Clinical Policy: Vandetanib (Caprelsa)

Reference Number: ERX.SPA.82
Effective Date: 03.01.14
Last Review Date: 08.18 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Vandetanib (Caprelsa®) is a kinase inhibitor.

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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Caprelsa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Thyroid Cancer (must meet all)**:**
1. Diagnosis of one of the following (a or b):
   a. Medullary thyroid cancer;
   b. Follicular, Hurthle cell, or papillary thyroid carcinoma (off-label);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is unresectable locally advanced or metastatic;
5. If follicular, Hurthle, or papillary thyroid carcinoma: Documentation supports failure of, or presence of clinically significant adverse effects or contraindication to, Lenvima® and Nexavar®;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 300 mg/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: Length of Benefit

B. Non-Small Cell Lung Cancer (off-label) (must meet all)**:**
1. Diagnosis of non-small cell lung cancer (NSCLC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of RET gene rearrangement;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 300 mg/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: Length of Benefit

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or documentation supports that member is currently receiving Caprelsa for a covered indication and has received this medication for at least 30 days;
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/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: Length of Benefit

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer

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 and may require prior authorization.

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

- Congenital long QT syndrome

Appendix D: Black Box Warning - QT Prolongation and Torsades de Pointes, and Sudden Death

- Caprelsa can prolong the QT interval. Torsades de pointes and sudden death have occurred in patients receiving Caprelsa.
- Do not use Caprelsa in patients with hypocalcemia, hypokalemia, hypomagnesemia,or long QT syndrome. Correct hypocalcemia, hypokalemia and/or hypomagnesemia prior to Caprelsa administration.
- Monitor electrolytes periodically.
- Avoid drugs known to prolong the QT interval.
- Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense Caprelsa.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Medullary thyroid cancer	300 mg PO QD	300 mg/day

VI. Product Availability
Tablets: 100 mg, 300 mg

VII. References
1. Caprelsa Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2016. Available at https://www.caprelsa.com/. Accessed June 27, 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 27, 2018.
3. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 1.2018. Available at https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed June 27, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.14	03.14
Policy converted to new template. Criteria: added max dose; removed upper age limit, drug interaction, safety, and disease progression or unacceptable toxicity criteria.	07.16	09.16
-Converted to new template. -Extended continued approval from 6 to 12 months -Added NCCN recommendations -Added Black Box Warning info to Appendix	07.01.17	08.17
3Q 2018 annual review: added specialist involvement in care; differentiated thyroid cancers: added requirement for prior trials of lenvatinib and sorafenib and removed requirements for clinical trial appropriateness/prior trial of iodine; added off-label use for NSCLC; increased approval durations to length of benefit; added COC; references reviewed and updated.	06.27.18	08.18

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.