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.

Drug Requested: Besponsa® (inotuzumab ozogamicin) **IV (J9999/C9028) (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 Form/Strength: _____

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

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

Weight: _____ **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.

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.

❑ Member is age 18 years or older

AND

(Continued on next page)

- ❑ Member has a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL)

AND

- **Select one of the conditions that corresponds to the member:**

- ❑ Member shown to be Philadelphia Chromosome-positive, and is either relapsed **OR** refractory CD22 as defined in either condition below:
  a. Member has undergone treatment with at least one tyrosine kinase inhibitor {imatinib (Gleevec®), dasatinib (Sprycel®), nilotinib (Tasigna®), bosutinib (Bosulif®), ponatinib (Iclusig®)}
  b. Member has undergone 1 or 2 induction chemotherapy regimens for **ALL; OR**
- ❑ Member shown to be Philadelphia Chromosome-negative and:
  - Member has undergone 1 or 2 induction chemotherapy regimens for **ALL**

AND

- **Select below the therapy regimen/cycle phase for approval:**

- ❑ **Cycle 1: 21 DAYS**

DAY 1 - 0.8 mg/m^2	**DAY 8 -** 0.5 mg/m^2	**DAY 15 -** 0.5 mg/m^2

Total dose/cycle 1: 1.8 mg/m^2

- ❖ Treatment cycle may be extended to 4 weeks if complete remission (CR) is achieved, **OR** CR with incomplete hematologic recovery (CRi) and/or to allow for recovery from toxicity.

Subsequent cycles:

- ❑ Members who achieve CR or CRi: 28 DAYS

DAY 1 - 0.5 mg/m^2	**DAY 8 -** 0.5 mg/m^2	**DAY 15 -** 0.5 mg/m^2

Total dose/cycle: 1.5 mg/m^2

- ❑ Members who do not achieve CR or CRi: 28 DAYS

DAY 1 - 0.8 mg/m^2	**DAY 8 -** 0.5 mg/m^2	**DAY 15 -** 0.5 mg/m^2

Total dose/cycle 1: 1.8 mg/m^2

- ❖ If CR or CRi is **NOT** achieved within 3 cycles, discontinue treatment.

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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 – PropriumRx**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara'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 the Pharmacy and Therapeutic Committee**: 2/15/2018.
UPDATED/REVISED: ~~6/19/2018;~~ **(Reformatted)** ~~3/14/2019; 7/6/2019;~~ **9/16/2019**.