Clinical Policy: Vandetanib (Caprelsa)

Reference Number: CP.PHAR.80
Effective Date: 10.01.11
Last Review Date: 05.22
Line of Business: Commercial, HIM, 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 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 or 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:
Medicaid/HIM: 6 months
Commercial: 12 months or duration of request, whichever is less

Legacy Wellcare – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Thyroid Cancer (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. 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:
Medicaid/HIM: 12 months
Commercial: 12 months or duration of request, whichever is less
Legacy Wellcare – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and 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
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
1Q 2019 annual review; no significant changes from previously approved corporate policy; 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.	11.13.18	02.19
1Q 2020 annual review: removed HIM disclaimer for HIM NF drugs; no clinically significant changes; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: commercial line of business added; oral oncology generic redirection language added; for lung cancer, recurrent, advanced, or metastatic disease added; references to HIM.PHAR.21 revised to HIM.PA.154; 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”; added legacy Wellcare auth durations (WCGCP.PHAR.80 to retire); references reviewed and updated.	11.09.21	02.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	01.20.22	05.22
Template changes applied to other diagnoses/indications.	10.12.22	

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.

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.