CALIFORNIA GRANDFATHERED GRIEVANCE PROCEDURES

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I. Definitions

- A. "Coverage decision" means the approval or denial of health care services by a health plan, or by one of its contracting entities, substantially based on a finding that the provision of a particular service is included or excluded as a covered benefit under the terms and conditions of the health contract. A coverage decision does not encompass a health plan or contracting provider decision regarding a disputed health care service.
- B. "Disputed health care service" means any health care service eligible for coverage and payment under a health contract that has been denied, modified, or delayed by a decision of the health plan, or by one of its contracting providers, in whole or in part due to a finding that the service is not medically necessary. A decision regarding a disputed health care service relates to the practice of medicine and is not a coverage decision.
- C. "Life-threatening" means either or both of the following:
 - 1. Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted;
 - 2. Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.
- D. "Medical and scientific evidence" means the following 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 of 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;
- 4. Either of the following reference compendia:
 - a. The American Hospital Formulary Service's Drug Information; or
 - b. The American Dental Association Accepted Dental Therapeutics.
- 5. Any of the following reference compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:
 - a. The Elsevier Gold Standard's Clinical Pharmacology;
 - b. The National Comprehensive Cancer Network Drug and Biologics Compendium; or
 - c. The Thomson Micromedex DrugDex.
- 6. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including 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; or
- 7. Peer-reviewed abstracts accepted for presentation at major medical association meetings.
- E. "Seriously debilitating" means diseases or conditions that cause major irreversible morbidity.
- F. "Terminal illness" means an incurable or irreversible condition that has a high probability of causing death within 1 year or less.

II. Internal Review of Grievances

A. Request:

- 1. An insured may submit a grievance regarding a *coverage decision* or a *disputed health care service*.
- 2. For grievances regarding *coverage decisions* involving an experimental or investigational medical procedure or treatment for an insured with a *terminal illness*, the insured or representative has the right to appeal the denial and obtain and participate in the review. The review will not be limited to written communication.

B. Expedited Review Request:

- 1. An expedited review of a *disputed health care service* can be requested if the *disputed health care service* has not been provided and the insured's provider certifies in writing that an imminent and serious threat to the health of the insured may exist, including, but not limited to, serious pain, the potential loss of life, limb, or major bodily function, or the immediate and serious deterioration of the health of the insured.
- 2. The California Department of Insurance (Department) may waive the requirement that the insured follow the health plan's grievance process in extraordinary and compelling cases, where the commissioner finds that the insured has acted reasonably.

C. Reviewer's Requirements:

- 1. If the grievance involves a *disputed health care service*, the health plan will consult with an independent medical practitioner who practices in an appropriate field of medicine.
- 2. If the grievance involves a *coverage decision* regarding experimental or investigational therapy, the health plan will consult with an independent medical practitioner who practices in an appropriate field of medicine.
- 3. All other grievances involving *coverage decisions* will be handled by a designated representative of the area responsible for the grievance who was not involved in the original determination.
- D. <u>Requirement of All Letters</u>: All letters, including, but not limited to, interim responses, and medical record requests must include the address and telephone number of the California Department of Insurance:

Consumer Services Division 300 South Spring Street, South Tower Los Angeles, CA 90013 Phone: (800) 927-HELP (4357)

- E. <u>Resolution Timeframe</u>: The health plan will notify the insured of the determination within:
 - 1. For reviews regarding *coverage decisions* involving an experimental or investigational medical procedure or treatment for an insured with a *terminal illness*:
 - a. 30 calendar days of receipt of the review request; or
 - b. **5 business days** if the treating physician determines, in consultation with the medical director of the health plan, based on standard medical practice, that the effectiveness of either the proposed treatment, services, or supplies or any alternative treatment, services, or supplies covered by the policy, would be materially reduced if not provided at the earliest possible date.
 - 2. For all other reviews:
 - a. 30 calendar days of the receipt of a standard grievance; or
 - b. 3 calendar days of the receipt of an expedited review request.

F. Notification of Determination:

- 1. For upheld, modified, or overturned decisions, the written notice of the decision must include the address and telephone number of the California Department of Insurance, as listed in Section II-D.
- 2. In addition, if the grievance determination denies, modifies, or delays health care services, the written notice must include:
 - a. The opportunity to request an external independent review;
 - b. The "Application for Independent Medical Review" in which the health plan has included on the form any information required by the Department to facilitate the IMR, such as the insured's diagnosis or condition, the nature of the *disputed health care service* sought by the insured, a means to identify the insured's case, and any other material information;
 - c. The "Authorization for Release of Medical Records and Designation of Independent Medical Review Agent" form;
 - d. For a determination involving an experimental or investigational therapy, the "Physician Certification Experimental/Investigational Denials" form;
 - e. An envelope addressed to;

California Department of Insurance

Health Claims Bureau

300 South Spring Street, South Tower

Los Angeles, CA 90013; and

f. A statement that, if the insured believes all or part of the claim has been wrongfully denied or rejected, he or she may have the matter reviewed by the California Department of Insurance.

