UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1015-9
Program	Prior Authorization/Notification
Medication	Caprelsa® (vandetanib)
P&T Approval Date	9/2011, 8/2012, 7/2013, 8/2014, 8/2015, 7/2016, 7/2017, 7/2018, 9/2019, 9/2020, 10/2021
Effective Date	2/1/2022; Oxford only: 2/1/2022

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]

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

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].

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. <u>Patients less than 19 years of age</u>

1. Caprelsa will be approved based on the following criterion:

(1) Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Thyroid Carcinoma</u>

UnitedHealthcare®

1. Initial Authorization

Caprelsa will be approved based on **one** of the following:

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

(a) Diagnosis of medullary thyroid cancer (MTC)

-AND-

(b) **One** 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.

C. 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.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

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. Accessed August 16, 2021.

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Change Control	
8/2014	Annual review with no changes to the coverage criteria. Updated formatting, Background and References.
8/2015	Annual review. Added coverage for folicullar, Hurthle Cell and papillary carcinomas per NCCN. Updated medullary carcinoma criteria. Updated background and references.
7/2016	Annual review. Revised criteria for thyroid carcinoma. Updated formatting, background and references.
7/2017	Annual review. Added criteria for NSCLC. Updated references.
7/2018	Annual review. Revised criteria for medullary thyroid cancer. Updated references.
9/2019	Annual review with no changes to the coverage criteria. Updated references. Added general NCCN recommended review criteria.
9/2020	Annual review with no changes to coverage criteria. Updated references.
10/2021	Annual review with no changes to coverage criteria. Updated references.