



# **PRESCRIPTION MEDICATION BENEFIT PROGRAM**

**2019**

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## THE DRUG BENEFIT PROGRAM OF THE VENTURA COUNTY HEALTH PLAN

The Ventura County Health Care Plan (VCHCP) offers its members an outpatient prescription medication benefit that includes generic and brand-name medications.

VCHCP provides a closed drug plan or Preferred Drug List (PDL) or Formulary that is based on Express Scripts' "High Performance Formulary". In addition to the generic and brand name drugs on its PDL, VCHCP also covers many other medications that are classified as "non-preferred". Medications not on the PDL may be available, through a prior authorization process and usually require a higher co-pay.

VCHCP utilizes a four-tier drug classification system to determine the amount of the patient's cost share, or copayment. Drugs classified as either Tier 1, Tier 2, or Tier 4 constitute VCHCP's Preferred Drug List (PDL). A description of the criteria for the four medication classification tiers follows:

**Tier 1** includes all covered generic medications and are available at the lowest copayment to the patient. When appropriate, physicians are encouraged to prescribe generic medications to help patients save money and to help control health care costs. If the patient or physician requests a brand-name medication when a generic is available, in addition to the copay, the patient pays the difference in cost between the brand-name medication and the generic.

**Tier 2** includes brand-name medications for which there is generally only a single manufacturing or distributing source. These medications are described in the industry as "single source brands." The patient pays a higher copayment for these than for Tier 1 generic medications.

**Tier 3** includes those covered medications considered to be non-preferred. Generally a medication is considered non-preferred if VCHCP's Pharmacy Benefit Manager (PBM) has determined that there are one or more therapeutically-equivalent drug alternatives available to the patient on either Tier 1 or Tier 2. The patient pays the highest copayment amount for these medications.

**Tier 4** includes "Specialty Medications" – Specialty pharmaceuticals, primarily injectables, represent a relatively new area of prescription medications, one with a small market in terms of patient populations. Yet it is the single most explosive market in terms of growth and cost. In 2009, VCHCP implemented an integrated approach to managing today's most sophisticated pharmaceuticals. Some of the components include:

- Specialty pharmacy management program, including delivery, pharmacy partnerships and home infusion network coordination to cover all delivery options.
- Utilization analysis and care management to ensure appropriate treatment initiation and continuation.
- Single source for specialty pharmacy efforts to simplify and standardize billing.

| 2018 MEMBER COST-SHARE  |  |  |
|---|--|--|
| PREFERRED DRUGS   |  | NON-PREFERRED DRUGS                            |
| Tier 1  | Tier 2   | Tier 3   |
| GENERIC   | SINGLE-SOURCE BRAND                            | MULTI-SOURCE BRAND                             |
| \$9 Retail Copay  | \$30 Retail Copay                              | \$45 Retail Copay                              |
| \$18 Mail-Order Copay   | \$60 Mail-Order Copay                          | \$90 Mail-Order Copay                          |
| \$18 Retail Copay (Voluntary Smart 90 Program)  | \$60 Retail Copay (Voluntary Smart 90 Program) | \$90 Retail Copay (Voluntary Smart 90 Program) |
| <b>Tier 4 – Specialty drugs:</b> 10% of cost per prescription, up to \$250 maximum per prescription per month |  |  |

| EXAMPLES   |                     |                     |
|--|---------------------|---------------------|
| PREFERRED DRUGS  |                     | NON-PREFERRED DRUGS |
| Tier 1   | Tier 2              | Tier 3              |
| GENERIC  | SINGLE-SOURCE BRAND | MULTI-SOURCE BRAND  |
| lovastatin   | Crestor             | Lipitor             |
| lisinopril   | Diovan              | Cozaar              |
| omeprazole   | Nexium              | Aciphex             |
| <b>Tier 4 – Specialty drugs:</b> Enbrel, Copaxone, Ribavirin, Pegasys, et. al. |                     |                     |

***This tiered copay structure pertains to commercial benefit plan members only.***

The Ventura County Health Care Plan Pharmacy and Therapeutics Committee (P&T Committee) has reviewed and accepted the DRUG BENEFIT PROGRAM. This Committee, comprised of physicians from various medical specialties (see included grid), reviews reports and recommendations from expert physician and pharmacist panels. The Committee in turn bases its recommendations on these sources of information, while making modifications to reflect local practice patterns and preferences.

