Regimen Reference Order

BRST – abemaciclib + endocrine therapy +/- LHRH agonist (Adjuvant)

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

Planned Course: **abemaciclib orally twice daily for 2 years (1 cycle of abemaciclib = 28 days)**
Endocrine therapy is administered concurrently with abemaciclib then continues to complete a total of 5-10 years, per prescriber-patient discretion

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

CVAD: Not Required

Proceed with treatment if:

abemaciclib:

- ***ANC equal to or greater than 1 x 10^9/L AND Platelets equal to or greater than 50 x 10^9/L***
- ***AST/ALT equal to or less than 5 times the upper limit of normal***
- ***Total bilirubin equal to or less than 2 times the upper limit of normal***

Note: abemaciclib dose adjustment is not required for elevated serum creatinine. See Additional Information

Endocrine Therapy and LHRH agonist:

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

SEQUENCE OF MEDICATION ADMINISTRATION

Treatment Regimen
BRST – abemaciclib + endocrine therapy +/- LHRH agonist* (Adjuvant)

Drug	Dose	CCMB Administration Guideline
abemaciclib	150 mg	Orally twice daily with or without food Swallow whole **(Self-administered at home)**
letrozole **OR** alternate Aromatase Inhibitor **OR** tamoxifen (see options on page 3)	Refer to table on Page 3	Orally once daily throughout therapy Take with or without food **(Self-administered at home)**
goserelin* **OR** alternate LHRH agonist* (see options on page 4)	Refer to table on Page 4	Subcutaneous once every 28 days **(goserelin or alternate LHRH agonist starts 28 days prior to the start of endocrine therapy then continues throughout therapy)**
***** LHRH agonists are only prescribed for pre- or peri-menopausal patients		

abemaciclib (VERZENIO®) available dosage strengths: 50 mg, 100 mg, 150 mg, 200 mg tablets
Classification: Non-Cytotoxic, Hazardous

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

REQUIRED MONITORING

Cycles 1 and 2
Day 1
- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders

Day 15
- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders

Cycle 3 and 4
Day 1
- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders

Cycle 5 and Onwards
Every 3 months or as clinically indicated
- CBC, serum creatinine, urea, electrolytes, liver enzymes and total bilirubin as per Physician Orders

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
loperamide	2 – 4 mg	Orally as directed below

INSTRUCTIONS FOR PATIENT

- At the first episode of diarrhea:
  - Take loperamide 4 mg (two 2 mg tablets) orally STAT; then
  - After every episode of diarrhea, take 2 mg (one 2 mg tablet) orally
  - If diarrhea has not stopped despite taking **8 tablets (16 mg) of loperamide over a 24-hour period,** please contact your clinic for further instructions. If this occurs after clinic hours, please call the Medical Oncologist on-call and/or report to the nearest emergency room/urgent care centre
- Patients should monitor for new or worsening respiratory symptoms (e.g. dyspnea, cough) due to risk of interstitial lung disease/pneumonitis
- abemaciclib has potential for drug-drug interactions. Patients should notify clinic prior to starting any new medication
- Avoid grapefruit and grapefruit juice, Seville oranges (i.e. orange marmalade) and starfruit
- Reinforce applicable safe handling precautions of medications, blood and body fluids while on abemaciclib

ADDITIONAL INFORMATION

- abemaciclib has been associated with an increase risk of venous thromboembolism and pulmonary embolism
- abemaciclib has potential for myelosuppression
- Pre- and peri-menopausal patients initiate LHRH agonist therapy at least 4 weeks before starting treatment with abemaciclib and endocrine therapy
- abemaciclib has been associated with elevated serum creatinine due to reduced renal tubular secretion of creatinine i.e. not related to reduced renal function; dose adjustment of abemaciclib is not specifically indicated for elevated serum creatinine
- There are multiple options for endocrine therapy and LHRH agonists used with abemaciclib. The tables on page 3 outline different drugs/dosing schedules which may be prescribed by Breast DSG oncologists

- **ARIA ordering**: Please note that ARIA regimens/protocols require each drug to be ordered separately
  - **BRST – [abemaciclib (ADJ)]** regimen is available as a 28-day cycle under the "Breast" treatment tab in ARIA
  - Support protocols are available for **anastrozole**, **exemestane**, **letrozole** and **tamoxifen** (90-day supply) under **Hormonal Therapy** in the "Breast Cancer" folder
  - Support protocols are available for **goserelin** and **leuprolide formulations** (either q 4 weeks OR q 12 weeks) under **LHRH Agonists** in the "Breast Cancer" folder

Options for Endocrine Therapy

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)**
OR		
tamoxifen	20 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

tamoxifen (NOLVADEX®) available dosage strengths: 10 mg and 20 mg tablets
Classification: Non-Cytotoxic, Hazardous

Options for LHRH agonists

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

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