RUCAPARIB

Generic	Brand	HICL	GCN	Exception/Other
RUCAPARIB	RUBRACA	44002		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of 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 has a deleterious BRCA mutation (germline and/or somatic) as confirmed by an FDA-approved test for Rubraca
   - The patient has been treated with two or more chemotherapies (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL with a quantity limit of #120 tablets per 30 days.**
   If no, continue to #2.

2. 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 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 with a quantity limit of #120 tablets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **RUCAPARIB (Rubraca)** requires a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer OR recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. In addition, the following criteria must be met:
   For diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval requires:
   - The patient is 18 years of age or older
   - The patient has a deleterious BRCA mutation (germline and/or somatic) as confirmed by an FDA-approved test for Rubraca
   - The patient has been treated with two or more chemotherapies (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   For diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval requires:
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to platinum based-chemotherapy
   - The requested medication will be used for maintenance treatment

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RATIONALE

Promote appropriate utilization of **RUCAPARIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Rubraca is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

- For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
- For the treatment of adult patients with deleterious *BRCA* mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.

DOSAGE AND ADMINISTRATION

The recommended dose of Rubraca is 600 mg (two 300 mg tablets) taken orally twice daily with or without food. Continue treatment until disease progression or unacceptable toxicity. If a patient misses a dose of Rubraca, instruct the patient to take the next dose at its scheduled time. Vomited doses should not be replaced.

To manage adverse reactions, consider interruption of treatment or dose reduction. Recommended dose reductions are indicated in Table 1.

Table 1. Recommended Dose Adjustments

Dose Reduction	Dose
Starting Dose	600 mg twice daily (two 300 mg tablets)
First Dose Reduction	500 mg twice daily (two 250 mg tablets **OR** one 300 mg tablet and one 200 mg tablet)
Second Dose Reduction	400 mg twice daily (two 200 mg tablets)
Third Dose Reduction	300 mg twice daily (one 300 mg tablet)

REFERENCES

- Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/18
Created: 12/16
Client Approval: 05/18
P&T Approval: 04/18