### **COVERAGE FOR MENTAL HEALTH PARITY PRESCRIPTIONS**

VCHCP requires a review for branded antidepressants, injectable psychotherapeutics, certain miscellaneous psychotherapeutic agents like Modafinil, Provigil, and Xyrem, and quantity limits for select antidepressants and antipsychotics. Branded antidepressants are reviewed for appropriate use of generic alternatives prior to use of brands as necessary. Prior authorizations on injectable products help ensure appropriate, FDA indicated use. Quantity limits ensure use of appropriate strength and dosage forms for antidepressants and antipsychotics with exceptions available upon request. A similar methodology of management is used for other medication classes outside of psychotherapeutics.

### **NON-PRESCRIPTION MEDICATION (OTC) POLICY**

With the exception of aspirin used for appropriate prophylactic indications, as well as certain OTC medications requiring a \$0 co-pay per the Affordable Care Act requirements, over-the-counter (OTC) products are not covered, although some may be listed here for informational purposes only.

Absent those exceptions, if an OTC product equivalent to a prescription product is available, then neither the prescription product nor the OTC product will be covered by the Plan. Physicians and pharmacists should refer members to the OTC equivalent product, which is then to be purchased over-the-counter by the member.

If an OTC product is available, and if that product exists in a different dose or in another form, and if that alternative product can **only** be obtained with a prescription, then that medicine is to be considered covered, and the usual rules for providing the prescription are in effect. (See **Copay Determination # 5** below.)

If the member or physician insists on the prescription equivalent product to the OTC drug, and the two preparations are equivalent, the member must pay the entire cost of the prescription, regardless of the cost, even if the prescribed medication would be more expensive than the OTC product.

## GENERIC DRUG POLICY

Specified drugs with generic equivalents should be prescribed and dispensed in the generic form. The generic drug will then be available at the Tier 1 level, with rare exceptions. The brand name drugs are indicated by CAPITALS in the drug formulary. The generic form is in *italics*. Providers are reminded of the following:

1. When generic substitution conflicts with state regulations or restrictions, the pharmacist must obtain approval from the prescribing medical care professional to use the generic equivalent.
2. Pharmacists are reminded that a drug in CAPITALS indicates that one or more (but not necessarily all) forms of the drug are subject to a “Maximum Allowable Cost” or “MAC”. In such a case, the pharmacist should consult the MAC list.
3. If a physician indicates “Dispense As Written” (“DAW”), or “Do Not Substitute” (“DNS”), or if a member insists on the brand named product for which an equivalent generic product is available, then the patient must pay the applicable copay plus the cost difference between the brand-name product and the MAC amount.

## UNAPPROVED USE OF FORMULARY MEDICATIONS

Medications are generally covered only if they are FDA-approved medications, and are used for non-experimental indications. Non-experimental indications include the labeled indication(s) (FDA-approved) and other indications accepted as effective by the balance of currently available scientific evidence and informed professional opinion. This so-called "off-label" use may place the medication in a higher tier for purposes of determining the copay, or it may be that such use is not a covered treatment, under any condition, in which case the member will bear the entire cost of the prescription. See Coverage of Prescription Medication For Off Label Use policy for details. Finally, drugs used for cosmetic purposes are not eligible for coverage, under any condition.

## QUANTITY LIMITS

Some formulary medications have a Quantity Limit which is applied against the written prescription. These are designated with QL on the formulary list, corresponding to the Drug

Quantity Management program adopted from the Plan’s Pharmacy Benefit Manager, Express Scripts (ESI). If, for instance, the number of doses of a certain drug exceeds the QL, then the member will receive only the allowed number, as shown in the QL list. With some exceptions, QLs are generally the amount allowed over a thirty (30) day period when purchased at a participating pharmacy, or for ninety (90) days if purchased by mail order. (It should be noted that not all drugs are available through mail order. In particular, **injectable drugs and drugs for insomnia, erectile dysfunction, and headaches may not be available by mail order.**)

## EXCLUDED MEDICATIONS

Certain medications are specifically excluded from coverage, as noted in the EVIDENCE OF COVERAGE. These include dietary supplements, cosmetics or medications used for cosmetic purposes (i.e. retinoic acid for wrinkles), and medications to treat baldness.

A few drugs are specifically excluded because they are not included in a competitive pricing category (CPC). In each case alternative drugs are available in that therapeutic category. These excluded drugs are therefore not covered by the plan.

