

Effective 2/15/00

Reviewed/Revised: April 06, April 07, April 08, Aug 09, April
2011, January 2012, January 2014, April 2014
Reviewed/No Updates: 1/28/13; 1/28/14; 1/27/15; 1/26/16;
1/24/17; 1/23/18, 1/22/19, 2/18/20, 2/2/21, 2/1/22, 1/31/23;
2/13/24; 2/18/25

Coverage of Prescription Medication for Off-label Use

Purpose and Scope

This policy defines VCHCP's coverage of medications prescribed for off-label use.

Policy

VCHCP covers off-label use of medically necessary FDA-approved prescription medications prescribed by a VCHCP-contracted provider for life-threatening, chronic, and seriously debilitating conditions. Medically necessary services associated with the administration of the drug are also covered, subject to conditions of the member's benefit plan. Coverage is subject to copayment according to the member's benefit plan.

Definitions

Life-threatening means either or both of the following:

- Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted
- Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

Chronic and seriously debilitating means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause serious long-term morbidity.

Off-label use means a drug is prescribed for a use other than the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA).

Procedure

1. The Medical Management (MM) Nurse, upon receipt of a request for an off-label use of a FDA-approved medication, shall request the VCHCP-contracted prescriber to submit the following documentation supporting the request:
 - a) Evidence that the drug has been recognized for treatment of that condition by one of the following:
 - The American Medical Association Drug Evaluations, The American Hospital Formulary Service Drug Information
 - The United States Pharmacopoeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional"

- Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective, unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal;

Plus

- b) Documentation that the patient has a life-threatening or chronic and seriously debilitating disease or condition, if the patient's condition is unknown to the Plan.
2. Upon receipt of the required information, the MM Nurse will contact the Medical Director or his/her designee for review of the requested prescription. Plan policies will be followed regarding the timeliness of the Plan's decision and the notification of the pharmacy, member, and physician as required.
 3. If the Plan denies coverage on the basis that the drug's use is investigational or experimental, that decision may be appealed to the Plan by the member or the provider and may be subsequently appealed to the Dept. of Managed Health Care as an Independent Medical Review (IMR). The IMR application and cover letter will be provided to the member by the UR Dept. in accordance with Plan policy.
- A. Attachments:** Health & Safety Code 1367.21
- B. References:** none
- C. History:** Reviewers: P&T Committee, Medical Director, QA Manager
Reviewed/Updated: Cynthia Wilhelmy, MD; Date: April 2006
Date Approved by P&T Committee: 4/24/06
Reviewed/Updated: Lita Catapang RN & Sheldon Haas, MD; Date: April 2007
Date Approved by P&T Committee: 4/30/07; QA Committee: 5/22/07
Reviewed/No Updates: Sheldon Haas, MD; Date: April 2008
Date Approved by P&T Committee: 4/28/08; QA Committee: 5/19/08
Reviewed/No Updates: Lita Catapang RN & Sheldon Haas MD; Date: August 2009
Reviewed/Updated: Faustine Dela Cruz RN & Albert Reeves, MD; Date: April 2011
Date Approved by P&T Committee: 4/26/11; QA Committee: 5/24/11
Reviewed/Updated: Faustine Dela Cruz RN, Cecilia Cabrera-Urango RN & Albert Reeves, MD; Date: January 2012
Date Approved by P&T Committee: 1/31/12; QA Committee: 2/28/12
Reviewed/No Updates: Albert Reeves, MD; Date: 1/28/13
Date Approved by P&T Committee: 1/29/13; QA Committee: 2/26/13
Reviewed/Updated: Catherine Sanders, MD; Date: 1/28/14
Date Approved by P&T Committee: 1/28/14; QA Committee: 2/25/14
Reviewed/Updated: Catherine Sanders, MD; Date: 1/28/14
Date Approved by P&T Committee: 4/22/14; QA Committee: 5/27/14
Reviewed/No Updates: Catherine Sanders, MD; Date: 1/27/15
Committee Review: P&T on 1/27/15; QAC on 2/24/15
Reviewed/No Updates: Catherine Sanders, MD; Robert Sterling, MD; Faustine Dela Cruz, RN Date: 1/26/16
Date Approved by P&T Committee: 1/26/16; QA Committee: 2/23/16

Reviewed/No Updates: Catherine Sanders, MD; Robert Sterling, MD; Faustine Dela Cruz, RN; Date: 1/24/17

Date Approved by P&T Committee: 1/24/17; QA Committee: 2/28/17

Reviewed/No Updates: Catherine Sanders, MD; Robert Sterling, MD; Faustine Dela Cruz, RN Date: 1/23/18

Date Approved by P&T Committee: 1/23/18; QA Committee: 2/27/18

Reviewed/No Updates: Robert Sterling, MD; Faustine Dela Cruz, RN Date: 1/22/19

Date Approved by P&T Committee: 1/22/19; QA Committee: 2/26/19

Reviewed/No Updates: Howard Taekman, MD; Faustine Dela Cruz, RN Date: 2/18/20

Date Approved by P&T Committee: 2/18/20; QA Committee: 2/25/20

Reviewed/No Updates: Howard Taekman, MD; Faustine Dela Cruz, RN Date: 2/2/21

Date Approved by P&T Committee: 2/2/21; QA Committee: 2/23/21

Reviewed/No Updates: Howard Taekman, MD; Faustine Dela Cruz, RN Date: 2/2/22

Date Approved by P&T Committee: 2/1/22; QA Committee: 2/22/22

Reviewed/No Updates: Howard Taekman, MD; Faustine Dela Cruz, RN Date: 1/31/23

Date Approved by P&T Committee: 1/31/23; QA Committee: 2/7/23

Reviewed/No Updates: Howard Taekman, MD; Faustine Dela Cruz, RN Date: 2/13/24

Date Approved by P&T Committee: 2/13/24; QA Committee: 2/27/24

Reviewed/No Updates: Howard Taekman, MD; Faustine Dela Cruz, RN Date: 2/18/25

Date Approved by P&T Committee: 2/18/25; QA Committee: 2/25/25

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/26/2016	No	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/24/2017	No	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual Review
1/23/2018	No	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual Review
1/22/19	No	Faustine DelaCruz, RN; Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/18/20	No	Faustine DelaCruz, RN; Howard Taekman, MD	Annual Review
2/2/21	No	Faustine DelaCruz, RN; Howard Taekman, MD	Annual Review
2/1/22	No	Faustine DelaCruz, RN; Howard Taekman, MD	Annual Review
1/31/23	No	Faustine DelaCruz, RN; Howard Taekman, MD	Annual Review
2/13/24	No	Faustine DelaCruz, RN;	Annual Review

		Howard Taekman, MD	
2/18/25	No	Faustine DelaCruz, RN; Howard Taekman, MD	Annual Review