Clinical Policy: Vandetanib (Caprelsa)

Reference Number: ERX.SPA.82
Effective Date: 03.01.14
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

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 (MTC) 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

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. Recurrent, unresectable or metastatic MTC;
   b. Recurrent, unresectable or metastatic 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. For Caprelsa requests, member must use vandetanib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. If DTC, failure of Lenvima® or Nexavar®, unless clinically significant adverse effects are experienced or both are contraindicated;
   **Prior authorization may be required for Lenvima and Nexavar*
6. 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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. 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. Thyroid Cancer (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. For Caprelsa requests, member must use vandetanib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

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

DTC: differentiated thyroid carcinoma
FDA: Food and Drug Administration
MTC: medullary thyroid carcinoma
NCCN: National Comprehensive Cancer Network

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)	DTC: 24 mg PO QD	24 mg/day
Nexavar (sorafenib)	DTC: 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/Boxed Warnings

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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MTC	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; June 2020. Available at: http://www.caprelsa.com/files/caprelsa-pi.pdf. Accessed November 9, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 9, 2021.
3. National Comprehensive Cancer Network. Thyroid Cancer Version 3.2021. Available at: http://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed November 9, 2021.
4. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 7.2021. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 9, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
1Q 2019 annual review: no significant changes; thyroid cancer diagnoses edited to reflect MTC vs. DTC for clarity and limited designation of advanced cancer to MTC while retaining a failed trial for DTC; references reviewed and updated.	11.13.18	02.19
1Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: oral oncology generic redirection language added; for lung cancer, recurrent, advanced, or metastatic disease added; references reviewed and updated.	11.15.20	02.21
1Q 2022 annual review: clarified DTC be recurrent, advanced or metastatic per NCCN; removed lung cancer indication as it now carries a NCCN category 2B rating; clarified oral oncology generic redirection language to "must use"; references reviewed and updated.	11.09.21	02.22

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.