III. External, Independent Review of *Coverage Decisions* Regarding Experimental or Investigational Therapies

A. Request:

- 1. An external, independent medical review (IMR) of a health plan's *coverage decision* regarding experimental or investigational therapy may be requested by an individual who meets all of the following criteria:
 - a. The insured has a *life-threatening* or *seriously debilitating* condition;
 - b. The insured's physician certifies that the insured has a condition for which standard therapies have not been effective in improving the condition of the insured, for which standard therapies would not be medically appropriate for the insured, or for which there is no more beneficial standard therapy covered by the health plan than the therapy proposed;
 - c. Either:
 - (1) The insured's contracting physician has recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the insured than any available standard therapies; or
 - (2) The insured, or the insured's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the insured's condition, has requested a therapy that, based on two documents from the *medical and scientific evidence* is likely

- to be more beneficial for the insured than any available standard therapy. The physician certification shall include a statement of the evidence relied upon in certifying the recommendation;
- d. The insured has been denied coverage by the health plan for a drug, device, procedure, or other therapy recommended or requested unless coverage for the specific therapy has been excluded by the health plan's contract; and
- e. The specific drug, device, procedure, or other therapy recommended would be a covered service except for the health plan's determination that the therapy is experimental or under investigation.
- 2. An insured may designate an agent to act on his or her behalf. The provider may join with, assist, or advocate on behalf of the insured. If the insured wants to have another person assist them with the IMR process, the insured must include a completed "Authorization for Release of Medical Records and Designation of Independent Medical Review Agent" form.
- B. <u>Expedited External Review Request</u>: An expedited external review can be requested if the proposed therapy has not been provided and the insured's provider determines that the proposed therapy would be significantly less effective if not promptly initiated.

C. Process:

- 1. When a completed application is received, the Department will determine if the insured's request qualifies for the IMR program. If the request does qualify, the insured will be notified. If the request does not qualify for the IMR program, then the insured's claim review request will be referred to the complaint/mediation program within the Department.
- 2. In an expedited review, the Department shall expeditiously review the request and immediately notify the insured in writing as to whether the request for an IMR has been approved, in whole or in part, and, if not, the reasons therefor.
- 3. The Department will send the case to an independent medical review organization (IMRO) with copies of all documents necessary to conduct the IMR.
- 4. Within **3 business days** (**24 hours** for expedited) of the health plan's notice from the Department that the insured has applied for an IMR, the health plan or its contracting providers, must provide to the designated IMRO the following documents:
 - a. A copy of all of the insured's medical records in the possession of the health plan or its contracting providers relevant to each of the following:
 - (1) The insured's medical condition;
 - (2) The health care services being provided by the health plan and its contracting providers for the condition;
 - (3) The experimental or investigational therapy requested by the insured for the condition;
 - b. A copy of all information provided to the insured by the health plan and any of its contracting providers concerning health plan and provider decisions regarding the insured's condition and care, and a copy of any materials the insured or the insured's provider submitted to the health plan and to the health plan's contracting providers in support of the insured's request for

- experimental or investigational therapy. This documentation must include the written response to the insured's grievance.
- c. A copy of any other relevant documents or information used by the health plan or its contracting providers in determining whether experimental or investigational therapy should have been provided, and any statements by the health plan and its contracting providers explaining the reasons for the decision to deny, modify, or delay experimental or investigational therapy on the basis of medical necessity. The health plan must concurrently provide a copy of these documents, except for any information found by the commissioner to be legally privileged information, to the insured and the insured's provider.
- 5. In an expedited review, the health plan must promptly issue a notification to the insured, after submitting all of the required material to the IMRO, that includes an annotated list of documents submitted and offers the insured the opportunity to request copies of those documents from the health plan.
- 6. Any newly developed or discovered relevant medical records in the possession of the health plan or its contracting providers after the initial documents are provided to the IMRO must be forwarded immediately to the IMRO. The health plan must concurrently provide a copy of these medical records to the insured or the insured's provider, if authorized by the insured, unless the offer of medical records is declined or otherwise prohibited by law.

D. Resolution Timeframe and Notification of Determination:

- 1. The IMRO shall complete its review and make its determination in writing to the director, the health plan, the insured, and the insured's provider within 30 days (7 days for expedited) of the receipt of the application for review and supporting documentation, or within less time as prescribed by the commissioner.
- 2. The deadlines for analyses and determinations may be extended by the commissioner for up to 3 days in extraordinary circumstances or for good cause.
- 3. At the request of the expert, the deadline shall be extended by up to 3 days for a delay in providing the documents required.
- 4. The commissioner shall immediately adopt the determination of the IMRO and shall promptly issue a written decision to the parties.

E. General Information:

- 1. An external review decision is binding on the health plan.
- 2. The health plan will pay for the costs of the external review performed by the independent reviewer.

