Prostate Cancer

Abiraterone/PredniSONE or MethylPREDNISolone

INDICATION:

Clinically localized disease: Very high risk group

Regional disease

Castration-naive metastatic (M1)

Castration-resistant metastatic (M1)

REFERENCES:

1. NCCN Guidelines® for Prostate Cancer V.1.2022.
2. James ND, et al. *N Engl J Med.* 2017;377(4):338-351.[a]
3. Fizazi K, et al. *N Engl J Med.* 2017;377(4):352-360.[a]
4. Ryan CJ, et al. *N Engl J Med.* 2013;368(2):138-48.[a]
5. Fizazi K, et al. *Lancet Oncol.* 2012;13(10):983-92.[a]
6. Stein CA , et al. *Urol Oncol.* 2018;36(2):81.e9-81.e16.[a]
7. Fizazi K , et al. *Lancet Oncol.* 2019;20(5):686-700.[a]

NCCN SUPPORTIVE CARE:

1. *Emetic risk:* Days of Abiraterone Oral Low/Minimal
2. *Febrile Neutropenia Risk:* Refer to Myeloid Growth Factor algorithms in the NCCN Guidelines for Hematopoietic Growth Factors

CHEMOTHERAPY REGIMEN

To ensure safe and effective treatment with oral anticancer therapy, develop a treatment plan with the patient that includes medication access, goals of therapy, frequency of monitoring (eg, visits, labs, symptom checks), instruction for toxicity management, screening of concomitant medications, and adherence assessment.

*28-day cycle for 2 years (regional disease or clinically localized disease: very high risk group) **or** until disease progression or unacceptable toxicity (castration-resistant metastatic (M1) or castration-naive metastatic (M1))*

- **Abiraterone** (conventional formulation) 1,000 mg PO daily on Days 1 – 28
  - Abiraterone is available in a conventional formulation as 250 mg and 500 mg tablets, and in a micronized (fine particle) formulation as 125 mg tablets. Use caution when selecting the dosage form, as the products are not interchangeable.
  - The choice of concurrent steroid depends on the formulation of abiraterone used.
- **PredniSONE** 5 mg PO daily on Days 1 – 28 (for regional, clinically localized disease: very high risk group or castration-naive metastatic (M1) disease)
  or
- **PredniSONE** 5 mg PO twice daily on Days 1 – 28 (for castration-resistant metastatic (M1) disease)

OR

*28-day cycle for 2 years (regional disease or clinically localized disease: very high risk group) **or** until disease progression or unacceptable toxicity (castration-resistant metastatic (M1) or castration-naive metastatic (M1))*

- **Abiraterone** (micronized formulation) 500 mg PO daily on Days 1 – 28
  - Abiraterone is available in a conventional formulation as 250 mg and 500 mg tablets, and in a micronized (fine particle) formulation as 125 mg tablets. Use caution when selecting the dosage form, as the products are not interchangeable.
  - The choice of concurrent steroid depends on the formulation of abiraterone used.
- **MethylPREDNISolone** 4 mg PO twice daily on Days 1 – 28

Abiraterone + PredniSONE or MethylPREDNISolone is used in combination with an LHRH agonist or LHRH antagonist, unless not indicated due to bilateral orchiectomy. Please see order templates PRO13: Goserelin, PRO14: Histrelin, PRO15: Leuprolide acetate, PRO16: Triptorelin, and PRO29 Leuprolide mesylate for LHRH agonist options and PRO17: Degarelix for LHRH antagonist.

SUPPORTIVE CARE

Antiemetic Therapy

PRN for breakthrough: All patients should be provided with at least one medication for breakthrough emesis. Please consult the NCCN Guidelines for Antiemesis for appropriate antiemetic therapy.

Other Supportive Therapy

- For abiraterone: This agent is associated with adrenal insufficiency. Patients may require increased corticosteroid dose.
- For predniSONE: Risk of stress ulcers may occur with treatment. Consider use of a H_2 blocker or proton pump inhibitor.
- For methylPREDNISolone: Risk of stress ulcers may occur with treatment. Consider use of a H_2 blocker or proton pump inhibitor.

Template continued on page 2

MONITORING AND HOLD PARAMETERS

- CBC with differential should be monitored as clinically indicated for potential dose modification.
- For abiraterone:
  - Monitor for signs and symptoms of adrenal insufficiency as clinically indicated.
  - Electrolytes (eg, magnesium, potassium) should be monitored prior to initiation of therapy, then monthly or as clinically indicated.
  - Hypertension may occur with therapy. Blood pressure should be monitored prior to initiation of therapy and as clinically indicated for potential dose modification.
  - Liver function should be monitored prior to initiation of therapy and as clinically indicated for potential dose modification or discontinuation.
  - Fluid retention may occur. Patient should be monitored as clinically indicated for signs and symptoms.
- For predniSONE:
  - Serum glucose should be monitored as clinically indicated.
  - Hypertension may occur with therapy. Blood pressure should be monitored as clinically indicated for potential dose modification.
- For methylPREDNISolone:
  - Serum glucose should be monitored as clinically indicated.
  - Hypertension may occur with therapy. Blood pressure should be monitored as clinically indicated for potential dose modification.

SAFETY PARAMETERS AND SPECIAL INSTRUCTIONS

- For abiraterone:
  - This agent has multiple potential drug-drug and/or drug-food interactions. Review patient medical profile and drug package insert for specific drug and food interactions and recommendations.
  - Abiraterone (Zytiga®) should be taken on an empty stomach. Abiraterone (Yonsa®) may be taken with or without food.
- For predniSONE: Take with food.
- For methylPREDNISolone: Take with food.