Regimen Reference Order – BRST - palbociclib + fulvestrant +/- goserelin

ARIA: BRST – [palbociclib]
BRST – [fulvestrant]
BRST – [LHRH Agonists]

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

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

CVAD: Not Required

Proceed with treatment if:

palbociclib

- ***ANC equal to or greater than 1 x 10^9/L AND Platelets equal to or greater than 75 x 10^9/L***

fulvestrant and LHRH agonist

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

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – BRST – palbociclib + fulvestrant +/- goserelin

Drug	Dose	CCMB Administration Guideline
palbociclib	125 mg	Orally once daily on **Days 1 to 21, then 7 days off** Take with or without food Swallow whole **(Self-administered at home)**
fulvestrant	500 mg (2 syringes of 250 mg)	**With Cycle 1 of palbociclib:** Intramuscular 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**
		Starting 4 weeks after first dose of fulvestrant: Intramuscular into ventrogluteal muscle over 1 to 2 minutes per injection (administer 500 mg dose as two 5 mL IM injections) **(fulvestrant administered once every 28 days)**
goserelin* **OR** alternate LHRH agonist* (see options on table on Page 3)	3.6 mg	Subcutaneous once every 28 days **(goserelin or alternate LHRH agonist starts 28 days prior to the start of fulvestrant then continues throughout therapy)**

* LHRH agonists are only prescribed for pre- or peri-menopausal patients

palbociclib (Ibrance®) available dosage strengths: 75 mg, 100 mg, 125 mg tablets
Classification: 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

For palbociclib
Cycles 1 and 2
Day 1
- CBC and biochemistry as per Physician Orders

Day 15
- CBC

Cycles 3 to 6
- CBC and biochemistry prior to Day 1 and as clinically indicated as per Physician Orders
- No blood work required on Day 15

Cycle 7 and Onwards
- CBC prior to Day 1 at physician's discretion
    - Each cycle (if ANC was less than 1 x 10^9/L during first 6 cycles) or
    - Every 3rd cycle (if ANC was 1 x 10^9/L or greater during first 6 cycles)
- Biochemistry periodically as clinically indicated as per Physician Orders

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
None required		

DISCHARGE INSTRUCTIONS

- palbociclib has potential for drug-drug interactions. Patients should notify clinic prior to starting any new medication
- palbociclib has potential for myelosuppression
- Avoid grapefruit and grapefruit juice, Seville oranges (i.e. orange marmalade), and starfruit with palbociclib
- Reinforce applicable safe handling precautions of medications, blood and body fluids while on palbociclib

ADDITIONAL INFORMATION

- 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 ventrogluteal muscle. Dorsogluteal injections are associated with increased possibility of damaging the sciatic nerve
- fulvestrant should be kept in the refrigerator
- Breast DSG oncologists may prescribe palbociclib in combination with different LHRH agonists
- Pre- and peri-menopausal patients initiate LHRH agonist therapy at least 4 weeks before starting treatment with palbociclib and fulvestrant
- Due to the various combinations used with palbociclib, this Regimen Reference Order provides only one example of possible combinations. The table below outlines different drugs/dosing schedules which may be prescribed:

Options for LHRH Agonists

Drug	Dose	CCMB Administration Guideline
goserelin	3.6 mg	Subcutaneous once every 28 days (4 weeks)
	OR	
	10.8 mg	Subcutaneous once every 84 days (12 weeks)
OR		
leuprolide	7.5 mg	Subcutaneous once every 28 days (4 weeks)
	OR	
	22.5 mg	Subcutaneous once every 84 days (12 weeks)

goserelin (Zoladex®) available dosage strengths: 3.6 mg, 10.8 mg syringe
Classification: Non-Cytotoxic, Hazardous

leuprolide (Eligard®) available dosage strengths: 7.5 mg, 22.5 mg syringe
Classification: Non-Cytotoxic, Hazardous

- palbociclib dose interruptions and/or reductions may be required for neutropenia; If palbociclib is held for toxicity reasons, fulvestrant and LHRH agonist therapy continue while palbociclib is held
- Please note that ARIA regimens/protocols require each drug to be ordered separately
  - **BRST – [palbociclib]** regimen is available as a 28-day cycle under the "Breast" treatment tab in ARIA
  - Support protocol is available for **fulvestrant** under **BRST – [fulvestrant]**
  - Support protocols are available for **goserelin** and **leuprolide** (either q 4 weeks OR q 12 weeks) under **BRST – [LHRH Agonists]**
- palbociclib will be dispensed by CCMB Pharmacy