SAN FRANCISCO HEALTH PLAN

CO-59 Experimental or Investigational Services

APPROVAL/REVIEW/REVISION HISTORY			
Signature	**Title**	**Date**	**Action**
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Signed by: Steve O'Brien 60DFB20814944C4...	CMO	11/26/2024	

SFHP POLICY AND PROCEDURE

Experimental or Investigational Services

Policy and Procedure Number:	CO-59
Department Owner:	Clinical Operations
Accountable Lead	Clinical Operations Analyst
Lines of Business Affected:	☒Medi-Cal ☐Medicare Advantage D-SNP ☒Healthy Workers HMO ☐Healthy SF ☐City Option ☐ All lines of business and coverage programs as listed above

POLICY STATEMENT

San Francisco Health Plan (SFHP) does not cover investigational or experimental services. Investigational or experimental services do not meet the criteria for "medically necessary services" because these services are not standard medical practice. This exclusion does not apply to services that are related to qualifying clinical trials for the prevention, detection, or treatment of cancer or other life-threatening diseases or conditions outlined in CO-47: Clinical Trials.

SFHP may cover investigational services, pursuant to 22 CCR section 51303(h), when it is clearly documented in the member's medical records that all of the following criteria are met:

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 a 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.

SFHP has an external, independent review process for decisions regarding experimental or investigational therapies. SFHP members may also seek an Independent Medical Review by contacting the Department of Managed Health Care (DMHC).

This policy pertains to the Clinical Operations Department's process for evaluating medical services as investigational or experimental in nature. Please refer to Pharm-02: Pharmacy Prior Authorization for the Pharmacy Department's evaluation of pharmaceuticals.

PROCEDURE

I. Services are investigational or experimental if any of the following apply:

A. The requested services do not have unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.

B. There is insufficient or inconclusive medical and scientific evidence to permit SFHP to evaluate the therapeutic value of the service. (Adequate evidence is defined as at least two documents of medical and scientific evidence that indicate that the proposed treatment is likely to be beneficial to the member.)

C. There is inconclusive medical and scientific evidence in peer-reviewed medical literature that the service, procedure, medical supply or durable medical equipment has a beneficial effect on health outcomes.

D. The service, procedure, medical supply or durable medical equipment under consideration is not as beneficial as any established alternatives.

E. There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, the service has a beneficial effect on health outcomes or is as beneficial as any established alternatives.

II. Authorization Procedure:

A. Clinical Operations (CO) Prior Authorization team evaluates authorization requests for services that may be investigational or experimental in nature.

B. If a Prior Authorization Nurse determines the request to be investigational or experimental, it is documented in the applicable authorization assessment (in JIVA) and routed to a SFHP Medical Director to evaluate whether it is investigational or experimental in nature.

C. If the request is determined not to be investigational or experimental, the regular review process described in CO-22: Authorization Requests will proceed.

D. The reviewing SFHP Medical Director may choose to consult with the Medical Review Institute of America Inc. (MRIoA) to assist in their decision making about whether the request is investigational or experimental in nature.

E. If the request is determined to be investigational or experimental, supporting documentation is required from the requesting physician. Acceptable supporting documentation includes:

1. A statement that the member has a condition or disease for which standard health service or procedures have been ineffective or would be medically inappropriate; or that there does not exist a more beneficial standard health service or procedure covered by the health care plan.

2. A statement of why the standard therapy available would not be beneficial, would be ineffective or would be inappropriate, including an assessment of the risks and benefits of the proposed treatment, specific goals and criteria for patient selection.
3. Copies of two published studies from the available peer-reviewed Medical and Scientific Evidence upon which the attending physician based their recommendation for the proposed treatment and an explanation why, in the opinion of the physician, these documents establish that the treatment or procedure is likely to be more beneficial to the member than any covered standard health service or procedure or would provide a positive effect on the member's condition or illness and that the benefits outweigh the harmful effects of the treatment.
4. Documentation that the attending physician is a board certified or board eligible physician qualified to practice in the area of practice appropriate to treat the member's condition.
5. A copy of the Member's informed consent form, when appropriate.
6. A copy of the Member's relevant medical and treatment records, including results of tests or studies, establishing the member's current condition and any treatment the member has received for the condition;
7. Any other relevant data that indicates the requested treatment's effectiveness.

