Regimen Reference Order – GENU – darolutamide + DOCEtaxel

To order this therapy in ARIA, refer to Additional Information below

Planned Course: **DOCEtaxel every 21 days for 6 cycles AND darolutamide twice daily until disease progression or unacceptable toxicity (1 cycle = 21 days)**

Indication for Use: **Prostate Cancer; Metastatic Castrate Sensitive**

CVAD: At Provider's Discretion

Proceed with treatment if:

Cycles 1 to 6

- ***ANC equal to or greater than 1.5 x 10^9/L AND Platelets equal to or greater than 100 x 10^9/L***

Cycles 7 and onwards

- ***ANC equal to or greater than 1 x 10^9/L AND Platelets equal to or greater than 50 x 10^9/L***
  - ❖ ***Contact Physician if parameters are not met***

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Cycles 1 to 6		
dexamethasone	8 mg	Orally twice daily the day before DOCEtaxel treatment and one dose the morning of DOCEtaxel treatment **(Self-administered at home)** **Nursing Alert: Notify physician if patient has not taken dexamethasone. dexamethasone is prescribed to prevent infusion reactions*
Cycle 7 and Onwards		
Not Applicable		

Treatment Regimen – GENU – darolutamide + DOCEtaxel

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Cycles 1 to 6 – darolutamide + DOCEtaxel **Note: darolutamide usually starts before DOCEtaxel treatment is initiated**		
Days 1 to 21		
darolutamide	600 mg	Orally twice daily with food Swallow whole **(Self-administered at home)**

Day 1 ONLY		
DOCEtaxel	75 mg/m^2	IV in normal saline 250 mL over 1 hour, following the administration rates below: • Administer at 100 mL/hour for 15 minutes, then • Administer remaining volume over 45 minutes *Use non-DEHP bags and non-DEHP administration sets* **OR** **For 500 mL bags** (when Pharmacy must prepare DOCEtaxel in 500 mL normal saline for concentration-dependent stability): IV in normal saline 500 mL over 1 hour, following the administration rates below: • Administer at 200 mL/hour for 15 minutes, then • Administer remaining volume over 45 minutes *Use non-DEHP bags and non-DEHP administration sets*
normal saline	100 mL	**ONLY** for patients with a PORT IV over 12 minutes **Nursing Alert: This volume is to be administered after standard flush*
Cycle 7 and Onwards – darolutamide		
darolutamide	600 mg	Orally twice daily with food Swallow whole **(Self-administered at home)**
darolutamide (NUBEQA®) available dosage strength: 300 mg tablet **Classification: Non-Cytotoxic, Hazardous**		

In the event of an infusion-related hypersensitivity reaction, refer to the '**Hypersensitivity Reaction Standing Order'**

REQUIRED MONITORING

Cycles 1 to 6

- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders
- testosterone level as per Physician Orders
- Baseline Bone density at physician's discretion
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O2 saturation) prior to DOCEtaxel and as clinically indicated
- No observation period required after DOCEtaxel administration. Patient can be discharged from treatment room if stable whether they had a reaction or not

Cycle 7 and Onwards

- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders
- testosterone level and PSA as per Physician Orders
    - Blood work monitoring every 3 months

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
metoclopramide	10 - 20 mg	Orally every 4 hours as needed for nausea and vomiting

DISCHARGE INSTRUCTIONS

Cycles 1 to 6

- Patients should be instructed to contact their cancer team immediately if symptoms of hypersensitivity reactions occur after discharge
- Instruct patient to continue taking anti-emetic(s) at home
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

All Cycles

- darolutamide has potential for drug-drug interactions. Patients should notify clinic prior to starting any new medication

ADDITIONAL INFORMATION

- LHRH analog treatment (i.e. leuprolide or goserelin) is continued during darolutamide treatment
- Patients are at increased fracture risk
- drug-induced liver injury and ischemic heart disease have been reported in patients treated with darolutamide
- Note that patient may be started on oral darolutamide (NUBEQA®) as an outpatient up to 9 weeks before DOCEtaxel treatment is started
- **ARIA ordering**: Note that ARIA regimens/protocols require each drug to be ordered separately
    - **GENU – [DOCEtaxel (mCSPC)]** regimen is available as a 21-day cycle under the “Prostate” treatment tab in ARIA
    - Support protocol is available for darolutamide under **GENU- [darolutamide]** in the “Prostate Cancer” folder