## COPAY DETERMINATION

The table below describes the copay which will be charged to the patient when filling a prescription. (See above “Generic Drug Policy” for additional conditions and payments which apply when certain non-generic drugs are provided.)

|    | Type of Prescription   | Member’s Co-Pay  | Comments   |
|----|--|--|--|
| 1. | Generic formulation is available and furnished by a network pharmacy.  | Tier 1<br>\$9 Retail Copay   | \$18 (if a 3 mo. supply by mail -Mail-Order Copay)<br>\$18 (if a 3 mo. supply via retail through voluntary Smart 90 Program – Retail Copay)  |
| 2. | Preferred Drug but only brand-name or single-source is available.  | Tier 2<br>\$30 Retail Copay  | \$60 (if a 3 mo. supply by mail - Mail-Order Copay)<br>\$60 (if a 3 mo. supply via retail through voluntary Smart 90 Program – Retail Copay) |
| 3. | Non-Preferred Drug except if excluded.<br>(See excluded drugs.)<br>Certain drugs must be prior authorized before the prescription will be covered by the Plan. | Tier 3<br>\$45 Retail Copay  | \$90 (if a 3 mo. supply by mail - Mail-Order Copay)<br>\$90 (if a 3 mo. supply via retail through voluntary Smart 90 Program – Retail Copay) |
| 4. | Brand Drug for which a generic preparation is available, but physician and/or member insist on a brand name drug.  | Member pays, in addition to copay, difference in cost between generic and brand drug, up to 100% of cost of brand drug | Tier 3 copay   |

|    | Type of Prescription   | Member's Co-Pay   | Comments  |
|----|--|---|---|
| 5. | Over the counter (OTC) preparation when the equivalent drug is available as a prescription drug and is equal in dosage.  | Member pays full cost if the OTC strength of the drug and the strength of the drug by prescription are the same | Although a physician may have written the prescription, this is not a covered benefit if the drug is available OTC at the same strength.  |
| 6. | Drugs for treatment of non-covered conditions.   | Member pays full cost   | Regardless of a drug being on or off the PDL, if a drug is prescribed for a non-covered condition, the member pays full cost.   |
| 7. | Investigational Drugs: FDA approved for retail sales, but investigation is for treatment of medical diagnoses not otherwise approved by the FDA (or not supported by informed medical opinion or the peer reviewed medical literature).  | Tier 3 copay or actual drug cost  | Can only be prescribed for the specific investigation of a condition(s) covered under the Plan; requires prior authorization.   |
| 8. | <u>Not</u> FDA approved for retail sales, but is in a formally approved study, (phase II or greater).  | Actual drug cost  | Not covered by Plan.  |
| 9. | All "specialty" medications, including injectables (see exceptions below) used for the treatment of chronic conditions (other than diabetes), such as hepatitis C, multiple sclerosis, rheumatoid arthritis, and HIV/AIDS.<br><br>VCHCP utilizes Accredo, a division of Express Scripts, to manage our specialty medication program. | Tier 4<br>10% of cost per prescription, up to \$250 maximum per prescription per month                          | All injectables (see exceptions below), require prior authorization and may also be subject to certain Drug Quantity Management Limits (DQM). (Does not include injectable(s) given during an office visit.) For the current QL list (at the time of publication) please see the PA/DQM/ST list on each page. |

Note that VCHCP complies with all mandated Healthcare Reform requirements regarding preventive items and services requiring a no copay designation. These items are notated on the formulary with an Affordable Care Act (ACA) requirements/limit which keys to a no copay.

**VCHCP** utilizes a 4-tier structure for the categorization of prescription medications and member cost share (copayments): Tier 1-Generics, Tier 2–Preferred brand drugs, Tier 3–Non-preferred brand drugs, and Tier 4-Specialty drugs.

The fourth tier, **Specialty Drugs**, are high-cost medications and biologicals, regardless of how they are administered (injectable, oral, transdermal, or inhalant). These drugs have the highest level of copayment within VCHCP's drug benefit program. These medications are often used to treat complex clinical conditions and usually require close management by a physician because of their potential side effects and the need for frequent dosage adjustments.

