Caprelsa® (vandetanib)
(Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

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

B. Max Units (per dose and over time) [HCPCS Unit]:

- 300 mg per day

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient at least 18 years of age; **AND**
- Prescriber is enrolled in the Caprelsa® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient does not have a baseline QTcF interval > 450 milliseconds; **AND**

Universal Criteria [1]

- Patient does not have uncorrected electrolyte abnormalities (i.e., hypocalcemia, hypokalemia, hypomagnesemia); **AND**
- Patient does not have a history of Torsades de pointes, congenital long QT syndrome, bradyarrhythmias, or uncompensated heart failure; **AND**
- Patient must not have had a major surgical procedure within the preceding 14 days or have a surgical wound that has not fully healed; **AND**
- Patient does not have moderate or severe hepatic impairment (i.e., Child-Pugh class B or C); **AND**

- Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
- Used as single agent therapy; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (i.e., rifampin, carbamazepine, phenytoin, St. John's Wort, etc.); **AND**
  - Coadministration with anti-arrhythmic drugs (i.e., amiodarone, disopyramide, procainamide, sotalol, dofetilide, etc.); **AND**
  - Coadministration with drugs that prolong the QT interval (i.e., chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide, etc.); **AND**

Thyroid Carcinoma † ‡ Φ [1-3]

- Patient has Papillary, Follicular, or Oncocytic Carcinoma ‡; **AND**
  - Patient has unresectable recurrence, persistent disease, or distant metastases; **AND**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy; **AND**
  - Treatment with clinical trials or other systemic therapies are not available or appropriate **OR**
- Patient has Medullary Carcinoma † ‡; **AND**
  - Patient has unresectable locally advanced, recurrent, or metastatic disease; **AND**
  - Patient has asymptomatic, symptomatic or progressive disease

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: interstitial lung disease (ILD) or pneumonitis, severe skin reactions (i.e., toxic epidermal necrolysis and Stevens-Johnson syndrome), hypertension, QT prolongation, Torsades de Pointes, ventricular tachycardia, ischemic cerebrovascular events, hemorrhage, heart failure, reversible posterior leukoencephalopathy syndrome (RPLS), severe diarrhea (i.e., ≥ grade 3 severity), hypothyroidism, impaired wound healing, renal failure, etc.

V. Dosage/Administration [1]

Indication	Dose
Thyroid Carcinoma	Administer 300 mg, orally, once daily until disease progression or unacceptable toxicity occurs.

VI. Billing Code/Availability Information

HCPCS Code:

- 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 2022. Accessed September 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for vandetanib. National Comprehensive Cancer Network, 2023. 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 September 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Thyroid Carcinoma. Version 4.2023. National Comprehensive Cancer Network, 2023. 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 September 2023.
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
5. Wells SA Jr, Robinson BG, Gagel RF, et al. Vandetanib in patients with locally advanced or metastatic medullary thyroid cancer: a randomized, double-blind phase III trial. J Clin Oncol. 2012 Jan 10;30(2):134-41. Epub 2011 Oct 24. Erratum in: J Clin Oncol. 2013 Aug 20;31(24):3049.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C73	Malignant neoplasm of thyroid gland

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/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/LCA): 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	Palmetto GBA, 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