Pharmacy Policy Bulletin: J-0894 VEGF and EGFR Kinase Inhibitors - Commercial and Healthcare Reform	
Number: J-0894	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes with Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0894-008	**Original Date:** 06/04/2003
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Caprelsa (vandetanib)
FDA-Approved Indication(s):	• Treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

Background:	• Vandetanib is a kinase inhibitor that has been shown to inhibit epidermal growth factor receptor (EGFR)-dependent cell survival in vitro. It inhibits epidermal growth factor (EGF)-stimulated receptor tyrosine kinase phosphorylation in tumor cells and endothelial cells, and vascular endothelial cell growth factor (VEGF)-stimulated tyrosine kinase phosphorylation in endothelial cells. In models of angiogenesis, it has been shown to inhibit endothelial cell migration, proliferation, survival, and new blood vessel formation.
	• Prescribing Considerations:
	  ◦ Caprelsa has a black box warning for QT prolongation, torsades de pointes, and sudden death.
	  ◦ Kinase inhibitors should be prescribed under the supervision of a hematologist/oncologist.
	  ◦ Use Caprelsa in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of Caprelsa.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Caprelsa may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of medullary thyroid cancer (ICD-10: C73).

C. Disease is classified as unresectable locally advanced or metastatic.

D. Disease is classified as symptomatic or progressive.

II. Reauthorization
When a benefit, reauthorization of Caprelsa may be approved when the following criterion is met **(A.)**:
A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as either one of the following **(1. or 2.)**:
1. Disease improvement
2. Delayed disease progression

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology medications listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None
Refer to J-699 for previous versions.

References:
1. Caprelsa [package insert]. Genzyme Corporation; Cambridge, MA: May 2025.