F. If the reviewing SFHP Medical Director decides not to authorize the treatment, SFHP will issue a Notice of Adverse Benefit Determination (NOA) letter specifically stating the medical and scientific reasons for the denial and any alternative treatment covered by SFHP. SFHP will provide the NOA letter to the member within five business days of denial decision.
    1. The NOA letter will include instructions on SFHP's Appeal process.
    2. The NOA letter will also include instructions on DMHC's Independent Medical Review (IMR) process, an application and envelope addressed to DMHC, the physician certification form, and DMHC's toll-free information number.
    3. DMHC IMR instructions and forms are available in threshold languages for members who requests materials in their preferred language.
G. If SFHP denies a service to a member with a Terminal Illness, SFHP provides a NOA within five (5) business days which includes or attaches all of the following:
    1. A statement with the specific medical and scientific reasons for denying authorization.
    2. A description of alternative treatment, services, or supplies that are covered by SFHP, if any.
    3. A copy of SFHP's Grievance Form and instructions for how to request an appeal ("Your Rights" attachment)
    4. Instructions for how to request a DMHC IMR ("Your Rights" attachment) and the DMHC IMR form
    5. An offer to the member to request a conference with SFHP.

III. Member Appeals of Decisions to Deny an Experimental/Investigational Service:

A. If a member disagrees with SFHP's decision to deny authorization for a service, procedure, medical supply or durable medical equipment because SFHP has determined it is experimental or investigational, the member may appeal the decision pursuant to GA-03: Member Appeals.

B. SFHP has an external, independent review process for decisions regarding experimental or investigational therapies for members who meet all of the following criteria:
   1. Member has a Life-Threatening or Seriously debilitating condition; and
   2. The member's physician certifies that the member has a Life-Threatening or Seriously Debilitating condition for which standard therapies have not been effective in improving the condition of the member, for which standard therapies would not be medically appropriate for the member, or for which there is no more beneficial standard therapy covered by SFHP than the therapy proposed; and
   3. Either:
      a) The member's physician, who is contracted with SFHP, has recommended a service, procedure, medical supply or durable medical equipment that the physician certifies in writing is likely to be more beneficial to the member than any available standard therapies, or
      b) The member, or the member's physician who is a licensed, board certified, or board-eligible physician qualified to practice in the area of practice appropriate to treat the member's condition, has requested a therapy that, based on two published studies from Medical and Scientific Evidence, is likely to be more beneficial for the member than any available standard therapy.
   4. The physician's certification must include a statement of the Medical and Scientific Evidence relied upon by the physician in certifying the recommendation; and
   5. SFHP denied coverage of the recommended drug, device, procedure, or other therapy; and
   6. The specific service recommended would be a covered service, except for the SFHP's determination that the therapy is experimental or investigational.

C. If a member meets all of the above criteria, SFHP forwards the case to its external independent medical review organization (MRIoA) for review.
   1. Written notification to eligible members of the opportunity to request the external independent review within five business days of the decision to deny coverage.
   2. If the requesting physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the MRIoA experts on the panel shall be rendered within seven days of the request for expedited review. At the request of

the MRIoA expert, the deadline shall be extended by up to three days for a delay in providing the documents required.

3. Each MRIoA expert's analysis and recommendation is in written form and states the reasons the requested therapy is or is not likely to be more beneficial for the enrollee than any available standard therapy, and the reasons that the MRIoA expert recommends that the therapy should or should not be provided by SFHP, citing the member'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 to support the MRIoA expert's recommendation.

D. If the member has a Terminal Illness, the member may appeal a decision to deny an experimental/investigational service by attending a conference:
   1. SFHP's representative at the conference is a staff member with authority to determine the resolution of the appeal.
   2. The member and member's representative may attend the conference telephonically or in person. The member is given the opportunity to attend the conference within 30 calendar days of the denied authorization.
      a) If the member's treating physician determines, after consultation of SFHP's Medical Director and based on standard medical practice, that the effectiveness of the proposed treatment would be materially reduced if not provided at the earliest possible date, the conference is held within five (5) business days.

IV. DMHC Independent Medical Review

A. Members may seek an Independent Medical Review by contacting DMHC.
B. SFHP does not require the member to participate in SFHP's grievance and appeal process prior to seeking a DMHC IMR.
C. To directly access DMHC Independent Medical Review process, the member, member's representative, or physician may submit application to DMHC for IMR review. The application documents are included in SFHP's denial NOA as described above.
D. When SFHP is notified of an IMR request, SFHP Compliance and Regulatory Affairs staff responds to the IMR request pursuant to CRA-24: Responding to State Inquiries about Member Complaints.

MONITORING

1. SFHP's Clinical Operations Department performs inter-rater reliability audits at least annually for both physician and nurse reviewers.

2. SFHP's Member Services and Health Services Departments evaluate member grievances and appeals, as well as SFHP's member and provider satisfaction survey responses, to identify patterns.

