blue california
Promise Health Plan

Policy Title: Evaluation & Review of Experimental & Investigational Therapies & IMR		POLICY #: 70.2.29 Line of business: ALL	
Department Name: Utilization Management	**Original Date** 10/98	**Effective Date** 5/19	**Revision Date** 12/18
Department Head: Sr. Director, UM		**Date: 3/21**	
Medical Services/P&T Committee: (If Applicable) PHP CMO		**Date: 3/21**	

PURPOSE

In accordance with the Health and Safety Code section 1370.4 Blue Shield of California Promise Health Plan (Blue Shield Promise) Utilization Management Department will provide a process for enrollees to access an external, independent review process to examine the plan's coverage decisions regarding experimental or investigational therapies when they meet specific criteria.

POLICY

Under some contracts with PPG's, Blue Shield Promise Health Plan may delegate the authority to perform functions in the area of Utilization Management (UM), but it does not delegate the responsibility for Technology Assessment. Therefore, the delegated providers are required to contact Blue Shield Promise with any potentially eligible experimental or investigational cases.

Any provider or Participating Provider Group (PPG) may request authorization for a drug, device, procedure or therapy; however, if the plan deems it experimental or investigational, the request will usually be denied. For all enrollees who meet the criteria, they will be provided the opportunity to seek an Independent Medical Review (IMR). The IMR process will be done through the Department Managed Health Care (DMHC).

Blue Shield Promise grants enrollees of their request for an independent medical review pursuant to Section 1370.4, 1370.30 through 1370.34 when Blue Shield Promise denied a therapy or medical service that would otherwise be covered based on Blue Shield Promise's determination that the therapy or medical service is experimental or investigational.

Members that Qualify to Request the E&I Review Process

1. The member has a "life threatening" or "seriously debilitating condition"
    a. "life threatening" means either or both of the following:
        i. Diseases or conditions where likelihood of death is high unless the course of the disease is interrupted
        ii. Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.
    b. "Seriously debilitating" means diseases or conditions that cause major irreversible morbidity

c. There is an imminent and serious threat to the health of the patient including severe pain, the potential loss of limb, or major bodily function

2. The member's physician certifies that the enrollee has a condition, as defined in #1, for which standard therapies have not been effective in improving the condition of the enrollee, or for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more beneficial standard therapy covered by the plan and:
3. (A) the member's physician, who is under contract with, or employed by Blue Shield Promise, has recommended a drug, device, procedure or other therapy that the physician certifies in writing is likely to be more beneficial to the member than any available standard therapies; or (B) the member

4. The member has been denied coverage by Blue Shield Promise for a drug, device, procedure or other therapy recommended or requested;

5. The specific drug, device, procedure or other therapy recommended pursuant to #3 would be covered service, except for a Blue Shield Promise determination that the therapy is experimental or investigational.

6. An independent medical reviewer shall base his/her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidences.

Investigational services means those drugs, equipment, procedures or services for which laboratory and animal studies have been completed and for which human studies are in progress but:

1. Testing is not complete;
2. The efficacy and safety of such services in human subjects are not yet established;
3. The service is not in the wide usage.

Criteria Determining Experimental

The determination that a service is experimental or investigational is based on:

1. Reference to relevant federal regulations, such as those contained in Title 42, Code of Federal Regulations, Chapter IV (Health Care Financing Administration) and Title 42, Code of Federal Regulations, Chapter IV (Health Care Financing Administration) and Title 21, Code of Federal Regulations, Chapter I (Food and Drug Administration);
2. Consultation with provider organizations, academic and professional specialists pertinent to the specific service;
3. Reference to current medical literature.

A. 51303 (h) Investigational services are not covered except when it is clearly documented that all of the following apply:
   a. Conventional therapy will not adequately treat the intended patient's condition;
   b. Conventional therapy will not prevent progressive disability or premature death
   c. The provider of the proposed service has a record of a safety and success with it equivalent or superior to that of other providers of the investigational service
   d. The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives
   e. The service is not being performed as a part of a research study protocol

f. There is reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living.

All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the above criteria or for associated inpatient care when a beneficiary needs to be in the hospital primarily because she/he is receiving such non-approved investigational services.

B. 51301 (g) Experimental services are not covered

Experimental services means those drugs, equipment, procedures or services that are in a testing phase undergoing laboratory and/or animal studies prior to testing in humans.

PROCEDURE

1. Blue Shield Promise shall notify eligible enrollees in writing of the opportunity to request the external independent review within 5 business days of the decision to deny coverage.

2. If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within 7 days of the request for expedited review.
    a. At the request of the expert, the deadline shall be extended by up to 3 days for a delay in providing the documents required.

3. Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the enrollee than an available standard therapy, and the reasons that the expert recommends that the therapy should or should not be provided by Blue Shield Promise, citing the enrollee's specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence, including, but not limited to the medical and scientific evidence, as defined in subsection (d), to support the expert's recommendation.

4. Upon the plan's decision to deny modify or delay the service the enrollee and the requesting provider will be notified in writing of the following:
    a. A statement setting forth the specific medical and scientific reasons for denying the coverage
    b. A description of alternative treatment, services or supplies covered by the plan if any
    c. The opportunity to request an external independent review through the DMHC within 5 business days of the decision.

5. At the time of the plan's denial of coverage for experimental or investigational therapy, the plan shall notify the enrollee of the ability to seek independent medical review.

6. The notification must include, at a minimum, information on the independent medical review process, and application and envelope addressed to DMHC, the physician

7. DMHC does not require that an enrollee participate in Blue Shield Promise's grievance system prior to seeking independent medical review.

8. Included with the enrollee's application to DMHC for independent medical review shall be a copy of Blue Shield Promise or contracted provider's written denial of the therapy or medical service based on the determination that the therapy or service is experimental or investigational.

9. A certification from the enrollee's treating physician shall be included with the application for independent medical review. The physician's certification shall be on a form from DMHC entitled, "Physician Certification Experimental/Investigational Denials" (DMHC/IMR 110-11/27/00), or containing all of the following information:

    a. Enrollee has a condition as defined in Health and Safety Code Section 1370.4(a)(1).
    b. Background information including the name of the enrollee and Blue Shield Promise Health Plan; physician's name, specialty, board certification, address, telephone and fax number, whether the physician is contracted with Blue Shield Promise; the enrollee's medical condition; and the specific drug, device, procedure, or other therapy recommended or requested for the enrollee's medical condition.

For non-contracted physicians, the certification shall also include the following:

    a. Physician's license, board certification or board eligibility to practice in the area appropriate to treat the enrollee's condition;
    b. Reference to, or copies of, two documents from the medical or scientific literature, specified in section 1370.4(d) of the Act
    c. The following statement and physician's signature: "I certify that the requested therapy is likely to be more beneficial than any standard therapy. The information provided herein is true and correct,"
    d. Where expedited review is requested the certification shall include a statement that imminent and serious threat to the health of the enrollee exists pursuant to Health and Safety Code section 1374.31, or the proposed therapy would be significantly less effective if not promptly initiated; and
    e. Attachments, including any additional references or copies of medical and/or scientific literature considered relevant to the requested therapy and any other information relevant to the request

10. If the adoption letter from the DMHC requires Blue Shield Promise to reverse its initial determination (the denial is overturned), Blue Shield Promise shall implement the determination and notify DMHC in writing of their compliance with the determination.

REFERENCES