PLAN POLICY AND PROCEDURE	
SHARP HEALTH PLAN Welcome home. **Title: SHP Pharmacy Management Procedure for Formulary and Pharmaceutical Management Procedures Development and Management**	**Product Line** (check all that apply)**:** ☒ All ☐ Group HMO ☐ Individual HMO ☐ PPO ☐ POS ☐ N/A
Division(s): Health Services	
Department(s): Pharmacy	
Owner (Title): Pharmacy Manager	
Relevant Regulatory/Accrediting Agencies/Citations (specify): ☐ CMS: _____ ☒ DMHC: RX-004, RX-005 ☒ NCQA-HP: UM 13.A, 13.B, 13.D ☐ NCQA-WHP: _____ ☐ OTHER: _____	
Approved by: (Signature of VP, Compliance Officer, or CEO)	**Approval date:** 3/9/2016

I. PURPOSE:

This Policy and Procedure establishes Sharp Health Plan's (Plan) policy and procedure for the development and management of the Formulary and Pharmaceutical Management procedures.

II. POLICY:

It is the policy of Sharp Health Plan (Plan) to maintain a dynamic program of managed care pharmacotherapy based on a carefully designed drug formulary, prescribing guidelines and pharmaceutical management procedures. The formularies, prescribing guidelines, and pharmaceutical management procedures are created to ensure Plan members receive high quality, cost-effective, safe and efficacious drug therapy.

III. DEFINITIONS:

A. Drug Formulary: A listing of preferred prescription medications approved for use and/or coverage by the plan and dispensed through participating pharmacies.

B. Quantity Limits: Recommended limitation of dispensed drug quantity to be

limited to a determined number of doses (e.g., quantity limit) based on criteria including but not limited to safety, potential overdose hazard, abuse potential, or approximation of usual doses per month.

C. 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 for the drug or the patient had adverse effects to the drug. The process of moving to secondary agents may involve information from prescribers, or may be automated by computer review of patient drug history to determine which drug(s) had been tried previously.

D. Therapeutic Interchange: The practice of replacing, with the prescribing physician's approval, a prescription drug originally prescribed for a patient with a prescription drug that is its therapeutic equivalent. Two or more drugs are considered therapeutically equivalent if they can be expected to produce similar levels of clinical effectiveness and sound medical outcomes in patients.

IV. PROCEDURE:

A. The SHP Pharmacy & Therapeutics (P&T) Committee meets quarterly to review and recommend medications for formulary consideration to assure that the Formulary remains responsive to physician and member needs.

B. The SHP P&T Committee is composed of pharmacists and physicians representing various medical specialties. With a primary consideration to provide a safe, effective and comprehensive Formulary, Prescribing Guidelines and Pharmaceutical Management Procedures, the Committee evaluates all therapeutic categories and selects the most efficacious and cost effective agent(s) in each class for inclusion on the Formulary.

At least annually and when new pharmaceutical information is received the committee reviews, updates and approves the Plan Formulary, Prescribing Guidelines, and the Pharmaceutical Management Procedures. The criteria used include:

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. Condition of 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

C. The Plan involves psychiatrists, pediatricians and other mental health prescribing

practitioners in the development of the formulary for psycho-pharmacologic drugs and pertinent behavioral health pharmacy management processes.

D. The P&T Committee reviews and approves recommendations to the formulary's prescribing guidelines such as age limits at least annually.

E. At least annually, The P&T Committee reviews and approves pharmaceutical management procedures including prior authorization criteria, formulary list and exceptions, quantity limitations or quotas, therapeutic interchange, step therapy, pharmaceutical classes (including preferred drugs at any level, prior authorization criteria, exception processes, generic substitution, evidence supporting preferred status, and limitations within each pharmaceutical class), and classes covered at any level following the evidence-based criteria listed above.

