BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

**PHARMACY COVERAGE GUIDELINES**
**SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE: 8/19/2021**
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# CAPRELSA® (vandetanib)

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

## CAPRELSA® (vandetanib)

**Criteria**:

- **Criteria for initial therapy:** Caprelsa (vandetanib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
2. Individual is 18 years of age or older
3. A confirmed diagnosis of **ONE** of the following:
    a. Symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease
    b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    a. Electrocardiogram
    b. Thyroid stimulating hormone
    c. Serum potassium, calcium, and magnesium are within normal limits
    d. Negative pregnancy test in a woman of child bearing potential
    e. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
5. There are **NO** FDA-label contraindications, such as:
    a. Congenital long QT syndrome
6. Individual does not have a QTcF interval greater than 450 ms
7. Individual does not have a history of Torsades de pointes, ventricular arrhythmia, bradyarrhythmia, uncompensated heart failure, or recent myocardial infarction
8. Individual does not have moderate (Child-Pugh Class B) or severe hepatic impairment (Child-Pugh Class C)
9. Individual does not have end-stage renal disease that requires dialysis
10. There are no significant interacting drugs such as agents that may prolong the QT interval and strong inducers of cytochrome P450 3A4 (CYP3A4)

**Initial approval duration**: 6 months

## CAPRELSA® (vandetanib)

- **Criteria for continuation of coverage (renewal request):** Caprelsa (vandetanib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

2. Individual's condition has responded while on therapy
    a. Response is defined as:
        i. No evidence of disease progression
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Torsades de points
        ii. Ventricular tachycardia
        iii. Toxic epidermal necrolysis (TEN)
        iv. Stevens-Johnson syndrome (SJS)
        v. Interstitial lung disease (ILD) or pneumonitis
        vi. Ischemic cerebrovascular event
        vii. Severe hemorrhage
        viii. Heart failure
        ix. Hypertension that cannot be controlled
        x. Reversible posterior leukoencephalopathy syndrome (RPLS)

5. Individual does not have a history of Torsades de pointes, ventricular arrhythmia, bradyarrhythmia, uncompensated heart failure, or recent myocardial infarction

6. Individual does not have moderate (Child-Pugh Class B) or severe hepatic impairment (Child-Pugh Class C)

7. Individual does not have end-stage renal disease that requires dialysis

8. There are no significant interacting drugs such as agents that may prolong the QT interval and strong inducers of cytochrome P450 3A4 (CYP3A4)

**Renewal duration**: 12 months

# CAPRELSA® (vandetanib)

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of a Non-Cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

**Description:**

Caprelsa (vandetanib) is indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

According to the National Comprehensive Cancer Network (NCCN) guideline on thyroid cancer (version 1.2021), the pace of disease progression should be taken into account regarding treatment decisions. Individuals with very indolent disease who are asymptomatic may not be appropriate candidates for kinase inhibitor therapy due to expected side effects that will adversely affect the individual's quality of life. Accordingly, the product label states that use of Capresla (vandetanib) in individuals with indolent, asymptomatic or slowly progressing disease should be undertaken only after careful consideration of the treatment related risks of Caprelsa (vandetanib).

Studies have shown that vandetanib inhibits the tyrosine kinase activity of the EGFR and VEGFR families, RET, BRK, TIE2, and members of the EPH receptor and Src kinase families. These receptor tyrosine kinases are involved in both normal cellular function and pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, and maintenance of the tumor microenvironment. In addition, a metabolite of the drug, has similar inhibitory activity to the parent compound for VEGF receptors (KDR and Flt-1) and EGFR.

Because of the risk of QT prolongation, Torsades de pointes, and sudden death, Caprelsa (vandetanib)is available only through a restricted distribution program called the CAPRELSA REMS Program. Only prescribers and pharmacies certified with the program are able to prescribe and dispense Caprelsa (vandetanib).

The goals of the CAPRELSA REMS Program are to mitigate the serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of Caprelsa (vandetanib) by:

Educate prescribers on the following:

- Serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of Caprelsa (vandetanib).
- The need to monitor for QT prolongation and electrolyte abnormalities.
- Appropriate management of QT prolongation to minimize the occurrence of Torsades de pointes and sudden death associated with use of Caprelsa (vandetanib).

Inform patients on the following:

- Serious risks of QT prolongation, Torsades de pointes, and sudden death associated with use of Caprelsa (vandetanib).

## CAPRELSA® (vandetanib)

**Resources:**

Caprelsa (vandetanib) product information, revised by Genzyme Corporation 12-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on June 09, 2021.

Sherman SI. Medullary thyroid cancer: Systemic therapy and immunotherapy. In: UpToDate, Ross DS, Mulder JE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on June 14, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Thyroid Cancer Version 1.2021 – Updated April 9, 2021. Available at https://www.nccn.org. Accessed on June 14, 2021.

National Comprehensive Cancer Network (NCCN) Compendium: Caprelsa. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. Available at: http://www.nccn.org. Accessed on June 14, 2021.

Wells SA, Robinson BG, Gagel RF, et al.: Vandetanib in patients with locally advanced or metastatic medullart thyroid cancer: A randomized, double-blind phase III trial. J Clin Oncol 2012 Jan 10; 30 (2):134-141. Accessed June 14, 2021. Erratum in J Clin Oncol 2013 Aug 20; 31 (24):3049. Accessed June 14, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.