The major conditions that these drugs treat include, but are not limited to:

- > Cancer
- > Hemophilia
- > Hepatitis C
- > HIV/AIDS
- > Infertility
- > Multiple sclerosis
- > Crohn's disease
- > Rheumatoid arthritis
- > Growth hormone deficiency
- > Pulmonary Arterial Hypertension

Because of the seriousness of the patients' medical conditions, the high cost of the drugs, and the complexity of medication management, effective December 1st, 2009, VCHCP utilizes a company known as Accredo to manage our specialty medication program. Accredo is a sub-division of Express Scripts, the plan's pharmacy benefit manager.

**Accredo's only business is to manage the care of patients receiving specialty medications. They realize that treatment with specialty medications can be difficult and stressful for patients, and they do everything they can to make it as simple as possible. They understand that each patient is different and has different needs. When a patient first enrolls in the program with Accredo, the first person they are contacted by is a patient care coordinator, a professional caregiver who is dedicated to making sure they receive the best possible treatment. Coordinators work with a team of pharmacists, nurses, the prescribing physician and VCHCP to make sure the member receives optimum care.**

## **MEDICATIONS REQUIRING PRIOR AUTHORIZATION**

Using the tier system described above, for Tiers 1, 2 and 3, most medications are available by proper prescription. However, the Pharmacy & Therapeutics Committee may designate any preferred or non-preferred medication as requiring prior authorization (PA). Generally these are high cost medications or medications for which medical necessity must be demonstrated. In general, the prior authorization list includes all injectables (with the exception of insulins, epinephrine, headache medications, medroxyprogesterone acetate and all approved immunization products); all growth hormones; all infertility drugs; and most antivirals/protease inhibitors except Acyclovir, Amantadine, Famciclovir, Valacyclovir, Denavir, Famvir, Flumist, Relenza, Ramiflu, Tyzeka, Valtrex and Xerese. This list is not all inclusive. For the most current list of PA drugs, please see the PA/QL/ST column on each page of the formulary. From time to time, additional drugs may be added to the prior authorization list. Physicians will receive updates on these additions as described under NOTIFICATIONS.

For those medications requiring prior authorization, the Plan should be notified by the prescribing physician who will submit medical justification for using the drug. See Prior Authorization of Medication Policy.

## **STEP THERAPY (ST)**

In collaboration with Express Scripts, VCHCP has implemented step therapy programs for several different classes of drugs for which specific medications, designated as Step 2 drugs, will only be approved after a trial of Step 1 medications has been documented or under certain other conditions. Examples of classes of medications covered by this program include Angiotensin Converting

Enzymes (ACE), Angiotensin Receptor Blockers (ARBs), Brand Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), COX 2 inhibitors, Proton Pump Inhibitors (PPIs), Selective Serotonin Reuptake Inhibitors (SSRIs), Other Antidepressants (SNRIs), Cholesterol Lowering medications (statins) and certain diabetic medications.

See the most recently approved Step Therapy Program for details.

If an exception from the step therapy protocol is sought, prior authorization should be obtained. If a physician or member insists on non-authorized use of a step therapy drug, the member will be responsible for 100% of the prescription cost.

## **SMOKING CESSATION**

In compliance with the Affordable Care Act requirements, the following smoking cessation interventions are covered without cost sharing (\$0 co-pay): FDA-approved smoking cessation drugs, including generics that require a prescription and generics available over the counter (OTC), for adults 18 years of age and older with a limit of 90 days in 365 days; brand name Chantix with a limit of 180 days in 365 days; other brand name interventions when generics are contraindicated. Once these limits are met, the drug is no longer covered.

## **VACCINES**

Refer to the formulary for available covered vaccines.

## **FORMULARY DEVELOPMENT AND MAINTENANCE PROCESS**

The Ventura County Health Care Plan (VCHCP) includes coverage for prescription medications throughout its various lines of business. The administration of a medication benefit program is highly complex, specialized, and subject to frequent change.

For those reasons VCHCP contracts with a company named “Express-Scripts”, referred to in the industry as a Pharmacy Benefit Manager, or PBM, to manage its program. Management of the program includes various functions and responsibilities such as: contracting with pharmacies, reimbursing contracted pharmacies for dispensed drugs, selecting and evaluating appropriate medications for the plan’s preferred drug list (formulary), providing customer services to plan members and providing the plan with member cost and utilization information.