3. The Utilization Management Committee (UMC) reviews Appeals, IMRs, and State Fair Hearings resulting from an authorization decision made by SFHP or one of its

delegated medical groups. The UMC recommends corrective action and/or identifies where the Clinical Operations Department can revise the authorization process, if necessary, to improve the member experience, to address any barriers, and ensure the utilization management criteria are consistent with current industry and evidence-based practices. The Quality Improvement and Health Equity Committee (QIHEC) reviews an Appeals Report (overturned and upheld appeals) every quarter regarding the activity of pharmacy and medical authorizations.

4. Dashboard and other reports regarding SFHP's Clinical Operations Department's monitoring activities are reviewed at the Utilization Management Committee (UMC) and are presented to the Quality Improvement and Health Equity Committee (QIHEC)) at least annually for evaluation and corrective actions as needed.

5. Medical groups delegated to perform utilization management are audited annually as outlined in DO-02: Oversight of Delegated Functions.

DEFINITIONS

Appeal: A request by a member for review of an Adverse Benefit Determination, including, delay, modification or denial of services based on medical necessity, or a determination that the requested service was not a covered benefit.

Experimental/Investigational Therapy: Any treatment, device, or procedure that is not currently approved as an accepted standard of practice but is subject to rigorous ethical and scientific investigative methods in a controlled setting.

Qualifying Clinical Trial: A clinical trial in any clinical phase conducted in relation to the prevention, detection, or treatment of cancer or another life-threatening disease or condition that meets at least one of the following:

1. The study or investigation is approved or funded, which may include funding through in-kind donations, by one or more of the following:
    a. The National Institutes of Health.
    b. The federal Centers for Disease Control and Prevention
    c. The Agency for Healthcare Research and Quality
    d. The federal Centers for Medicare and Medicaid Services.
    e. A cooperative group or center of any of the entities described in (a) to (d) above, as well as the Department of Defense, or the United States Department of Veterans Affairs.
    f. A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
    g. One of the following departments, if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of the United States Department of Health and Human Services determines is comparable to the system of peer review used by the National Institutes of Health and ensures unbiased review of the highest

scientific standards by qualified individuals who have no interest in the outcome of the review:

i. The United States Department of Veterans Affairs.
ii. The United States Department of Defense.
iii. The United States Department of Energy.

2. The study or investigation is conducted under an investigational new drug application reviewed by the United States Food and Drug Administration.
3. The study or investigation is a drug trial that is exempt from an investigational new drug application reviewed by the United States Food and Drug Administration.

Experimental Services: As defined in 22 CCR section 51056.1(a), experimental services are drugs, equipment, procedures or services that are in a testing phase undergoing laboratory and/or animal studies prior to testing in humans.

Investigational Services: As defined in 22 CCR section 51056.1(b**),** any drug, 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.

Grievance: An expression of dissatisfaction by a member about an issue other than an Adverse Benefit Determination, including but not limited to, the quality of care or services provided, aspects of interpersonal relationships such as rudeness of a provider or employees, and the member's right to dispute an extension to make an authorization decision.

Independent Medical Review (IMR): The expert review of disputed health care services by an outside organization that contracts with the Department of Managed Health Care (DMHC).

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.

Medical/Scientific Evidence: As defined in HSC 1370.4(d):

(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.
(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.
(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.
(7) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

Notice of Action (NOA): A formal letter telling members that a medical service has been denied, deferred, or modified.

Notice of Adverse Benefit Determination (NABD): same definition of NOA. DHCS has retained use of NOA for ease of understanding by members.

Seriously Debilitating: Diseases or conditions that cause major irreversible morbidity.

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

AFFECTED DEPARTMENTS/PARTIES

Delegated Groups
Medical Directors
Network Providers

RELATED POLICIES AND PROCEDURES AND OTHER RELATED DOCUMENTS

CO-03: Major Organ Transplants
CO-38: Durable Medical Equipment (DME)
CO-47: Clinical Trials

CO-54: Evaluation of New Technology
CO-55: Exception Handling of Medi-Cal Non-Covered Services
CO-57: UM Clinical Criteria
CRA-24: Responding to State Inquiries about Member Complaints
Evidence of Coverage (Healthy Workers and Healthy Kids LOB)
Member Handbook (Medi-Cal LOB)
Pharm-02: Pharmacy Prior Authorization
Provider Manual
GA-01 Clinical Member Grievances
GA-03 Member Appeals

REVISION HISTORY

Effective Date: October 10, 2019
Revision Date(s): November 19, 2020; November 17, 2022; November 21, 2024

REFERENCES

1. CA Health and Safety Code 1370.4.
2. CA Health and Safety Code § 1300.70.4. Independent Medical Reviews Experimental and Investigational Therapies
3. CA Health and Safety Code 1368.1
4. DMHC Technical Assistant Guide
5. 22 CCR section 51303
6. 22 CCR section 51056.1