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.

Non-Preferred Vykoura & levoleucovorin Products – Oncology Indications

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]	
❑ **J0641 levoleucovorin** (generic Fusilev®)	❑ **J0642 Khapzory®** (levoleucovorin)
❑ **J3490/C9399 Vykoura®** (leucovorin calcium)*	

*For a product approved through the Food and Drug Administration's (FDA) 505(b)(2) approval pathway, the provider must document showing that the patient did not respond adequately or could not tolerate all other generic formulations of the same product, or that all other products are not obtainable as confirmed by the FDA Drug shortage website located at, http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

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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 #: _____

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.

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: 6 months

❑ The requesting provider is an oncologist

AND

❑ Use of the requested oncology therapy is documented in literature and found in **ONE** of following **(please ensure diagnosis is documented above; please access the following webpage, https://www.sentarahealthplans.com/en/providers/clinical-reference/medical-policies/medical, for the detailed policy description (Chemotherapy and Supportive Care Medical 316))**

❑ FDA labeling – in accordance with a specific indication

OR

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Accepted off-label indication found in the most recent edition of any of the following:

- ❑ American Hospital Formulary Service Drug Information **(Supportive)**
- ❑ National Comprehensive Cancer Network's Drugs & Biologics Compendium **(use must be consistent with NCCN recommendations carrying a Category 1 or 2A level of evidence)**
- ❑ Elsevier Gold Standard's Clinical Pharmacology **(Supportive)**
- ❑ Thompson Micromedex DrugDex® **(Class I, IIa, or IIb)**
- ❑ Wolters Kluwer Lexi-Drugs® **(Level A)**

OR

- ❑ For medical necessity **(Please provide clinical rationale and submit any chart notes/literature you feel would be pertinent in support of medical necessity. Note: experimental/investigational use as defined by the chemotherapy administration policy precludes medical necessity.)**

_____

_____

_____

_____

AND

- ❑ **If a biomarker/genetic component is required for the drug's site of action please ensure the following:**
  - ❑ Submit/attach all genetic mutation, receptor, biomarker, laboratory documentation using an FDA-approved test including both the results and which test was utilized

    NOTE: Experimental/investigational use as defined by the chemotherapy administration policy precludes medical necessity

AND

- ❑ Member has tried and failed current treatment-guideline and FDA label-recommended first-line agents [or has a documented intolerance, FDA-labeled contraindication, or hypersensitivity to first line therapies]

AND

- ❑ Provider must submit documentation of a contraindication, failure, or intolerance to leucovorin calcium injection (J0460) prior to approval of a non-preferred product (NOTE: Step therapy applies to all overlapping compendia supported indications/regimens)

AND

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- ❑ Please list all previous chemotherapy regimens and dates **(please attach chart notes)**

Chemotherapy Regimen	Dates/Cycles Completed
1.	
2.	
3.	
4.	

AND

- ❑ Requested dose must meet **ONE** of the following:
  - ❑ The quantity (dose) requested is in accordance with FDA approved labeling, and if applicable or necessary, age and weight conditions are met
    - What is the quantity requested per DAY? _____

OR

  - ❑ The quantity (dose) requested is higher than the maximum dose recommendation found in FDA approved labeling (i.e., the package insert), and the prescriber has submitted clinical literature and medical documentation in support of the safety and efficacy of the higher dose (such as evidence from practice guidelines or clinical trials from peer-reviewed medical literature)

    **** Please note: Chart documentation of the above is required to be submitted along with this request ****

    _____

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    _____

    _____

AND

- ❑ If requesting the brand formulation of any therapy with generic availability, provider must submit documentation to confirm treatment failure, contraindication or intolerance to the generic product

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Reauthorization: 6 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. **Applicable to ALL continuation of therapy requests.**

- ❑ Member is currently receiving the requested medication and must meet **BOTH** of the following:
  - ❑ All initial authorization criteria continues to be met
  - ❑ Provider must submit documentation of contraindication, failure, or intolerance to leucovorin calcium injection (J0460) prior to continued approval of the non-preferred products **(NOTE: please see initial authorization section; step therapy applies to all overlapping compendia supported indications/regimens)**

AND

- ❑ Member requires continuation of therapy and is **NOT** experiencing disease progression

AND

- ❑ Ongoing treatment is consistent with FDA-labeling or compendia support

AND

- ❑ Member is **NOT** experiencing an FDA-labeled limitation of use or toxicity

AND

- ❑ The quantity (dose) requested is in accordance with FDA approved labeling
  - **IF** there is an adjustment in quantity (dose) requested, higher than the maximum dose recommendation in FDA-approved labeling (i.e., the package insert), the prescriber must submit clinical literature and medical documentation in support the safety and efficacy of the higher dose (such as evidence from practice guidelines or clinical trials from peer-reviewed medical literature).

**** Please note: Chart documentation of the above is required to be submitted along with this request ****

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Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

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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