

Clinical Policy: Vandetanib (Caprelsa)

Reference Number: IL.PHAR.80

Effective Date: 1.1.20

Last Review Date: 04.18.22

Line of Business: 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 (including 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 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 one of the following (a or b):
 - a. Recurrent, unresectable or metastatic medullary thyroid carcinoma (MTC);
 - b. Recurrent, unresectable or metastatic differentiated thyroid carcinoma (DTC; i.e., follicular, Hurthle cell, or papillary thyroid carcinoma) (off-label) Prescribed by or in consultation with an oncologist;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. 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. 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): 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 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 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 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): 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 – CP.PMN.53 for Medicaid 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 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

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 |
|---|-----------|-------------------|
| New policy created, adapted from CP.PHAR.80 Vandetanib (Caprelsa) policy. | 12.17.19 | 1.7.20 |
| 1Q2021 annual review: Added diagnosis lung cancer, recurrent, advanced, or metastatic disease; references reviewed and updated. | 3.11.2021 | |
| 2Q2022 annual review: Added oncologist; clarified DTC be recurrent, advanced or metastatic per NCCN; removed lung cancer indication as it now carries a NCCN category 2B rating; references reviewed and updated. | 4.18.22 | |

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. 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.

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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.

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