IV. External, Independent Review of Disputed Health Care Services

A. Request:

- 1. All insured grievances involving a *disputed health care service* are eligible for review under the IMR if the conditions in Section IV-A-3 are met.
- 2. The Department shall have the final authority to determine whether a grievance is regarding a *disputed health service* or a *coverage decision*.

- 3. An insured may apply to the Department for an IMR using the "Application for Independent Medical Review" within 6 months of the health plan upholding its decision within the grievance process if all of the following conditions are met:
 - a. One of the following conditions is met:
 - (1) The insured's provider has recommended a health care service as medically necessary; or
 - (2) The insured has received urgent care or emergency services that a provider determined was medically necessary;
 - b. The *disputed health care service* has been denied, modified, or delayed by the health plan, or by one of its contracting providers, based in whole or in part on a decision that the health care service is not medically necessary; and
 - c. The insured has filed a grievance with the health plan or its contracting provider, and the disputed decision is upheld or the grievance remains unresolved after 30 days (3 days for expedited reviews).
- 4. The commissioner may extend the application deadline beyond 6 months if the circumstances of a case warrant the extension.
- 5. An insured may designate an agent to act on his or her behalf. The provider may join with, assist, or advocate on behalf of the insured. If the insured wants to have another person assist them with the IMR process, the insured must include a completed "Authorization for Release of Medical Records and Designation of Independent Medical Review Agent" form.

B. Expedited External Review Request:

- 1. An expedited external review can be requested if the *disputed health care service* has not been provided and the insured's provider or the Department certifies in writing that an imminent and serious threat to the health of the insured may exist, including, but not limited to, serious pain, the potential loss of life, limb, or major bodily function, or the immediate and serious deterioration of the health of the insured.
- 2. The Department may waive the requirement that the insured follow the health plan's grievance process in extraordinary and compelling cases, where the commissioner finds that the insured has acted reasonably.

C. Process:

- 1. When a completed application is received, the Department will determine if the insured's request qualifies for the IMR program. If the request does qualify, the insured will be notified. If the request does not qualify for the IMR program, then the insured's claim review request will be referred to the complaint/mediation program within the Department.
- 2. In an expedited review, the Department shall expeditiously review the request and immediately notify the insured in writing as to whether the request for an IMR has been approved, in whole or in part, and, if not, the reasons therefor.
- 3. The Department will send the case to an IMRO with copies of all documents necessary to conduct the IMR.
- 4. Within **3 business days** (**24 hours** for expedited) of the health plan's notice from the Department that the insured has applied for an IMR, the health plan or its

contracting providers, must provide to the designated IMRO the following documents:

- a. A copy of all of the insured's medical records in the possession of the health plan or its contracting providers relevant to each of the following:
 - (1) The insured's medical condition;
 - (2) The health care services being provided by the health plan and its contracting providers for the condition;
 - (3) The *disputed health care services* requested by the insured for the condition;
- b. A copy of all information provided to the insured by the health plan and any of its contracting providers concerning health plan and provider decisions regarding the insured's condition and care, and a copy of any materials the insured or the insured's provider submitted to the health plan and to the health plan's contracting providers in support of the insured's request for *disputed health care services*. This documentation must include the written response to the insured's grievance.
- c. A copy of any other relevant documents or information used by the health plan or its contracting providers in determining whether *disputed health care services* should have been provided, and any statements by the health plan and its contracting providers explaining the reasons for the decision to deny, modify, or delay *disputed health care services* on the basis of medical necessity. The health plan must concurrently provide a copy of these documents, except for any information found by the commissioner to be legally privileged information, to the insured and the insured's provider.
- 5. In an expedited review, the health plan must promptly issue a notification to the insured, after submitting all of the required material to the IMRO, that includes an annotated list of documents submitted and offers the insured the opportunity to request copies of those documents from the health plan.
- 6. Any newly developed or discovered relevant medical records in the possession of the health plan or its contracting providers after the initial documents are provided to the IMRO must be forwarded immediately to the IMRO. The health plan must concurrently provide a copy of these medical records to the insured or the insured's provider, if authorized by the insured, unless the offer of medical records is declined or otherwise prohibited by law.

D. Resolution Timeframe and Notification of Determination:

- 1. The IMRO shall complete its review and make its determination in writing to the director, the health plan, the insured, and the insured's provider within 30 days (3 days) of the receipt of the application for review and supporting documentation, or within less time as prescribed by the commissioner.
- 2. The deadlines for analyses and determinations may be extended by the commissioner for up to 3 days in extraordinary circumstances or for good cause.
- 3. The commissioner shall immediately adopt the determination of the IMRO and shall promptly issue a written decision to the parties.

E. General Information:

1. An external review decision is binding on the health plan.

2. The health plan will pay for the costs of the external review performed by the independent reviewer.

V. Department of Insurance's Review

If the Department finds that an insured grievance involving a *disputed health care service* does not meet the requirements for review under the IMR, the insured's request for review shall be treated as a request for the Department to review the grievance.

All other grievances, including grievances involving *coverage decisions*, remain eligible for review by the Department.