SACT PROTOCOL

The Clatterbridge Cancer Centre NHS Foundation Trust

Systemic Anti Cancer Therapy Protocol

Adjuvant Zoledronic Acid Early Breast Cancer

PROTOCOL REF: MPHAADZOL
(Version No. V1.0)

Approved for use in:

- Post-menopausal women with a diagnosis of early breast cancer

For more information please see the Adjuvant Zoledronic Acid Clinical Policy and the Aduvant Zoledronic Acid Service Standard operating procedure which accompanies this protocol on the intranet.

Dosage:

Dosage is dependent in creatinine clearance using the Cockcroft and Gault equation.

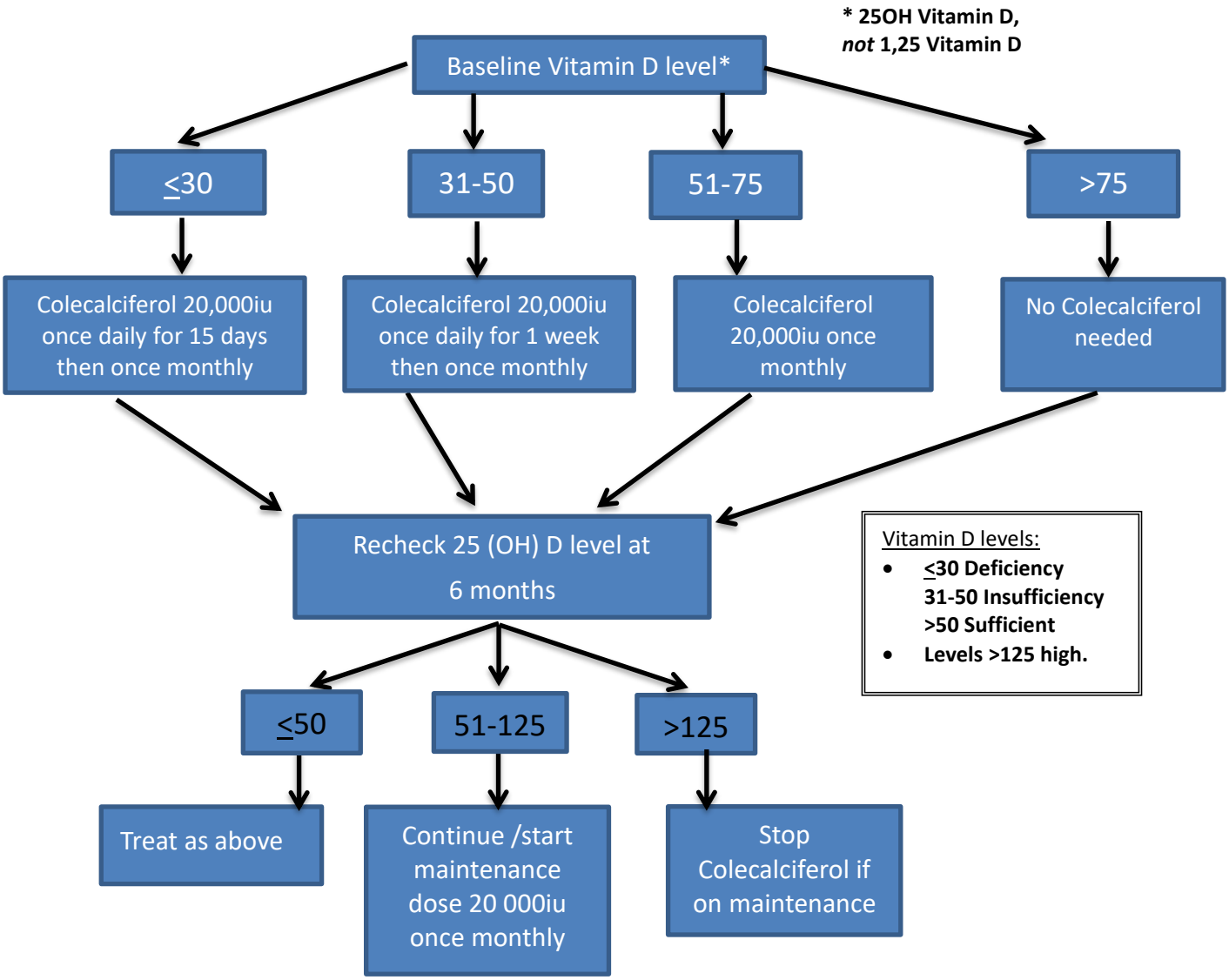
Drug	Creatinine Clearance (mL/min)	Dose	Route	Frequency with SACT	Frequency without SACT
Zoledronic Acid	**>60**	**4mg**	IV	****Cycles 1-3** = 4-6 weekly alongside chemotherapy **Cycle 4** = 12 weeks after cycle last cycle alongside chemotherapy **Cycles 5-10** = 6 monthly (6 months after cycle 4)	**For Breast patients post XRT or patients not receiving SACT or XRT = 6 cycles only** Given every 6 months for 6 cycles all cycles delivered in Adjuvant Zoledronic acid clinics
	50-60	**3.5mg**			
	40-49	**3.3mg**			
	30-39	**3mg**			
	<30	**Contraindicated**			

