

Pharmacy

PRIOR AUTHORIZATION FORM

For Prior Authorization, please fax to: (877) 974-4411 toll free, or (616) 942-8206

This form applies to: Commercial Plan Medicaid Plan Medicare Plan

Caprelsa[®] (vandetanib)

URGENT (life threatening)

Non-Urgent (standard review)

A claim involving "urgent care" applies when then standard review time will seriously jeopardize the life or health of the member, or subject the member to severe pain that cannot be managed without the care or treatment requested in the subject of this request. **Priority Health averages between 1 and 3 business days for our standard review response time.**

Member Information

Member Name:	Member No.:
DOB:	Gender:
Member's PCP:	

Provider Information

Provider Name:	
Office Contact Name:	Provider Phone:
Provider NPI:	Provider Fax:
Provider Address:	

Provider Signature _____

Date _____

PRODUCT INFORMATION

- Caprelsa[®] 100 mg tablet
 Caprelsa[®] 300 mg tablet

Dose: _____ **Start Date:** _____

Note: When authorized, Caprelsa[®] will be limited to one tablet daily. In patient's with moderate to severe renal impairment needing a dose of 200 mg daily, please submit documentation.

PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for Caprelsa (vandetanib) requires the following information to certify:

Authorization for Caprelsa[®], given for 3 months, requires:

1. Diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease.
2. A baseline ECG must be obtained to monitor the QT at baseline, 2-4 weeks, and 8-12 weeks after starting treatment.
3. Due to safety concerns with use of Caprelsa[®], patients must not have uncorrected hypocalcemia, hypokalemia, hypomagnesemia, or long QT syndrome.

Continued authorization for Caprelsa[®], given in 6 month intervals, requires:

1. ECG must be obtained to monitor QT every 3 months.
2. Labs to monitor calcium, potassium, and magnesium levels are obtained every 6 months.
3. The patient is compliant in taking the medication as scheduled
4. The patient tolerated the medication
5. The patient did not experience any severe adverse reactions while taking the medication
6. The patient has responded to treatment, as determined by the prescribing physician

PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for Caprelsa[®] (vandetanib) requires the following information to certify:

A. What is the patient's diagnosis?

- a. Medullary Thyroid Cancer (MTC)
- i. Which of the following describes the patient's disease progression?
- Unresectable locally advanced or metastatic disease
- Indolent, asymptomatic, or slowly progressive disease (authorization will not be given)
- b. Other: _____
- Rationale for use: _____

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug's use for the identified indication.

B. A baseline ECG has been obtained to monitor QT at baseline, 2-4 weeks, 8-12 weeks, and then every 3 months after starting medication.

- Yes – Date: _____
- No – Rationale: _____

C. Which of the following apply to the patient?

(Due to safety concerns with Caprelsa[®], authorization will not be given if any of the below apply)

- Hypocalcemia (uncorrected)
- Hypokalemia (uncorrected)
- Hypomagnesemia (uncorrected)
- Congenital long QT syndrome
- History of Torsades de pointes
- None of the above

Note: Drugs known to prolong QT interval should be avoided, including but not limited to St. John's Wort, chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide, amiodarone, disopyramide, procainamide, sotalol, and dofetilide.

PRIORITY HEALTH PRECERTIFICATION REQUIREMENTS

Authorization for continuation of Caprelsa[®] (vandetanib) requires the following information to certify:

Patient must have met the following requirements:

- Patient lab results confirming the patient has not developed hypocalcemia, hypokalemia, or hypomagnesemia have been completed *within the previous 6 months*. **Date:** _____
- Updated ECG has been obtained *within the previous 3 months*. **Date:** _____
- The patient is compliant in taking the medication as scheduled
- The patient tolerated the medication
- The patient did not experience any severe adverse reactions while taking the medication
- The patient has responded to treatment, as determined by the prescribing physician

OTHER INFORMATION

Note: Prescribers and pharmacies must be enrolled in the Caprelsa REMS program to prescribe and dispense this medication. For additional information, go to <http://www.caprelsarems.com>.

FOR MEDICARE ONLY

If none of the above precertification criteria is applicable to this member, please check off which, if any, of the following apply:

1. All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects
2. The number of doses available under a dose restriction for the prescription drug:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition, or
 - b. Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
3. The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition, or
 - b. Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
 - c. Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.
4. None of the above apply

****If you selected 1, 2, or 3 above, supporting evidence/documentation is required for review. If no supporting evidence/documentation is provided, this request will not be approved.**

***** All fields must be complete and legible for Prior Authorization Review*****

**Please fax this request to: (877)974-4411 toll free or (616)942-8206
YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX**