SAN FRANCISCO HEALTH PLAN

CO-69: Physician Administered Drugs (PADs)/Medicare Part B Drugs

APPROVAL/REVIEW/REVISION HISTORY			
Signature	**Title**	**Date**	**Action**
DocuSigned by: Nina Maruyama 9D4617B1400D431...	CCO	12/23/2025	New Policy
Signed by: Steve O'Brien 60DFB20814944C4...	CMO	12/23/2025	

San Francisco Health Plan℠

SFHP POLICY AND PROCEDURE

PHYSICIAN ADMINISTERED DRUGS (PADS)/MEDICARE PART B DRUGS

Policy and Procedure Number:	CO-69
Department:	Clinical Operations
Accountable Lead:	Clinical Operations Policy Analyst
Lines of Business and Coverage Programs Affected:	☒Medi-Cal ☒ SFHP Care Plus (HMO 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's (SFHP) Clinical Operations Department conducts utilization management (UM) by reviewing authorization requests and applying clinical criteria to make evidence-based decisions, in accordance with the benefits covered under SFHP contracts and other program agreements, thereby ensuring the medical necessity of services provided to members. The purpose of this policy is to define the determination process for drugs administered under the medical benefit including Physician Administered Drugs (PADs) and Medicare Part B drugs

PADs are a medical benefit and are subject to the prior authorization procedures outlined below. Prescription drugs dispensed at a walk in pharmacy are not a medical benefit and not within the scope of this policy.

All sections within this policy apply to SFHP's three (3) managed care lines of business unless otherwise specified.

PROCEDURE

A. Authorization and Turnaround Times

1. SFHP requires Prior Authorization for medications and supplies as indicated in the SFHP Code Look Up tool..

2. SFHP adheres to Authorization timelines and notification requirements outlined in CO-22 Medical Authorization and Decision Timeframes and CO-66 Prior Authorization.

3. SFHP reviews all Prior Authorization requests based on the member's individual needs, in accordance with criteria established by CO-57 UM Clinical Criteria
4. SFHP monitors FDA Market Withdrawals for safety reasons. When a Market Withdrawal of a PAD is identified, SFHP identifies and notifies affected members within 30 calendar days of the FDA notification.

B. Physician Administered Drugs (PADS)

1. SFHP is responsible for members' medications administered at the physician's office or hospital and billed through SFHP's medical benefit. These drugs are excluded from the federal definition of "covered outpatient drug" as stated in SSA 1927(k)(3) as these medications are provided as part of, or as incident to and in the same setting as, any of the following: inpatient hospital services, physicians' services, or outpatient hospital services.
2. In alignment with Medicare Part B requirements, PADs are defined as drugs and biologicals that are not usually self-administered, and are furnished incident to a physician's service or administered under physician supervision. Covered drugs must be reasonable and necessary for the diagnosis or treatment of illness or injury, and include infused or injectable medications such as chemotherapy, biologics, and long-acting injectables
3. SFHP and its Contractors do not impose quantitative or non-quantitative treatment limitations more stringently for mental health and substance use disorder PADs than for medical/surgical PADs, in accordance with 42 CFR 438.900 et. seq.

C. Medicare Part B Drugs

1. Medicare Part B requests for coverage may be made by a member, a member's Authorized Representative, or prescribing Provider.
2. The Medicare program provides coverage of drugs and biologicals that are not usually self-administered by patients.
3. Generally, drugs and biologicals are covered if they meet all of the following requirements:
    1. They meet the definition of drugs or biologicals;
    2. They are of the type that are not usually self-administered;
    3. They meet all the general requirements for coverage of items as incident to a physician's services;
    4. They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
    5. They are not excluded as noncovered immunizations; and
    6. They have not been determined by the FDA to be less than effective.
4. Medicare Part B generally does not cover self-administered drugs such as drugs in pill form or are used for self-injections however, there are some instances where self-administered drugs are medically necessary and covered under Medicare statute.

1. Examples of self-administered drugs that are covered include:
    A. Blood-clotting factors,
    B. Drugs used in immunosuppressive therapy,
    C. erythropoietin for dialysis patients,
    D. osteoporosis drugs for certain homebound patients, and
    E. certain oral cancer drugs.
2. For guidance regarding self-administered drug exceptions, see Chapter 15 of Medicare policy manual.

