

3.0 PATIENT ELIGIBILITY AND EXCLUSIONS

3.1 Eligible Patients

- 3.11 All patients with Surgical Stage III or IVA endometrial carcinoma per FIGO 2009 staging criteria, including clear cell and serous papillary and undifferentiated carcinomas. (06/07/2010)(01/03/2011)

Surgical Stage III disease includes those patients with positive adnexa, parametrial involvement, tumor invading the serosa, positive pelvic and/or para-aortic nodes, or vaginal involvement. (01/03/2011)

Surgical Stage IVA includes patients with bladder or bowel mucosal involvement, but no spread outside the pelvis.

- 3.12 Patients with FIGO 2009 surgical Stage I or II endometrial clear cell or serous carcinoma and with positive peritoneal cytology. (01/03/2011)

- 3.13 Surgery must have included a hysterectomy and bilateral salpingo-oophorectomy. Pelvic lymph node sampling and para-aortic lymph node sampling are optional.

- 3.14 Patients with a GOG Performance Status of 0, 1, or 2.

- 3.15 Patients with adequate organ function, reflected by the following parameters:

WBC \geq 3000/mcl

Absolute neutrophil count (ANC) \geq 1500/mcl

Platelet count \geq 100,000/mcl

SGOT, SGPT, and alkaline phosphatase \leq 2.5 X upper limit of normal (ULN) (06/07/2010)

Bilirubin \leq 1.5 X ULN (06/07/2010)

Creatinine \leq institutional ULN (06/07/2010)

- 3.16 Patients who have met the pre-entry requirements specified in Section 7.0; testing values/results must meet eligibility criteria specified in Section 3.1.

- 3.17 Patients who have signed an approved informed consent and authorization permitting release of personal health information.

- 3.18 Patients must be 18 years of age or older.

- 3.19 Entry into the study is limited to no more than 8 weeks from the date of surgery. (06/07/2010)

3.2 Ineligible Patients

- 3.21 Patients with carcinosarcoma.
- 3.22 Patients with recurrent endometrial cancer.
- 3.23 Patients with residual tumor after surgery (any single site) exceeding 2 cm in maximum dimension.
- 3.24 Patients who have had pelvic or abdominal radiation therapy.
- 3.25 Patients with positive pelvic washings as the only extra-uterine disease are NOT eligible if the histology is other than **clear cell or papillary serous carcinoma**.
- 3.26 Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer, are excluded if there is any evidence of active malignancy within the last five years. Patients are also excluded if their previous cancer treatment contraindicates this protocol therapy.
- 3.27 Patients with a history of serious co-morbid illness or uncontrolled illnesses that would preclude protocol therapy.
- 3.28 Patients with an estimated survival of less than three months.
- 3.29 Patients with FIGO 2009 Stage IVB endometrial cancer. **(01/03/2011)**
- 3.210 Patients with parenchymal liver metastases.
- 3.211 Patients who have received prior chemotherapy for endometrial cancer.
- 3.212 Patients with a history of myocardial infarction, unstable angina, or uncontrolled arrhythmia within 3 months from enrollment.