POLICY AND PROCEDURE	
Policy # and TITLE: PH08 Managed Drug Limitations	
Primary Policy owner: Pharmacy	**POLICY #:** PH08
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 (BH) 3) ☐Benefits Administration (BA) 4) ☐Care 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)
PRODUCT TYPE: ☒Medi-Cal	**Supersedes Policy Number:** Policy # and Policy Title

I. PURPOSE

To define Managed Drug Limitations (MDL) and how San Joaquin County Health Commission ("Commission"), operating and doing business as Health Plan of San Joaquin and Mountain Valley Health Plan ("Health Plan") applies them to the medical benefit as well as processes for consideration of claims submitted following a procedure that exceeds the MDL of a medication.

II. POLICY

Managed Drug Limitations (MDL) (also known as Quantity Limits), based on treatment duration or maximum dosing limits as approved by the FDA or as reflected in current authoritative sources, are used to improve patient safety and to prevent overuse of medications.

III. PROCEDURE

A. MDL include limits on both:
   1. The quantity or amount of medication that can be provided at the time of service.
   2. The duration of the service/medication provided, such as 30, 60, or 90 days.

B. Drugs are considered for MDL when any of the following criteria are met:
   1. There is significant clinical concern about potential overuse of an agent.
   2. There is potential for significant use that is deemed not to be cost effective.
   3. There are scientifically supported maximum use guidelines, which if exceeded, have the potential to increase the risk of harm.

C. Managed Drug Limitations are based upon information from authoritative sources considering the characteristics of the Health Plan's member population and local practice conditions.

D. Information sources considered in the development, revision, and approval of Managed Drug Limitations include:

1. Food and Drug Administration.
2. FDA-approved manufacturer labeling information.
3. Published scientific literature.
4. Facts and Comparison Formulary Services.
5. Micromedex.
6. Medical and pharmacy review services.
7. National Guidelines Clearinghouse of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.
8. American Hospital Formulary Services.
9. Recommendations of medical and health care specialty and standard-setting organizations.
10. The recommendations of governmental health care, research, and regulatory bodies.

E. Upon P&T Committee approval of an MDL, the Pharmacy Director:

1. Verifies documentation of the approved MDL requirement in the P&T meeting minutes.
2. Notifies individuals responsible for implementing the requirement of the MDL requirement and of the relevant messaging.
3. Formally documents the MDL.
4. Ensures that:
    a. Affected providers are notified in writing no less than 45 business days before the changes take effect.
    b. Member and Provider quarterly newsletters remind their recipients that the medical benefit has been updated and updates can be viewed on the organization's website.

F. For quantities that exceed the MDL upon claims submission, a pharmacist must review the submitted claim to verify medical necessity of the higher quantity used.

   1. If sufficient information is not available, the reviewing pharmacist will contact the provider to obtain additional information.
   2. If the claim submitted for a quantity exceeding the MDL is not supported by chart records and does not meet medical necessity for use, only the quantity up to the MDL will be covered.
   3. If medically necessary, the MDL can be approved by the reviewing pharmacist.

G. The health Plan makes all reasonable attempts to obtain information needed to make a timely determination by contacting the prescribing practitioner or designated staff to obtain needed information.

H. PA requests will not impose quantity limits more stringently on mental health and substance use disorder drugs as compared to medical/surgical drugs prescriptions in accordance with 42 CFR 438.900 et. seq.

I. The processes outlined in policy UM01, Authorization/Referral Process, and policy UM07, Notification to Members of Denial, Deferral, Modification Actions, are followed in making determinations.

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

IV. ATTACHMENT(S)

1. DHCS Medi – Cal Managed Care Plans Definitions (Exhibit A, Attachment I, 1.0 Definitions)
2. Glossary of Terms Link
3. 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. NCQA Standard UM13 – Procedures for Pharmaceutical Management
C. Title 22, §51313, 51513, 51003
D. UM07 – Notification to Members of Denial, Deferral, Modification Actions

VI. REVISION HISTORY

*Version 001 as of 01/01/2023

Version*	Revision Summary	Date
000	03/08, 05/12, 09/14, 09/15, 09/16, 09/17, 12/18, 07/19, 12/19, 07/20, 06/21, 12/21, 12/22	N/A
001	Moved PH08 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
• Privacy & Security Oversight Committee (PSOC)		
• Program Integrity Committee		
• Audits & Oversight Committee		
• Policy Review	002	12/20/2023
Quality and Utilization Management	001	1/18/2023
• Quality Of Care		
• 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	
	Chief Executive Officer	

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