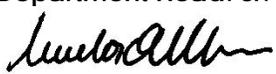
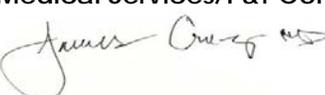


Policy Title: Experimental and Investigational Services for the Terminally III		POLICY #: 10.2.100.22	
Department Name: Utilization Management		Original Date 4/11	Effective Date 5/19
		Line of business: Medi-Cal	
		Revision Date 12/18	
Department Head: Sr. Director, UM 			Date: 3/21
Medical Services/P&T 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 of California Promise (Blue Shield Promise) shall provide investigational services when a service is determined to be investigational and all requirements are clearly documented.

Blue Shield Promise Health Plan 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.

DEFINITION:

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 or 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

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

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

1. Reference to relevant 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 1 (Food and Drug Administration));

2. Consultation with provider organizations, academic and professional specialists pertinent to the specific service;
3. Reference to current medical literature

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 PROCESS FOR TERMINALLY ILL:

If a request for treatment, service, or supplies deemed experimental for a patient with "terminal illness" is denied, Blue Shield Promise Health Plan will provide to the enrollee the following within 5 business days:

1. A statement setting forth the specific medical and scientific reasons for denying the coverage.
2. A description of alternative treatment, services, or supplies covered by Blue Shield Promise, if any.
3. Copies of the plan's grievance procedures or complaint form, or both. The complaint form shall provide an opportunity for the enrollee to request a conference as part of the plan's grievance system provided under Section 1368.
4. Blue Shield Promise Health Plan will provide, within 30 calendar days, an opportunity to attend a conference, to review the information provided to the terminally ill enrollee, conducted by the Plan representative having authority to determine the disposition of the complaint, upon receiving a complaint from requesting a conference. The conference shall be held within 5 business days if the treating participating physician determines that the effectiveness of proposed treatment, services, or supplies covered by Blue Shield Promise Health Plan would be materially reduced if not provide at the earliest possible date. The plan shall allow attendance, in person, at the conference, by an enrollee, a designee of the enrollee, or both, or if the enrollee is a minor or incompetent, the parent, guardian, or conservator of the enrollee, as appropriate.

Upon receiving a complaint form requesting a conference, Blue Shield Promise Health Plan will provide, within 30 calendar days, an opportunity to attend a conference. The conference shall be held within 5 business days if the treating participating physician determines that the

effectiveness of proposed treatment, services, or supplies covered by Blue Shield Promise Health Plan would be materially reduced if not provided at the earliest possible date.

Complaint Form:

This form provides an opportunity for the enrollee to request a conference as part of Blue Shield Promise Health Plan's grievance system under Health & Safety Code, Section 1368.

Blue Shield Promise Health Plan shall provide the enrollee, within 30 calendar days, an opportunity to attend a conference, to review the information provided to the enrollee. Blue Shield Promise Health Plan shall allow attendance, in person, at the conference, by an enrollee, a designee of the enrollee, or both, or, if the enrollee is a minor or incompetent, the parent, guardian, or conservator of the enrollee, as appropriate.

The conference shall be held within five (5) business days if the treating participating physician determines, after consultation with Blue Shield Promise Medical Director or his designee, based on the standard medical practice that the effectiveness of either the proposed treatment, services, or supplies or any alternative treatment, services, or supplies covered by Blue Shield Promise Health Plan, would be materially reduced if not provided at the earliest possible date.

REFERENCES

CCR Title 22 Section 51056.1

CCR Title 22 Section 51303 (h)

Health & Safety Code Section 1368.1 (a)(b)