Guidelines for Adjuvant Bisphosphonate treatment for Post-Menopausal Women with Early Breast Cancer

Category:	Guideline
Summary:	Adjuvant Bisphosphonate treatment for Post-Menopausal Women with Early Breast Cancer
Valid From:	November 2021
Distribution:	Healthcare professionals involved in care of post-menopausal women with early breast cancer
Related Documents:	TVSCN treatment protocols
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Endorsement

Endorsee Name:	Endorsee Job Title
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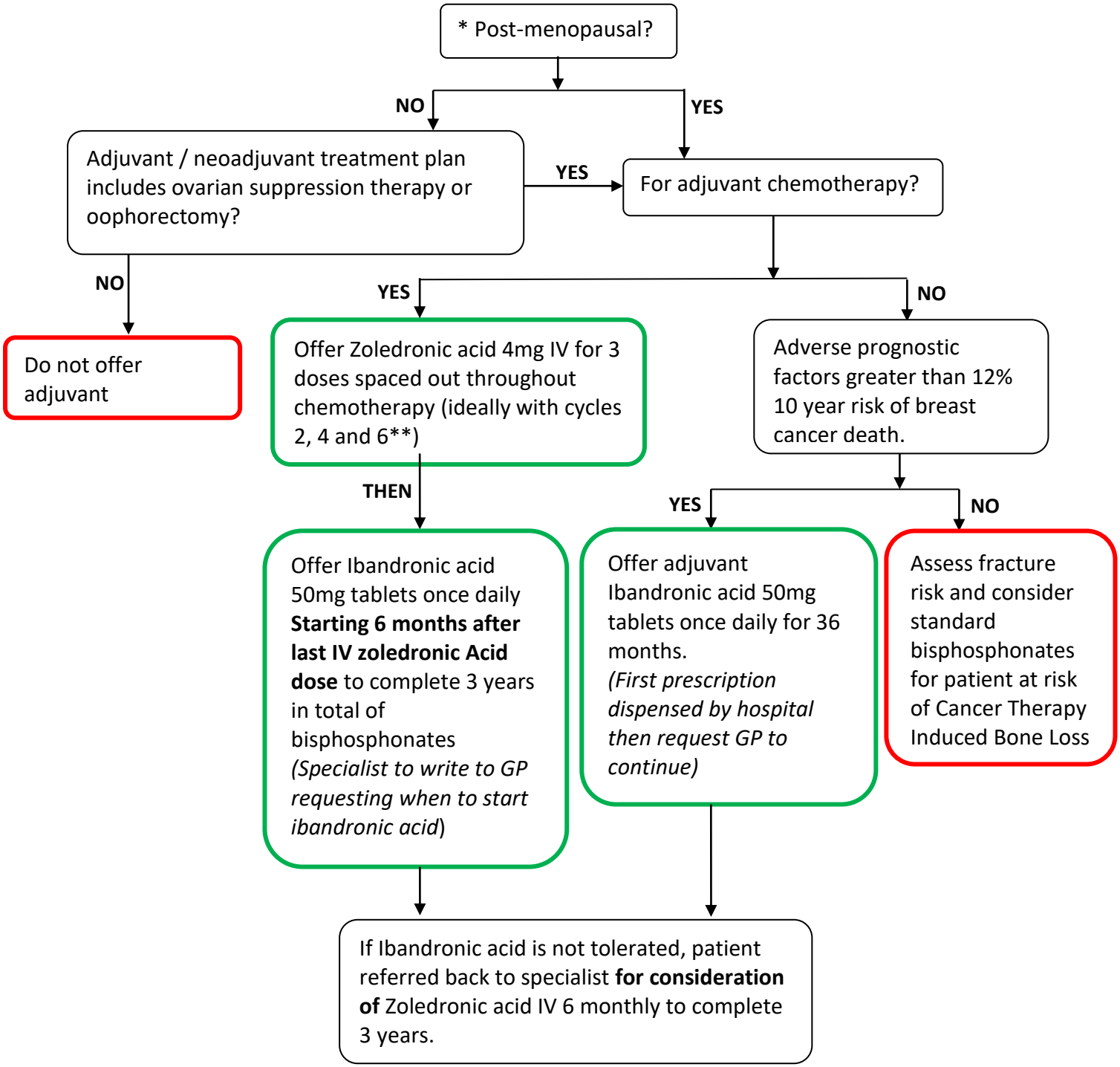
1. Treatment Pathway



* Post-menopausal is defined as age over 55years +/or serum FSH in post-menopausal range

** If start is delayed due to need for Vitamin D replacement then doses can be given with latter chemotherapy cycles at minimum of 3 weekly intervals

2. Monitoring

- Baseline
  - Renal function – as per SPC
  - Calcium – Ensure in normal range prior to initiation
  - Vitamin D – Ensure in normal range prior to initiation

- Prior to each dose of Zoledronic Acid
  - Renal function – As per SPC
  - Calcium – Ensure in normal range

3. Responsibilities of Hospital Specialist

- Discuss rationale for treatment with patient and make them aware of unlicensed indication
  - Indication is not included in patient information leaflet for ibandronic acid 50mg tablets.
  - Verbal consent from patient regarding unlicensed use is acceptable.

