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

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

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***

Aromatase Inhibitor and LHRH agonist

- ***Continued throughout therapy regardless of CBC. If palbociclib is held for toxicity, Aromatase Inhibitor 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 + letrozole +/- 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)**
letrozole **OR** alternate Aromatase Inhibitor (see options on table on Page 3)	2.5 mg	Orally once daily throughout therapy Take with or without food **(Self-administered at home)**
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 aromatase inhibitor 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**		

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

REQUIRED MONITORING

Cycles 1 and 2 (for palbociclib)
Day 1
- CBC and biochemistry as per Physician Orders

Day 15
- CBC

Cycles 3 to 6 (for palbociclib)
- 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 (for palbociclib)
- 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

- Breast DSG oncologists may prescribe palbociclib in combination with different aromatase inhibitors and LHRH agonists
- Pre- and peri-menopausal patients initiate LHRH agonist therapy at least 4 weeks before starting treatment with palbociclib and aromatase inhibitor
- Due to the various combinations used with palbociclib, this Regimen Reference Order provides only one example of possible combinations. The tables on page 3 outline different drugs/dosing schedules which may be prescribed
- palbociclib dose interruptions and/or reductions may be required for neutropenia; If palbociclib is held for toxicity reasons, aromatase inhibitor and LHRH agonist therapy continue while palbociclib is held
- **ARIA ordering**: 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 protocols are available for **anastrozole, exemestane,** and **letrozole** (90-day supply) under BRST – [Hormonal therapy] in "Breast" folder
  - Support protocols are available for **goserelin** and **leuprolide** (either q 28 days OR q 12 weeks) under BRST – [LHRH Agonists] in "Breast" folder
- palbociclib will be dispensed by CCMB Pharmacy

Options for Aromatase Inhibitors

Drug	Dose	CCMB Administration Guideline
anastrozole	1 mg	Orally once daily throughout therapy Take with or without food **(Self-administered at home)**
OR		
exemestane	25 mg	Orally once daily throughout therapy Take after a meal **(Self-administered at home)**
OR		
letrozole	2.5 mg	Orally once daily throughout therapy Take with or without food **(Self-administered at home)**

anastrozole (ARIMIDEX®) available dosage strength: 1 mg tablet
Classification: Non-Cytotoxic, Hazardous

exemestane (AROMASIN®) available dosage strength: 25 mg tablet
Classification: Non-Cytotoxic, Hazardous

letrozole (FEMARA®) available dosage strength: 2.5 mg tablet
Classification: Non-Cytotoxic, Hazardous

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