

Exkivity (mobocertinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Exkivity (mobocertinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Exkivity (mobocertinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 2A); **AND**
- II. Lung Cancer has epidermal growth factor receptor (EGFR) exon 20 insertion mutations, with test results confirmed; **AND**
- III. Individual has demonstrated disease progression on or after platinum-based chemotherapy; **AND**
- IV. Individual has not progressed on prior therapy with Exkivity (mobocertinib); **AND**
- V. Individual is using Exkivity (mobocertinib) as monotherapy.

NOTE:

Exkivity (mobocertinib) has a black box warning for QTc prolongation and Torsades de Pointes. Monitor QTc and electrolytes at baseline and periodically during treatment. Increase monitoring frequency in patients with risk factors for QTc prolongation. Avoid concomitant drugs known to prolong QTc as well as strong or moderate CYP3A inhibitors. Withhold, reduce dose, or permanently discontinue Exkivity based on the severity of QTc prolongation.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 28, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 28, 2022.
 - a. Non-Small Cell Lung Cancer. V3.2022. Revised March 16, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.