****First 3 cycles may not always be given alongside chemotherapy due to unforeseen delays. When there is a delay the next cycle of treatment, once chemotherapy has been completed, should be administered 12 weeks later.**

Supportive treatments:

- Paracetamol for flu like symptoms
- Oral supplements of cholecalciferol as per Vitamin D Level Flow Chart below

Adjuvant Zoledronate Vitamin D Level Flow Chart



Please note: Patients with low vitamin D levels **AND** low calcium levels/ inadequate dietary calcium will need to be on cholecalciferol as above **AND** Adcal D3/Calfovit or equivalent which may be already prescribed from GP

Administration:

Day	Drug	Dosage	Route	Diluent and Rate
1	Zoledronic acid	Dependent on creatinine clearance	IV	Diluted in 100mL of 0.9% w/v sodium chloride solution and given over 15 minutes

Withdraw an appropriate volume of the concentrate needed, as follows:

- 5 ml for 4.0mg dose
- 4.4 ml for 3.5 mg dose
- 4.1 ml for 3.3 mg dose
- 3.8 ml for 3.0 mg dose

Note that if a patient attends for chemotherapy and zoledronate but is not fit for chemotherapy (eg neutropenia) s/he should go ahead with zoledronate unless not fit to do so.

Contra-indications:

- Hypersensitivity to the active substance, to other bisphosphonates or to any of the excipients

Extravasation risk:

Zoledronic acid is not a vesicant

Drug Interactions:

Thalidomide: Increased risk of renal impairment with concomitant thalidomide

Aminoglycosides: Increased risk of renal impairment

Main Toxicities:

Serious side effects

Osteonecrosis of the jaw (dental assessment prior to treatment and withhold zoledronic acid for at least 6 weeks pre and post any dental intervention).

Common Side effects

- Flu like symptoms
- pain flare
- bone pain
- myalgia
- arthralgia
- hypocalcaemia
- hypophosphatemia

Other side effects

- Numbness around mouth (sign of low calcium)
- Conjunctivitis
- Headache
- Renal impairment
- Nausea

Investigations and treatment plan:

	Pre	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Comments
Informed Consent	X					
Clinical Assessment	X					
Dental assessment	X					6 monthly
SACT Assessment (Bone Directed Therapy Assessment) (to include PS and toxicities)	X	X	X	X	X	Every cycle
U&E	X		X	X	X	Every cycle
CrCl	X		X	X	X	Every cycle
Calcium	X		X	X	X	Every cycle
Vitamin D levels	X					6 monthly
Phosphate	X		X	X	X	Every cycle
Weight recorded	X		X	X	X	Every cycle
Height recorded	X					

*All investigati**ons have a validity period of 28** days before treatment. Please ensure bloods are taken within a 48 hour window if Zoledronic Acid given alongside Chemotherapy treatments (not Vitamin D levels) or the patient has received chemotherapy within the last 6 weeks.

References:

1. EMC. *Zoledronic acid 4mg/5ml concentrate for solution for infusion.* Available from https://www.medicines.org.uk/emc
2. R.Coleman, J.J Body et al. Bone health in cancer patients, ESMO Clinical practice guidelines. 2014 Vol 25.
3. NICE guidelines. *Vitamin D supplement use in specific population groups*. Available from: https://www.nice.org.uk/guidance/ph56
4. Early Breast Cancer Trialists Collaborative Group (October 2015). Adjuvant bisphosphonate treatment in early breast cancer: meta-analysis of individual patient data from randomised trials. The Lancet, 386, 1353-1361
5. Breast Cancer Service Guidance 2016
6. Coleman RE, Hadji P et al. Bone Health in Cancer: ESMO Clinical Practice Guidelines. Annals of Oncology, 31 12: 1650-1663
7. Hadji P, Coleman RE et al. Adjuvant bisphosphonates in early breast cancer: consensus guidance for clinical practice from a European Panel. Annals of Oncology, 2016; 27: 379-39

Circulation/Dissemination

Date added into Q-Pulse	For completion by DCM
Date document posted on the Intranet	For completion by DCM

Version History

Date	Version	Author name and designation	Summary of main changes
Aug 2023	**1.0**	**Claire Bennett – Matron Network Services CBU1**	New Protocol