blue california
Promise Health Plan

Policy Title: Experimental and Investigational Services		**POLICY #:** 10.02.47	
		Line of business: Medi-Cal	
Department Name: Utilization Management	**Original Date** 4/10	**Effective Date** 11/22	**Revision Date** 9/24
Governing Committee: Medical Services Committee			
Governing Committee Approval: Jennifer Nuovo, MD, Blue Shield Promise Chief Medical Officer		**Date: 9/9/24**	
Vice President (VP) Approval: Tracy Alvarez, VP, Medical Care Solutions		**Date: 9/9/24**	

A. PURPOSE

To establish a process for Blue Shield Promise Health Plan (Blue Shield Promise) to provide investigational services and comply with the requirements set forth in Title 22, Health & Safety Code (HSC) §51056.1 and §§51303(g) and (h) of the California Code of Regulations (CCR).

B. DEFINITIONS

1. "Experimental" services according to 22 CCR §51056.1(a) are those drugs, equipment, procedures, or services that are in a testing phase undergoing laboratory and/or animal studies prior to testing in humans. Experimental services are not covered per 22 CCR §51303(g).

2. "Investigational" services according to 22 CCR §51056.1(b) are 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; and
    2. The efficacy and safety of such services in human subjects are not yet established; and
    3. The service is not in wide usage.

C. POLICY

I. Blue Shield Promise Utilization Management (UM) will authorize medically necessary services in accordance with the regulations, even though the procedures or services may not be listed as covered by Medi-Cal. The "Treatment Authorization Request (TAR) and Non-Benefit List" published by the Department of Health Care Services will be used as a guideline only.

II. Decisions to approve, deny, delay, or modify will be based on medical necessity. These decisions will reflect appropriate application of Blue Shield Promise approved criteria/guidelines. Any decision to deny, modify, or delay a request will be made by a physician. Physician consultants from appropriate specialty areas of medicine and surgery who are eligible for certification by the applicable American Board of Medical Specialties will be utilized as necessary. Blue Shield Promise does not compensate practitioners or other individuals for denials of coverage or service.

III. The determination that a service is experimental or investigational is based on the following elements pursuant to 22 CCR §51056.1(c):
   a. 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);
   b. Consultation with provider organizations, academic and professional specialists pertinent to the specific service;
   c. Reference to current medical literature.

IV. 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.

D. PROCEDURE

I. All investigational services require prior authorization. Blue Shield Promise will cover investigational services as defined in 22 CCR §51056.1(b) when a service is determined to be investigational pursuant to 22 CCR §51056.1(c), and all requirements in 22 CCR §51303(h) are met and documented in the member's medical record. The request will be reviewed by the UM Medical Director for medical necessity and follow the standard timeliness decisions; see policy UM 10.2.22 Utilization Management Decision Making & Timeframes.

II. Investigational services <u>are not</u> covered except when it is clearly documented, in accordance with 22 CCR §51303(h), that all the following apply:
   a. Conventional therapy will not adequately treat the member's condition;
   b. Conventional therapy will not prevent progressive disability or premature death;

c. 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;
d. The investigational service is the lowest cost item or service that meets the member's medical needs and is less costly than all conventional alternatives;
e. The service is not being performed as part of a research study protocol; and
f. There is a reasonable expectation that the investigational service will significantly prolong the member's life or will maintain or restore a range of physical and social function suited to activities of daily living.

III. Decisions about "experimental" or "investigational" requests that are always excluded and never covered under any circumstances do not require medical necessity review. In these instances, Blue Shield Promise will either:
a. Identify the specific service or procedure excluded from the benefits plan, or
b. If benefits plan materials include broad statements about exclusions but do not specify excluded services or procedures, ensure the materials state that members have the opportunity to request information on excluded services or procedures and Blue Shield Promise maintains internal policies or criteria for these services or procedures (2024 NCQA UM 10).

DENIALS, MODIFICATIONS, AND/OR DELAYS

I. Upon the decision to deny, modify, or delay the service, Blue Shield Promise will notify the member and the requesting provider in writing within five (5) business days of the decision. The following elements will be included in the written notification:
a. A statement setting forth the specific medical and scientific reasons for denying coverage.
b. A description of alternative treatment, services, or supplies covered by the plan, if any.
c. Copies of the plan's grievance procedures or complaint form, or both. The complaint form will provide an opportunity for the member to request a conference as part of the plan's grievance system provided under HSC §1368.
d. The notice to the member will inform the member:
i. 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.
ii. How to initiate an expedited appeal at the time they are notified of the denial.
iii. The member's right to, and method for obtaining, a State Fair Hearing, and the member's right to represent himself/herself at the State Fair Hearing or to be represented by legal counsel or another spokesperson.
iv. The member's right to request an external Independent Medical

Review (IMR) through the Department of Managed Health Care (DMHC).

v. The name and address of the entity making the determination.

vi. The State's toll-free telephone number for obtaining information on legal service organizations for representation.

vii. The DMHC's toll-free telephone number for receiving complaints regarding grievances against Blue Shield Promise that have not been resolved by Blue Shield Promise to the member's satisfaction.

INDEPENDENT MEDICAL REVIEW

I. Blue Shield Promise will notify eligible members in writing of the opportunity to request the external independent review within 5 business days of the decision to deny, modify, or delay coverage.

a. If the member'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 will be rendered within 7 days of the request for expedited review. At the request of the expert, the deadline will be extended by up to 3 days for a delay in providing the documents required.

b. Each expert's analysis and recommendation will be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the member than an available standard therapy, and the reasons that the expert recommends that the therapy should or should not be authorized by Blue Shield Promise, citing the member's specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence to support the expert's recommendation, including, but not limited to, the sources outlined in HSC §1370.4(d).

II. DMHC does not require that a member participate in Blue Shield Promise's grievance system prior to seeking independent medical review.

III. For additional information on the IMR process, see Member Appeals and Grievances P&P 10.19.5 Beneficiary Grievance Management System.

E. MONITORING

N/A

F. REPORTING

The Medical Services Committee (MSC) performs quarterly reviews of UM reports to assure and improve quality of care for Blue Shield Promise members. Quarterly reports reviewed at the MSC include:

a. Prior Authorization Decisions (approvals, denials, and modifications)

b. Over/Under Utilization

c. Continuity of Care

d. PHP AGD Appeals and Grievance Log (including overturns)

Report reviews and associated quarterly workplan updates are then reported to the Quality Management Committee (QMC) as part of the Blue Shield Promise quality improvement oversight.

G. ATTACHMENTS

N/A

H. REFERENCES

1. 22 CCR §51056.1(a)(b)
2. 22 CCR §51303(g)(h)
3. BSCPHP Member Handbook
4. DHCS Contract, Exhibit A, Attachment III, Section 5.3.8(A)
5. HSC §1368
6. HSC §1368.1(a)(b)
7. HSC §1370.4(a)(1)
8. HSC §1374.31
9. 28 CCR §1300.70.4(d)
10. 10.2.22 Utilization Management Decision Making & Timeframes
11. 10.19.5 Beneficiary Grievance Management System
12. 2024 NCQA UM 10

I. REVISION HISTORY

Date	Modification (Reviewed and/or revised)	E-filing Number
9/24	2024 Annual Review • Formatting updates • Reviewed/updated references	
10/23	Annual Review • Updated regulatory references • Formatting changes for readability	
10/22	Annual Review • Renamed policy • Regulatory Requirements DHCS, DMHC	