



PLAN POLICY AND PROCEDURE	
 <p><b>Title: SHP Pharmacy Management Procedure for Step-Therapy for Prescription Drugs</b></p>	<p><b>Product Line</b> (check all that apply):</p> <input checked="" type="checkbox"/> All <input type="checkbox"/> Group HMO <input type="checkbox"/> Individual HMO <input type="checkbox"/> PPO <input type="checkbox"/> POS <input type="checkbox"/> N/A
<b>Division(s):</b> Health Services	
<b>Department(s):</b> Pharmacy	
<b>Owner (Title):</b> Pharmacy Manager	
<b>Relevant Regulatory/Accrediting Agencies/Citations (specify):</b>	
<input type="checkbox"/> CMS: _____ <input checked="" type="checkbox"/> DMHC: <u>          RX-005          </u> <input checked="" type="checkbox"/> NCQA-HP: <u>          UM 13 B4          </u> <input type="checkbox"/> NCQA-WHP: _____ <input type="checkbox"/> OTHER: _____	
<p><b>Approved by:</b> (Signature of VP, Compliance Officer, or CEO)</p> 	<p><b>Approval date:</b></p> <p style="text-align: center;">3/9/2016</p>

**I. PURPOSE:**

This Policy and Procedure establishes Sharp Health Plan's (Plan) policy and procedure for Step-Therapy for prescription drugs.

**II. POLICY:**

It is the policy of Sharp Health Plan to maintain effective drug utilization management procedures. Such procedures include step therapy for prescription drugs. It is the policy of the Plan to use and accept only prior authorization requests submitted on the Prescription Drug Prior Authorization Request Form, numbered No 61-211.

**III. DEFINITIONS:**

A. Step-Therapy: A logical succession of drug therapy for a particular medical condition. In such a succession of agents, the most cost effective preferred agent might be required to be used first with the prescriber moving to another agent next if the first drug was not successful or the patient was an inappropriate candidate or the patient had adverse effects. The process of

moving to secondary agents may involve information from prescribers, or

may be automated by computer review of a patient drug history of which drug(s) had been tried previously.

- B. Medical necessity:** Treatment considered to be reasonable and necessary for the diagnosis or treatment of illness or injury.

#### **IV. PROCEDURES:**

##### **A. Step Therapy Guidelines**

The P&T Committee recommends formulary placement and appropriate prescribing guidelines, including step therapy, to assist with the placement of products in relation to the drug formulary.

Recommendations are based on the objective evaluation of the products' relative therapeutic efficacy, safety, patient outcome and cost-effectiveness. Step therapy criteria are recommended and approved by the Pharmacy and Therapeutics Committee.

The Committee reviews information such as, but not limited to, the following:

1. Safety
2. Efficacy: the potential outcome of treatment under optimal circumstances.
3. Strength of scientific evidence and standards of practice through review of relevant information from the peer-reviewed medical literature, accepted national treatment guidelines, and expert opinion where necessary.
4. Cost-effectiveness: the actual outcome of treatment under real life conditions including consideration of total health care costs, not just drug costs, through utilization of pharmacoeconomic principles and/or published pharmacoeconomic or outcomes research evaluations where available.
5. Relevant benefits of current formulary agents of similar use.
6. Potential duplication of similar drugs currently on formulary.
7. Any restrictions that should be delineated to assure safe, effective or proper use of the drug.
8. Nationally recognized treatment algorithms, when available.

##### **B. Requests for approval of medication requiring a Step-Therapy**

The Step Therapy process and information required from the prescribing practitioner is included in the Pharmacy Management Procedures distributed to practitioners annually and posted on the Plan's website in accordance with the Plan's policy and procedure.

Requests for coverage of drugs with a step therapy requirement are reviewed against the member's pharmacy benefit.

The Plan reviews the member's medical records and supporting documentation from the prescribing physician as described herein.

#### C. Step Therapy Exception Request Review Process

The Plan's Step-Therapy request process is conducted under the direct supervision of Health Plan licensed personnel (Pharm D, or MD) to ensure timely and appropriate clinical review according to the Plan's standards as outlined in Pharmacy policy and procedures. Turnaround time standards are documented in the SHP Pharmacy Management Procedure for Pharmacy Denial Process (HS-RX-106).

