

PRIOR AUTHORIZATION PROGRAM POLICY AND PROCEDURE

POLICY:

Prior authorization is the utilization review process to determine whether a requested prescription drug meets VCHCP's clinical criteria for coverage.

Using a tiered system, most medications on Tiers 1, 2 and 3 are available by proper prescription from the physician to the Plan member. These prescriptions, whether for preferred or nonpreferred drugs as set forth in the Plan's Preferred Drug List (PDL), are filled upon presentation of a valid prescription at a participating pharmacy. There are, however, certain medications that require prior authorization (PA). The Pharmacy and Therapeutics (P&T) Committee may designate any preferred or non-preferred medication as requiring PA by the Plan. Generally these medications are high cost medications or medications for which medical necessity must be demonstrated. These are so labeled and documented in the PDL. Prior authorization encourages the appropriate and costeffective use of a drug by allowing coverage only when certain conditions are met. The PDL has been compiled by the Pharmacy Benefit Manager (PBM) after extensive research and adopted by VCHCP's P&T and Quality Assurance (QA) Committees using, in part, current medical findings, FDAapproved manufacturer labeling information, pharmaceutical class coverage and medication availability to treat disease and medical conditions. Additionally, the PDL is regularly reviewed with additions and deletions made as appropriate.

The following drug categories require prior authorization regardless of their status (Preferred or Non-Preferred). Note that this list is not all inclusive. Refer to the current VCHCP Preferred Drug List.

- All injectables with the exception of Insulins, headache medications, epinephrine, medroxyprogesterone acetate & approved immunization products
- All growth hormones
- All infertility drugs
- Most antivirals/protease inhibitors, except Acyclovir, Amantadine, Famciclovir, Valacyclovir, Denavir, Famvir, Flumist, Relenza, Tamiflu, Tyzeka, Valtrex, Xerese
- All specialty drugs require prior authorization.

No prior authorization is required for non-preferred drugs based on their non-preferred status alone. However, the Plan, upon review with the P&T Committee, may institute prior authorization criteria for specific drugs.



PROCEDURE:

Submissions:

When a physician requests a medication that has a prior authorization (PA) requirement, the pharmacy or the prescribing physician must contact the Plan explaining the medical necessity of the request, including past therapeutic attempts, contraindications to medications and allergies when applicable.

Providers are required to use Form No. 61-211 to submit prior authorization requests for prescription drugs. The Plan allow providers to submit prior authorization requests for prescription drugs through CERNER, an electronic prior authorization request system. The Plan's electronic prior authorization system utilize Form No. 61-211. The Plan has the Form 61-211 electronically available on its website.

The Plan utilizes a step therapy process for prescription drugs. The Plan require providers to use Form No. 61-211 to submit step therapy exception requests. The Plan follows its prior-authorization policy and procedure which treats and responds to step therapy exception requests in the same manner as requests for prior authorization for prescription drugs. Requests for exceptions to step therapy processes for prescription drugs may be submitted in the same manner as a request for prior authorization for prescription drugs and shall be treated in the same manner. (See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications).

Requests for authorization during regular business hours may be made by telephone, in writing, or by facsimile by the pharmacy or the prescribing physician to the Plan. A DMHC Pharmacy Prior Authorization Form is available for submission convenience. Requests for emergency authorization during regular working hours are handled by the Plan's UM staff.

Requests for emergency authorization after regular business hours are to be made by telephone by the pharmacy or the prescribing physician to the Plan's voice mail system which connects the caller to the Plan's answering service, available 24 hours a day, 7 days a week. The service will contact the Plan Medical Director and/or designated Administrator on call having the authority to approve medications requiring prior authorization.

The process by which enrollees may obtain medically necessary non-formulary drugs is described in the Plan's evidence of coverage and disclosure forms. (See Evidence of Coverage and Disclosure Forms)



Timelines for Decisions:

The Plan has an expeditious process in place to authorize exceptions to step therapy and nonformulary prescription drugs, as medically necessary.

