Exkivity® (mobocertinib)
Effective 11/01/2022

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Exkivity® (mobocertinib) is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Advanced or metastatic NSCLC
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documentation that the cancer has EGFR exon 20 insertion mutation
5. Physician documentation of an inadequate response or adverse reaction to at least one platinum-based chemotherapy regimen or contraindication to the use of platinum-based chemotherapy
6. Request is within quantity limit of 4 units/day

Continuation of Therapy

Reauthorizations requires physician documentation of continuation of therapy and positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

Exkivity® (mobocertinib)	120 capsules per 30 days

References

1. Exkivity (mobocertinib) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc: September 2021.
2. Riely GJ, Neal JW, Camidge DR, et al. Activity and safety of mobocertinib (TAK-788) in previously treated non-small cell lung cancer with EGFR exon 20 insertion mutations from a phase I/II trial. Cancer Discov. 2021;11(7):1688-1699. doi:10.1158/2159-8290.CD-20-1598[PubMed 33632775]
3. Zar T, Graeber C, Perazella MA. Recognition, treatment, and prevention of propylene glycol toxicity. Semin Dial. 2007;20(3):217-219. doi:10.1111/j.1525-139X.2007.00280.x[PubMed 17555487]
4. Zhou C, Ramalingam SS, Kim TM, et al. Treatment outcomes and safety of mobocertinib in platinum-pretreated patients with EGFR exon 20 insertion-positive metastatic non-small cell lung cancer: a phase 1/2 open-label nonrandomized clinical trial. JAMA Oncol. 2021;7(12):e214761. doi:10.1001/jamaoncol.2021.4761[PubMed 34647988]

Review History

09/21/2022 – Reviewed and Created for September P&T. Matched MH criteria. Effective 11/1/22.

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