PREMERA HMO

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# PHARMACY / MEDICAL POLICY – 5.01.585

# Pharmacologic Treatment of Phenylketonuria

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|---|---|---|
| Effective Date: | June 1, 2023 | RELATED MEDICAL POLICIES: |
| Last Revised: | May 22, 2023 | None |
| Replaces: | N/A | |

**Select a hyperlink below to be directed to that section.**

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

## Introduction

Phenylketonuria (PKU) is a rare, genetic disease that is typically screened for at birth. Children with untreated PKU have increasing trouble with thinking and reasoning that usually shows up when they are babies. They can also have problems with mood and attention span, bone growth, heart and seizures. This affects quality of life for the child and their parents. If PKU is appropriately managed from birth through adolescence, individuals usually are normal mentally when they are adults. Lifelong treatment is needed.

About 1 in 13,500 to 19,000 children born in the US have PKU, and two-thirds of adults with PKU have uncontrolled disease. It is more common in White and Native American people, and less common in African Americans, Hispanics, and Asians.

Palynziq® (pegvaliase-pqpz) is an enzyme that helps reduce the amount of phenylalanine in the body. Sapropterin is an oral product that is used for PKU. This policy describes when Kuvan® (sapropterin), generic sapropterin, Javygtor™ (sapropterin), and Palynziq® and may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

| Drug | Medical Necessity |
|---|---|
| **Generic sapropterin oral, Javygtor™ (sapropterin) oral**<br><br>**Phenylalanine hydroxylase activator** | **Generic sapropterin and Javygtor™ (sapropterin) may be considered medically necessary for the treatment of individuals with phenylketonuria when:**<br>• Individual is 1 month of age or older<br>**AND**<br>• Is on a phenylalanine restricted diet<br>**AND**<br>• Medication is not being used in combination with Palynziq® (pegvaliase-pqpz) |
| **Kuvan® (sapropterin) oral**<br><br>**Phenylalanine hydroxylase activator** | **Kuvan® (sapropterin) may be considered medically necessary for the treatment of individuals with phenylketonuria when:**<br>• Individual is 1 month of age or older<br>**AND**<br>• Is on a phenylalanine restricted diet<br>**AND**<br>• Kuvan® (sapropterin) is not being used in combination with Palynziq® (pegvaliase-pqpz)<br>**AND**<br>• The individual has tried generic sapropterin or Javygtor™ (sapropterin) and had an inadequate response or intolerance to medication |
| **Palynziq® (pegvaliase-pqpz) SC**<br><br>**Phenylalanine-metabolizing enzyme** | **Palynziq® (pegvaliase-pqpz) may be considered medically necessary for the treatment of individuals with phenylketonuria when:**<br>• Individual is 18 years of age or older<br>**AND**<br>• Phenylalanine level is >600 micromoles/liter on a phenylalanine restricted diet<br>**AND**<br>• Have failed a trial of generic sapropterin, Javygtor™ (sapropterin), or Kuvan® (sapropterin)<br>**AND** |

| Drug | Medical Necessity |
|---|---|
| | • Palynziq® (pegvaliase-pqpz) is not being used in combination with generic sapropterin, Javygtor™ (sapropterin), or Kuvan® (sapropterin) |

| Drug | Not Medically Necessary |
|---|---|
| **Generic sapropterin, Javygtor™ (sapropterin), Kuvan® (sapropterin), Palynziq® (pegvaliase-pqpz)** | **All other uses of generic sapropterin, Javygtor™ (sapropterin), Kuvan® (sapropterin), or Palynziq® (pegvaliase-pqpz) for conditions not outlined in this policy are considered not medically necessary.** |

| Length of Approval | |
|---|---|
| **Approval** | **Criteria** |
| **Initial authorization** | **Generic sapropterin, Javygtor™ (sapropterin), Kuvan® (sapropterin), and Palynziq® (pegvaliase-pqpz) may be approved up to 6 months.** |
| **Re-authorization criteria** | **Future re-authorization of generic sapropterin, Javygtor™ (sapropterin), and Kuvan® (sapropterin) may be approved up to two years in duration when documentation provided at the time of re-authorization show:**<br>• The coverage criteria as outlined above are met<br>**AND**<br>• The individual has shown and continues to show a ≥ 30% decrease in blood phenylalanine levels from baseline<br><br>**Future re-authorization of Palynziq® (pegvaliase-pqpz) may be approved up to two years in duration when documentation provided at the time of re-authorization show:**<br>• The coverage criteria as outlined above are met<br>**AND**<br>• The individual has shown and continues to show a phenylalanine level <600 micromoles/liter while on treatment<br>**OR**<br>• The individual has shown and continues to show a ≥ 20% decrease in blood phenylalanine levels from baseline |

