PLAN POLICY AND PROCEDURE	
SHARP HEALTH PLAN make life better. **Title: SHP Pharmacy Management Procedure for Brand Only Medication Requests**	**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: _____ ☒ NCQA-HP: UM 13 B.4 ☐ NCQA-WHP: _____ ☐ OTHER: _____	
Approved by: (Signature of VP, Compliance Officer, or CEO)	**Approval date:** 3/09/2016

I. PURPOSE:

This Policy and Procedure establishes Sharp Health Plan's (Plan) policy and procedure for coverage of Brand medications when a generic is available.

II. POLICY:

It is the policy of Sharp Health Plan (Plan) that when a generic is available, Sharp Health Plan does not cover the corresponding brand-name medication. The Plan requires the dispensing pharmacy to dispense the generic medication unless prior authorization for the brand is obtained. Prior Authorization for brand will only be given after it has been determined that the brand name drug is medically necessary. 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. Medical Necessity for Brand Only Medication: Medical necessity for the brand is defined as ineffectiveness or inability to tolerate any generic version of the medication from any manufacturer and the ineffectiveness or inability to tolerate a formulary alternative on the Sharp Health Plan drug formulary.

B. MEDWATCH: The FDA MEDWATCH program collects reports of adverse reactions and quality problems, primarily with drugs and medical devices, but also for other FDA-regulated products (e.g., dietary supplements, cosmetics, medical foods, and infant formulas). Voluntary reporting by healthcare professionals, consumers, and patients is conducted on a single, one-page reporting form (Form FDA 3500). Reporting can be conducted online, by phone 1-800-FDA-1088, or by submitting the MedWatch 3500 form to the FDA by mail or fax to 1-800-FDA-0178.

IV. PROCEDURES:

A. With the annual distribution of the Plan's Provider Operation Manual, practitioners and members are notified of the need for Prior Authorization when requesting a brand name drug when there is generic available.

B. The request for brand name approval is reviewed following the Plan's Prior Authorization Policy and Procedure.

C. Brand name drugs may be approved under the following circumstances:

1. It has been demonstrated to the Plan that the member has a) tried the FDA approved generic medication (verified in the member's Sharp Health Plan electronic prescription history or medical record provided to the Plan) **and** b) it is medically necessary for the member to take the brand.
2. If the requesting provider states that it is medically necessary to take the brand medication due to an adverse event or side effect experienced with all generic forms of the medication by all generic manufacturers, the requesting provider must provide evidence that a MEDWATCH form has been completed and submitted to the FDA documenting the adverse event experienced with the generic drug but not with the brand name drug. MEDWATCH forms are used to report safety concerns and adverse events to the FDA. This includes problems with different manufacturers of the same medication. MEDWATCH forms can be found at the FDA website (http://www.fda.gov/downloads/aboutfda/reportmanualsforms/forms/ucm163919.pdf) and are identified as FDA Form 3500.

D. Brand name drugs will generally be denied (and SHP Denial Process Policy and Procedure is followed) if any of the following apply:

3. The member has not tried the generic version of the drug.
4. The member's use of the generic version cannot be verified in their Sharp Health Plan electronic drug history or medical record provided to the Plan
5. Medical justification has not been provided documenting why formulary alternatives cannot be used.
6. A completed MEDWATCH form has not been submitted to the Plan in the event the member or provider states that the generic drug but not the brand drug causes an adverse event or side effect.

V. REFERENCES :

A. Federal Drug Administration website (http://www.fda.gov).
B. SHP Pharmacy Management Procedure for Formulary and Pharmaceutical Management Procedures Development and Management (HS-RX-101)
C. SHP Pharmacy Management Procedure for Prior Authorization Required for Prescription Drugs (HS-RX-102)
D. SHP Pharmacy Management Procedure for Pharmacy Denial Process (HS-RX 106)

VI. 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