UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Caprelsa

Program	Prior Authorization
Medication	Caprelsa® (vandetanib)
Markets in Scope	Arizona, Colorado, Hawaii, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, Nevada, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Caprelsa® (vandetanib) is a kinase inhibitor indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.[1] The National Cancer Comprehensive Network (NCCN) recommends use of Caprelsa for the treatment of medullary, follicular, Hürthle cell, and papillary carcinomas.[2] In addition, the National Cancer Comprehensive Network (NCCN) recommends use of Caprelsa as a targeted therapy for Non-Small Cell Lung Cancer in patients with RET rearrangements[2].

Caprelsa may be used in patients with indolent, asymptomatic or slowly progressing disease after careful consideration of the treatment related risks.[1]

Black boxed warnings include QT prolongation, Torsades de Pointes, and sudden death.

2. Coverage Criteria:

A. <u>Thyroid Carcinoma</u>

1. <u>Initial Authorization</u>

a. **Caprelsa** will be approved based on **<u>one</u>** of the following:

(1) **<u>All</u>** of the following criteria:

(a) Diagnosis of medullary thyroid cancer (MTC)

-AND-

(b) **<u>One</u>** of the following:

i. Unresectable locally advanced disease
ii. Metastatic disease

-AND-

(c) **One** of the following:

i. Patient has symptomatic disease
ii. Patient has progressive disease

-OR-

(2) **All** of the following criteria:

(a) **One** of the following diagnosis:

i. Follicular Carcinoma
ii. Hürthle Cell Carcinoma
iii. Papillary Carcinoma

-AND-

(b) **One** of the following:

i. Unresectable recurrent
ii. Persistent locoregional disease
iii. Metastatic disease

-AND-

(c) **One** of the following:

i. Patient has symptomatic disease
ii. Patient has progressive disease

-AND-

(d) Disease is refractory to radioactive iodine treatment

Authorization will be issued for 12 months.

2. Reauthorization

a. **Caprelsa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Caprelsa therapy

Authorization will be issued for 12 months.

B. Non-Small Cell Lung Cancer

1. Initial Authorization

a. **Caprelsa** will be approved based on **both** of the following:

(1) Diagnosis of Non-Small Cell Lung Cancer (NSCLC)

-AND-

(2) Disease is positive for RET gene rearrangement

Authorization will be issued for 12 months.

2. Reauthorization

a. **Caprelsa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Caprelsa therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Caprelsa** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Caprelsa** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Caprelsa therapy

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Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Caprelsa [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. AccessedJuly 29, 2020.

Program	Prior Authorization –Caprelsa (vandetanib)
Change Control	
Date	Change
9/19/2013	New guideline
7/2016	Updated clinical criteria to align with Employer and Individual's notification policy and updated policy to new template
7/2017	Added criteria for NSCLC. Updated references.
7/2018	Revised criteria for medullary thyroid cancer. Added NCCN recommended regimen criteria. Updated references.
9/2019	Annual review. No changes to criteria. Updated references.
9/2020	Annual review with no changes to coverage criteria. Updated references. Added Additional Clinical Rules section.