| POLICY AND PROCEDURE | |
|---|---|
| **TITLE:**<br>Step Therapy | |
| **DEPARTMENT:**<br>Medical Management - Pharmacy | **POLICY #:**<br>PH09 |
| **EFFECTIVE DATE:**<br>09/12/12 | **REVIEW/REVISION DATE:**<br>09/12, 11/15, 09/16, 09/17, 12/18, 07/19 |
| **COMMITTEE APPROVAL DATE:**<br>P&T 12/11/2018<br>PRC 06/19/2019<br>QMUM 07/10/2019 | **RETIRE DATE:**<br>None |
| **PRODUCT TYPE:**<br>Medi-Cal | **REPLACES:**<br>None |

## I. PURPOSE

To define step therapy and and how Health Plan of San Joaquin (HPSJ) applies them to the formulary as well as processes for consideration of step therapy exception requests.

## II. POLICY

The Health Plan of San Joaquin (HPSJ) uses Step Therapy to promote cost-effective pharmaceutical management when there are multiple effective drugs to treat a condition.

## III. PROCEDURE

A. Step Therapy is used to promote the use of cost-effective drugs before progressing to less cost-effective alternatives.

1. Step Therapy requires that one or more “prerequisite” first step drugs be tried before progressing to second step drugs.
2. First step medications and the corresponding second step medications are FDA-approved and are used to treat the same conditions.

B. Drugs are considered for Step Therapy based on any of the following criteria:

1. There are efficacious, cost effective drugs to treat the condition in addition to expensive alternatives.
2. There is expert consensus on an appropriate sequence of drugs or drug classes to treat a specific condition.
3. There is expert consensus that specific drugs are not considered first line treatment.

C. Step Therapy protocols 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 Step Therapy protocols include:

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

E. Upon P&T Committee approval of a Step-Therapy protocol the Pharmacy Director:

1. Verifies documentation of the approved Step Therapy protocol in the P&T meeting minutes.
2. Notifies individuals responsible for implementing the Step Therapy protocol of the change and of the relevant point-of-service messaging.
3. Formally documents the Step Therapy protocol.
4. Arranges for automated messaging to request the prescriber change to a first line drug and to inform the prescriber of alternative(s).
5. 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.

F. If medically necessary, a second step medication can be obtained without first trying a first step medication.

1. The treating practitioner can request an exemption from the Step Therapy protocol by submitting a completed Medication Request Form, available on HPSJ's web site and from the Pharmacy Department.

G. 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.

H. 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.

I. The Appeals process described in policy UM13, Provider Grievances/Appeals, is available for any non-authorization determination.

## IV. ATTACHMENT(S)

None

## V. REFERENCES

NCQA Standard UM13 – Procedures for Pharmaceutical Management

## 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. |