F. Requests for additions to SHP formularies received from physicians, members, pharmacists or other sources are submitted to the SHP Chief Medical Officer (CMO) or SHP Clinical Pharmacist. Requests are researched by the SHP Clinical Pharmacist and/or Pharmacy Benefit Manager (PBM) following the criteria defined above in section (B). If added to the P&T agenda, information is prepared for the P&T Committee review following the criteria defined above in section (B). Also presented at the P&T meeting is the SHP CMO/Clinical Pharmacist/PBM recommendation to include or exclude the medication from formulary.

G. The SHP P&T Committee reviews reference materials and monographs provided by the MedImpact Pharmacy & Therapeutics Advisory Panel to make decisions which are based on the criteria listed above. Monographs of drugs and therapeutic classes or disease states and any prescribing guidelines presented to the Committee are to include references from government agencies, medical associations, national commissions, peer-reviewed journals, and authoritative compendia used in the compilation of the materials presented and included for documentation and review, such as the US FDA, American Medical Association, American Hospital Formulary Drug Information and United States Pharmacopeia-Drug Information. References may also include guidelines or algorithms from National Medical Societies, such as the American Association of Clinical Endocrinologists, the American College of Rheumatology or guidelines from the National Guidelines Clearinghouse.

H. Additions to the Formulary: New outpatient medications are routinely reviewed for addition to the SHP Formulary. Recommendations are presented to the P&T Committee for consideration, where they are reviewed using the criteria described above.

I. Deletions to the Formulary: Deletions to the Formulary may occur based on the recommendation of the P&T Committee, using the criteria listed above.

J. Rationale regarding additions to or deletions from the Formulary are discussed during the committee meetings and documented in the SHP P&T Committee minutes.

K. Exceptions: Member specific consideration for use of non-formulary medications (exceptions) will be evaluated at the time of the request by the SHP Medical Director or Physician Reviewer per the SHP Pharmacy Management Procedure for Pharmacy Exceptions for Prescription Drugs (HS-RX-103).

L. Vacation Overrides are covered for a 90 day period only. Controlled substances may or may not be approved for vacation overrides.

M. Replacement of lost, stolen or destroyed medications is not a covered benefit. If the Plan approves a request for lost medication the medication is replaced at the amount

necessary to provide the member medication until his/her next refill date. Lost narcotic medications are not replaced.

N. The Sharp Health Plan Formulary is available to members, physicians and pharmacy providers on the Sharp Health Plan website. The Plan updates the Sharp Health Plan website with changes to the drug formulary, pharmacy management procedures and limitations. changes are posted to the website within 30 days of formulary changes becoming effective.

O. Formulary changes are communicated to Plan physicians annually and when changes are made through faxed distribution of the Prescription Post. The Prescription Post is distributed to the Customer Care Department to assist with answering member and provider questions. Copies of the Prescription Post are posted on the Sharp Health Plan website for access by providers and members annually and when changes are made. Provider copies can be found by looking under Providers/Provider Updates/Fax Alert Archives. The Sharp Health Plan pharmacy management procedures are communicated to Plan physicians annually and when changes are made. Provider communication includes information about how to use pharmacy management procedures, how practitioners must provide information for pharmacy exception requests, an explanation of the Plan's generic-based formulary, therapeutic interchange and step therapy protocols, and pharmacy limits and quotas. The Pharmacy management procedures are posted on the Sharp Health Plan website for access by providers and members annually and when changes are made. The Member Handbook and and Provider Operations Manual provide information about the availability of the Plan formulary and pharmacy management procedures online. Providers and members without access to the website are notified of the ability to contact the Customer Care Department to have hard copy versions and updates mailed to them if desired.

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 (103)

C. SHP Pharmacy Management Procedure for Quantity Limits on Prescription Drugs (HS-RX-110)

D. SHP Pharmacy Management Procedure for Step-Therapy for Prescription Drugs (HS-RX-111)

E. SHP Pharmacy Management Procedure for Brand Only Medication Requests (HS-RX-113)

VII. REVISION HISTORY:

Date	Modification (Reviewed and/or Revised)
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