

POLICY AND PROCEDURE	
TITLE: Exception Process for Non-Formulary Medications	
DEPARTMENT: Medical Management - Pharmacy	POLICY #: PH06
EFFECTIVE DATE: 09/18/12	REVIEW/REVISION DATE: 09/12, 09/15, 09/16, 09/17, 02/18, 12/18, 07/19
COMMITTEE APPROVAL DATE: P&T 12/11/2018 PRC 06/19/2019 QMUM 07/10/2019	RETIRE DATE: None
PRODUCT TYPE: Medi-Cal	REPLACES: None

I. PURPOSE

To explain how non-formulary drugs may obtain coverage at Health Plan of San Joaquin (HPSJ).

II. POLICY

HPSJ's Pharmacy Department manages the pharmaceutical Exception process which allows for the coverage of non-Formulary drugs when requested by a prescribing practitioner and deemed medically necessary by HPSJ.

III. PROCEDURE

- A. Prescribing practitioners and members may request coverage for non-formulary medications.
- B. The prescribing practitioner must submit information to support the medical necessity of the request.
- C. The information needed to support an Exception request and the Medication Request Form are on HPSJ's website, and are also available upon request from the Pharmacy Department. Once the required form and information are received, the request will go through the prior authorization review process. For more info on this process, please see the Prior Authorization policy.
- D. The information needed to process an Exception request includes:
 1. Member's plan.
 2. Member name and identification number.
 3. Member date of birth.

4. Prescribing physician name.
 5. Contact person at physician's office.
 6. Physician phone number.
 7. Physician office fax number.
 8. Dispensing pharmacy name.
 9. Pharmacy telephone number.
 10. Diagnosis.
 11. Drug requested.
 12. Reason for exception.
 13. Strength, quantity, route, frequency.
 14. Duration of therapy.
 15. Other drugs tried and failed.
 16. Medication allergies.
 17. Whether drug is injectable.
 18. Whether drug is self-administered injectable.
 19. Physician's signature.
 20. Date of completion.
- E. HPSJ makes all reasonable attempts to obtain the information needed to make a timely determination by contacting the prescribing practitioner or designated staff as appropriate.
- F. The Exception request is reviewed against the following criteria:
1. One of the following criteria must be met:
 - a. Three Formulary drugs have been tried in adequate therapeutic trials without a positive therapeutic response.
 - b. The member has or develops contradictions to, or an intolerance of, all Formulary alternatives.
 - c. No Formulary alternatives exist to treat the member's condition.
 - d. The member has been established on and has responded to the non-Formulary agent prior to enrollment in HPSJ and the member's physician chooses to defer switching the member to another medication.
 2. The request will be denied if the Medical Director, Director of Pharmacy or Plan Pharmacist determines that the potential harm to the member is greater than the potential benefit.
- G. If a medication has previously been approved for a member's medical condition and the physician continues to prescribe for the same medical

condition, HPSJ will continue to approve the use of that medication, even if the medication is no longer on the Formulary, provided the medication is safe and effective for the use.

1. This does not apply to a medication that has been previously prescribed for a medical condition of a limited timeframe, and then discontinued.
 2. A medication will be approved if a physician medical chart documents the use of the product (given via samples) and can verify that the patient is stable and would be at risk if the medication is stopped.
- H. If authorization for a non-Formulary medication is denied after retrospective review, HPSJ will continue to cover the non-formulary medication up to sixty (60) days if medically necessary to allow the practitioner time to transition the member to a Formulary agent.
- I. 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.
- J. The Appeals process described in policy QM 65 Member Appeals Policy, is available for any non-authorization determination.

IV. ATTACHMENT(S)

None

V. REFERENCES

- A. HPSJ Policy UM01 – Authorization/Referral Process
- B. HPSJ Policy UM07 – Notification to Members of Denial, Deferral, Modification Actions
- C. HPSJ Policy UM65 – UM Appeals Policy
- D. NCQA Standard UM11 – Procedures for Pharmaceutical Management

VI. REGULATORY AGENCY APPROVALS

DHCS Approved on 07/08/16, 04/24/18.

VII. Glossary

[Policy and Procedure Glossary Link](#)

VIII. REVISION HISTORY

STATUS	DATE REVISED	REVISION SUMMARY
Reviewed	09/30/16	No content change, annual review.

STATUS	DATE REVISED	REVISION SUMMARY
Reviewed	09/12/17	No content change, annual review.
Revised	02/23/18	Removed TPA line of business, added in sentence about referring to the Prior Authorization policy.
Reviewed	12/11/18	No content change, annual review.
Revised	07/30/19	Added purpose statement, updated template.