- Advise patient on treatment regimen
  - For Zoledronic Acid
    - 3 x IV infusions given alongside chemotherapy, ideally with cycles 2, 4 and 6, given on DTU. Given as a 15 minute infusion
  - For Ibandronic acid
    - 50mg tablet once daily orally
    - To be taken on an empty stomach, first thing in the morning, swallowed whole with at least 200 ml of water, sit upright or stand when taking and for next 60minutes, do not eat, drink or take other medications for 30 minutes after taking ibandronic acid.

- Review current medicines:
  - Advise patient to stop any other bisphosphonate that they may be taking; for example: risedronate or alendronate.
  - For patients taking a regular NSAID consider whether this can be discontinued.

- Ensure patient has had recent dental check and has had any necessary dental work carried out prior to starting bisphosphonates and reports any arising dental issues

- Baseline blood tests:
  - Renal function:
    - Follow SPC guidelines for prescribing in renal impairment (CrCl less than 60mls/min)
    - Contraindicated in CrCl less than 30mls/min

  - Serum Calcium:
    - Ensure calcium in normal range prior to initiation (Adj. Calcium greater than 2.2mmol/L). If calcium is low ensure replacement prior to initiation of bisphosphonate

- Vitamin D level:
  - Ensure vitamin D level in normal range prior to initiation (greater than 50nmol/L). If vitamin D level is low ensure high dose replacement prior to initiation of bisphosphonate.

- Prescribe initial bisphosphonate treatment as per algorithm in section 1:
  - Prescribe 3 x zoledronic acid on ARIA as (supportive regimen) alongside chemotherapy
    OR
  - Prescribe first 28 days of ibandronic acid on EPR and ask patient to collect from hospital pharmacy

- Prescribe first month of Calcium and Vitamin D supplements

- Write to GP and ask that they:
  - Prescribe ongoing Calcium and Vitamin D supplements for duration of adjuvant bisphosphonate treatment
    (note: there is some evidence that excess calcium supplementation can increase cardiovascular risk. If patient has a calcium rich diet and the risk is considered to outweigh the benefit to bone health, supplementation with vitamin D only can be considered)
  - Prescribe ongoing oral Ibandronic acid 50mg once daily
    - Starting 6 months after last zoledronic acid to complete total of 3 years
      OR
    - For full 3 years if not having adjuvant chemotherapy

- Discuss potential side effects with patient, provide written information and consent on CRUK SACT form for IV treatment

4. Responsibilities of GP

- Start ibandronic acid 6 months after last zoledronic acid dose. Add to repeats when request received form specialist with instructions on when to start e.g. 'START MARCH 2023'. Patient will be reminded by specialist at their last clinic appointment.

- Issue on-going prescriptions for ibandronic acid 50mg daily for length of time specified by hospital specialist

- Add duration of treatment in the to dosage instructions on the prescription so it is reviewed after a total of 3 years

- Prescribe ongoing Vitamin D (+/- Calcium) supplements

- Ensure other bisphosphonates are stopped during this period (note there is no data to support the use of Alendronic Acid or Risedronate for this indication).

- For patients taking a regular NSAID review and consider whether this can be discontinued.

- Annual medication review / blood tests as per usual practice in primary care

5. Information for Patients

- Patients need to be aware that this is an unlicensed indication **(responsibility of specialist).**

- Patients should be advised to take a daily supplement of Calcium and Vitamin D obtained as repeat prescription from GP (unless patient has a calcium rich diet, in which case vitamin D only can be considered – see 'Calcium for Bones' leaflet https://www.ouh.nhs.uk/osteoporosis/documents/calcium-for-bones.pdf)

- Patients should be advised on how to take Ibandronic Acid and be referred to the manufacturer's Patient Information Leaflet for full details. Patients and carers should be advised to stop tablets and seek medical attention for symptoms of oesophageal irritation such as dysphagia, pain on swallowing, retrosternal pain, or heartburn.

- During treatment patients should maintain good oral hygiene, receive routine dental check-ups, and report any oral symptoms such as dental mobility, pain or swelling, non-healing sores or discharge to a doctor and dentist.

- The recommended dose of Ibandronic Acid is 50mg OD, however, consensus amongst OUH Oncologists is that less frequent dosing is likely to be as effective. Therefore if a patient misses doses or cannot tolerate daily dosing, taking Ibandronic Acid 50mg 2-3 times per week could be considered. **Note: There is, however, no trial data to support this dosing schedule and this is expert opinion only.**

6. Follow-up in Secondary Care

Patients do not require follow up in secondary care outside of the normal pathway for patients with early stage breast cancer. Patients should follow the usual early discharge pathway where appropriate.