

## Caprelsa® (vandetanib) (Oral)

Document Number: IC-0024

Last Review Date: 10/31/2017

Date of Origin: 11/01/2012

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### I. Length of Authorization

Coverage is provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 100 mg tablet - 2 tablets per day
- 300 mg tablet - 1 tablet per day

#### B. Max Units (per dose and over time) [Medical Benefit]:

- N/A

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient at least 18 years of age; **AND**
- Patient has no electrolyte abnormalities; **AND**
- Patient does not have long QT syndrome; **AND**

#### Thyroid Carcinoma†

- Follicular/Hurthle Cell/Papillary Carcinoma‡; **AND**
  - Patient's disease is one of the following: metastatic, unresectable, recurrent and/or persistent locoregional; **AND**
  - Patient's disease is progressive and/or symptomatic iodine refractory; **AND**
    - Clinical trials are not available; **OR**
    - Systemic therapy is not available/appropriate; **OR**
- Medullary Carcinoma†
  - Treatment of progressive and/or symptomatic disease that is unresectable, locally advanced or metastatic

### Non-Small Cell Lung Cancer‡

- Patient’s tumor is confirmed to have RET gene rearrangements

†FDA Approved Indication(s); ‡Compendia Approved Indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples include: Interstitial lung disease, severe skin reactions, high blood pressure, QT prolongation, ischemic cerebrovascular events, hemorrhage, heart failure, reversible posterior leukoencephalopathy syndrome, severe diarrhea.

#### V. Dosage/Administration

Indication	Dose
All indications	300 mg PO daily

#### VI. Billing Code/Availability Information

Jcode:

J8999 – Prescription drug, oral, chemotherapeutic, not otherwise specified

NDC:

- Caprelsa 100 mg tablet – 58468-7820-xx
- Caprelsa 300 mg tablet – 58468-7840-xx

#### VII. References

1. Caprelsa [package insert]. Cambridge, MA; Genzyme Corporation; December 2016. Accessed August 2017.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for vandetanib. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most

recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2017.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 8.2017. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2017.
4. Lee SH, Lee JK, Ahn MJ, et al. Vandetanib in pretreated patients with advanced non-small cell lung cancer-harboring RET rearrangement: a phase II clinical trial. *Ann Oncol.* 2017 Feb 1;28(2):292-297

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C73	Malignant neoplasm of thyroid gland
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

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: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC