



5.21.16

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Antineoplastic Agents	Original Policy Date:	February 10, 2012
Subject:	Caprelsa	Page:	1 of 5

Last Review Date: March 12, 2021

Caprelsa

Description

Caprelsa (vandetanib)

Background

Caprelsa (vandetanib) is a kinase inhibitor approved for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. Caprelsa inhibits endothelial cell migration, proliferation, survival and new blood vessel formation in *in vitro* models of angiogenesis. Caprelsa inhibits EGFR-dependent cell survival *in vitro*. In addition, Caprelsa inhibits epidermal growth factor (EGF)–stimulated receptor tyrosine kinase phosphorylation in tumor cells and endothelial cells and VEGF-stimulated tyrosine kinase phosphorylation in endothelial cells (1).

Regulatory Status

FDA-approved indication: Caprelsa is a kinase inhibitor indicated for symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease (1).

Use Caprelsa in patients with indolent, asymptomatic, or slowly progressing disease only after careful consideration of the treatment related risks of Caprelsa (1).

Caprelsa carries a boxed warning of QT prolongation and torsades de pointes. Caprelsa can prolong the QT interval. Torsades de pointes and sudden death have been reported in patients receiving Caprelsa. Caprelsa should not be used in patients with hypocalcemia, hypokalemia, hypomagnesemia, or congenital long QT syndrome. Hypocalcemia, hypokalemia, and/or

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hypomagnesemia must be corrected prior to Caprelsa administration and should be periodically monitored. Drugs known to prolong the QT interval should be avoided. 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 Caprelsa, and every 3 months thereafter. Following any dose reduction for QT prolongation or any dose interruptions of more than 2 weeks, QT assessment should be conducted as previously described. Because of the 19-day half-life, adverse reactions, including a prolonged QT interval, may not resolve quickly (1).

Caprelsa is available only through a restricted distribution program called Caprelsa REMS. Only prescribers and pharmacies certified by the program may prescribe and dispense Caprelsa. The Risk Evaluation and Mitigation Strategy (REMS) program for Caprelsa is required by the FDA and is intended to help manage known and potential serious risks associated with Vandetanib as well to ensure the benefits outweigh the risks for each patient (1).

Safety and effectiveness of Caprelsa in pediatric patients have not been established (1).

Related policies

Retevmo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Caprelsa may be considered **medically necessary** for patients 18 years of age or older for treatment of symptomatic or progressive medullary thyroid cancer if the conditions indicated below are met.

Caprelsa is considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

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Patient must have the following:

Symptomatic or progressive medullary thyroid cancer

AND ALL of the following:

1. Unresectable locally advanced disease or metastatic disease
2. **NO** hypocalcemia, hypokalemia, or hypomagnesemia before the initiation of Caprelsa
3. **NO** congenital long QT syndrome
4. Physician must complete Risk Evaluation and Mitigation Strategy (REMS) program

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Symptomatic or progressive medullary thyroid cancer

AND the following:

1. Physician must complete Risk Evaluation and Mitigation Strategy (REMS) program

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
100 mg	270 tablets per 90 days OR

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300 mg	90 tablets per 90 days
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Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Caprelsa is a kinase inhibitor indicated for symptomatic or progressive medullary thyroid cancer in patients 18 years of age or older, with unresectable locally advanced or metastatic disease. Caprelsa should not be used in patients with hypocalcemia, hypokalemia, hypomagnesemia, or congenital long QT syndrome. Hypocalcemia, hypokalemia, and/or hypomagnesemia must be corrected prior to Caprelsa administration and should be periodically monitored. The Risk Evaluation and Mitigation Strategy (REMS) program for Caprelsa is required by the FDA (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Caprelsa while maintaining optimal therapeutic outcomes.

References

1. Caprelsa [package insert]. Cambridge, MA: Genzyme Corporation; June 2020.

Policy History

Date	Action
February 2012	New Addition
March 2013	Annual editorial review and reference update
March 2014	Annual review and reference update
June 2015	Annual editorial review
June 2016	Annual editorial review and reference update Policy number changed from 5.04.16 to 5.21.16
June 2017	Annual editorial review and reference update
June 2018	Annual editorial review Addition of quantity limits to criteria
June 2019	Annual review and reference update
June 2020	Annual review
September 2020	Annual review and reference update

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March 2021 Annual editorial review

Keywords

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