PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Kuvan (sapropterin)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Kuvan, a synthetic form of the cofactor tetrahydrobiopterin, is a phenylalanine hydroxylase (PAH) activator approved by the FDA in 2007 for the treatment of tetrahydrobiopterin- (BH4-) responsive phenylketonuria

DATE	ACTION/DESCRIPTION
05/05/2021	New policy for Kuvan created.
10/31/2022	Annual review; no updates.

References:

1. Kuvan [prescribing information]. Novato, CA: Biomarin Phermaceutical Inc.; February 2021.
2. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline [published correction appears in Genet Med. 2014 Apr;16(4):356]. *Genet Med*. 2014;16(2):188-200. doi:10.1038/gim.2013.157
3. van Spronsen FJ, van Wegberg AM, Ahring K, et al. Key European guidelines for the diagnosis and management of patients with phenylketonuria. *Lancet Diabetes Endocrinol*. 2017;5(9):743-756. doi:10.1016/S2213-8587(16)30320-5
4. Camp KM, Parisi MA, Acosta PB, et al. Phenylketonuria Scientific Review Conference: state of the science and future research needs. *Mol Genet Metab*. 2014;112(2):87-122. doi:10.1016/j.ymgme.2014.02.013
5. Somaraju UR, Merrin M. Sapropterin dihydrochloride for phenylketonuria. *Cochrane Database Syst Rev*. 2015;2015(3):CD008005. Published 2015 Mar 27. doi:10.1002/14651858.CD008005.pub4

Effective date: 04/01/2023
Revised date: 10/31/2022