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Malignant Ovarian Germ Cell Tumors

The American Society of Clinical Oncology offers the following clinical guidance on treatment alternatives during shortages of antineoplastic agents. Decisions should be based on specific goals of the therapy where evidence-based medicine has shown survival outcomes and life-extending benefits in both early and advanced stages. For more information on ASCO's general principles during drug shortages, please visit ASCO's <u>Clinical Guidance page</u>. For further consideration of ethical guidance, please visit ASCO's <u>Ethical Principles and Implementation Strategies page</u>.

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General Principles for Malignant Ovarian Germ Cell Tumors (OGCT)

- 1. Surgical staging and primary cytoreduction are standard for all OGCTs.
- There are several settings in which there are no platinum alternatives. While non-platinumcontaining regimens exist, based upon inferior outcomes with older regimens, the preference is for the patient to travel to an area where platinum is available or to obtain the drug for the individual patient.

Clinical Guidance

1. Early-Stage Disease (Stage I-III dysgerminoma, stage II-III immature teratoma, any stage embryonal tumor, any stage endodermal sinus tumor, or any stage non-gestational choriocarcinoma)

Recommended treatment:

- For patients with stage IA or IB dysgerminoma or stage I unruptured, grade 1 Immature teratoma, surgery is the standard of care and is the preferred approach.
- For patients with stage IC, II, or III dysgerminoma or stage I ruptured or stage I unruptured, grade 2 or 3, or stage II or III Immature teratoma, surgery plus three cycles of bleomycin, etoposide, cisplatin (BEP) is the standard of care and is the preferred approach.

ALTERNATIVES:

- If cisplatin is not available, carboplatin plus etoposide (CE)
- If neither cisplatin nor carboplatin are available, see General Principle #2.
- 2. Gross Residual or Stage IV Disease (dysgerminoma or immature teratoma)

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Recommended treatment:

- For patients who present with de novo stage IV dysgerminoma, surgery, including resection of metastatic disease if applicable, plus four cycles of BEP
- For patients with stage IV non-dysgerminoma, surgery (if patient is a candidate) plus four to six cycles of BEP

ALTERNATIVES:

- If cisplatin is not available, carboplatin plus etoposide (CE)
- If neither cisplatin nor carboplatin are available, see General Principle #2

3. Recurrent/Persistent Disease (dysgerminoma or immature teratoma)

Recommended treatment:

For patients with recurrent or persistent dysgerminoma or immature teratoma that is
potentially curable, paclitaxel/ifosfamide/cisplatin (TIP) or high-dose platinum-based
chemotherapy (regimens vary by institution) + hematopoietic cell transplant (HCT)

ALTERNATIVES:

- If cisplatin is not available for the potentially curative setting, see General Principle #2.
- If cisplatin is not available for the palliative setting:
 - Docetaxel alone
 - Docetaxel/carboplatin
 - Oral etoposide
 - o Gemcitabine/paclitaxel/oxaliplatin
 - o Gemcitabine/oxaliplatin
 - o Paclitaxel
 - Paclitaxel/carboplatin
 - Paclitaxel/gemcitabine
 - Paclitaxel/ifosfamide
 - Vincristine, dactinomycin, cyclophosphamide