Cabometyx (cabozantinib)
Effective 08/01/2022

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

CABOMETYX is a prescription medicine used to treat:

- Patients with advanced kidney cancer (renal cell carcinoma [RCC])
- Patients with liver cancer (hepatocellular carcinoma [HCC]) who have been previously treated with the medicine sorafenib
- Adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGR-targeted therapy and who are radioactive iodine-refractory or ineligible

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are currently receiving treatment with Cabometyx, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets **ALL** following criteria and documentation has been submitted:

<u>Advanced renal cell carcinoma (RCC)</u>

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. **ALL** of the following:
        i. Member has clear cell histology

ii. Requested agent will be used in combination with Opdivo (nivolumab)
iii. Physician documented of inadequate response, adverse reaction, or contraindication to Inlyta (axitinib) used in combination with Keytruda (pembrolizumab)

b. **ALL** of the following:
i. Member has clear cell histology
ii. Member has received a previous treatment in the metastatic setting *(e.g., cabozanitinib + nivolumab, axitnib + pembrolizumab, lenvatinib + pembrolizumab. Other treatment options may be found in the NCCN guideline)*
iii. Requested agent will be used as monotherapy

c. Member has non-clear cell histology

5. Quantity requested is ≤1 tablet/day*

Unresectable Hepatocellular Carcinoma (HCC)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documented of inadequate response, adverse reaction, or contraindication to Nexavar® (sorafenib)
5. Quantity requested is ≤1 tablet/day*

Locally recurrent, advanced, and/or metastatic thyroid carcinoma
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documented of inadequate response, adverse reaction, or contraindication to **ONE** of the following:
   a. Lenvima® (lenvatinib)
   b. Nexavar® (sorafenib)
5. **ONE** of the following:
   a. Member is refractory to radioactive iodine
   b. Radioactive iodine treatment is not appropriate
6. Quantity requested is ≤1 tablet/day*

Continuation of Therapy
Reauthorization requires physician attestation 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:

Cabometyx	30 tablets per 30 days

*Any requests for over the quantity limit must be reviewed against the Global Quantity Limit criteria.

References

1. Cabometyx (cabozantinib) tablet [prescribing information]. Alameda, CA: Exelixis Inc; September 2021.

Review History

10/9/2020: Created criteria to be in compliance with the Masshealth partial unified formulary requirements effective 1/1/21.
06/22/2022 - Reviewed and updated for June P&T; matched MH UPPL. Criteria update for Cabometyx for expanded indication for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible. Updated References. Effective 08/01/22.

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