D. Coverage of HIV Preexposure Prophylaxis (PrEP)

1. In accordance with DMHC APL 25-011, SFHP ensures comprehensive coverage of HIV Preexposure Prophylaxis (PrEP) for eligible Medi-Cal or Healthy Workers members, including both oral and long-acting injectable formulations.
2. All FDA-approved PrEP medications must be covered without cost-sharing.
3. Prior authorization and step therapy are not permitted for PrEP medications, unless multiple FDA-approved therapeutic equivalents exist.

MONITORING

A. Monthly, the utilization management (UM) workgroup monitors authorization and appeal metrics, clinical member grievance (including Independent Medical Reviews, State Fair Hearings, and Consumer Complaints) trends, as well as service utilization trends. The UM workgroup submits reports to the Utilization Management Committee (UMC) and Quality Improvement and Health Equity Committee (QIHEC) for oversight, input, and strategic direction. Collaboratively, the committees make recommendations for corrective action and/or identify where UM processes can be revised, if necessary, to improve member experience, address barriers, and ensure the UM criteria are consistent with current industry and evidence-based practices and state/federal regulations.

B. Quarterly, the Clinical Operations Nurse Trainer Auditor conducts an internal audit of authorization files including adverse and favorable determinations. The purpose of the internal audit is to ensure authorization files meet the statutory/regulatory requirements of CMS/DHCS/DMHC as well as accreditation guidelines of NCQA. The audit follows NCQA's 8/30 audit sample methodology.

C. Annually, inter-rater reliability audits are conducted for both physician and nurse reviewers to ensure decision making accuracy and consistency.

D. Annually, the Clinical Operations Director leads a cross-functional evaluation of the UM Program's effectiveness. The evaluation process includes reassessment of program structure, scope, processes and sources used to determine benefit coverage and medical necessity. It considers member and practitioner experience, regulatory compliance,

data trends, and a status assessment of annual goals and activities. The UM Evaluation informs the UM Workplan. The UM Evaluation, UM Workplan, and UM Program Description are reviewed and approved by the UMC and QIHEC.

E. The SFHP Chief Medical Officer (CMO), Medical Director, or physician designee identifies potential quality issues (PQI), including provider preventable conditions (PPCs), and follows the PQI process defined in QI-18 and the PPC process defined in QI-19.

F. Annually, medical groups delegated to perform utilization management are audited as outlined in DO-02 Oversight of Delegated Functions. In addition, to provide real-time oversight, SFHP's Delegation Oversight Nurse conducts quarterly authorization files review audits.

DEFINITIONS

Physician-Administered Drug (PAD) or Medical Benefit Medications: A physician-administered drug is an outpatient drug that is typically administered by a health care provider in a physician's office or other outpatient clinical setting. For example, drugs that are infused or injected are typically physician administered drugs. The provider bills the appropriate state Medicaid program (fee for service, managed care plan, or county operated health system) for the drug using the appropriate national drug code (NDC) and Healthcare Common Procedure Coding System (HCPCS) code.

AFFECTED DEPARTMENTS/PARTIES

Pharmacy
Provider Network Management
Grievance and Appeals
Compliance and Regulatory Affairs
Claims
Member Services

RELATED POLICIES & PROCEDURES, DESKTOP PROCESS and PROCESS MAPS

CO-22 Medical Authorization Requests and Decision Timeframes
CO-57 UM Clinical Criteria
Pharmaceutical Patient Safety Issues Medical Benefit - Physician Administered Drugs (PADs) Desktop Procedure

REVISION HISTORY

Original Date of Issue: December 18, 2025
Revision Approval Date(s):

REFERENCES

1. California Health and Safety Code, Section 1367.01 and 1367.215(a)
2. California Welfare and Institutions Code, Sections 14185 and 14094.13(d)
3. Department of Health Care Services (DHCS) Policy Letter (PL) 14-002: Requirement to Use Food and Drug Administration Approved Drugs, Rather Than Compounded Alternatives.
4. Social Security Act, § 1927(d)(5)(A) M. Title 22, California Code of Regulations, §§ 51003, 51303, 53894 and 438.404
5. Title 42, California Code of Regulations, §§ 431.213-214, 438.10, 438.210(c),438.3(s)(6), 438.910(b)
6. Medicare Benefit Policy Manual, Chapter 15, Section 50, Drugs and Biologicals
7. Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues
8. DMHC APL 25-011 Coverage of HIV Preexposure Prophylaxis (PreEP)