ALEXANDRIA, Va. — The American Society of Clinical Oncology (ASCO) today issued a provisional clinical opinion (PCO) on the use of second-line hormonal therapy for men with castration-resistant prostate cancer (CRPC) who have not yet received chemotherapy.

“In the last few years we have seen an unprecedented number of new systemic therapies showing improvements in survival and quality of life for men with CRPC,” said Katherine S. Virgo, PhD, co-chair of the Expert Panel that developed the provisional clinical opinion. “However, due to lack of guidelines on second-line hormone therapy for chemotherapy-naïve patients, there has been uncertainty regarding optimal treatment among clinicians.”

Many men with hormone-sensitive prostate cancer experience cancer recurrence or progression despite first-line hormonal (androgen deprivation) therapy, meaning the cancer is castration-resistant. The PCO addresses use of second-line hormonal therapy in chemotherapy-naïve men with CRPC ranging from asymptomatic men with only biochemical evidence of recurrence to those with measurable metastases but minimal symptoms.

Clinical trials have shown that second-line hormonal treatments such as abiraterone acetate and enzalutamide slow cancer growth, extend survival, and provide meaningful improvement in quality of life for men with CRPC.

“To develop these recommendations, we used evidence from clinical trials as well as a formal consensus technique that relied on clinical experience, training, and judgement, when evidence was limited,” said Eric A. Singer, MD, MA, FACS, co-chair of the Expert Panel that developed this PCO. “We hope that this PCO it will offer clinicians and patients timely direction to help inform treatment planning and shared decision making.”
Key PCO recommendations:

- For men who develop CRPC despite castrate levels of testosterone, a castrate state should be maintained indefinitely.
- For chemotherapy-naïve patients with M0 CRPC (no radiographic evidence of metastases) who are at **high risk** for developing metastases (high risk is defined as having rapid PSA doubling time or velocity), second-line hormonal therapies may be offered, following a discussion with the patient about the limited scientific evidence, potential harms, benefits, cost, and patient preferences.
- Second-line hormonal therapy is not suggested for chemotherapy-naïve men with M0 CRPC who are at **low risk** for developing metastases (low risk defined as low PSA and slow PSA doubling time).
- For chemotherapy-naïve men who develop CRPC and have radiographic evidence of metastases (M1a/M1s CRPC), second-line hormonal treatment (abiraterone acetate plus prednisone, or enzalutamide) should be offered as these agents significantly increase radiographic progression-free survival (rPFS) and overall survival (OS). Palliative care should also be offered.
- A prostate serum antigen (PSA) evaluation every four to six months should be performed for men with M0 CRPC who have a low risk of developing metastases; every three months for men with MO CRPC who are at high risk for developing metastases or already have radiographic evidence of metastases (M1 CRPC).
- When imaging is performed for men with CRPC, a bone scan and either CT or MRI of the abdomen and pelvis should be offered. The appropriate frequency of imaging is variable and largely dependent on symptoms. Radiographic imaging is not indicated for men with CRPC and a rising PSA unless treatment selection would be altered based on radiographic findings or if symptoms potentially attributable to prostate cancer develop or worsen (e.g., bone pain). Routine surveillance radiographic restaging is also not indicated, with the exception of for patients for whom PSA is not a reliable marker of disease.

The recommendations of this PCO were informed by evidence from systematic review of literature published from 1985 through October 2016, consensus opinion, and clinical experience. The *Second-Line Hormonal Therapy for Men with Chemotherapy-Naïve Castration-Resistant Prostate Cancer (CRPC): American Society of Clinical Oncology Provisional Clinical Opinion* was published today in the *Journal of Clinical Oncology*.

The PCO is available [here](https://www.asco.org/guidelines). Information for patients about prostate cancer is available at cancer.net/prostate.

ASCO encourages feedback on its guidelines from oncologists, practitioners, and patients through the ASCO Guidelines Wiki at asco.org/guidelineswiki.

For an embargoed copy of the PCO, please contact Amanda Narod, amanda.narod@asco.org, 571-483-1795.

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