

| <b>POLICY AND PROCEDURE</b>  |   |
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| <b>TITLE:</b><br>Dispensing of Off-Label Prescriptions                                 |   |
| <b>DEPARTMENT:</b><br>Medical Management - Pharmacy                                    | <b>POLICY #:</b><br>PH10  |
| <b>EFFECTIVE DATE:</b><br>02/01/96   | <b>REVIEW/REVISION DATE:</b><br>10/08, 05/12, 09/12, 09/15, 09/16, 09/17, 02/18, 12/18, 07/19 |
| <b>COMMITTEE APPROVAL DATE:</b><br>P&T 12/11/2018<br>PRC 06/19/2019<br>QMUM 07/10/2019 | <b>RETIRE DATE:</b><br>None   |
| <b>PRODUCT TYPE:</b><br>Medi-Cal   | <b>REPLACES:</b><br>None  |

## I. PURPOSE

To establish that requests for off-label use of any drug will be evaluated for medical necessity as well as via the processes described in PH06 – Formulary Exception Process.

## II. POLICY

The Health Plan of San Joaquin (HPSJ) will 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. Prescriptions will be submitted electronically by the pharmacist.
- B. Those prescriptions that fail the electronic authorization system will be referred to the HPSJ Director of Pharmacy, Plan Pharmacist, or a Medical Director for authorization.
- C. If the prescription that fails the authorization system is for an “off label” use, the Director of Pharmacy or Plan Pharmacist will evaluate 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 and is on the HPSJ formulary.

- D. If the drug is not on HPSJ's formulary, 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 as part of the Exception Process for Non-Formulary Medications described in PH06.
  - 1. In addition to the Medical Necessity decision-making criteria described in that policy, if there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal the request will be denied.
- E. 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.
- F. The Appeals process described in policy QM65, Provider Grievances/Appeals, is available for any non-authorization determination.
- G. 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)**

None

#### **V. REFERENCES**

- A. Health and Safety Code, Section 1367.21
- B. NCQA Standard UM13 – Procedures for Pharmaceutical Management

#### **VI. REGULATORY AGENCY APPROVALS**

DHCS Approved on (pending).

#### **VII. Glossary**

[Policy and Procedure Glossary Link](#)

- A. Chronic and Seriously Debilitating Condition – Disease or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.
- B. Life-Threatening Condition – Disease or conditions where the likelihood of death is high unless the course of the disease is interrupted. Disease or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

## VIII. REVISION HISTORY

| <b>STATUS</b> | <b>DATE REVISED</b> | <b>REVISION SUMMARY</b>  |
|---------------|---------------------|--|
| Reviewed      | 09/30/16            | No content change, annual review.  |
| Reviewed      | 09/12/17            | No content change, annual review.  |
| Revised       | 02/23/18            | Grammatical edit, updated policy names that were being referred to within this policy. |
| Reviewed      | 12/11/18            | No content change, annual review.  |
| Revised       | 07/31/19            | Added purpose statement, updated policy template.                                      |