The Plan processes requests for prescriptions (including prior authorization of non-formulary drugs, and if applicable, certain formulary drugs, and any request for a step therapy exception, according to the following timelines:

- For new prescriptions: Within 24 hours of the Plan's receipt of the request.
- For all exigent circumstances (step therapy & formulary exception requests): Within
- 24hours of the Plan's receipt of the request.
- For urgent refills: Within 24 hours of the Plan's receipt of the request.
- For other refills: Within 24 hours of the Plan's receipt of the request.
- For non- urgent prior authorization, step therapy and formulary exception requests, the Plan responds within 72 hours of the Plan's receipt of the request.

"Exigent circumstances" exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug. "Urgent" means any otherwise Covered Service including medications necessary to prevent serious deterioration of the health of a Member, resulting from an unforeseen illness, injury, or complication of an existing condition, including pregnancy, for which treatment cannot be delayed until the Member is able to see his or her PCP.

The Plan requires a response to exigent prior authorization, step therapy and formulary exception requests within 24 hours. If the Plan fails to respond to the request within this timeframe, the request is deemed granted.

The Plan requires a response to non-urgent prior authorization, step therapy and formulary exception requests within 72 hours. If the Plan fails to respond to the request within this timeframe, the request is deemed granted.

Request by providers for authorization of appropriately prescribed pain management medications for an enrollee who has been determined to be terminally ill shall be approved or denied in a timely fashion, appropriate for the nature of the enrollee's condition, not to exceed 72 hours of the Plan's receipt of the information requested by the Plan to make the decision.

See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications.

See Drug Policy: Pain Management for Terminally III Patients

Review/Decision Making:



The Ventura County Health Care Plan policy is that the Medical Management (MM) staff may apply the adopted criteria to approve drugs requiring prior authorization. The Plan adopted all Express Scripts Drug Policies including the following hierarchy use of policy/criteria: (1) Express Scripts Drug Policy; (2) MCG if there is no Express Scripts Drug Policy; (3) Custom VCHCP Drug Policy if there is no Express Script Drug Policy and no MCG; (4) Send to Physician Reviewers to use compendia such as UpToDate or NCCN, if there is no Express Scripts Drug Policy, no MCG, no Custom VCHCP Drug Policy. All requests that do not meet criteria are referred to the Medical Director or his/her designee for a decision.

The VCHCP Medical Director or Utilization Review physician approves or denies all requests for prior authorization of Preferred or Non-Preferred Drug List medications that do not meet the prior authorization criteria established by the Pharmacy & Therapeutics Committee.

The Medical Director or his/her designee may do any or all of the following before making a coverage decision for a requested medication requiring prior authorization:

- Review Pharmacy and Therapeutics Committee criteria for prior authorization of medication in question.
- Review patient medical records that document the need for the requested drug, the efficacy of any sample medications tried and the contraindications or ineffectiveness of other drugs tried, including allergies
- Review correspondence from the prescribing physician supporting the requested drug
- Review the patient's prescription drug usage history under the Plan
- Review written information about the requested drug provided by the Plan's pharmacy benefit manager, in UpToDate or any other source of reliable information or provided by the drug manufacturer.
- Contact the following individuals for additional information to support the medical necessity of the request: the prescribing physician, a qualified clinical pharmacist (with at least 3 years clinical experience or completion of a pharmacy residency) or a qualified physician (a board-certified physician with special training or expertise in an area related to the proposed use of the drug).

When the authorization is approved, the Plan's Medical Management (MM) staff either enters the authorization in the PBM's network system or contacts the PBM's customer service representative by phone, who then enters the authorization in the PBM's network system. The Plan's MM staff completes the authorization process in its medical management/documentation system, known as QNXT, where a fax approval notification is created and faxed to the provider and a member approval letter is created and mailed to the member.

A verbal authorization may be given to the pharmacy or requesting physician.

When the request for prior authorization comes from the dispensing pharmacy, the Plan's MM staff informs the dispensing pharmacy via phone that authorization for the medication is in place.

When an authorization is denied, the denial shall be made in writing to the member and to the prescribing physician and will include the following information:



- a. Reason for the denial
- b. Any alternative drug or treatment offered by the Plan
- c. Information to the member regarding the Plan's Appeal/Grievance process.
- d. Information to the member regarding the Independent Medical Review (IMR) process if the drug is denied because it is experimental or investigational.
- e. Name and contact information for person who made the denial decision.