| Documentation Requirements |
| --- |
| **The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:**<br>• Chart notes showing the individual's overall progress<br>**AND**<br>• Recent lab report showing individual's phenylalanine level |

## Coding

| Code | Description |
| --- | --- |
| **HCPCS** | |
| J3590 | Unclassified biologics (use to report Palynziq®) |

## Related Information

### Consideration of Age

The U.S. Food and Drug Administration (FDA) labeling for Kuvan indicates the drug has been studied in pediatric individuals with PKU ages 1 month to 16 years and that the efficacy and safety of Kuvan has not been established in neonates. The FDA labeling for Palynziq indicates this agent is for use in adult individuals. The safety and effectiveness of Palynziq is pediatric individuals have not been established.

### Benefit Application

Generic sapropterin, Javygtor™ (sapropterin), and Kuvan® (sapropterin) are managed under the pharmacy benefit. Palynziq® (pegvaliase-pqpz) may be managed under either the medical benefit (if administered by a provider) or pharmacy benefit (if administered by the individual or a nonprofessional caregiver).

## Evidence Review

# Description

## Medical Condition

PKU is a rare, genetic, metabolic disease that is typically screened for at birth. The hallmark sign of untreated PKU is cognitive decline, which can manifest in early infancy. Other adverse effects include mood disorders, attention problems, osteopenia, cardiovascular disease, seizures, executive function deficits, and decreased quality of life. If PKU is appropriately managed from birth through adolescence, individuals usually do not suffer intellectual deficits in adulthood, but may exhibit the other adverse effects cited above if disease management measures are discontinued later in life.

PKU results from a deficiency in the enzyme phenylalanine hydroxylase (PAH), which is necessary for the metabolism of phenylalanine (Phe). PAH deficiency leads to excessive levels of Phe and the clinical sequelae described above. High concentrations of Phe in the brain damage white matter and consequently adversely affects neurologic functioning. Secondary PAH deficiency is caused by inadequate activity of tetra-hydrobiopterin (BH4), a co-factor in the metabolism of Phe.

PKU occurs in approximately 1 in 13,500 to 19,000 births in the US. The National PKU Alliance estimates the prevalence of PKU is approximately 16,500. About two-thirds of adults with PKU have uncontrolled disease, which is about three times the rate as in individuals under the age of 18 years. The incidence of PKU varies by race/ethnicity, with a higher rate in Caucasians and Native Americans, and a lower rate in African Americans, Hispanics, and Asians. No information was found on the economic impact of PKU in the US.

## Kuvan® (sapropterin)

Kuvan® (sapropterin) is a synthetic form of BH4, the cofactor for the enzyme phenylalanine hydroxylase (PAH). PAH hydroxylates Phe through an oxidative reaction to form tyrosine. In individuals with PKU, PAH activity is absent or deficient. Treatment with BH4 can activate residual PAH enzyme activity, improve the normal oxidative metabolism of Phe, and decrease Phe levels in some individuals.

## Rationale

## Efficacy/Effectiveness

The efficacy of Kuvan was evaluated in five clinical studies in individuals with PKU. The information provided highlights three of these five clinical studies. Response to Kuvan treatment was defined as a ≥ 30% decrease in blood Phe from baseline for all three of these studies. Study 1 was a multicenter, open-label, uncontrolled clinical trial of 489 individuals with PKU, ages 8 to 48 years (mean 22 years), who had baseline blood Phe levels ≥ 450 micromoles/L and who were not on Phe-restricted diets. All individuals received treatment with Kuvan 10 mg/kg per day for 8 days. At Day 8, 96 individuals (20%) were identified as responders. Study 4 was a multicenter study of 90 pediatric individuals with PKU, ages 4 to 12 years, who were on Phe-restricted diets and who had blood Phe levels ≤ 480 micromoles/L at screening. All individuals were treated with open-label Kuvan 20 mg/kg per day for 8 days. At Day 8, 50 individuals (56%) had a ≥30% decrease in blood Phe. Study 5 was an open label, single arm, multicenter trial in 93 pediatric individuals with PKU, aged 1 month to 6 years, who had Phe levels greater than or equal to 360 micromoles/L at screening. All individuals were treated with Kuvan at 20 mg/kg per day and maintained on a Phe-restricted diet. At Week 4, 57 individuals (61%) were identified as responders.