Express Scripts maintains a staff of clinical professionals who develop and maintain all clinical programs, including formulary development and maintenance, on behalf of the Ventura County Health Care Plan. Given the amount of research and specialized knowledge needed to evaluate all aspects of a given medication, Express Scripts’ clinical professionals, which include registered pharmacists and doctors of pharmacy (PharmDs), are divided into several committees for purposes of drug evaluation and formulary development. Each committee is dedicated to a specific area of research and performs a specific step in the formulary evaluation process.

Express Scripts' Drug Evaluation Unit, Therapeutic Assessment Committee, and Value Assessment Committee follow a three-step evaluation process for all medications before forwarding their recommendations to the Express Scripts National P&T Committee for final formulary placement decisions and formulary placement recommendations to clients with their own P&T committees. Steps include:

- Primary Research (Drug Evaluation Unit)
- Comparative Evaluation (Therapeutic Assessment Committee)
- Financial Evaluation (Value Assessment Committee)

During the first two stages, Express Scripts considers only clinical information. The Value Assessment Committee only evaluates a product's cost-effectiveness when the clinical parameters have first been established by the Therapeutic Assessment Committee.

## **PRIMARY RESEARCH**

Express Scripts' Drug Evaluation Unit pharmacists research all drugs newly approved by the FDA. The unit develops and writes clinical evaluations on new products. The unit's primary responsibility involves evaluating the safety and efficacy concerns for each drug for both approved and non-approved (i.e., "off-label") indications. Pharmacists in the Drug Evaluation Unit also determine the drug's clinical position relative to therapeutic alternatives such as within the same class of medications.

Drug Evaluation Unit pharmacists use specialized medical databases that feature published clinical trials and peer-reviewed medical literature. The Drug Evaluation Unit also contacts pharmaceutical manufacturers for FDA-approved package inserts, and any data from pivotal trials that were submitted to the FDA. The unit may also contact primary investigators, physicians and medical specialists, or use information from medical associations, national commissions or authoritative compendia to obtain additional information. The unit uses all the information collected to evaluate relevant aspects of new drugs, including side effects profiles, drug interactions, dosing issues, clinical efficacy, and comparative efficacy.

For each new drug, the Drug Evaluation Unit compiles its findings and recommendations into a formulary evaluation document. This document is forwarded to the Therapeutic Assessment Committee.

## **COMPARATIVE EVALUATION**

The Therapeutic Assessment Committee performs comparative evaluation of products. This committee includes clinical pharmacists with advanced training in general or specialized clinical practice, including clinical research and clinical study design.

Members of the Therapeutic Assessment Committee perform the following tasks for new products being considered for formulary placement:

- Establish one of the following parameters for a drug product: include, optional, exclude.
- Establish the clinical parameter for competitive product categories or therapeutic category (that is, establishes the clinical threshold for the level of product exclusivity).
- Outline the clinical attributes for each product within a therapeutic category and/or competitive product category by evaluating evidence showing how recommended preferred-status pharmaceuticals can produce similar or better results for a majority of the population than other pharmaceuticals in the same class.

Based on the Drug Evaluation Unit's findings, the committee critically evaluates a new drug to identify issues related to its use. The committee also compares the drug's clinical merits with any therapeutic alternatives that are already on the market and available to physicians.

Based on the assessment of clinical factors, the Therapeutic Assessment Committee determines the drug's viability for placement on a formulary. The committee decides whether the new product is essential or optional for formulary inclusion, or identifies clinical concerns that make it ineligible for formulary inclusion.

The Therapeutic Assessment Committee then forwards its recommendations to the Value Assessment Committee.

## **FINANCIAL EVALUATION**

The Value Assessment Committee establishes formulary recommendations in accordance with the clinical parameter, clinical attributes, and financial considerations. The committee's recommendations must be consistent with the clinical recommendations set forth by the Therapeutic Assessment Committee.

The committee includes both clinical and financial professionals from several Express Scripts departments, including:

- Formulary management
- Pharmaceutical manufacturer contracting
- Drug administration
- Clinical program managers from each business division
- The Express Scripts associate medical officer

The Value Assessment Committee ultimately combines the clinical recommendations with cost considerations and makes an official formulary recommendation.

Finally, recommendations from the Value Assessment Committee and Therapeutic Assessment Committee are presented to the Express Scripts National P&T Committee. The Express Scripts National P&T Committee makes final formulary placement decisions for Express Scripts formularies.

