blue california
Promise Health Plan

Policy Title: Experimental and Investigational Services for the Terminally Ill		POLICY #: 70.2.29A Line of business: ALL	
Department Name: Utilization Management	**Original Date** 4/10	**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

To establish a process to provide investigational services and comply with the requirements set forth in Title 22, Health & Safety Code 51056.1 and Section 51303(g) (h) of the California Code of Regulations.

To establish a process of notification for enrollees with terminal illness when a request for investigational service is denied, as set forth in the Health and Safety Code Section 1368.1 of the California Code of Regulations.

POLICY

Blue Shield Promise Health Plan (Blue Shield Promise) does not delegate the responsibility for technology assessment, experimental or investigational services, therefore, the delegated providers and participating groups are required to notify the health plan for such services.

PROCEDURE

Experimental services are not covered.

Investigational services are not covered except when it is clearly documented that all of the following apply:

1. Conventional therapy will not adequately treat the intended patient's condition;
2. Conventional therapy will not prevent progressive disability or premature death;
3. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service;
4. 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;
5. The service is not being performed as part of a research study protocol;
6. There is a 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 is not 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.

DENIAL OF REQUEST:

For a denial of the request for Experimental Investigational Treatment Blue Shield Promise shall provide a written response to the member has to include clear and concise explanation of the reason for the denial or modification of requested service(s), and the specific clinical criteria used for the determinations to the denial or modification letters.

- The notice to the member will inform the member that he/she may file an appeal concerning the determination using the appeal process (as proscribed by the statute), prior to or concurrent with the initiation of a State Fair Hearing process.
- How to initiate an expedited appeal at the time they are notified of the denial.
- The member's right to, and method for obtaining, a State Fair Hearing The member's right to represent himself/herself at the State Fair Hearing or to be represented by legal counsel or other spokesperson.
- The member's right to request an Independent Medical Review (IMR).
- The name and address of the entity making the determination.
- The State's toll-free telephone number for obtaining information on legal service organizations for representation.
- The Department of Managed Health Care's toll free telephone number to receive complaints regarding a grievance against the Plan that has not been satisfactorily resolved by the Plan to the member's satisfaction.
- Possible alternative treatments or care.

DEFINITIONS:

Terminal Illness – means an incurable or irreversible condition that has a high probability of causing death within one year or less.

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.

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, and
(3) The service is not in wide usage

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 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; Reference to current medical literature.

REFERENCES

CCR Title 22 Section 51056.1
CCR Title 22 Section 51303(h)
Health & Safety Code Section 1368.1(a)(b)