POLICY AND PROCEDURE	
TITLE: Managed Drug Limitations	
DEPARTMENT: Medical Management - Pharmacy	**POLICY #:** PH08
EFFECTIVE DATE: 02/01/96	**REVIEW/REVISION DATE:** 03/08, 05/12, 09/14, 09/15, 09/16, 09/17, 12/18, 07/19
COMMITTEE APPROVAL DATE: P&T 12/11/2018 PRC 06/19/2019 QMUM 07/10/2019	**RETIRE DATE:** None
PRODUCT TYPE: Medi-Cal	**REPLACES:** None

I. PURPOSE

To define Managed Drug Limitations (MDL) and how Health Plan of San Joaquin (HPSJ) applies them to the formulary as well as processes for consideration of exception requests to 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 dispensed per time period, such as 30, 60, or 90 days.
2. The number of days' supply of medication that may be dispensed to a patient at any one time.

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 considered in light of the characteristics of HPSJ'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. The recommendations of medical and health care specialty and standard-setting organizations.
10. The recommendations of governmental health care, research, and regulatory bodies.

E. If the amount of a drug dispensed is reduced because of a Managed Drug Limitation, refills to equal the original quantity will be permitted, within the appropriate time frame if applicable, unless the item is designated "no refills allowed" in the Formulary.

F. Quantities over the MDL will not be covered under prescription drug benefit. Members may purchase additional quantities, but this cost will not be reimbursed by HPSJ.

G. 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 point-of-service messaging.
3. Formally documents the MDL.
4. Ensures that:
    a. The on-line Formulary is updated prior to the effective date of the change.
    b. Affected members and providers are notified in writing no less than 30 days before the changes take effect.

c. Member and Provider quarterly newsletters remind their recipients that formulary and/or formulary management policies are available online and/or in the Provider Manual (for providers).

d. The hard copy Formulary is updated at the next printing.

H. The dispensing pharmacist is notified of the MDL medications via point of sale messaging.

I. The pharmacist must review compliance at the time of dispensing.

1. If sufficient information is not available, the dispensing pharmacist will contact the prescriber to verify compliance with MDL criteria.

J. If medically necessary, Quantity Limits can be overridden.

1. The treating practitioner can request an override of the Quantity Limit by submitting a completed Medication Authorization Form, available on HPSJ's web site and from the Pharmacy Department.

K. HPSJ 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.

L. When reviewing Exception Requests (prior authorizations), the reviewing pharmacist may at his/her discretion and professional judgment modify the requested medication to an alternate dose to ensure optimal use of the medication based on the patient's profile and drug properties. This may include but is not limited to dose optimization in a requested medication due to chronic kidney disease and required alternate dosing of the medication because of the medical condition.

1. This decision is based off of the listed approved drug information references above and the individual patient profile.

2. The dose may only be optimized in situations where it will clinically benefit the patient to have dose optimization performed.

M. When reviewing Exception Requests (prior authorizations), the reviewing clinical pharmacist may at his/her discretion and professional judgment consolidate multiple units in the request into a single tablet if a higher strength of the drug in question exists.

1. This decision is based off of the listed approved drug information references above and the individual patient profile.

Example: Two (2) 10mg tablets daily = One (1) 20mg tablet once daily

N. 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.

O. The Appeals process described in policy UM13, Appeals of UM Decisions, is available for any non-authorization determination.

IV. ATTACHMENT(S)

None

V. REFERENCES

A. NCQA Standard UM13 – Procedures for Pharmaceutical Management
B. Title 22, §51313, 51513, 51003
C. UM07 – Notification to Members of Denial, Deferral, Modification Actions

VI. REGULATORY AGENCY APPROVALS

DHCS Approved on 03/14/16.

VII. Glossary

Policy and Procedure Glossary Link

VIII. REVISION HISTORY

STATUS	DATE REVISED	REVISION SUMMARY
Reviewed	09/30/16	No content change, annual review.
Reviewed	09/12/17	No content change, annual review.
Reviewed	12/11/18	No content change, annual review.
Revised	07/31/19	Added purpose statement, updated policy template.