Clinical Policy: Vandetanib (Caprelsa)

Reference Number: PA.CP.PHAR.80
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for vandetanib (Caprelsa®).

FDA Approved Indication(s)
Caprelsa is indicated for the 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.

Policy/Criteria
Vandetanib (Caprelsa®) is a kinase inhibitor.

I. Initial Approval Criteria

A. Thyroid Cancer (must meet all):

1. Diagnosis of one o the following (a or b):
   a. Recurrent, unresectable, or metastatic medullary thyroid cancer;
   b. Differentiated thyroid carcinoma (DTC; i.e., follicular, Hurthle cell, or papillary thyroid carcinoma) (off-label);

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. If DTC, failure of Lenvima® or Nexavar® unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required.*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 300 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Non-Small Cell Lung Cancer (off-label) (must meet all)**:**

1. Diagnosis of non-small cell lung cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years.
4. Documentation of RET gene rearrangement;

5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
    a. New dose does not exceed 300 mg per day;
    b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Vandetanib is a kinase inhibitor. *In vitro*, vandetanib inhibits the activity of tyrosine kinases including members of the epidermal growth factor receptor family (EGFR), vascular endothelial cell growth factor receptors (VEGF), 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. Vandetanib inhibits endothelial cell migration, proliferation, survival, and new blood vessel formation in *in* vitro models of angiogenesis. Vandetanib also inhibits EGFR-dependent cell survival *in vitro*. Vandetanib inhibits epidermal growth factor-stimulated receptor tyrosine kinase phosphorylation in tumor cells and endothelial cells and VEGF-stimulated tyrosine kinase phosphorylation in endothelial cells. *In vivo*, vandetanib reduced tumor cell-induced angiogenesis, tumor vessel permeability, and inhibited tumor growth and metastasis in mouse models of cancer.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
DTC: differentiated thyroid carcinoma
FDA: Food and Drug Administration
MTC: medullary thyroid carcinoma

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Lenvima (lenvatinib)	DTC: 24 mg PO QD	24 mg/day
Nexavar (sorafenib)	DTC: 400 mg PO QD	400 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): Congenital long QT syndrome
- Boxed warning(s): QT prolongation, Torsades de pointes, sudden death

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MTC	300 mg PO QD	300 mg/day

V. Product Availability

Tablets: 100 mg, 300 mg

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Added non-small cell lung cancer as a covered off-label indication per NCCN 2A recommendation. Added oncologist and age limit restrictions. Added requirement of prior trials of lenvatinib and sorafenib for non-medullary thyroid carcinoma; removed requirement for prior trial of iodine. Extended reauthorization duration from 6 months to 12 months. References reviewed and updated		
1Q 2019 annual review; thyroid cancer diagnoses edited to reflect MTC vs. DTC for clarity and limited designation of advanced cancer to MTC while retaining a failed drug trial for DTC; references reviewed and updated.	01/19	

References

1. Caprelsa Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2016. Available at: http://www.caprelsa.com/files/caprelsa-pi.pdf. Accessed October 15, 2018.
2. Clinical Pharmacology. Tampa, FL: Gold Standard; 2018. Available at www.clinicalpharmacology.com. Accessed October 15, 2018.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed October 15, 2018.
4. National Comprehensive Cancer Network. Thyroid Cancer Version 2.2017. Available at: http://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed October 15, 2018.
5. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 1.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed October 15, 2018.