## Safety/Tolerability

The safety of Kuvan was evaluated in 7 clinical studies in individuals with PKU (aged 1 month to 50 years). The most common adverse reactions (≥4% of individuals) were headache, rhinorrhea, pharyngolaryngeal pain, diarrhea, vomiting, cough, and nasal congestion. Hypersensitivity reactions including anaphylaxis have occurred in individuals treated with Kuvan.

## Palynziq® (pegvaliase-pqpz)

Palynziq® (pegvaliase-pqpz) is pegylated recombinant Anabaena variabilis-derived phenylalanine ammonia lyase (PAL), which is an enzyme that catalyzes the degradation of Phe to ammonia and trans-cinnamic acid, thus reducing Phe levels in the body. Pegylation acts to reduce the immunogenicity of this non-humanized product and increase its plasma half-life. Taking a somewhat different approach, sapropterin (Kuvan) acts to reduce Phe blood levels by activating PAH, which in turn oxidizes Phe to tyrosine. So, the activity of sapropterin relies on PAH activity while pegvaliase does not, it is simply a replacement for naturally occurring PAL.

## Rationale

## Efficacy/Effectiveness

Fair quality evidence from open-label, single arm, Phase 3 trials (PRISM 1&2) shows that pegvaliase 20mg or 40mg subcutaneously daily is effective in reducing blood phenylalanine (Phe) levels in 273 PKU subjects 16-70 years of age with a baseline of >600 micromoles per liter. About half of individuals maintained a blood Phe level below 600 micromoles per liter after one-year of treatment, but only 11.6% of individuals were within target Phe blood levels established by treatment guidelines (120-360 micromoles/liter) at the one-year mark. At two years of use, 68.4% of individuals are able to maintain Phe levels below 600 micromoles/liter and 9.5% of individuals are within target Phe levels. Steady improvements are seen in measures of inattention over a 24-month observation period, however, the clinical significance of this 8-point change is unknown. Results of a Phase 3 substudy (n=9) looking at changes in executive function are not yet available. In an 8-week, double-blind, placebo-controlled Phase 3 study (Part 2 of PRISM 2, n=86), mean Phe levels returned to baseline (~1300 micromoles/liter) upon withdrawal of pegvaliase while Phe levels were constant (~ 500 micromoles/liter) in those who remained on pegvaliase. The difference in Phe levels between groups of 812 micromoles/liter was statistically significant at the end of the study. No difference between groups in inattention scores was seen in this double-blind, placebo-controlled trial.

## Safety/Tolerability

Acute hypersensitivity reactions (HAEs), including anaphylaxis, have been observed with pegvaliase. There were twelve such events in the early part of the Phase 3 studies, however, no anaphylaxis has been reported after the institution of pre-medication with antihistamines and antipyretics was adopted. No serious long-term complications from these HAEs were observed and six subjects continued on treatment. The number of hypersensitivity reactions peaks at around three months of treatment, then steadily declines over a period of two years. Neutralizing and non-neutralizing antibody titers rise soon after treatment, however, no association was found between the severity of hypersensitivity reactions and antibody titers. Nearly all adverse events (99%) seen with pegvaliase are mild to moderate in severity, the most common being injection site reaction and arthralgia (62% and 70% respectively). In the 8-week double blind trial (part 2 of PRISM 2) the overall rate of adverse reactions was similar between pegvaliase and placebo, but a higher percentage of HAEs were due to injection site reactions with pegvaliase compared to placebo (39% vs. 14%).

