SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

<u>Directions:</u> 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; <u>fax to 1-844-668-1550</u>. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. <u>If information provided is not complete, correct, or legible, authorization can be delayed.</u>

<u>For Medicare Members:</u> 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.

<u>Drug Requested</u>: Datroway[®] (datopotamab deruxtecan-dlnk) (J9011) MEDICAL

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 <u>NOT</u> enrolled in the OncoHealth program, please fax requests to Sentara Health plans at fax number 1-800-750-9692.

MEMBER & PRESCRIBER INF	ORMATION: Authorization may be delayed if incomplete.	
Member Name:		
Member Sentara #:	Date of Birth:	
Prescriber Name:		
Prescriber Signature:		
Office Contact Name:		
hone Number: Fax Number:		
NPI #:		
DRUG INFORMATION: Authoriz	zation 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	t, the timeframe does not jeopardize the life or health of the member	

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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]:

• 6 mg/kg once every 3 weeks; maximum dose: 540 mg in patients weighing \geq 90 kg

B. Max Units (per dose and over time):

osimertinib)

• 1 mg = 1 billable unit; maximum 540 billable units per dose

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.

1			1			
Initial Authorization: 6 months						
	Me	mb	er is 18 years of age or older			
	Pro	vid	der is a specialist in oncology			
	Me	mb	er must have <u>ONE</u> of the following diagnoses:			
			ember has a diagnosis of breast cancer meeting <u>ALL</u> the following:			
			Human epidermal growth factor receptor 2 (HER2)-negative disease (IHC 0, IHC 1+ or IHC 2+/ISH-)			
			Hormone receptor (HR)-positive disease			
			Datopotamab will be used as a single agent for unresectable or metastatic disease			
			Disease progression recorded with, and is not suitable for continued, endocrine therapy			
			Datopotamab will be used as subsequent therapy to systemic chemotherapy (e.g., doxorubicin, paclitaxel)			
			Member must meet ONE of the following:			
			☐ For patients with HER2 IHC 1+ or IHC 2+/ISH negative disease member must meet BOTH of the following:			
			☐ Datopotamab deruxtecan-dlnk will be used as subsequent therapy to fam-trastuzumab deruxtecan-nxki (Enhertu)			
			☐ There must be a medical reason why sacituzumab govitecan-hziy (Trodelvy) cannot be used			
			☐ For patients with HER2 IHC 0/ISH negative disease:			
			☐ There must be a medical reason why sacituzumab govitecan-hziy (Trodelvy) cannot be used			
			Must <u>NOT</u> have experienced disease progression on or following prior treatment with a TROP2-targeted therapy (e.g., Trodelvy)			
			Epidermal growth factor receptor (EGFR)-mutated [EGFR Exon 19 Deletion or Exon 21 L858R] disease			
			Disease progression recorded with platinum-based chemotherapy (e.g., cisplatin or carboplatin)			
			Datopotamab used as subsequent therapy to EGFR-directed therapy (e.g., afatinib, erlotinib,			

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provi	ided or request may be denied. Applicable to ALL continuation of therapy requests.			
	Member is currently receiving the requested medication and all initial authorization criteria continues to be met			
	Member requires continuation of therapy and is NOT experiencing disease progression			
	Ongoing treatment is consistent with FDA-labeling or compendia support			
	☐ Member is NOT experiencing an FDA-labeled limitation of use or toxicity			
	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 **			
Med	dication being provided by: Please check applicable box below.			
_ I	Location/site of drug administration:			
	NPI or DEA # of administering location:			
	<u>OR</u>			

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

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.

Specialty Pharmacy