The Plan provides a process for an enrollee, and enrollee's designee, or a prescribing provider to request that the original formulary exception request and subsequent denial of such request be reviewed by an independent review organization. (See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications).

Notifications:

(See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications. See UM Policy: TAR Timeframe Workflow Grid). See Drug Policy: Pain Management for Terminally III Patients

The Plan make its determination on the external exception review request and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than 72 hours following receipt of the request, if the original request was a standard request for nonformulary prescription drugs.

The Plan make its determination on the external exception review request and notify the enrollee or the enrollee's designee and the prescribing provider of its coverage determination no later than 24 hours following receipt of the request, if the original request was an expedited formulary exception request

The Plan notifies the prescribing provider and the enrollee or the enrollee's designee of its decision within 24 hours of receipt of an exigent request.

The Plan notify the prescribing provider and the enrollee or the enrollee's designee of its decision within 72 hours of receipt of a non-urgent request

If the Plan delays, denies and/or modifies the request:

- The Plan's written notices include a clear and concise explanation of the reasons for the Plan's decision.
- In addition, the Plan's written denials include a description of the criteria or guidelines as well as the clinical reasons for the decision regarding medical necessity.
- The Plan's written notices to the requesting provider include the name and direct telephone number or telephone extension of the professional that made the determination.
- Only licensed physicians or health care professionals (competent to evaluate the clinical issues) make decisions to deny pain management for terminally ill patients and any denials and modifications of medication requests.



Continuation of Drug Therapy:

The Plan will continue to cover a drug for an enrollee if the drug previously had been approved for coverage by the Plan for the enrollee's medical condition and the Plan's prescribing practitioner continues to prescribe the drug for the medical condition, provided that it is appropriately prescribed, and is considered safe and effective for treating the enrollee's medical condition.

If the Plan grants a formulary exception request, the Plan does not limit or exclude coverage if the prescribing provider continues to prescribe the drug and the drug is appropriately prescribed for treating the enrollee's medical condition. In addition, the Plan provides coverage of the nonformulary drug for the duration of the prescription, including refills.

If the Plan grants an expedited formulary exception request, the Plan provides coverage of the nonformulary drug for the duration of the exigency.

If the Plan grants an external exception review request for a standard nonformulary and expedited nonformulary request, the Plan provide coverage of the non-formulary drug for the duration of the prescription and exigency.

The Plan conforms effectively and efficiently with the continuity of care requirements of the Act and regulations. In circumstances where an enrollee is changing plans and VCHCP is the new Plan, VCHCP does not require the enrollee to repeat step therapy when that enrollee is already being treated for that medical condition by a prescription drugs provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. Nothing in this section shall preclude the new Plan from imposing prior authorization requirement pursuant to Section 1367.24 for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former plan, or preclude the prescribing provider from prescribing another drug covered by the new plan that is medically appropriate for the enrollee. For purposes of this section, "step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

For Renewal of Prior Authorized Medications, the MM Nurse may renew the following:

Medications requiring a prior authorization previously authorized by the MM Nurse (according to Pharmacy and Therapeutics Committee criteria) or by the Medical Director or Utilization Review Physician when a VCHCP physician continues to prescribe the drug without a break for >130 days for the member for the same condition.

Authorization numbers are valid for prescription refills up to one year. If the member has paid for the refill, and it would be otherwise approved, retroactive authorization may be made by the MM Nurse. The member may return to the Pharmacy for a refund or the member may submit a claim form to the PBM.

Exceptions/Limitations include the following:



- Claims processed in error related to member's eligibility are excluded.
- Drugs prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA are excluded.
- Generic drug substitution is required, unless the prescriber indicates "dispense as written" and the brand name drug is authorized by the Plan.
- Coverage is subject to the copayments and maximums of the member's pharmacy benefit.
- When the Competitive Pricing Class closes and the drug is no longer available through our PBM, written notification is made to those members with recent claims for the deleted drug and to their prescribing providers. The letter will provide the names of alternate drugs of similar efficacy covered by the Plan and a reasonable grace period to transition to the new drug.
- A. Supporting Documents: See Drug Policy: Pain Management for Terminally III Patients; See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards; TAR Timeframe Workflow Grid
- B. References: None
- C. History: Created: Catherine Sanders, MD July 2013

