

POLICY AND PROCEDURE	
Policy # and TITLE: PH10 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) <input type="checkbox"/> All Departments 2) <input type="checkbox"/> Behavioral Health (BH) 3) <input type="checkbox"/> Benefits Administration (BA) 4) <input type="checkbox"/> Care Management (CM) 5) <input type="checkbox"/> Claims (CLMS) 6) <input type="checkbox"/> Community Marketplace & Member Engagement (MAR) 7) <input type="checkbox"/> Compliance (CMP/HPA) 8) <input type="checkbox"/> Configuration (CFG) 9) <input type="checkbox"/> Provider Contracting (CONT) 10) <input type="checkbox"/> Cultural & Linguistics (CL) 11) <input type="checkbox"/> Customer Service (CS)	12) <input type="checkbox"/> Facilities (FAC) 13) <input type="checkbox"/> Finance (FIN) 14) <input type="checkbox"/> Human Resources (HR) 15) <input type="checkbox"/> Information Technology / Core Systems (IT) 16) <input checked="" type="checkbox"/> Pharmacy (PH) 17) <input type="checkbox"/> Provider Networks (PRO) 18) <input type="checkbox"/> QI Health Equity (GRV/HE/HEQ/PHM/QM) 19) <input type="checkbox"/> Utilization Management (UM)
PRODUCT TYPE: <input checked="" type="checkbox"/> Medi-Cal	Supersedes Policy Number: N/A

I. PURPOSE

The purpose of this policy is to establish that requests for off-label use of any drug will 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 will be 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 will be denied.
 2. If there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal, the request will be denied.
- D. The processes outlined in policy UM01, Authorization and Referral Review, 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. NCQA Standard UM13 – Procedures for Pharmaceutical Management

VI. REVISION HISTORY

**Version 001 as of 01/01/2023*

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	3/31/2023
002	Reviewed and no changes made	9/6/2023
Initial Effective Date: 2/1/1996		

VII. Committee Review and Approval

Committee Name	Version	Date
Compliance Committee	002	2/15/2024

<ul style="list-style-type: none"> Privacy & Security Oversight Committee (PSOC) 		
<ul style="list-style-type: none"> Program Integrity Committee 		
<ul style="list-style-type: none"> Audits & Oversight Committee 		
<ul style="list-style-type: none"> Policy Review 	002	11/20/2023
Quality and Utilization Management	001	1/18/2023
<ul style="list-style-type: none"> Quality Of Care 		
<ul style="list-style-type: none"> Grievance 		

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	



Signature	Name Title	Date
	Chief Executive Officer	

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