Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran

CAPRELSA (vandetanib)

GPI CODING:

215340850003**

DESCRIPTION:

CAPRELSA (vandetanib), a kinase inhibitor, is FDA approved for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. Use of this agent in patients with indolent, asymptomatic or slowly progressing disease should be carefully considered due to treatment related risks. Specifically, vandetanib is associated with a black box warning regarding the risks of QT prolongation, Torsades de Pointes and sudden death. Furthermore, due to these risks, vandetanib is available only through a restricted distribution program. Vandetanib is a multikinase inhibitor as it has been shown to inhibit the activity of multiple tyrosine kinases including members of the epidermal growth factor receptor family, vascular endothelial cell growth factor receptors, rearranged during transfection (RET), protein tyrosine kinase 6 (BRK), TIE2, members of the EPH receptors kinase family and members of the Src family of tyrosine kinases. In animal cancer models, vandetanib reduced tumor-cell induced angiogenesis, tumor vessel permeability and inhibited tumor growth and metastasis. There is no evidence of a relationship between RET mutations and efficacy with vandetanib.

APPROVAL DURATION:

Quantity Limits
Vandetanib 100 mg tablets: 2 tablets/day
Vandetanib 300 mg tablets: 1 tablet/day

Initial approvals and renewals: 12 months

CRITERIA FOR CAPRELSA

I. Patient has a diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease **OR**
II. Off label uses for oncology drugs if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN.)) *A use is identified by a compendium as medically accepted if the:*
    A. *Indication is a Category 1 or 2A in NCCN,*
    B. *Indication is a Class I, Class IIa or Class IIb in DrugDex,*
    C. *Narrative text in AHFS or Clinical Pharmacology is supportive; or*
    D. *The use is supported by clinical research in 2 or more peer-reviewed medical journals*

AND

III. Patient does not have congenital long QT syndrome

Authorization for continued use shall be reviewed at least every 12 months to confirm the following: patient has experienced an objective response to therapy