Regimen Reference Order – alpelisib + fulvestrant

To order this therapy in ARIA, refer to ADDITIONAL INFORMATION

Planned Course: **Until disease progression or unacceptable toxicity (1 cycle = 28 days)**

Indication for Use: **Breast Cancer Metastatic, Hormone Receptor Positive, HER2 negative, PIK3CA-mutated**

CVAD: Not Required

Proceed with treatment if:

alpelisib

- ***ANC equal to or greater than 1 x 10^9/L AND Platelets equal to or greater than 50 x 10^9/L***

fulvestrant

- ***Continued throughout therapy regardless of CBC. If alpelisib is held for toxicity, fulvestrant is continued***
  - ❖ **Contact Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – BRST – alpelisib + fulvestrant

Drug	Dose	CCMB Administration Guideline
Cycle 1		
alpelisib	300 mg	Orally once daily with food on **Days 1 to 28** Swallow whole **(Self-administered at home)**
fulvestrant	500 mg (2 syringes of 250 mg)	Intramuscular injection into ventrogluteal muscle over 1 to 2 minutes per injection (administer 500 mg dose as two 5 mL IM injections) on **Days 1 and 15**
Cycle 2 and Onwards		
alpelisib	300 mg	Orally once daily with food on **Days 1 to 28** Swallow whole **(Self-administered at home)**
fulvestrant	500 mg (2 syringes of 250 mg)	Intramuscular injection into ventrogluteal muscle over 1 to 2 minutes per injection (administer 500 mg dose as two 5 mL IM injections) on **Day 1 only**

alpelisib (PIQRAY®) available dosage strengths: 50 mg, 150 mg, 200 mg tablets
Classification: Non-Cytotoxic, Hazardous

fulvestrant (FASLODEX®) available dosage strength: 250 mg per 5 mL syringe
Classification: Non-Cytotoxic, Hazardous

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

REQUIRED MONITORING

Cycle 1 (for alpelisib)

Day 1

- CBC, biochemistry, glucose and Hemoglobin A1C as per Physician Orders

Day 8

- Glucose as per Physician Orders

Day 15

- CBC, biochemistry and glucose as per Physician Orders

Cycle 2 and Onwards (for alpelisib)

Day 1

- CBC, biochemistry and glucose as per Physician Orders
- Hemoglobin A1C every 3 months as per Physician Orders

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
loratadine	10 mg	Orally once daily throughout alpelisib therapy

DISCHARGE INSTRUCTIONS

- alpelisib has potential for drug-drug interactions. Patients should notify clinic prior to starting any new medication
- Patient should be instructed to monitor for signs of hyperglycemia (excessive thirst, urinating more often than usual or higher amount of urine than usual, increased appetite with weight loss)
- Patient should be instructed to notify clinic if they develop a skin rash

ADDITIONAL INFORMATION

- Grade 3/4 toxicities are very common with alpelisib
- alpelisib can cause severe hyperglycemia, including diabetic ketoacidosis
- alpelisib can cause severe cutaneous reactions
- alpelisib can prolong QT interval
- The length of the needle provided with fulvestrant is 1.5 inches (38 mm)
- The patient's body habitus and ventrogluteal fat thickness should be evaluated to ensure the delivery of drug into the muscle
- The preferred site of administration for fulvestrant is into the ventrogluteal muscle. Dorsogluteal injections are associated with increased possibility of damaging the sciatic nerve
- fulvestrant should be kept in the refrigerator
- **ARIA ordering**: Please note that ARIA regimens/protocols require each drug to be ordered separately
    - **BRST – [alpelisib]** regimen is available as a 28-day cycle under the "Breast" treatment tab in ARIA
    - Support protocol is available for fulvestrant under **fulvestrant** in the "Breast Cancer" folder