INDICATION:

Castration-naive metastatic (M1)

Castration-resistant M0: PSADT ≤10 months

REFERENCES:

1. NCCN Guidelines® for Prostate Cancer V.1.2022.
2. Smith MR , et al. *N Engl J Med.* 2018;378(15):1408-1418.[a]
3. Chi KN , et al. *N Engl J Med.* 2019;381(1):13-24.[a]
4. Smith MR , et al. *Eur Urol.* 2021;79(1):150-158.[a]

NCCN SUPPORTIVE CARE:

1. *Emetic risk:* Days of Apalutamide 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 until disease progression or unacceptable toxicity

- **Apalutamide** 240 mg PO daily on Days 1 – 28
  - Apalutamide is available as 60 mg tablets.

Apalutamide 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 apalutamide: This agent may cause a decrease in bone mineral density. Consider vitamin D and calcium supplementation when appropriate.

MONITORING AND HOLD PARAMETERS

- CBC with differential should be monitored as clinically indicated for potential dose modification.
- For apalutamide:
  - An increased risk of myocardial infarction, sudden cardiac death, and stroke may occur with therapy. Use with caution and monitor for potential discontinuation.
  - This drug has been associated with seizures. Monitor for signs and symptoms in patients with a history or risk of developing seizures. Modification or discontinuation of therapy may be warranted.
  - Hypertension may occur with therapy. Blood pressure should be monitored prior to initiation of therapy and as clinically indicated for potential dose modification.
  - Monitor bone mineral density prior to initiation of therapy and as clinically indicated.
  - Thyroid function should be monitored prior to initiation of therapy and as clinically indicated.
  - Cholesterol and triglycerides should be monitored prior to initiation of therapy and as clinically indicated.
  - Serum glucose should be monitored as clinically indicated.
  - This agent is associated with an increased risk of falls and fractures. Evaluate risk of falls prior to initiation of therapy, then monitor for ongoing fall risk as clinically indicated for potential dose modification or discontinuation.
  - This agent may cause dermatologic toxicities. Evaluate risk of dermatologic toxicity prior to initiation of therapy, then monitor for signs and symptoms as clinically indicated for potential dose modification or discontinuation.
  - Calcium and vitamin D should be monitored as clinically indicated. Supplemental medication should be administered as needed.

SAFETY PARAMETERS AND SPECIAL INSTRUCTIONS

- For apalutamide:
  - Take with or without food.
  - 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.