

## Regimen Monograph

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## A - Regimen Name

# OLAP Regimen

Olaparib

**Disease Site**      Gynecologic  
Ovary

**Intent**              Adjuvant  
Palliative

**Regimen Category**      **Evidence-Informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

**Rationale and Uses**      Maintenance treatment for high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with documented BRCA1 or BRCA2 mutation (germline or somatic):

- As monotherapy after first line platinum-based chemotherapy (at least 4 cycles) in which radiological response (complete or partial) is demonstrated,  
OR
- As monotherapy in relapsed disease after receiving >1 prior course of platinum-based chemotherapy\*, and there is radiologic response (complete or partial) to the most recently completed course of platinum-based treatment

\* in which platinum sensitive disease was demonstrated with one completed treatment course

**Supplementary  
Public Funding**

**[olaparib](#)**

Exceptional Access Program (olaparib - For the maintenance treatment of BRCA-mutated, high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer in adult patients, with specific criteria) ([EAP Website](#))

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## B - Drug Regimen

**[olaparib](#)**

300 mg

PO

BID

To be eligible for EAP funding, olaparib should be started within 8 weeks of the patient's final dose of platinum-based chemotherapy or within 12 weeks with restaging to confirm no disease progression, if delay of more than 8 weeks since last dose of chemotherapy has occurred (Refer to EAP for possible case-by-case scenarios).

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## C - Cycle Frequency

### CONTINUOUS TREATMENT

#### Maintenance after first line platinum-based therapy:

- For a usual total of 24 months unless disease progression or unacceptable toxicity occurs.

#### Maintenance in relapsed, platinum-sensitive disease:

- Until disease progression or unacceptable toxicity.

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## D - Premedication and Supportive Measures

**Antiemetic Regimen:** Low – No routine prophylaxis; PRN recommended

- Also refer to [CCO Antiemetic Recommendations](#).

**Screen for hepatitis B virus in all cancer patients starting systemic treatment.** Refer to the [hepatitis B virus screening and management](#) guideline.

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## E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Patients should have recovered from prior hematologic toxicities before starting olaparib (Hgb, ANC and platelets  $\leq$  grade 1).

### **Dosage with toxicity**

Dose Level	Olaparib Dose
0	300 mg BID
-1	250 mg BID
-2	200 mg BID
-3	Discontinue

Toxicity	Severity	Action
Platelets or ANC	$\geq$ Grade 3 or blood transfusion dependence	Hold up to 4 weeks* and monitor CBC.  Then, may consider dose reduction.
Hemoglobin		Hold up to 4 weeks* and monitor CBC.  Then, consider dose reduction after severe anemia, to avoid multiple transfusions.

Signs and symptoms of pneumonitis	Any	Hold and investigate.  If confirmed, discontinue and treat appropriately.
MDS, AML or other clonal disorders		Hold and investigate.  If confirmed, discontinue and treat appropriately.
Other non-hematologic	Grade 3 or 4	Hold up to 4 weeks**  Upon recovery, consider dose reduction.

\*Hold until  $\leq$  grade 1. If blood parameters remain abnormal after 4 weeks, bone marrow analysis and/or blood cytogenetic analysis are recommended.

\*\*Hold until  $\leq$  grade 1. If toxicity recurs, reduce an additional dose level. Discontinue if more than 2 dose reductions are required.

### **Hepatic Impairment**

<b>Hepatic Impairment</b>	<b>Olaparib Dose</b>
Child-Pugh A or B	No dose adjustment required
Child-Pugh C	Not recommended (not studied)

### **Renal Impairment**

<b>Creatinine Clearance (mL/min)</b>	<b>Olaparib Dose</b>
> 50	No dose adjustment required
31-50	200 mg BID
$\leq$ 30 or end stage renal disease	Not recommended (limited data)

### **Dosage in the Elderly**

Dose adjustment is not required. There is limited data in patients aged 75 and older.

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## F - Adverse Effects

Refer to [olaparib](#) drug monograph(s) for additional details of adverse effects.

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
<ul style="list-style-type: none"> <li>• Nausea, vomiting</li> <li>• Fatigue</li> </ul>	<ul style="list-style-type: none"> <li>• Myelosuppression, anemia ± infection, bleeding (May be severe)</li> <li>• Diarrhea</li> <li>• Constipation</li> <li>• Dysgeusia</li> </ul>	<ul style="list-style-type: none"> <li>• Headache</li> <li>• Anorexia</li> <li>• Dizziness</li> <li>• Abdominal pain</li> <li>• Cough, dyspnea</li> <li>• Dyspepsia</li> <li>• Mucositis</li> <li>• Rash</li> </ul>	<ul style="list-style-type: none"> <li>• Hypersensitivity</li> <li>• Secondary malignancy (MDS, AML)</li> <li>• Pneumonitis</li> <li>• Venous thromboembolism</li> </ul>

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## G - Interactions

Refer to [olaparib](#) drug monograph(s) for additional details.