The national P&T committee approves or disapproves recommended clinical designations presented by the Therapeutic Assessment Committee. The P&T committee decides whether a product should be included or excluded, or whether it is optional for formulary inclusion. In making its decision, the P&T committee has access to average wholesale price information only, which is publicly available. However, AWP information is not used in making an inclusion or exclusion decision. In addition, the committee does not have access to, nor does it consider, any

information regarding Express Scripts' rebates or negotiated discounts, or the net cost of the drug after application of all discounts.

The Express Scripts National P&T Committee includes 19 independent physician members. The committee elects its own physician chair. The Express Scripts medical director and five clinical pharmacists provide ongoing staff support to the national P&T committee. The P&T committee board membership affirms a sufficient number of clinical specialties to adequately meet the need of enrollees and consists of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs. Membership includes psychiatrists, pediatricians and other specialty physicians. Members of the P&T committee board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the health plan or pharmaceutical manufacturer.

At least 20 percent of the P&T board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.

The VCHCP P&T Committee retains the final decision making for all Pharmaceutical Management recommendations from Express Scripts and other sources.

## **REQUESTING COPIES OF THE PREFERRED DRUG LIST**

Copies of the most current PDL are available to members and providers, upon request. Requests are submitted to the Plan at the contact information as noted below.

## **REVISING THE PREFERRED DRUG LIST**

Express Scripts, the PBM, reviews the current PDL on a quarterly basis, evaluates any new pharmaceutical information available and researches medications newly approved by the FDA as the information becomes available. The PBM's recommendations for any changes are forwarded to VCHCP's P&T Committee for review and adoption.

In the case that a physician desires that a product, presently non-preferred, be placed on the preferred drug list, or a newly approved drug to be added to the formulary, an application should be made to the Pharmacy & Therapeutics Committee (P&T) of the Plan. The application should include a description and explanation of the product, including but not limited to, the nature of the drug and the therapeutic benefits to be derived from using it, the presence or absence of alternatives, the cost-benefit ratio of the drug, and the general use of the drug by the medical community. This information will help the P&T Committee make recommendations to the Pharmacy Benefits Manager. Physicians, members or pharmacists may also forward any concerns regarding adding, deleting or changing tiers of pharmaceuticals on the formulary to the P&T Committee.



All inquiries or requests should be directed to:

Ventura County Health Care Plan  
Attn: Utilization Department  
2220 E. Gonzales Road #210-B  
Oxnard, CA 93036

Telephone: (805) 981-5050  
Facsimile: (805) 981-5026  
E-mail to [VCHCP.Admin@ventura.org](mailto:VCHCP.Admin@ventura.org)

Upon receiving any information or input regarding pharmaceuticals, the requestor will be sent an acknowledgement of receipt of information and follow-up procedure, by mail or fax, depending on how the request was received. If received by phone call, the information will be given at the time of the call, or if message left, the information will be sent by mail. The Plan will forward the received information to the PBM for evaluation through the Formulary Development and Maintenance Process. The decision from the PBM will then be brought to the VCHCP P&T Committee for final determination and formulary will be updated if appropriate. The final determination decision will be sent to the requestor by mail or fax as above.

#### **SUBMITTING EXCEPTION REQUESTS TO THE PREFERRED DRUG LIST**

Members can initiate individual exception requests to the preferred drug list through their primary care practitioner or directly to VCHCP by phone or through the VCHCP website. Practitioners may themselves also initiate a petition for consideration of coverage. Practitioners and/or members should include relevant clinical history, previous medications prescribed and tried, contraindications or allergies to medications and any other contributory information deemed useful. VCHCP will review the information according to the Prior Authorization (PA) policy. Because the PA requests are reviewed by the plan and not the PBM, if the medication does not meet criteria on initial review by the nurse reviewer, it is reviewed by a physician reviewer and special consideration is given to the exception request based on the information received. When needed, the physician reviewer may contact pharmacist specialists at ESI for additional information. The physician reviewers are also available by phone to discuss an exception request with the practitioner or member. See the PA policy for more information. Note that as for any medical necessity denial, with a denial of an exception request, the reason for the denial is clearly stated and the formal appeals process is available.

#### **Patient Safety Issues:**

VCHCP has delegated to Express Scripts the identification and notification of members and practitioners affected by Class I and Class II recalls and drug withdrawals for patient safety reasons, including voluntary withdrawals by the manufacturer or those under an FDA requirement. See attached policy from Express Scripts for details.

