

POLICY AND PROCEDURE	
Policy # and TITLE: PH09 Step Therapy	
Primary Policy owner: Pharmacy	POLICY #: PH09
Impacted/Secondary policy owner: Select the department(s) that are responsible for compliance with all, or a portion of the policy or procedure as outlined	
1) <input type="checkbox"/> All Departments 2) <input type="checkbox"/> Behavioral Health (BH) 3) <input type="checkbox"/> Benefits Administration (BA) 4) <input type="checkbox"/> Care Management (CM) 5) <input type="checkbox"/> Claims (CLMS) 6) <input type="checkbox"/> Community Marketplace & Member Engagement (MAR) 7) <input type="checkbox"/> Compliance (CMP/HPA) 8) <input type="checkbox"/> Configuration (CFG) 9) <input type="checkbox"/> Provider Contracting (CONT) 10) <input type="checkbox"/> Cultural & Linguistics (CL) 11) <input type="checkbox"/> Customer Service (CS)	12) <input type="checkbox"/> Facilities (FAC) 13) <input type="checkbox"/> Finance (FIN) 14) <input type="checkbox"/> Human Resources (HR) 15) <input type="checkbox"/> Information Technology / Core Systems (IT) 16) <input checked="" type="checkbox"/> Pharmacy (PH) 17) <input type="checkbox"/> Provider Networks (PRO) 18) <input type="checkbox"/> QI Health Equity (GRV/HE/HEQ/PHM/QM) 19) <input type="checkbox"/> Utilization Management (UM)
PRODUCT TYPE: <input checked="" type="checkbox"/> Medi-Cal	Supersedes Policy Number: N/A

I. PURPOSE

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

I. POLICY

The Health Plan of San Joaquin (HPSJ) uses Step Therapy to promote use of cost-effective medications that are highly utilized and are standard of care for specific diagnoses and would result in reduced PA burden for providers by enrolling it into the Step Therapy program.

II. PROCEDURE

1. Step Therapy is used to promote the use of cost-effective medications before progressing to less cost-effective alternatives.
 - a. Step Therapy requires that one or more “prerequisite” components are met otherwise a Prior Authorization is required.
 - b. On the medical benefit, Step Therapy is applied by requiring that a medication is billed with certain diagnoses codes in order to be processed without an active approved Prior Authorization on file.
2. Medications are considered for Step Therapy based on any of the following criteria:
 - a. There are efficacious, cost-effective medications to treat the condition in addition to expensive alternatives.
 - b. The medications are standard of care and highly utilized for specific diagnoses.
3. 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.
4. Information sources considered in the development, revision and approval of Step Therapy protocols include:
 - a. Published scientific literature.
 - b. Facts and Comparison Formulary Services.
 - c. Micromedex.
 - d. National Guidelines Clearinghouse, of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.

- e. American Hospital Formulary Services.
 - f. Food and Drug Administration.
 - g. FDA-approved manufacturer labeling information.
 - h. Recommendations of medical and health care specialty and standard-setting organizations.
 - i. The recommendations of governmental health care, research, and regulatory bodies.
5. Upon P&T Committee approval of a Step-Therapy protocol the Pharmacy Director:
- a. Verifies documentation of the approved Step Therapy protocol in the P&T meeting minutes.
 - b. Notifies individuals responsible for implementing the Step Therapy protocol of the change.
 - c. Formally documents the Step Therapy protocol.
 - d. Arranges for automated messaging within the medical benefit system to inform the prescriber that the medication code is available without Prior Authorization in only certain diagnoses.
 - e. Ensures that:
 - i. Providers and members are notified via provider alert no less than forty-five (45) business days before the changes take effect.
 - ii. Member and Provider quarterly newsletters remind their recipients that the medical benefit has been updated and updates can be viewed on the organization's website.
6. The treating practitioner can request an exemption from the Step Therapy protocol by submitting a completed Prior Authorization Request Form, available on HPSJ's web site and from the Pharmacy Department.
7. PA requests will not impose quantity limits (QTL) or non-quantitative limits (NQTL) more stringently on mental health and substance use

disorder drugs as compared to medical/surgical drugs prescriptions in accordance with 42 CFR 438.900 et. seq.

8. 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.
9. The processes outlined in policy UM01, Authorization and Referral Review, and policy UM07, Notice of Action for Delayed, Denied, Modified, or Terminated Services, are followed in making determinations and submitting notification letters to members and providers.
10. The Appeals process described in policy QM65, Member Appeals Policy, is available for any non-authorization determination.

III. ATTACHMENT(S)

1. DHCS Medi – Cal Managed Care Plans Definitions (Exhibit A, Attachment I, 1.0 Definitions)
2. [Glossary of Terms Link](#)
3. Medi-Cal Managed Care Contract Acronyms List (Exhibit A, Attachment I, 2.0 Acronyms)

IV. REFERENCES

1. NCQA Standard UM11 – Procedures for Pharmaceutical Management

V. REVISION HISTORY

**Version 001 as of 01/01/2023*

Version*	Revision Summary	Date
000	09/16, 09/17, 12/18, 07/19, 12/19, 07/20	N/A
001	Brought PH09 out of retirement and updated content to reflect step therapy in physician administered drugs on the medical benefit.	09/08/2023
002		
Initial Effective Date: 09/12/2012		

VI. Committee Review and Approval

Committee Name	Version	Date
Compliance Committee		
<ul style="list-style-type: none"> Privacy & Security Oversight Committee (PSOC) 		
<ul style="list-style-type: none"> Risk Management 		
<ul style="list-style-type: none"> Delegation Oversight 		
<ul style="list-style-type: none"> Policy Review 	001	09/20/2023
Quality and Utilization Management		
<ul style="list-style-type: none"> Quality Operations Committee 		
<ul style="list-style-type: none"> Grievance 		
Pharmacy & Therapeutics Committee		

VII. REGULATORY AGENCY APPROVALS

Department	Reviewer	Version	Date
Department of Healthcare services (DHCS)	N/A	N/A	N/A
Department of Managed Care (DMHC)	N/A	N/A	N/A

VIII. Approval signature*

Signature	Name Title	Date
	PRC Chairperson	
	Policy Owner	
	Department Executive	
	Chief Executive Officer	

*Signatures are on file, will not be on the published copy