CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES
Michelle Baass | Director

DATE: March 13, 2026

CCS Information Notice: 26-02

TO: All California Children's Services (CCS) Program Administrators; CCS Metabolic Special Care Center (SCC) Providers and Staff; Genetically Handicapped Persons Program (GHPP) Providers and Staff, and Stakeholders

SUBJECT: Temporary Shortage of Compounded High-Dose Hydroxocobalamin for CCS and GHPP Members with Cobalamin C and Related Inborn Errors of Metabolism

PURPOSE:
The purpose of this Information Notice (IN) is to inform County CCS Programs, GHPP, SCCs, and stakeholders of the process to follow, now and in the future, to ensure member access to compounded high-dose hydroxocobalamin.

BACKGROUND:
Cobalamin C deficiency and related inborn errors of intracellular cobalamin metabolism are rare genetic disorders that impair the conversion of vitamin B12 into its active forms.[1] These defects disrupt methylation and mitochondrial energy pathways causing neurological, vascular, and systemic complications. Affected conditions include, but are not limited to, the following ICD-10 diagnoses:

- E71.120 Cobalamin C deficiency / Methylmalonic acidemia (MMA)
- E72.11 Homocystinuria
- E53.8 Other specified B-group vitamin deficiency
- D51.2 Transcobalamin II deficiency
- D51.1 Vitamin B12 deficiency anemia due to selective malabsorption with proteinuria

[1] Carrillo-Carrasco N, Venditti CP. *Cobalamin C disease: clinical, biochemical, and treatment overview.* Journal of Inherited Metabolic Disease. 2012;35(1):9-20. doi:10.1007/s10545-011-9361-x.

Eligibility for CCS and GHPP coverage of these metabolic conditions is established in applicable regulation and statute.[2,3]

Effective treatment for cobalamin metabolism disorders requires lifelong, targeted pharmacologic cobalamin replacement, typically administered as daily intramuscular injections to maintain metabolic stability and prevent acute and chronic complications.[4] Because treatment interruption can precipitate rapid clinical deterioration - including stroke, hemolytic uremic syndrome (HUS), metabolic decompensation, or death - continuous access is medically necessary.[5] Commercial cyanocobalamin (1 mg/mL) depends on intact intracellular processing and is therefore not therapeutically effective for these conditions. At concentrations of 20–50 mg/mL, hydroxocobalamin is capable of partially bypassing the intracellular metabolic block characteristic of Cobalamin C and related disorders. These high-concentration formulations must be prepared through sterile compounding processes that comply with United States Pharmacopeia (USP) 797 standards to ensure product integrity and patient safety.[6]

Because uninterrupted access to high-dose hydroxocobalamin is medically necessary for affected members, the following sections summarize current supply limitations and the pathways available to maintain access during this temporary disruption.

HYDROXOCOBALAMIN ACCESS LIMITATION:
The Medicine Shoppe in Riverside, California is the sole Medi-Cal recognized pharmacy authorized to compound high-dose hydroxocobalamin for CCS and GHPP members. Following a change of address, the Medicine Shoppe has temporarily suspended multi-dose production and is currently awaiting issuance of a new sterile compounding license from the California Board of Pharmacy.

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[2] CCS eligibility: Cal. Code Regs., tit. 22 §§ 41516.1 and § 41515.1 et seq.
[3] GHPP eligibility: Cal. Code Regs., tit.17, § 2932 and Cal. Health & Safety Code §125130.
[4] Carrillo-Carrasco N, Venditti CP. *Cobalamin C disease: clinical, biochemical, and treatment overview.* Journal of Inherited Metabolic Disease. 2012;35(1):9-20. doi:10.1007/s10545-011-9361-x.
[5] Martinelli D, et al. *Long-term effectiveness of hydroxocobalamin therapy in cobalamin C disease.* Molecular Genetics and Metabolism. 2011;103(3):201-205. doi:10.1016/j.ymgme.2011.03.019.
[6] United States Pharmacopeia (USP). *USP 797 Pharmaceutical Compounding—Sterile Preparations.* United States Pharmacopeial Convention; most recent official revision.

During this interim period, the pharmacy received a permit to produce limited batches with a four-day beyond-use date (BUD) under its single-dose authorization while multi-dose sterile compounding authority remains pending. Four-day supplies will be shipped to members every Monday and Thursday to maintain continuous availability. Full compounding operations are anticipated to resume by late March 2026.

LONG-TERM BACK-UP ACCESS OPTIONS:
Hopewell Pharmacy in New Jersey will serve as a back-up out-of-state source of high-dose compounded hydroxocobalamin. The pharmacy is actively seeking Medi-Cal enrollment to support recurring dispensing for CCS and GHPP members. Once enrollment is finalized, California Ordering, Referring or Prescribing (ORP) providers with a Type 1 National Provider Identifier (NPI) may submit a prescription - including a relevant ICD-10 diagnosis code - directly to Hopewell Pharmacy. The pharmacy will then compound the medicine, ship it to the member, and submit the claim to Medi-Cal Rx for processing.

Hopewell Pharmacy Contact Information:

- Phone: 800-792-6670
- Phone: 609-466-1960
- Fax: 609-466-8222
- info@hopewellrx.com

If you have any questions regarding this IN or require assistance with interim hydroxocobalamin access, please email:

- For CCS members, the DHCS Integrated Systems of Care Division Medical Policy team at ISCD-MedicalPolicy@dhcs.ca.gov.
- For GHPP members, the DHCS Clinical Assurance Division at faxghpp@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY

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