SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

Drug Requested: Unituxin® (dinutuximab) **C9399, J9999 (MEDICAL)**

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight: _____ **Height:** _____

Date: _____

☐ 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.

A. Quantity Limit (max daily dose) [NDC Unit]:

- Unituxin 17.5 mg/5 mL per vials: 12 vials every 24 days
- Recommended Dose: 17.5 mg/m^2/day for 4 consecutive days for a maximum of 5 cycles
  - Infuse on days 4, 5, 6, and 7 during cycles 1, 3, and 5 (cycles 1, 3, and 5 are 24 days in duration)
  - Infuse on days 8, 9, 10, and 11 during cycles 2 and 4 (cycles 2 and 4 are 32 days in duration)

B. Max Units (per dose and over time) [HCPCS Unit]:

- 52.5 mg per day for four doses every 24-day cycle

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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.

Authorization Criteria: 1 time approval for 5 cycles, 20 doses

- ❑ Member is less than 18 years of age
- ❑ Member has a diagnosis of high-risk neuroblastoma (please provide documentation of risk classification such as age at diagnosis, International Neuroblastoma Risk Group (INRG) Stage (ST-1), tumor MYCN status (presence or absence of MYCN amplification), histopathology (favorable or unfavorable based on International Neuroblastoma Pathology Classification [INPC]))
- ❑ Member had at least partial response to first-line multiagent, multimodality therapy (e.g., topotecan, cyclophosphamide, cisplatin, etoposide, vincristine administered at varying cycles)
- ❑ Requested therapy will **NOT** be used in combination with other GD2-binding monoclonal antibodies (i.e., naxitamab)
- ❑ Requested medication will be used in combination with the following:
  - ❑ A granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim)

    AND
  - ❑ A 13-cis-retinoic acid (e.g., isotretinoin)

    AND/OR
  - ❑ An interleukin-2 [IL-2] (e.g., aldesleukin) **(NOTE: Although the manufacturer's labeling includes aldesleukin (IL-2) as part of the original protocol, this may be excluded due to requesting provider's concern for increased toxicity)**

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: 3/21/2024**
REVISED/UPDATED/REFORMATTED:4/26/2024