POLICY AND PROCEDURE	
Title: Dispensing of Off-Label Prescriptions	
Primary Policy owner: Pharmacy	**Policy#:** PH10
Impacted/Secondary policy owner: Select the department(s) that are responsible for compliance with all, or a portion of the policy or procedure as outlined	
1) ☐All Departments 2) ☐Behavioral Health & Social Services (BH/SS) 3) ☐Benefits Administration (BA) 4) ☐Case Management (CM) 5) ☐Claims (CLMS) 6) ☐Community Marketplace & Member Engagement (MAR) 7) ☐Compliance (CMP/HPA) 8) ☐Configuration (CFG) 9) ☐Provider Contracting (CONT) 10) ☐Cultural & Linguistics (CL) 11) ☐Customer Service (CS)	12) ☐Facilities (FAC) 13) ☐Finance (FIN) 14) ☐Human Resources (HR) 15) ☐Information Technology / Core Systems (IT) 16) ☒Pharmacy (PH) 17) ☐Provider Networks (PRO) 18) ☐QI Health Equity (GRV/HE/HEQ/PHM/QM) 19) ☐ Utilization Management (UM) 20) ☐ Procurement (PRM) 21) ☐ Administration (SAF/BC/EM) 22) ☐ Medical Management (MM)
Product Type: ☒Medi-Cal ☐D-SNP	**Supersedes Policy Number:** N/A

I. PURPOSE

The purpose of this policy is to establish that requests for off-label use of any drug shall be evaluated for medical necessity.

II. POLICY

San Joaquin County Health Commission ("Commission"), operating and doing business as Health Plan of San Joaquin and Mountain Valley Health Plan ("Health Plan"), do not limit or exclude coverage for an "off-label" drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the Federal Food and Drug Administration (FDA), provided that all of the conditions as described in the Procedure section have been met.

III. PROCEDURE

A. The treating practitioner can request for "off label" use of a prescription by submitting a completed Medical Authorization Form, available on the Health Plan's website or via submission through the Provider Portal.

B. The Director of Pharmacy or Plan Pharmacist evaluates the request to see that it meets the following criteria:

   1. The drug requested is FDA Approved.
   2. The drug is prescribed by a participating licensed health care professional for the treatment of a Life-Threatening Condition, or treatment of a Chronic and Seriously Debilitating Condition.
   3. The drug is medically necessary to treat the condition.
   4. There are no alternatives with on-label indications that could be used by the member.

C. The prescribing physician is requested to submit two clinical studies from major peer reviewed medical journals that present data supporting the proposed off-label use as generally safe and effective.

   1. If medical necessity cannot be established for the "off label" use, the request is denied.
   2. If there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal, the request is denied.

D. The processes outlined in policy UM01 - Authorization and Referral Review, PH05 – Prior Authorization Review, UM06 – Medical Review Criteria, and policy UM07 - Notice of Action for Delayed, Denied, Modified, or Terminated Services, are followed in making determinations.

E. The Appeals process described in policy QM65, Member Appeals, is available for any non-authorization determination.

F. If the decision to deny coverage is on the basis that its use is experimental or investigation, that decision is subject to review under Health and Safety Code, Section 1370.4.

IV. ATTACHMENT(S)

A. DHCS Medi – Cal Managed Care Plans Definitions (Exhibit A, Attachment I, 1.0 Definitions)
B. Glossary of Terms Link
C. Medi-Cal Managed Care Contract Acronyms List (Exhibit A, Attachment I, 2.0 Acronyms)

V. REFERENCES

A. DHCS - APL 22-012 – Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx
B. Health and Safety Code, Section 1367.21
C. Health and Safety Code, Section 1370.4
D. Health Plan Policy PH05 – Prior Authorization Review
E. Health Plan Policy UM01 – Authorization/Referral Process
F. Health Plan Policy UM06 – Medical Review Criteria
G. Health Plan Policy UM07 – Notification to Members of Denial, Deferral, Modification Actions
H. NCQA Standard UM11 – Procedures for Pharmaceutical Management

VI. REVISION HISTORY

Version*	Revision Summary	Date

000	10/08, 05/12, 09/12, 09/15, 09/16, 09/17, 02/18, 12/18, 07/19, 12/19, 06/21, 12/21, 12/22	N/A
001	Moved PH10 onto new 2023 template.	03/31/2023
002	Reviewed and no changes made.	09/06/2023
003	Included PH05 as a policy referenced for authorization reviews.	08/30/2024
004	Included UM06 as a policy referenced for authorization reviews. Reviewed and updated references sections.	03/06/2025
005	Formatting edits were made. Reviewed with no further changes.	03/04/2026
Initial Effective Date: 2/1/1996		
Published Date:08/20/2026		

VII. Committee Review and Approval to be Completed by Compliance

Committee Name	Version	Date
Compliance Committee (CC)	005	08/14/2026
• Privacy & Security Oversight Committee (PSOC)		
• Program Integrity Committee (PIC)		
• Audits & Oversight Committee (AOC)		
• Policy Review Committee (PRC)	002	11/20/2023
Quality Improvement Health Equity Committee (QIHEC)	005	05/20/2026
• Quality Operations Committee (QOC)		
• Grievance Committee (GC)		

VIII. REGULATORY AGENCY APPROVALS

Department	Reviewer	Version	Date
Department of Healthcare services (DHCS)	N/A	N/A	N/A
Department of Managed Care (DMHC)	N/A	N/A	N/A

IX. Approval *signature**

Signature	Name Title	Date
	PRC Chairperson	
	Policy Owner	
	Department Executive	
	Chief Executive Officer	

*Signatures are on file, not be on the published copy