Oversight and monitoring of this policy occurs regularly. Express Scripts notifies the Medical Director with any recall information and if any of the plan's members are affected. Annually, the Medical Director monitors Express Scripts for timeliness of notification as well as reviewing the FDA database for identified recalls and appropriate application of Express Scripts' policy.

See ESI delegation policy and delegation oversight plan document.

## **NOTIFICATIONS**

Annually and after updates, VCHCP communicates the procedures for Pharmaceutical Management to members through a variety of vehicles such as a mailed annual summary of benefit booklet, semiannual newsletters that are available via mail and e-mail and through the Plan's website. This information supplies a list of pharmaceuticals, including restrictions and preferences, explanations of the use of the pharmaceutical management procedures and an explanation of quantity limits, generic substitutions, step therapy and exceptions process protocols. Also included is information regarding how additional formulary updates made throughout the year will be communicated. When the Plan notifies members with fax or e-mail access, it uses an alternative approach, such as direct mailings, for members without fax or e-mail access. When information is distributed through the Website, the Plan uses the appropriate mail, fax or e-mail to notify members that the information is available.

For any "negative" formulary changes (i.e. changes that result in restrictions or replacements) occurring during the year, members are notified of such changes through the VCHCP website and individually affected members are notified by mail.

Annually and after updates, VCHCP communicates the procedures for Pharmaceutical Management to practitioners through a variety of vehicles such as mail, fax, email, newsletters and through the Plan's Website. This information describes the use of the Pharmaceutical Management procedures including prior authorization criteria and timelines, the specialty medication program, exception request procedure and formulary including tiers, preferred and restricted medications, quantity limits, step therapy, excluded medications, copays and generic substitutions. Also included in the annual notification is information regarding how additional formulary updates made throughout the year will be communicated. When the Plan notifies practitioners with fax or e-mail access, it uses an alternative approach, such as direct mailings, for practitioners without fax or e-mail access. When information is distributed through the Website, the Plan uses the appropriate mail, fax or e-mail to notify practitioners that the information is available. For any "negative" formulary changes occurring during the year, VCHCP may elect to notify only the affected providers by mail.

The PBM has an expedited process for prompt identification and notification of members and prescribing practitioners affected by a Class I Recall. The PBM also identifies and notifies members and prescribing practitioners affected by a Class II recall or voluntary drug withdrawal from the market for safety reasons within 30 calendar days of the FDA notification.

## **ANNUAL REVIEWING AND UPDATING OF PROCEDURES**

The VCHCP Pharmacy and Therapeutics Committee (P&T Committee) meets quarterly and, at least annually, reviews and updates, as appropriate, the Pharmaceutical Management policies and procedures. VCHCP and Express Scripts P&T Committees are committed to the following:

1. Develop and document procedures to ensure appropriate drug review and inclusion
2. Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other related information
3. Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs
4. Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange
5. Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually
6. Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug
7. Review new United States Food Administration-approved drugs and new uses for existing drugs
8. Ensure that the plan's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and do not discourage enrollment by any group of enrollees
9. Ensure that the plan's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

The formulary is reviewed semiannually, initially through the ESI P&T Committee and subsequently through the VCHCP P&T Committee, and updated as appropriate. The ESI P&T Committee and subsequently through the VCHCP P&T Committee, develops, maintains and oversees the Plan's drug formulary list. The Plan retains the ultimate responsibility for its drugs formularies. Upon adoption of the updated formulary, Member Services refers to the updated formulary grid as of the effective date of the changes. The ESI website, including benefit information, is also updated as of the effective date of the changes. The most up-to-date ESI website formulary information is accessible to members and providers at [www.express-scripts.com](http://www.express-scripts.com) and through a link on the VCHCP website at [www.vchealthcareplan.org](http://www.vchealthcareplan.org) or by calling Express Scripts. Procedures and the formulary may also be updated on an ongoing such as on a monthly basis and, as needed basis when new pharmaceutical information is received or requested by members, pharmacists, practitioners or other sources, using the expertise of the PBM. For any new drugs made

available, requests for formulary changes by VCHCP or any recalls or other “negative” formulary changes that occur between these semiannual updates, ESI formats the changes and communicates this to VCHCP. Member Services staff uses the updated formulary and ESI updates their website as of the effective date of the occurrence. Since the material used by member services is the ESI formulary, the members receive the most up to date information regarding their pharmaceutical information. Similarly, ESI telephone staff use the ESI website to communicate to the members the most recent information available regarding pharmaceuticals and benefits. See attached ESI policies and the Member Services Program Description for details of formulary updates and information given to members.