It is worth noting that the safety population includes a small number of subjects (N=350), however that rep-resents approximately 2% of the U.S. population with PKU, which is acceptable per FDA guidance on the study of rare diseases.

## 2019 Update

Reviewed Palynziq® (pegvaliase-pqpz) prescribing information and conducted a literature search from August 1, 2018, through August 20, 2019. Updated the re-authorization criteria to also include individuals who achieve at least a 20% reduction in blood phenylalanine levels from pre-treatment baseline. Added Kuvan® (sapropterin) to policy and changed policy name to Pharmacologic Treatment of Phenylketonuria.

## 2020 Update

Reviewed Kuvan® (sapropterin) and Palynziq® (pegvaliase-pqpz) prescribing information and conducted a literature search from August 1, 2019, through October 31, 2020. Added generic sapropterin to policy and updated Kuvan® (sapropterin) criteria to require the individual to try generic sapropterin first.

## 2021 Update

Reviewed Kuvan® (sapropterin) and Palynziq®(pegvaliase-pqpz) prescribing information and conducted a literature search on the management of phenylketonuria. No new information was identified that would result in changes to policy statements.

## 2022 Update

Reviewed prescribing information for all drugs listed in policy and reviewed product availability. Added a new generic product identified called Javygtor™ (sapropterin) with the identical coverage criteria as generic sapropterin.

## 2023 Update

Reviewed prescribing information for all drugs listed in policy. No new information were identified which could result in changes to the policy statements.

## References


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3. Longo N, Thomas J, Wasserstein M, et al. Evaluation of long-term safety and efficacy of pegvaliase for adults with phenylketonuria: updated year 4 results. J Inher Metab Dis 2016 (39) Suppl 1:S39 (abstract O013).
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12. Kuvan® (sapropterin dihydrochloride) prescribing information. BioMarin Pharmaceutical, Novato, CA. Revised February 2021.
13. Javygtor™ (sapropterin dihydrochloride) prescribing information. Dr. Reddy's Laboratories Inc., Princeton, NJ. Revised January 2022.
14. Palynziq® (pegvaliase-pqpz) prescribing information. BioMarin Pharmaceutical, Novato, CA. Revised November 2020.
15. van Spronsen FJ, de Groot MJ, Hoeksma M, Reijngoud D-J, van Rijn M. Large neutral amino acids in the treatment of PKU: from theory to practice. J Inher Metab Dis (2010) 33:671-6.

## History

| Date | Comments |
|---|---|
| 08/01/18 | New policy, approved July 10, 2018. Add to Prescription Drug section. Palynziq (pegvaliase-pqpz) may be considered medically necessary when criteria are met. |
| 09/21/18 | Minor update. Consideration of Age statement added. |
| 10/01/19 | Annual Review, approved September 10, 2019. Changed policy title from "Palynziq (pegvaliase-pqpz)" to "Pharmacologic Treatment of Phenylketonuria". Added Kuvan (sapropterin) to policy and updated the re-authorization criteria for Palynziq (pegvaliase-pqpz). Removed HCPCS code J3490. |
| 12/01/20 | Annual Review, approved November 19, 2020. Added generic sapropterin to policy and updated Kuvan (sapropterin) criteria to require the patient to try generic sapropterin first. Updated Palynziq (pegvaliase-pqpz) criteria to include not being used in combination with generic sapropterin or Kuvan (sapropterin). |
| 01/01/22 | Annual Review, approved December 2, 2021. No changes to policy statements. |
| 11/01/22 | Annual Review, approved October 24, 2022. Added a new generic product called Javygtor (sapropterin) with the identical coverage criteria as generic sapropterin. Added generic Javygtor as a prerequisite drug an individual must try prior to brand Kuvan (sapropterin). Added Javygtor as a prerequisite drug within criteria for Palynziq (pegvaliase-pqpz) and as one of the drugs Palynziq is not to be used in combination with. Changed the wording from "patient" to "individual" throughout the policy for standardization. |
| 06/01/23 | Annual Review, approved May 22, 2023. No changes to the policy statements. |



**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

PREMERA HMO

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## Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 844-722-4661 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 844-722-4661（TTY：711）。

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ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 844-722-4661 (TTY: 711)។

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ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 844-722-4661 (رقم هاتف الصم والبكم: 711).

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