STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUCAPARIB CAMSYLATE	RUBRACA	44002		GPI-10 (2153557020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic)
   - The patient is in complete or partial response to platinum-based chemotherapy
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic) based on an FDA-approved companion diagnostic for Rubraca
   - The patient has been treated with an androgen receptor-directed therapy and a taxane-based chemotherapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RUCAPARIB

GUIDELINES FOR USE (CONTINUED)

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 **RUCAPARIB (Rubraca)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that has returned)
   2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life)
   3. You are in complete or partial response to platinum-based chemotherapy (a type of therapy to treat cancer)
   4. The requested medication will be used for maintenance treatment

C. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Rubraca
   3. You have been treated with an androgen receptor-directed therapy and a taxane-based chemotherapy (types of therapy to treat cancer)
   4. You meet ONE of the following:
      a. You previously received a bilateral orchiectomy (removal of testicles)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin)

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

REFERENCES

- Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 12/16
Client Approval: 01/23
P&T Approval: 01/23