Reviewers: Pharmacy & Therapeutics Committee; Quality Management Committee; Medical Director; Senior Level Physician; Director of Health Services Date Approved by P&T Committee: 7/23/13; QA Committee: 8/27/13 Date Approved by P&T Committee: 1/28/14; QA Committee: 2/25/14 Date Approved by P&T Committee: 1/27/15; QA Committee: 2/24/15 Date Approved by P&T Committee: 1/26/16; QA Committee: 2/23/16 Date Approved by P&T Committee: 10/25/16; QA Committee: 11/22/16 Date Approved by P&T Committee: 1/24/17; & QA Committee: 2/28/17 Date Approved by P&T Committee: 1/23/18; & QA Committee: 2/27/18 Date Approved by P&T Committee: 10/30/18; & QA Committee: 11/27/18 Date Approved by P&T Committee: 1/22/19; & QA Committee: 2/26/19 Date Approved by P&T Committee: 4/23/19; & QA Committee: 5/28/19 Date Approved by P&T Committee: 2/28/20; & QA Committee: 2/25/20

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
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1/26/2016	No	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual review
10/25/16	Yes	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Updated with DMHC definition of urgent and including prior authorization of non- formulary drugs, and if applicable, certain formulary drugs, and any request for a step therapy exception in the Plan's processing of request for prescriptions.
1/24/17	Yes	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual Review and updated with DMHC definition of "exigent circumstances" and review turnaround time of 24 hours from receipt of request.
1/23/18	No	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual review
9/13/18	Yes	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	See UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards for details of authorization process and timeline standards for medications.
1/22/19	Yes	Faustine DelaCruz, RN; Meriza Ducay, RN; Robert Sterling, MD Catherine Sanders, MD	 DMHC required updates: Annual Review Provider submission of request procedure with the use of DMHC required form Added reference to EOC for enrollees to request nonformulary drugs Timelines for Decisions especially with Exigent request Review/Decision making: verbal authorization to pharmacy or requesting physician Appeals process to clarify how members can obtain Independent Medical Reviews



Drug Policy:

Prior Authorization of Medications Effective: 07/23/2013 Review Date: 01/28/14; 1/27/15; 1/26/16; 10/25/16; 1/24/17; 1/23/18, 10/30/18, 1/22/19, 4/23/19; 2/18/20

			 Notification process especially exigent requests Continuation of drug therapy: clarified that the Plan grants approval for the duration of exigency and if drug is appropriately prescribed Reference to: Drug Policy: Pain Management for Terminally III Patients Reference to UM Policy: Treatment Authorization Request: Authorization Process and Timeline Standards; TAR Timeframe Workflow Grid
1/22/19	Yes	Faustine DelaCruz, RN; Meriza Ducay, RN; Robert Sterling, MD Catherine Sanders, MD	The Plan adopted all Express Scripts Drug Policies including the following hierarchy use of policy/criteria: (1) Express Scripts Drug Policy; (2) MCG if there is no Express Scripts Drug Policy; (3) Custom VCHCP Drug Policy if there is no Express Script Drug Policy and no MCG; (4) Send to Physician Reviewers to use compendia such as UpToDate or NCCN, if there is no Express Scripts Drug Policy, no MCG, no Custom VCHCP Drug Policy.
4/23/19	Yes	Faustine DelaCruz, RN; Meriza Ducay, RN; Robert Sterling, MD Catherine Sanders, MD	The Plan conforms effectively and efficiently with the continuity of care requirements of the Act and regulations. In circumstances where an enrollee is changing plans and VCHCP is the new Plan, VCHCP does not require the enrollee to repeat step therapy when that enrollee is already being treated for that medical condition by a prescription drugs provided that the drug is appropriately prescribed and is considered safe and effective for



2/18/20	No	Faustine DelaCruz, RN;	the enrollee's condition. Nothing in this section shall preclude the new Plan from imposing prior authorization requirement pursuant to Section 1367.24 for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former plan, or preclude the prescribing provider from prescribing another drug covered by the new plan that is medically appropriate for the enrollee. For purposes of this section, "step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.
2,10,20		Howard Taekman, MD	Annual Review