SPECIALTY GUIDELINE MANAGEMENT

CAPRELSA (vandetanib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease

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

B. Compendial Uses

- 1. Follicular, Hürthle cell, and papillary thyroid carcinoma
- 2. Non-small cell lung cancer with RET gene rearrangements

All other indications are considered experimental/investigational and not medically necessary.

II.DOCUMENTATION

Submission of RET gene rearrangement documentation is necessary to initiate the prior authorization review for the indication of non-small cell lung cancer.

III.CRITERIA FOR INITIAL APPROVAL

A. Thyroid carcinoma

Authorization of 12 months may be granted for treatment of thyroid carcinoma when any of the following criteria are met:

- 1. Member has radioiodine refractory follicular, Hürthle cell, or papillary thyroid carcinoma
- 2. Member has medullary thyroid carcinoma.

B. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of NSCLC with RET gene rearrangements.

IV.CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting authorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V.REFERENCES

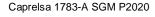
Caprelsa 1783-A SGM P2020

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