ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Caprelsa® (vandetanib) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Caprelsa® (vandetanib)

Diagnosis (documentation supportive of diagnosis is required)

☐ Symptomatic or progressive medullary thyroid cancer that is unresectable, locally advanced, or metastatic disease
☐ Other (please state): _____

Note: *Use in patients with indolent, asymptomatic, or slowly progressing medullary thyroid cancer should be carefully considered due to treatment related risks with use*

Clinical Consideration (for approval, please acknowledge and provide documentation of the following):

☐ Past medical history NEGATIVE for congenital long QT syndrome
☐ Baseline QTcF interval is less than 450 milliseconds
☐ Baseline labs (serum potassium, calcium, magnesium and TSH) are within normal limits
☐ Enrolled in the Caprelsa REMS Program; 1-800-236-9933; www.caprelsarems.com

Physician Specialty

☐ Oncologist
☐ Endocrinologist
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Caprelsa® (vandetanib)

CLASSIFICATION

- Antineoplastic agent, Tyrosine Kinase Inhibitor

DESCRIPTION

- Vandetanib is indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. In patients with indolent, asymptomatic or slowly progressing disease, treatment with vandetanib should be cautiously considered because of treatment-related risks of therapy.
- Progression-free survival was significantly improved with vandetanib compared with placebo in a double-blind, randomized study (n=331) in patients with unresectable locally advanced or metastatic medullary thyroid cancer.
- Vandetanib is a tyrosine kinase inhibitor. *In vitro* studies have shown that vandetanib inhibits the activity of tyrosine kinases in tumor cells and endothelial cells. This includes the epidermal growth factor receptor (EGFR) family, vascular endothelial cell growth factor (VEGF) receptors, rearranged during transfection (RET), protein tyrosine kinase 6 (BRK), TIE2, members of the EPH receptors kinase family, and members of the Src family of tyrosine kinases. There is no evidence of a relationship between RET mutations and efficacy with vandetanib. In *in vitro* models of angiogenesis, vandetanib inhibits endothelial cell migration, proliferation, survival and new blood vessel formation.
- In a randomized, double-blind, placebo-controlled, phase 3 trial (n=331) in individuals with unresectable, locally advanced, or metastatic medullary thyroid cancer, progression-free survival was significantly improved with vandetanib (22.6months) compared with placebo (16.4 months). No significant difference in overall survival was shown between the two groups. The overall objective response rate (all partial responses) was 44% for the vandetanib group compared with 1% for the placebo group.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 3
Commercial Formulary:	Tier 3
Medicare Part D coverage:	Tier 5

COVERAGE CRITERIA

Caprelsa® (vandetanib) meets the definition of **medical necessity** for any FDA approved indication, not otherwise excluded from Part D, including the following:

- Symptomatic or progressive medullary thyroid cancer that is unresectable locally advanced or metastatic disease *(documentation of diagnosis required).*

Note: Use of vandetanib in patients with indolent, asymptomatic or slowly progressing medullary thyroid cancer should be carefully considered due to treatment related risks with use of vandetanib.

Caprelsa® (vandetanib) is considered **experimental** for the following:

- Other forms of malignancy not otherwise supported in CMS approved drug compendia

Required Provider Specialty:

- Approval is limited to Oncology and Endocrinology

DOSAGE/ADMINISTRATION:

Normal Dosing:

- The recommended dose of vandetanib for the treatment of medullary thyroid cancer in adults is 300mg orally once daily with or without food; continue treatment until treatment benefit no longer seen or unacceptable toxicity occurs.
- Prescribers and pharmacies must be registered with the Caprelsa REMS program and meet all of the requirements to prescribe and dispense vandetanib; the Caprelsa REMS program details and registration are available at 1-800-236-9933 or www.caprelsarems.com.

Dosage in Renal Failure

- Dose reduction to 200mg orally once daily is recommended in patients with moderate renal impairment (CrCl 30 to 50 mL/min) and severe renal impairment (CrCl <30 mL/min).

Dosage in Hepatic Insufficiency

- Vandetanib is not recommended for use in patients with moderate hepatic impairment (Child-Pugh Class B) or severe hepatic impairment (Child-Pugh Class C). Safety and efficacy have not been established.

Dosage Reductions with Toxicity

- In the event of corrected QT interval, Fridericia (QTcF) greater than 500ms, interrupt dosing until QTcF returns to less than 450ms, then resume at a reduced dose.
- For CTCAE (Common Terminology Criteria for Adverse Events) grade 3 or greater toxicity, interrupt dosing until toxicity resolves or improves to CTCAE grade 1, and then resume at a reduced dose.
- Because of the 19-day half-life, adverse reactions including a prolonged QT interval may not resolve quickly
- The 300mg daily dose can be reduced to 200mg (two 100-mg tablets) and then to 100mg for CTCAE grade 3 or greater toxicities.

