

Pharmacy Policy

Sapropterin

Policy Number: 9.626

Version Number: 2.0

Version Effective Date: 9/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth ACO

MassHealth MCO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Sapropterin tablet
- Sapropterin packet

The Plan may authorize coverage of the above products for members meeting the following criteria:

Required Medical Information	<ol style="list-style-type: none"> 1. Diagnosis of phenylketonuria (PKU); AND 2. Member has baseline blood phenylalanine level $\geq 600 \mu\text{mol/L}$ (lab records within 90 days must be provided); AND 3. The prescribing physician is a metabolic disease specialist; AND 4. Tetrahydrobiopterin (BH4) deficiency has been ruled out; AND 5. The requested dose and frequency is in accordance with FDA-approved labeling; AND 6. Documentation that the Member is following a phenylalanine-restricted diet
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Coverage Duration	Initial: 8 weeks Reauthorization: 12 months
Other criteria	Reauthorization: <ol style="list-style-type: none"> 1. Prescribing physician is a metabolic disease specialist; AND 2. Member has demonstrated at least a 30% reduction in phenylalanine levels compared to baseline; AND 3. Documentation that the Member is following a phenylalanine-restricted diet

Clinical Background Information and References

1. Kuvan [package insert]. Novato, CA: BioMarin Pharmaceutical Inc. March 2020.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	P&T review: Move brand Kuvan tablet to non formulary,; add generic sapropterin tablet and packet to formulary with PA	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other

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Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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