Clinical Policy: Vandetanib (Caprelsa)

Reference Number: CP.PHAR.80
Effective Date: 10.01.11
Last Review Date: 02.18
Line of Business: Health Insurance Marketplace, 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 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 (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Caprelsa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Thyroid Cancer (must meet all)**:**

1. Diagnosis of medullary thyroid cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is unresectable locally advanced or metastatic, and is progressive or symptomatic;
5. Dose does not exceed 300 mg/day.

Approval duration: 6 months

B. Thyroid Carcinoma (off-label) (must meet all)**:**

1. Diagnosis of follicular, Hurthle or papillary thyroid carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Unresectable, locally advanced or metastatic disease that is progressive or symptomatic;
5. Documentation supports failure of, or presence of clinically significant adverse effects or contraindication to lenvatinib and sorafenib;

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: 6 months

C. 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. Request meets one of the following (a or b):
   a. Dose does not exceed 300mg/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

D. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Caprelsa for covered indications and has received this medication for at least 30 days;
2. Member is responding positively to therapy (e.g., no disease progression, no significant toxicity);
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: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

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)	24 mg PO QD	24 mg/day
Nexavar® (sorafenib)	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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Medullary Thyroid Cancer	300 mg PO QD; The starting dose is 200 mg in patients with moderate to severe renal impairment	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: http://www.caprelsa.com/files/caprelsa-pi.pdf. Accessed November 21, 2017.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 21, 2017.
3. National Comprehensive Cancer Network. Thyroid Cancer Version 2.2017. Available at: http://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed November 21, 2017.
4. 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 November 21, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Removed prospective ECG monitoring question from algorithm	03.14	03.14

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added additional drug names to Appendix B		
Updated occurrence stats Updated Safety section Updated References	02.15	03.15
Policy converted to new template. Criteria: added max dose, expanded contraindications/safety concerns per PI; removed upper age limit, drug, QT and ECG monitoring requirement, and disease progression or unacceptable toxicity general statement. Background: limited to description/MOA and FDA indications. Appendices: removed Appendix A: QT Monitoring and Electrocardiogram (ECG) Recommendations for Caprelsa, and Appendix B: Examples of Drugs Known to Prolong the QT Interval. Added boxed warning safety information.	01.16	03.16
Age restriction removed. The following cautions/contraindications are covered by the Caprelsa REMS program and so are not listed separately: Congential long QT syndrome, Torsades de pointes, bradyarrhythmias, uncompensated heart failure, electrolyte monitoring, drug interactions, dosing.Safety criteria were removed unless they meet all the following: represent contraindications or black box warnings not covered by a REMS program, that can be objectively measured and diagnosed/ruled out with a single test.	02.17	03.17
1Q18 annual review: - Policies combined for Medicaid and HIM lines of business - 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. - Allowed for Continuation of Care requirements for reauthorization. - References reviewed and updated	11.21.17	02.18

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.