- Co-administration with strong and moderate CYP3A inducers is not recommended due to the potential for decreased olaparib efficacy.
- Co-administration with strong and moderate CYP3A inhibitors is not recommended due to the increased risk of toxicity. If unavoidable, olaparib dose should be reduced to 100 mg bid (with strong inhibitors) or 150 mg bid (with moderate inhibitors).
- Co-administration with myelosuppressive agents should be avoided due to potentiation and prolongation of myelosuppression.

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## H - Drug Administration and Special Precautions

Refer to [olaparib](#) drug monograph(s) for additional details.

### **Administration:**

- Olaparib can be taken with or without food.
- Tablets should be swallowed whole and not chewed, crushed, dissolved or divided.
- Avoid grapefruit, starfruit, pomegranate, Seville oranges, their juices or products during treatment.
- If a dose is missed, the next dose should be taken at the regular scheduled time. A double dose should not be taken to make up for forgotten tablets.
- Store between 2 to 30°C in original packaging to protect from moisture.

### **Contraindications:**

- Patients who have a hypersensitivity to this drug or any of its components.

### **Other Warnings/Precautions:**

- Do not co-administer with other myelosuppressive agents.
- Use with caution in patients who have received prior DNA damaging agents. MDS and AML have been reported.
- Use with caution in patients with lung cancer or metastases to the lungs, underlying pulmonary disease, smoking history and/or previous chemotherapy and radiotherapy as these patients are at increased risk of pneumonitis.
- Patients experiencing fatigue and dizziness should use caution when driving or operating machines.

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**Pregnancy and lactation:**

- This regimen is not recommended for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is not recommended during treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility effects: Documented in animals

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**I - Recommended Clinical Monitoring**

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Refer to the [hepatitis B virus screening and management](#) guideline for monitoring during and after treatment.

**Recommended Clinical Monitoring**

- CBC; Baseline and monthly for the first 12 months, then periodically thereafter, and as clinically indicated
- Liver function tests; baseline and as clinically indicated
- Renal function tests; baseline and as clinically indicated
- Clinical toxicity assessment for nausea and other GI and respiratory effects, fatigue, anemia, MDS, infection and bleeding, venous thromboembolism; At each visit
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

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**J - Administrative Information**

Outpatient prescription for home administration

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## K - References

Ledermann J, Harter P, Gourley C, et al. Olaparib maintenance therapy in patients with platinum-sensitive relapsed serous ovarian cancer: a preplanned retrospective analysis of outcomes by BRCA status in a randomised phase 2 trial. *Lancet Oncol.* 2014 Jul;15(8):852-61.

Moore K, Colombo N, Scambia G et al. Maintenance olaparib in patients with newly diagnosed advanced ovarian cancer. *N Engl J Med* 2018;379:2495-505.

Olaparib drug monograph, Ontario Health (Cancer Care Ontario).

Phase II Randomised, Double Blind, Multicentre Study to Assess the Efficacy of AZD2281 in the Treatment of Patients With Platinum Sensitive Relapsed Serous Ovarian Cancer Following Treatment With Two or More Platinum Containing Regimens (Study 19). Retrieved from <https://clinicaltrials.gov/ct2/show/study/NCT00753545> (Identification No. NCT00753545)

Pujade-Lauraine E, Ledermann JA, Selle F, et al. Olaparib tablets as maintenance therapy in patients with platinum-sensitive, relapsed ovarian cancer and a BRCA1/2 mutation (SOLO2/ENGOT-Ov21): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2017 Jul 25 (published online).

## **PEBC Advice Documents or Guidelines**

- [Systemic Therapy for Recurrent Epithelial Ovarian Cancer](#)
- [Consolidation or Maintenance Systemic Therapy for Newly Diagnosed Stage II, III, or IV Epithelial Ovary, Fallopian Tube, or Primary Peritoneal Carcinoma](#)

**November 2023** Modified Dose modifications, Pregnancy/lactation and Monitoring sections

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## M - Disclaimer

### ***Regimen Abstracts***

*A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for*



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the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

### **Regimen Monographs**

Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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