

Adjuvant Abemaciclib - TVCA Pathway Guidance

Indication: Early breast cancer

***note: this pathway guidance should be used as an appendix to the TVCA clinical protocol for abemaciclib for adjuvant breast cancer ***

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Distribution:	TVCA Breast CAG members TVCA SACT CAG members
Related Documents:	TVCA Protocol for Abemaciclib with endocrine treatment, for Adjuvant Breast Cancer NHSE Blueteq list
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Aims and Objectives

The aim of this guidance is to improve efficiency, equity and streamlining of services across the TVCA network hospitals and to support best practice for patients on adjuvant abemaciclib for early breast cancer.

It is recognised that different hospitals within the network have varying staffing levels and skill mix and therefore will structure their pathway accordingly within this general guidance.



Suggested Roles and Responsibilities

Below are suggested roles and responsibilities where those roles are available at an individual Trust to best utilise the skill mix of the wider team. If, for example, there is no NMP available at a Trust, these roles and responsibilities would continue to be completed by a Doctor within the team

Consultant / Registrar

- Initiation of treatment – incl. initial prescribing, consent, blueteq
- Document any decisions that deviate from treatment protocol
- Involved in any decision to stop if unacceptable toxicity before completing 2 years of treatment
- Support NMP / SACT nurses regarding any queries outside of competence

Non- Medical Prescriber (NMP) - (Advanced Nurse Practitioner or Advanced Pharmacist)

- Review toxicity
- Check bloods trend
- Prescribe ongoing treatment and supportive treatments
- Make dose reductions

SACT nurse

- Carry out Oral Education SACT Clinic (OEC)
- Blood Monitoring in first 4 months (as detailed below)
- Basic reviews with patient to check bloods and fitness to proceed
- Delay treatment within protocol parameters
- Liaise with NMP / medical team if patient meets criteria for dose reductions or any concerns - ideally book patient back into urgent clinic slot (NMP or medical)

Pharmacy – Clinically verify, order and dispense prescriptions

Breast CNS team

- Holistic Needs Assessment (HNA) and ongoing support
- Point of contact for patient for non-SACT related problems (urgent SACT concerns to be reported to triage as per normal process)

Pre-Starting Abemaciclib

- Patients suitable for Adjuvant Abemaciclib are identified at MDT
 - Patient booked into Consultant Oncologist clinic following completion of radiotherapy to discuss and consent to Abemaciclib
- *note: abemaciclib must start within 12 weeks of completion of last treatment for early breast cancer (Surgery, chemotherapy or radiotherapy)

Consultant / Registrar

- Consent
- Blueteq and prescribe 3 cycles
- Request baseline bloods
- Complete referral and submit according to local practice (e.g. via SACT admin team)
- Write to GP to prescribe ongoing Aromatase Inhibitor, bisphosphonates, Calcium/Vit D, Ovarian suppression (as needed)
- Order follow-up screening – e.g. annual mammograms
- Request next appointments:
 - o Next clinic appointment (ideally NMP if available) in 2-3-months' time (~ 8 weeks after starting abemaciclib)
 - o HNA with breast nurses in next 4-5 months
 - o Next Consultant clinic ~6 months

SACT nurse or Pharmacist – Oral SACT Education Clinic (OEC)

- Completed as per agreed local SACT education procedure
- Book day 14 bloods review
- Check next review with a prescriber is in place (~ 2 months' time) and prescriptions are done to cover until then

Pharmacy

- Clinically screen and dispense cycle 1 prescription

Minimum Schedule of Ongoing Reviews

*Note: NMP review to be substituted with Medical review if no NMP in place

Cycle Number	Week 1	Week 2	Week 3	Week 4
Cycle 1	SACT nurse: OEC Check C1d1 bloods		Day 15 – SACT nurse - check bloods & basic toxicity	Pharmacy: Screen and dispense cycle 2
Cycle 2	SACT nurse: Check C2d1 bloods & basic toxicity		Day 15 – SACT nurse - check bloods & basic toxicity	Pharmacy: Screen and dispense cycle 3
Cycle 3	NMP (or Doctor) review + Check bloods + Prescribe cycle 4-6			Pharmacy: If no concerns, screen and dispense cycle 4-6
Cycle 4	SACT nurse: Check C4d1 bloods			
Ensure patient has next prescriber OPA in place and discharge from SACT nurses No further bloods arranged beyond this point unless clinically indicated				
Cycle 6		Doctor review + Prescribe cycle 7-12 + Give discharge information		Pharmacy: Screen and dispense cycle 7-9
Cycle 9				Pharmacy: Screen and dispense cycle 10-12
Cycle 12		NMP (or Doctor) review + Prescribe cycle 13-18		Pharmacy: Screen and dispense cycle 13-15
Cycle 15				Pharmacy: Screen and dispense cycle 16-18
Cycle 18		NMP (or Doctor) review + Prescribe cycle 19-24 + Document discharge from service		Pharmacy: Screen and dispense cycle 19-21
Cycle 21				Pharmacy: Screen and dispense cycle 22-24

Notes

Plan to discharge all patients from SACT nurse follow up after 3-4 months. Patients SHOULD NOT be having ongoing toxicity / blood abnormalities at this point. If patients are having unresolving toxicity, book back to clinic early (NMP or medical clinic) for review and for consideration of dose reductions.

After initial 4 months of close monitoring, no further routine bloods tests will be organised. Additional blood tests only to be requested at 3 monthly reviews if there are any clinical concerns

Abemaciclib is continuous so bloods don't have to be scheduled to 'Day 1'. Bloods (when needed) should be done with plenty of time for OPA, prescribing and dispensing before patient runs out of supplies.

After initial 6 months, prescribe 6 months of abemaciclib at a time and pharmacy will dispense in 3-month instalments (due to cost and risk of wastage)

At **Consultant / Registrar** review after 6 months of abemaciclib:

- Prescribe next 6 months
- Go through discharge information and request admin attaches information leaflet to letter as usual, BUT at bottom of clinic letter request next OPA in 6 months in NMP clinic rather than discharge

At final OPA in pathway (normally **NMP**) at 18 months:

- Prescribe final 6 months of abemaciclib
- Request 'Discharge' at bottom of letter and admin will move patient onto the patient initiated follow up' (PIFU) worklist as per early discharge workflow

Any new breast symptoms etc. to be reported via breast CNS team and rapid access pathway.

Further consultant review, after first 6-month appointment, is only required if there are concerns or consultant deems necessary. If consultant does not request further OPA, patient will be discharged from service by NMP at end of the 2 years.

Adjuvant patients DO NOT require regular scans. Annual screening, such as mammograms, are ordered by clinical team at start of this pathway and radiology write to patient with results.

Adjuvant patients DO NOT require monitoring of CA153 tumour markers.

Protocol adherence and deviations

SACT nurses and NMPs will follow TVCA protocols for delays and dose reductions for patients on treatment. Only a Consultant / SpR can authorise deviation from protocol, and this must be clearly documented on ARIA for the individual patient.