidence for each existing intervention shall be considered first and, to the greatest extent possible, shall be the basis for determinations of medical necessity. If no scientific evidence is available, professional standards of care shall be considered. If professional standards of care do not exist, or are outdated or contradictory, decisions about existing interventions shall be based on expert opinion. Coverage of existing interventions shall not be denied solely on the basis that there is an absence of conclusive scientific evidence. Existing interventions may be deemed to meet this regulation’s definition of medical necessity in the absence of scientific evidence if there is a strong consensus of effectiveness and benefit expressed through up-to-date and consistent professional standards of care or, in the absence of those standards, convincing expert opinion.



(ppp) “Medical necessity in psychiatric situations” means that there is medical documentation that indicates either of the following:

- (1) The person could be harmful to himself or herself or others if not under psychiatric treatment; or
- (2) the person is disoriented in time, place, or person.



**Attachment 3: Examples of medical necessity definitions from publicly available sources**

Carrier/Public Program	Plan type/Source	“Medical Necessity” definition
Anthem Blue Cross/CalPERS	CalPERS PPO products/2009 PERS Choice Basic Plan Evidence of Coverage	<p>Medical necessity means services and supplies as determined through the Plan’s review process to be necessary, appropriate, and established as safe and effective for treatment of the patient’s illness or injury. The Plan’s review processes are consistent with acceptable treatment patterns found in established managed care environments and consistent with Anthem Blue Cross Medical Policy. The fact that a provider may prescribe, order, recommend or approve a service, supply, or hospitalization does not in itself make it medically necessary, even though it is not specifically listed as an exclusion or limitation. A service may be determined not to be medically necessary even though it may be considered beneficial to the patient.</p> <p>Established medical criteria for medical necessity must be met before that service, procedure, equipment or supply is determined to be medically necessary.</p> <p>Services, procedures, equipment and supplies that are medically necessary must:</p> <ul style="list-style-type: none"> <li>• be appropriate and necessary for the diagnosis or treatment of the medical condition;</li> <li>• be consistent with the symptoms or diagnosis in treatment of the illness, injury, or condition;</li> <li>• be within standards of good medical practice within the organized medical community;</li> <li>• not be furnished primarily for the convenience of the patient, the treating physician, or other provider;</li> <li>• be consistent with Anthem Blue Cross Medical Policy;</li> <li>• not be for custodial care; and</li> <li>• be the most appropriate procedure, supply, equipment, or service which can be safely provided. The most appropriate procedure, supply, equipment or service must satisfy the following requirements:             <ol style="list-style-type: none"> <li>a. There must be valid scientific evidence demonstrating that the expected health benefits from the procedure, supply, equipment or service are clinically significant and produce a greater likelihood of benefit, without a disproportionately greater risk of harm or complications, for you with the particular medical condition being treated than other possible alternatives; and</li> <li>b. Generally accepted forms of treatment that are less invasive have been tried and found to be ineffective or are otherwise unsuitable; and</li> <li>c. For hospital stays, acute care as an inpatient is necessary due to the kind of services you are receiving or the severity of your condition, and safe and adequate care cannot be received in an outpatient setting or in a less intensified medical setting.</li> </ol> </li> </ul>



Carrier/Public Program	Plan type/Source	“Medical Necessity” definition
Blue Shield of California/CalPERS & Medicare	CalPERS HMO products/2009 Blue Shield of California Health Maintenance Organization (HMO) Access+ HMO Combined Evidence of Coverage and Disclosure Form for the Basic Plan and the HMO Supplement to Original Medicare Plan	<p>Services which are medically necessary include only those which have been established as safe and effective and are furnished in accordance with generally accepted professional standards to treat an illness, injury, or medical condition, and which, as determined by Blue Shield, are:</p> <ul style="list-style-type: none"> <li>• consistent with Blue Shield medical policy; and,</li> <li>• consistent with the symptoms or diagnosis; and,</li> <li>• not furnished primarily for the convenience of the patient, the attending physician or other provider; and,</li> <li>• furnished at the most appropriate level which can be provided safely and effectively to the patient.</li> </ul>
Health Net/FEHBP	All plans associated with Federal Employee Health Benefits/2009 Health Net of California Statement of Benefits for Federal Employees Health Benefits Program	<p>Medical necessity is the criteria used by us and the participating physician group to provide covered services in the prevention, diagnosis, and treatment of your illness or condition. Medically necessary services are determined to be:</p> <ul style="list-style-type: none"> <li>• Not experimental or investigational</li> <li>• Appropriate and necessary for the symptoms, diagnosis, or treatment of a condition, illness or injury</li> <li>• Provided for the diagnosis or care and treatment of the condition, illness or injury</li> <li>• Not primarily for the convenience of the member, member’s physician, or anyone else</li> <li>• The most appropriate supply or level that can safely be provided. For example, outpatient rather than inpatient surgery may be authorized when the setting is safe and adequate.</li> </ul>
Kaiser Foundation Health Plan/CalPERS & Medicare Advantage	CalPERS HMO products/2009 Kaiser Permanente Health Maintenance Organization Combined Evidence of Coverage and Disclosure Form for the Basic Plan and the Managed Medicare Health Plan	A service is Medically Necessary if it is medically appropriate and required to prevent, diagnose, or treat your condition or clinical symptoms in accord with generally accepted professional standards of practice that are consistent with a standard of care in the medical community.
Medi-Cal	All Medi-Cal plans/ Manual of Criteria for Medi-Cal Authorization, California Department of Health Care Services; nd Welfare and Institution Code Section 14059.5	A service is “medically necessary” or a “medical necessity” when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.
Medicare	Medicare and Medicare Advantage plans/Medicare Glossary of Terms, Centers	Services or supplies that are needed for the diagnosis or treatment of your medical condition, meet the standards of good medical practice in the local area, and aren’t mainly for the convenience of you or your



Carrier/Public Program	Plan type/Source	“Medical Necessity” definition
	for Medicare and Medicaid Services	doctor.
PacifiCare/FEHBP	All plans associated with Federal Employee Health Benefits/2009 PacifiCare of California Statement of Benefits for Federal Employees Health Benefits Program	<p>Medical necessity refers to medical services or hospital services that are determined by us to be:</p> <ul style="list-style-type: none"> <li>• Rendered for the treatment or diagnosis of an injury or illness; and</li> <li>• Appropriate for the symptoms, consistent with diagnosis, and otherwise in accordance with sufficient scientific evidence and professionally recognized standards; and</li> <li>• Not furnished primarily for the convenience of the member, the attending physician, or other provider of service; and</li> <li>• Furnished in the most economically efficient manner which may be provided safely and effectively to the member.</li> </ul>