### **VCHCP PHARMACY AND THERAPEUTICS COMMITTEE**

The P&T Committee is comprised of VCHCP physicians and QA management staff, community physicians from different specialties and management staff and pharmacists from the PBM. The P&T Committee reports to the QA Committee which reports to the Standing Committee.

### **RELATED POLICIES:**

1. Coverage of Medication for Off-Label Use
2. Pain Management for Terminally Ill Patients
3. Prior Authorization Program Policy and Procedure

### **A. Attachments:**

### **B. References:**

### **C. History:**

Committee Reviewers: Pharmacy & Therapeutics Committee;  
Quality Management Committee; Medical Director; Senior Level Physician; Health  
Services Director; QA/CM Manager: Effective Date: April 24, 2006  
Reviewed/Approved: P&T: April 24, 2006  
Reviewed/Approved: QAC: May 23, 2006  
Reviewed/Approved: P&T: April 30, 2007  
Reviewed/Approved: QAC: May 22, 2007  
Reviewed/Approved: P&T: February 4, 2008  
Reviewed/Approved: QAC: April 28, 2008  
Reviewed/Approved: P&T: January 25, 2011  
Reviewed/Approved: QAC May 24, 2011  
Reviewed/Approved: P&T: January 31, 2012  
Reviewed/Approved: P&T: July 23, 2013  
Reviewed/Approved: QAC August 27, 2013  
Reviewed/Approved: P&T: July 17, 2014  
Reviewed/Approved: QAC: August 7, 2014  
Reviewed/Approved: October 20, 2014

Reviewed/Approved: P&T: October 28, 2014  
 Reviewed/Approved: QAC: November 25, 2014  
 Reviewed/Approved: P&T: January 27, 2015  
 Reviewed/Approved: QAC: February 24, 2015  
 Reviewed/Approved: P&T: January 26, 2016  
 Reviewed/Approved: QAC: February 23, 2016  
 Reviewed/Approved: P&T: October 25, 2016  
 Reviewed/Approved: QAC: November 22, 2016  
 Reviewed/Approved: P&T: January 24, 2017  
 Reviewed/Approved: QAC: February 28, 2017  
 Reviewed/Approved: P&T: January 23, 2018  
 Reviewed/Approved: QAC February 27, 2018  
 Reviewed/Approved: P&T: January 22, 2019  
 Reviewed/Approved: QAC February 26, 2019

| Revision Date | Content Revised (Yes/No) | Contributors  | Review/Revision Notes  |
|---------------|--------------------------|---|--|
| 1/26/2016     | Yes                      | Faustine DelaCruz, RN;<br>Catherine Sanders, MD;<br>Robert Sterling, MD | Annual review, Tier 4 Specialty Medication Co-Payment Update   |
| 10/25/2016    | Yes                      | Faustine DelaCruz, RN;<br>Catherine Sanders, MD;<br>Robert Sterling, MD | DMHC language requirement  |
| 1/24/17       | Yes                      | Faustine DelaCruz, RN;<br>Catherine Sanders, MD;<br>Robert Sterling, MD | Annual Review, under Non-Prescription Medication (OTC) Policy, removed Prilosec OTC as an exception                                |
| 1/23/2018     | Yes                      | Faustine DelaCruz, RN;<br>Catherine Sanders, MD;<br>Robert Sterling, MD | Annual Review, added retail copayment information for a 3-month supply via retail pharmacy through the voluntary Smart 90 Program. |
| 2/28/2018     | Yes                      | Faustine DelaCruz, RN;<br>Catherine Sanders, MD;<br>Robert Sterling, MD | Removed reference to AIM program under Prior Authorization section.  |
| 10/9/2018     | Yes                      | Faustine DelaCruz, RN;<br>Catherine Sanders, MD;<br>Robert Sterling, MD | Vaccines: Refer to the formulary for available covered vaccines.   |
| 1/22/19       | No                       | Faustine DelaCruz, RN;<br>Meriza Ducay, RN;                             | Annual Review, added Coverage for  |

|  |  |                     |  |
|--|--|---------------------|--|
|  |  | Robert Sterling, MD | Mental Health Parity Prescriptions, clarified that P&T membership includes psychiatrists, pediatricians and other specialty physicians and formulary update monthly. |
|--|--|---------------------|--|