SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Vykoura® (leucovorin calcium) in Cerebral Folate Transport Deficiency

The Sentara Health Plans Oncology Program is administered by OncoHealth

- **For any oncology indications**, the most efficient way to submit a prior authorization request is through the **OncoHealth OneUM Provider Portal** at https://oneum.oncohealth.us. Fax to **1-800-264-6128.** OncoHealth can also be contacted by Phone: 1-888-916-2616.
- Commercial customers **NOT** enrolled in the OncoHealth program, please fax requests to Sentara Health plans at fax number 1-800-750-9692.

Drug Requested: select one drug below

PREFERRED [No Prior Authorization Required]
☐ **J0640 leucovorin calcium injection**
NON-PREFERRED [Prior Authorization Required]
☐ **J3490/C9399 Vykoura® (leucovorin calcium)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

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DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage:

- Initial: 1 to 2 mg/kg/day once daily or in divided doses up to 6 times/day (based on oral dosing – see criteria below for medical necessity of intravenous route of administration)
- Maximum dose: 330 mg/day in divided doses up to 6 times/day
- For patients <40 kg, maximum dose is 8.5 mg/kg/day in divided doses up to 6 times/day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Requesting provider is a pediatric neurologist, a metabolic specialist, or a specialist in treating patients with Cerebral Folate Transport Deficiency
- ❑ Member has a confirmed diagnosis of hereditary Cerebral Folate Transport Deficiency meeting **ONE** of the following:
  - ❑ Molecular genetic testing confirming biallelic pathogenic variants in the FOLR1 gene
  - ❑ A lumbar puncture to measure 5-methyltetrahydrofolate (5-MTHF) levels in the cerebrospinal fluid (CSF) **[NOTE: A definitive diagnosis of cerebral folate deficiency (CFD) is established when CSF 5-MTHF levels are extremely low (typically <10nmol/L) or undetectable in the presence of completely normal peripheral folate, vitamin B12, and homocysteine levels.]**
- ❑ A serum assay has been submitted confirming the absence of Folate Receptor Alpha (FRα) blocking and binding autoantibodies
- ❑ Provider has submitted documentation of neurological complications (e.g., developmental delay, ataxia, movement disorders, or refractory seizures)

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- ❑ Provider has submitted documentation of medical necessity for the intravenous injection route over oral therapy satisfying **ONE** of the following:
  - ❑ Gastrointestinal Malabsorption: History of severe malabsorption syndrome, short bowel syndrome, or other GI conditions that preclude the absorption of oral folates
  - ❑ Inability to Swallow/Aspiration Risk: Clinical documentation that the patient cannot safely swallow tablets and that alternative oral preparations (liquid/crushed) are contraindicated or unavailable
  - ❑ Severe Neurological Impairment: Presence of intractable emesis or severe dysphagia requiring parenteral nutrition or bypass of the oral route
  - ❑ Clinical Failure of Oral Therapy: Documentation of continued neurological decline or failure to achieve therapeutic CSF 5-MTHF levels despite optimized oral dosing (typically 0.5–2.0 mg/kg/day)
- ❑ Provider must submit documentation of a contraindication, failure, or intolerance to leucovorin calcium injection (J0460) prior to approval of a non-preferred product

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., severe hypersensitivity including anaphylactic reactions and urticaria, seizure, stomatitis)
- ❑ Provider has submitted documentation of stabilized or improved neurological function (e.g., reduced seizure frequency, improved motor coordination, or progress in developmental milestones)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR
- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.**

***Approved by Pharmacy and Therapeutics Committee**: 5/28/2026
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