#### D. Review of Step Therapy Exception Requests from Prescribing Practitioners

1. Requests for a drug requiring Step Therapy may be faxed or telephoned or mailed to the Plan and follow the review process outlined in the SHP Pharmacy Management Procedure for Pharmacy Exceptions for Prescription Drugs (HS-RX-103) and SHP Pharmacy Management Procedure for Prior Authorization Required for Prescription Drugs (HS-RX-102).
2. Step Therapy Exception Requests are evaluated as follows:
  - a. If step-therapy has been met, based on the criteria defined by the P&T Committee, the medication request is approved.
  - b. If step-therapy has not been met, the request will be evaluated based on the following basic guidelines:
    - i. The use of drugs required as pre-requisites in the step-therapy process is contraindicated in the patient.
    - ii. The use of drugs required as pre-requisites in the step-therapy process pose a patient safety concern.
    - iii. The use of drugs required as pre-requisites in the step-therapy process may provoke an underlying condition, which would be detrimental to patient care.
3. If upon review, the step-therapy has not been met, and/or the above basic guidelines have not been met, the medication request is not approved and the Plan follows procedures outlined in the Pharmacy Management Procedure for Pharmacy Denial Process (HS-RX-106).
4. If the information submitted meets the Step-Therapy criteria and/or the medical necessity criteria as defined above the request will be approved.
  - a. Documentation is entered in MedResponse indicating an approved referral, to include personnel issuing the authorization and length of

time for which drug authorization is valid. Entries into MedResponse are communicated to the MedAccess. Entry into this claims adjudication system allows the approved claim to adjudicate for the approved drug and duration.

5. If the information submitted does not meet criteria for coverage or there is no written policy for that drug :
  - a. The request file is forwarded to the Plan Medical Director or Plan Medical Reviewer to review for medical appropriateness and necessity.
  - a. If the Plan Medical Reviewer authorizes the request, the Plan Medical Reviewer electronically signs/annotates the request and provides the rationale. The request is returned to the Pharmacy Technician for finalization. Authorization, documentation and notification are then completed as described above.
  - c. If the Plan Medical Reviewer denies Prior Authorization based on medical necessity, the Plan Medical Reviewer notes the reason in MedResponse, electronically signs/annotates the form, and returns it to the Pharmacy Technician. Denial documentation and notification is then completed as described in the SHP Pharmacy Management Procedure for Pharmacy Denial Process Policy & Procedure (HS-RX-106), Sections V C, D, E, F, G and H.

#### **E. Therapeutic Interchange, Incomplete Requests**

If the requested medication has a therapeutic equivalent on the Plan Drug Formulary that does not require Step-Therapy, the name of the Plan Drug Formulary medication(s) alternative(s) may be faxed to the prescribing physician for reconsideration within one working day of receipt of request. The physician may submit medical justification to support the Prior Authorization request. For more information on Therapeutic Interchange see the SHP Pharmacy Management Procedure for Therapeutic Interchange (HS-RX-112)

#### **F. Policy Compliance**

1. Written documentation, MedAccess referral entries, and MedImpact pharmacy database will be audited quarterly to evaluate consistency and compliance to policy.
2. Audit results will be reported on activities reports.

#### **V. ATTACHMENTS: N/A**

**VI. REFERENCES:**

- A. SHP Pharmacy Management Procedure for Prior Authorization Required for Prescription Drugs (HS-RX-102)
- B. SHP Pharmacy Management Procedure for Pharmacy Exceptions for Prescription Drugs (HS-RX-103)
- C. SHP Pharmacy Management Procedure for Pharmacy Denial Process (HS-RX-106)
- D. SHP Pharmacy Management Procedure for Therapeutic Interchange (HS-RX-112)

**VII. REVISION HISTORY:**

<b>Date</b>	<b>Modification (Reviewed and/or Revised)</b>
06/08/2011	Original Document
03/14/2012	Approved by P&T Committee
03/13/2013	Approved by P&T Committee
03/19/2014	Approved by P&T Committee
03/18/2015	Approved by P&T Committee
03/09/2016	Approved by P&T Committee