UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1015-13
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, 10/2022, 10/2023, 10/2024, 10/2025
Effective Date	1/1/2026

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. The National Cancer Comprehensive Network (NCCN) recommends the use of Caprelsa for the treatment of medullary, follicular, oncocytic, and papillary carcinomas.

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

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]:

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

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

a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Thyroid Carcinoma</u>

1. <u>Initial Authorization</u>

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

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

(a) Diagnosis of medullary thyroid cancer (MTC)

-AND-

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

i. Unresectable locoregional disease that is symptomatic or progressing
ii. Asymptomatic recurrent or persistent distant metastatic disease if unresectable and progressing
iii. Recurrent or persistent distant metastases if symptomatic disease or progression

-OR-

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

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

i. Follicular Carcinoma
ii. Papillary Carcinoma

-AND-

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

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

-OR-

(3) **All** of the following:

(a) Diagnosis of Oncocytic Carcinoma

-AND-

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

i. Unresectable locoregional recurrent
ii. Persistent disease
iii. Distant metastatic disease

-AND-

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

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

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

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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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; May 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed September 3, 2025.

Program	Prior Authorization/Notification – Caprelsa® (vandetanib)
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 follicular, 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.
10/2022	Annual review. Updated background and removed criteria for NSCLC as no longer recommended by NCCN. Added state mandate. Updated references.
10/2023	Annual review. Updated hürthle cell carcinoma to oncocytic carcinoma. Updated references.
10/2024	Annual review. Updated criteria for medullary thyroid carcinoma. Updated references.
10/2025	Annual review. Updated criteria for oncocytic, papillary, and follicular carcinoma per NCCN. Updated references.