PLAN POLICY AND PROCEDURE	
SHARP HEALTH PLAN make life better. **Title: Pharmacy Management Procedure for Pharmacy Exceptions for Prescription Drugs**	**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-001 A. RX-003 ☒ NCQA-HP: UM13.B; UM13.E ☐ 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 authorizing Exceptions for Prescription Drugs.

II. POLICY:

It is the policy of Sharp Health Plan (Plan) to review requests for non-formulary medications (formulary exceptions) when equivalent formulary medications are either inappropriate or have proven ineffective to treat certain medical conditions, or when there is no equivalent or comparable medication on the formulary. 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. Exception: Approval of a non-formulary medication for coverage.

B. MedAccess: SHP portal into the Pharmacy Benefits Management (PBM – MedImpact) claims adjudication system. Authorized SHP personnel access this system to view pharmacy claims status and to input approved Prior Authorizations so that qualified claims will approve at the point of sale.

C. MedResponse: Paperless electronic document retrieval system used to intake, house and process incoming documents (such as Prior Authorization (PA) requests and chart notes). For example, incoming PA requests are faxed into MedResponse, where a copy of the document can be viewed during the review process.

B. PROCEDURE:

A. Non-Formulary Drug Requests

Requests for coverage of drugs that are not included on the Plan Drug Formulary are reviewed under the member's Pharmacy benefit.

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

B. Exceptions Process Supervision and Timeliness

The Plan's non-formulary request process is conducted under the direct supervision of Health Plan licensed personnel (RN, Pharm D, or MD) to ensure timely and appropriate clinical review according to professionally recognized standards. Clinical urgency is considered when reviewing exception requests. Urgent cases are flagged to alert staff of the urgent status and reviewed as soon as possible but no later than twenty-four (24) hours after receipt, within the required timeframe.

C. Medical Necessity Review of Drug Formulary Exception Requests

1. Requests for non-formulary drugs may be faxed, telephoned or mailed into the Plan with the following clinical information, as appropriate:

a. Patient's diagnosis

b. Patient's medical history, which may include:

(1) Pertinent lab/diagnostic results

(2) Previous treatments and/or medications and results

(3) Current treatment plan

(4) Documentation from prescribing practitioner that the medication was part of a prescribed therapy in effect immediately prior to new member's enrollment in SHP (for new members only).

(5) Documentation that the requested prescription drug has been previously approved by the Plan for ongoing treatment of a member's chronic medical condition. In these cases the Plan will continue approval as long as the contracted provider continues to prescribe the drug for the condition, and it is determined to be safe and effective for treating the member's medical condition.

2. All requests and all medical information received are housed and date-stamped in MedResponse to record the date received by the Health Services Pharmacy department.

3. To ensure immediate access to medications without delays, a telephone request may be submitted by the physician. In this instance, a request form is completed by Plan staff and will include the date and time of call and appropriate medical information.

4. Documentation of the request, medical records, and the criteria used to make determinations, and any other information deemed pertinent, is maintained in

MedResponse for tracking.

5. All requests are reviewed by a technician or appropriate practitioner and the determination is made within seventy-two (72) hours of receipt for routine requests and twenty-four (24) hours of receipt for urgent requests. The request is reviewed for medical appropriateness, necessity, and compliance with criteria.

6. Requests are evaluated as follows:
The request is evaluated on the following basic guidelines:
   a. The use of Formulary drugs is contraindicated in the patient.
   b. The patient has failed an appropriate trial of Formulary or related agents.
   c. The choices available in the Drug Formulary are not suited for the present patient care need, and the drug selected is required for patient safety.
   d. The use of a Formulary drug may provoke an underlying condition, which would be detrimental to patient care.
   e. If a specific medication Prior Authorization guideline exists, the criteria listed in that guideline also apply.

7. If the information submitted meets medical necessity criteria as defined above, or meets the criteria in the drug's Prior Authorization guideline, the request is authorized.
   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.
   b. Entries into MedResponse are communicated to MedAccess. Entry into this claims adjudication system allows the approved claim to adjudicate for the approved drug and duration.

8. 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.
   b. 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 in 8a.
   c. If the Plan Medical Reviewer determines that no exception should be made based on medical necessity, the Plan Medical Reviewer will note the reason in MedResponse, electronically sign/annotate the form, and return it to the Pharmacy Technician. As with other denials, the denial notification to members and practitioners includes:
      - The opportunity for prescribing practitioner to discuss the denial decision with the reviewer.
      - The specific reasons for the denial in easily understandable language
      - A reference to the benefit provision, guideline protocol or similar criterion on which the denial decision is based.
      - A statement that the member can obtain a copy of the benefit provision, guideline protocol or similar criterion on which the

denial decision is based.
- A description of the appeal process, including the right to member representation and timeframes.
- A description of the expedited appeal process for urgent requests.
- Notification that expedited external reviews can occur concurrently with the internal appeal process for urgent care and on-going treatment.

D. Therapeutic Interchange, Incomplete Requests

If the requested Non-Formulary medication has a therapeutic equivalent on the Plan Drug Formulary, the name of thePlan Drug Formulary medication(s) alternative(s) may be faxed to the prescribing physician for reconsideration within one working day of receipt of request. The Plan reviews the request following the SHP Pharmacy Management Procedure for Therapeutic Interchange Policy & Procedure (HS-RX-112).

D. Re-Authorizations/Extensions

PA extension requests shall be evaluated for appropriate prescribing given the member's diagnosis. If the medication is considered safe and effective for treating the member's medical condition, the drug had previously been approved by the Plan, and the Plan's prescribing provider continues to prescribe the drug for the medical condition, a PA extension will be approved. A generic equivalent may be approved by the Plan in cases where a generic was not available at the time of the original PA request. (See the SHP Pharmacy Management Procedure for Brand Only Medication Requests, HS-RX113).

E. Medication Emergency Dispensing During Hours of Non-Operation

During hours of non-operation (i.e., evenings, weekends, holidays), the Plan provides that pharmacies will dispense at least a 72-hour and up to a 5 day supply of a covered outpatient drug. The Plan has also directed the pharmacies to dispense at least a 72-hour supply of any non-formulary prescription medication that is needed during hours of non-operation. These instructions are documented in the PBM Help Desk notes for reference during after-hours and weekends.

F. Policy Compliance

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

V. ATTACHMENTS: None

VI. TAGS:

VII. REFERENCES:

A. SHP Pharmacy Management Procedure for After Hours Emergency Dispensing (HS-RX-104)

B. SHP Management Procedure for Pharmacy Denial Process (HS-RX-106)

C. SHP Pharmacy Management Procedure for Therapeutic Interchange (HS-RX-112)
D. SHP Pharmacy Management Procedure for Brand Only Medication (HS-RX-113)

VIII. REVISION HISTORY:

Date	Modification (Reviewed and/or Revised)
06/08/2011	Original Document
11/01/2011	Revised
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
09/09/2015	Approved by P&T Committee
03/09/2016	Approved by P&T Committee