

Effective: 10/6/2000

Reviewed: 11/7/2011, 4/17/2012

Reviewed/No Updates: 1/28/13, 2/13/14, 2/12/15, 2/11/16, 2/9/17, 2/8/18, 2/14/19, 2/13/20, 2/11/21, 2/17/22, 2/2/22,

2/8/24, 2/20/25

PKU (PHENYLKETONURIA) COVERAGE OF TESTING AND TREATMENT

Policy

VCHCP covers the testing for and treatment of phenylketonuria (PKU) for members of any age when deemed medically necessary to avert the development of serious physical or mental disabilities or to promote normal development or function because of PKU. VCHCP also covers special enteral formulas and specially formulated food, when such products are used in place of normal products and to the extent that their cost exceeds the cost of a normal diet (see below).

Coverage of Special Formulas

Coverage includes special formulas and diet powders for use in the dietary management of members with PKU. Their restriction in phenylalanine content differentiates these metabolites from other products. These enteral products are available in liquid form or in a diet powder intended to be mixed with semisolid food, water or other appropriate beverages. Certain PKU formulas are on the Plan's Drug Formulary. The names of these products can be obtained by contacting the Customer Service Department (805-981-5050 option 1). Other PKU formulas and diet powders are covered if prior approval is obtained from the plan.

Coverage of Special Food Products

Coverage of special food products is limited to food products that are specially formulated to have less than one gram of protein per serving and to be used in place of normal food products. Not included are foods that are naturally low in protein or available to the general population in a grocery store. Examples are apple fiber or low protein flour used in baking, and low protein spaghetti, flour, crackers, cookies, pretzels, Jello and tomato sauce. Plan prior authorization is required. For each food item, the member must submit unit price, Nutrition Facts (including protein grams per serving), quantity requested and expected monthly consumptionNot covered is the cost of cookbooks, recipes, subscriptions, catalogues or cooking equipment (such as bread machines).

PKU (PHENYLKETONURIA), COVERAGE OF TESTING AND TREATMENT



Effective: 10/6/2000

Reviewed: 11/7/2011, 4/17/2012

Reviewed/No Updates: 1/28/13, 2/13/14, 2/12/15, 2/11/16, 2/9/17, 2/8/18, 2/14/19, 2/13/20, 2/11/21, 2/17/22, 2/2/22,

2/8/24, 2/20/25

Coverage Criteria

The following criteria are used by the plan in making coverage determinations:

- a) The prescribed diet must be deemed medically necessary to avert the development of serious physical or mental disabilities or to promote normal development or function because of PKU. A blood phenylalanine of more than 6 mg/dl may signify that a special diet is needed.
- b) The prescribing provider should have expertise and experience in the treatment and care of PKU, ideally in consultation with a contracted endocrinologist.

A. Attachments: None

B. References:

SB148 (1999), Health and Safety Code §1374.56

Mead Johnson, Product Description for Health Care Professionals, Dietary management of

Individuals with Metabolic Disorders

National PKU News website: www.pkunews.org

C. History:

Reviewers: Pamela K. Lindeman Chief Operations Officer, Richard O. Ashby, MD

Reviewed/Revised: Faustine Dela Cruz, RN & Albert Reeves, MD; Date: November 7, 2011

Committee Review: UM: November 10, 2011; QAC: November 22, 2011

Reviewed/No Updates: Albert Reeves, MD; Date: April 17, 2012 Committee Reviews: UM: May 10, 2012; QAC: May 22, 2012

Reviewed/No Updates: Albert Reeves, MD; Date: January 28, 2013 Committee Review: UM: February 14, 2013; QAC: February 26, 2013

Reviewed/No Updates: Catherine Sanders, MD

Committee Review: UM: February 13, 2014; QAC: February 25, 2014

Reviewed/No Updates: Catherine Sanders, MD

Committee Review: UM: February 12, 2015; QAC: February 24, 2015 Reviewed/No Updates: Faustine Dela Cruz, RN & Catherine Sanders, MD Committee Review: UM: February 11, 2016; QAC: February 23, 2016



Effective: 10/6/2000

Reviewed: 11/7/2011, 4/17/2012

Reviewed/No Updates: 1/28/13, 2/13/14, 2/12/15, 2/11/16, 2/9/17, 2/8/18, 2/14/19, 2/13/20, 2/11/21, 2/17/22, 2/2/22,

2/8/24, 2/20/25

Reviewed/No Updates: Catherine Sanders, MD & Robert Sterling, MD Committee Review: UM: February 9, 2017; QAC: February 28, 2017 Reviewed/No Updates: Catherine Sanders, MD & Robert Sterling, MD Committee Review: UM: February 8, 2018; QAC: February 27, 2018 Reviewed/No Updates: Catherine Sanders, MD & Robert Sterling, MD Committee Review: UM: February 14, 2019; QAC: February 26, 2019 Reviewed/No Updates: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 13, 2020; QAC: February 25, 2020 Reviewed/No Updates: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 11, 2021; QAC: February 23, 2021 Reviewed/No Updates: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 17, 2022; QAC: February 22, 2022 Reviewed/No Updates: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 2, 2023; QAC: February 7, 2023 Reviewed/No Updates: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 8, 2024; QAC: February 27, 2024 Reviewed/Updated by: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 20, 2025; QAC: February 25, 2025

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
2/9/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/8/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/14/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/13/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/11/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/17/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/2/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/8/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/20/25	Yes	Howard Taekman, MD and Robert Sterling, MD	Added ph# to
			Customer Service
			Department "(805-
			981-5050 option 1)"
			Removed "The
			members are also
			encouraged to



Effective: 10/6/2000

Reviewed: 11/7/2011, 4/17/2012

Reviewed/No Updates: 1/28/13, 2/13/14, 2/12/15, 2/11/16, 2/9/17, 2/8/18, 2/14/19, 2/13/20, 2/11/21, 2/17/22, 2/2/22,

2/8/24, 2/20/25

	submit comparison
	costs of normal
	foods. After
	coverage is
	authorized, the
	member is required
	to pay out of pocket
	and seek
	reimbursement
	from the plan (see
	form below)."