PRECAUTIONS:

Black Box Warning: QT Prolongation, Torsades de Pointes, and Sudden Death

- Vandetanib can prolong the QT interval. Torsades de pointes and sudden death have been reported in patients receiving vandetanib.

- Vandetanib should not be used in patients with hypocalcemia, hypokalemia, hypomagnesemia, or long QT syndrome. These electrolyte imbalances must be corrected prior to vandetanib administration and should be periodically monitored.
- Drugs known to prolong the QT interval should be avoided. If a drug known to prolong the QT interval must be administered, more frequent ECG monitoring is recommended. Given the half-life of 19 days, ECGs should be obtained to monitor the QT interval at baseline, at 2 to 4 weeks and 8 to 12 weeks after starting treatment with vandetanib and every 3 months thereafter. Following any dose reduction for QT prolongation, or any dose interruptions greater than 2 weeks, QT assessment should be conducted as described above.
- Because of the 19-day half-life, adverse reactions including a prolonged QT interval may not resolve quickly. Monitor appropriately. Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense vandetanib

Contraindications:

- Congenital long QT syndrome

Precautions:

- Do not start therapy if QTcF interval > 450ms.
- If QTcF interval > 500ms during therapy, temporarily discontinue therapy and resume at reduced dose.
- Concomitant use with antiarrhythmic drugs and other drugs known to prolong the QT interval (e.g. clarithromycin, chloroquine, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide) should be avoided; if concomitant use is necessary, frequent monitoring is recommended.
- Restricted distribution program (Caprelsa REMS); enroll by calling 1-800-236-9933 or www.caprelsarems.com.
- If history of torsades de pointes, bradyarrhythmias or uncompensated heart failure, do not use because torsades de pointes, ventricular tachycardia, and sudden death have been reported.
- Temporarily discontinue therapy if Common Terminology Criteria for Adverse Events (CTCAE) grade 3 or greater toxicity; may resume at reduced dose.
- Avoid concomitant use with strong CYP3A4 inducers (e.g. carbamazepine, dexamethasone, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, St. John's Wort) should be avoided.
- Diarrhea, including severe cases that may result in electrolyte imbalances, has been reported; close monitoring recommended; interruption of therapy and dose reduction may be warranted.
- Heart failure has been reported (including fatal cases). Monitor and discontinue therapy if warranted.
- Use not recommended if recent history of hemoptysis of 1/2 teaspoon of red blood or greater.
- Hemorrhagic events, some fatal, have been reported; discontinue treatment for severe hemorrhage.
- Use not recommended if moderate to severe hepatic impairment (Child-Pugh B and C); no studies available.
- Hypertension, including hypertensive crisis, has been reported. Monitoring is recommended. Interruption of therapy or dose reduction may be warranted.
- Hypothyroidism has been reported; monitoring recommended.
- Interstitial lung disease (pneumonitis), resulting in death, has been reported; interruption or permanent discontinuation of therapy may be necessary depending on severity of symptoms.
- Ischemic cerebrovascular events, including fatal cases, have been reported; discontinue treatment in severe cases.
- Photosensitivity reactions have been reported; protective clothing and sunscreen recommended during therapy and for 4 months after discontinuation.

- Moderate (CrCl 30 to < 50 mL/min) and severe (CrCl < 30 mL/min) renal impairment require initial dose reduction and close monitoring.
- Reversible posterior leukoencephalopathy syndrome (RPLS) has been reported; consider treatment discontinuation in patients presenting with seizures, headache, visual disturbances, confusion, or altered mental function.
- Serious skin reactions, including Stevens-Johnson syndrome, with some cases resulting in death, have been reported; hold therapy until improvement if CTCAE grade 3 or greater skin reactions occur; continued treatment with a dose reduction or permanent discontinuation should be considered.
- Women of childbearing potential; known teratogen; pregnancy should be avoided with effective contraception during treatment and for at least 4 months following discontinuation.

Billing/Coding information

CPT Coding:

C9399	Unclassified drugs or biologicals
J8999	Prescription drug, oral, chemotherapeutic, Not otherwise specified

HCPCS Coding:

COST

- AWP (September 2011): 300mg tablet (1): $396.00; 100mg tablet (1): $198.00
- AWP (April 2015): 300mg tablet (1): $481.17; 100mg tablet (1): $240.59

COMMITTEE APPROVAL:

September 2011

GUIDELINE UPDATE INFORMATION:

September 2011	Medical Policy Created
NCCN 2.2011 Version	Vandetanib was added as an option for the treatment of recurrent or persistent medullary thyroid carcinoma
May 2015	Coverage policy reviewed; AWP updated

REFERENCES:

- DRUGDEX®, accessed 09/20/2011, 5/26/15
- Product Information: CAPRELSA® (vandetanib) tablets. AstraZeneca Pharmaceutical LP, Wilmington, DE, 2011.
- Version 2.2011, 03/25/11 © National Comprehensive Cancer Network, Inc. 2011.