

**Last Review Date:** 04/22

# Investigational and Experimental Treatment for Health Plan Members Policy

## PURPOSE

The purpose of this policy is to outline the criteria necessary for Investigational and Experimental Treatment approval.

## POLICY

It is policy to appropriately review Investigational and Experimental Treatment requests, when Sutter is delegated to review as indicated by the Health Plan contract.

## SCOPE

This policy applies to Sutter Health and any legal entity for which Sutter Health or its affiliate is the sole member or directly or indirectly controls greater than 50% of the voting power or equity interest, to the extent that entity performs delegated Utilization Management (UM) for specific benefit or service (herein after referred to as Sutter).

Sutter is not responsible for reviewing and/or making a final determination on a request that has been identified as Health Plan Responsibility to review.

## DEFINITIONS

**Attending Physician** is a medical doctor who is responsible for the overall care of a Member in a hospital or clinic setting and who must be board certified or a board eligible physician (who holds an unrestricted license in California) qualified to practice in the area appropriate to treat the Member's condition.

**Health Plan** means health care service plans, health maintenance organizations, and other purchasers of covered services that arrange for the provision of health care services for their Members.

**Investigational and Experimental Treatment** are medical treatments and procedures that have not successfully completed a phase III trial, have not been approved by the United States Food and Drug Administration (FDA) and are not generally recognized as the accepted standard treatment for the disease or condition from which the patient suffers. Investigational and Experimental Treatment can also include off-label therapies.

**Disclaimer:** This policy is for informational purposes and does not constitute medical advice or medical care and is not intended to replace medical judgment for treatment of individuals.

**Member** is a person covered under a Health Plan, either the enrollee or eligible dependent.

**Qualified Health Care Professional (QHCP)** is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within their scope of practice and independently reports that professional service.

**Utilization Management (UM)** means the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provisions of the applicable Health Plan, sometimes called 'utilization review.'

## PROCEDURE

- A. Appropriate documentation must be submitted to Sutter demonstrating that criteria (see Procedure section B below) has been satisfied.
- B. The following supporting criteria/documentation must be provided by the Member or the Member's QHCP for consideration of proposed Investigational and Experimental Treatment approval:
  1. Certification from the Member's Attending Physician which includes:
    - a. A statement that the Member has a condition or disease for which standard health service or procedures has been ineffective or would be medically inappropriate; or there does not exist a more beneficial standard health service or procedure covered by the Health Plan.
    - b. A statement of why the standard therapy available would not be beneficial, would be ineffective or would be inappropriate. This would include an assessment of the risks and benefits of the proposed treatment and specific goals and criteria for Member selection.
    - c. Copies of two (2) documents from the available peer-reviewed medical and scientific evidence, upon which the Attending Physician based their recommendation for the proposed treatment. Also included should be 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/procedure or would provide a positive effect on the Member's condition and that the benefits outweigh any potential harmful effects of the treatment.
  2. A copy of the Member's informed consent form, when appropriate;

**Disclaimer:** This policy is for informational purposes and does not constitute medical advice or medical care and is not intended to replace medical judgment for treatment of individuals.

3. A copy of the Member's medical and treatment records, including results of tests or studies showing the Member's current condition and any treatment the Member has received for the condition; and
  4. Any other relevant data that indicates the treatment effectiveness.
- C. If all necessary documentation is not received, Sutter can deny the request for Investigational and Experimental Treatment.
- D. Sutter will respond to requests for Investigational and Experimental Treatment in accordance with established regulatory timelines.
- E. If Sutter decides to deny the treatment, a denial letter will be issued that specifically states the medical and, if applicable, scientific reasons for the denial and any alternative treatment covered by the Health Plan. Included with the denial letter will be an application and instructions for the Member to utilize the Department of Managed Health Care (DMHC) Independent Medical Review (IMR) program.

## REFERENCE

None

## ATTACHMENTS

None