STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CABOZANTINIB S-MALATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CABOZANTINIB S-MALATE	COMETRIQ, CABOMETYX	39815		GPI-10 (2153301010)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

COMETRIQ

1. Does the patient have a diagnosis of progressive, metastatic medullary thyroid cancer (MTC)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #112 per 28 days for the requested daily dose pack. (NOTE: Cometriq is available in three dosage packs each containing 7 days supply)**
   - **Cometriq 140mg daily dose pack.**
   - **Cometriq 100mg daily dose pack.**
   - **Cometriq 60mg daily dose pack.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires the following rule be met for approval:
   A. You have progressive, metastatic medullary thyroid cancer (type of thyroid cancer that has spread)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB S-MALATE

GUIDELINES FOR USE (CONTINUED)

CABOMETYX

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
   - Cabometyx will be used as a single agent
   - Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (no prior treatment for advanced RCC)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - The patient has previously been treated with Nexavar (sorafenib)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, continue to #3.

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GUIDELINES FOR USE - CABOMETYX (CONTINUED)

3. Does the patient have a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has disease progression following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy
   - The patient is radioactive iodine-refractory or ineligible

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      2. Hepatocellular carcinoma (HCC: type of liver cancer)
      3. Locally advanced or metastatic differentiated thyroid cancer (DTC: type of thyroid cancer)
   B. **If you have advanced renal cell carcinoma, approval also requires ONE of the following:**
      1. Cabometyx will be used as a single agent (used alone)
      2. Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (You have not received prior treatment for advanced renal cell carcinoma)
   C. **If you have hepatocellular carcinoma, approval also requires:**
      1. You have previously been treated with Nexavar (sorafenib)
   D. **If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:**
      1. You are 12 years of age or older
      2. You have disease progression (disease has gotten worse) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (a type of cancer therapy)
      3. You are radioactive iodine-refractory (resistant to) or ineligible

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB S-MALATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cometriq or Cabometyx.

REFERENCES

- Cometriq [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; February 2020.
- Cabometyx [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/04/21
Created: 01/13
Client Approval: 09/21
P&T Approval: 10/21