

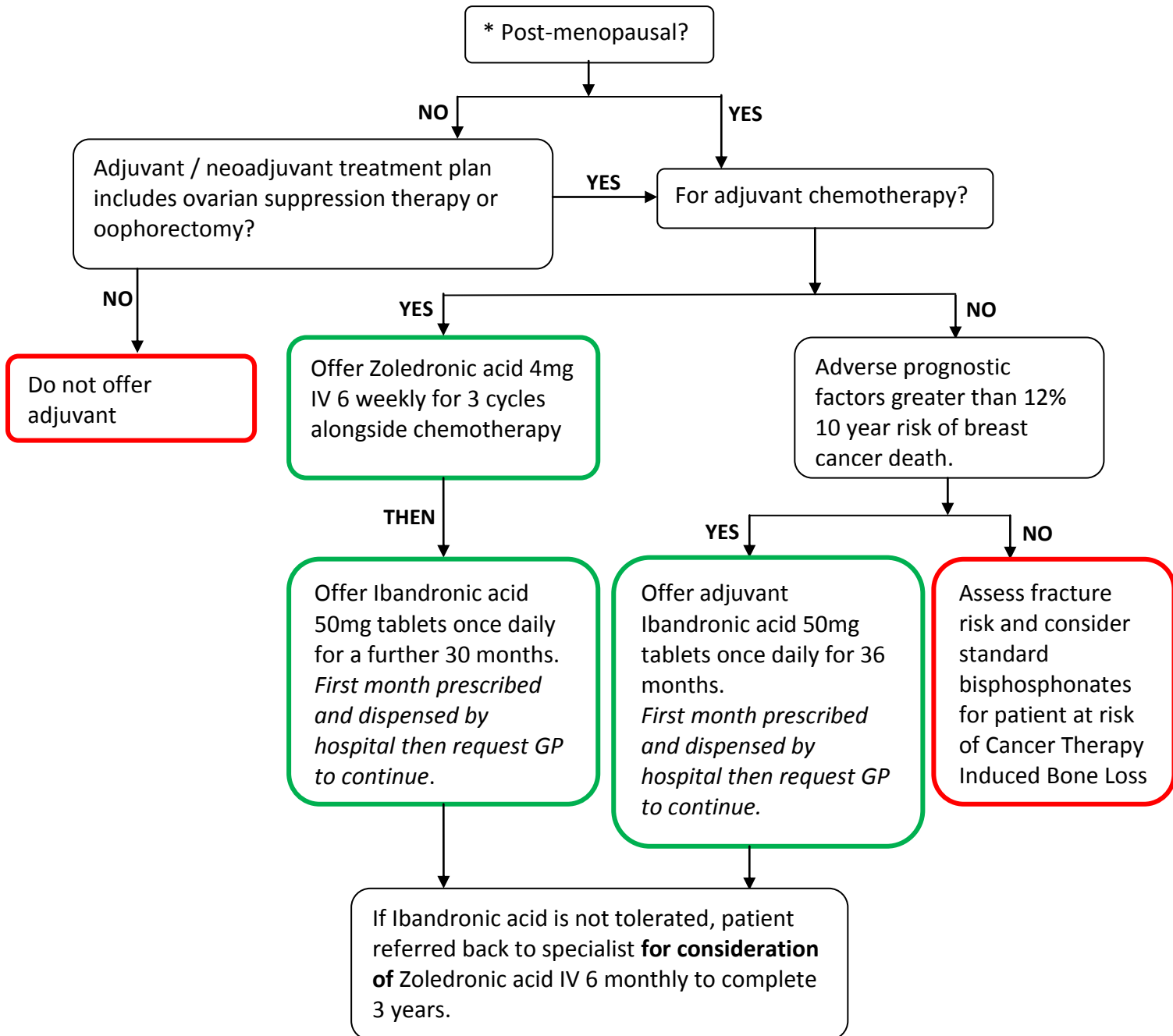
Oxford University Hospitals Guidelines for Adjuvant Bisphosphonate treatment for Post-Menopausal Women with Early Breast Cancer

Category:	Guideline
Summary:	Adjuvant Bisphosphonate treatment for Post-Menopausal Women with Early Breast Cancer
Valid From:	18/10/2017
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

2. Monitoring

- Baseline
 - Renal function
 - Calcium
 - Vitamin D levels
- Prior to each dose of Zoledronic Acid
 - Renal function
 - Calcium
- Whilst on Ibandronic Acid
 - Annual check of calcium level as minimum

3. Responsibilities of hospital specialist

- Baseline blood tests – including renal function, serum calcium and vitamin D level
- 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.
- Prescribe initial bisphosphonate treatment as per algorithm in section 1. Where applicable:
 - Prescribe 3 x zoledronic acid on ARIA as (supportive regimen) alongside chemotherapy
 - Prescribe first 28 days of ibandronic acid on EPR and ask patient to collect from hospital pharmacy
- Write to GP and ask that they prescribe oral Ibandronic acid 50mg once daily continuation to complete 3 years of adjuvant treatment. Also highlight need to monitor renal function and creatinine clearance at annual medication review
- 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 with cycle 1, 3 and 5 of chemotherapy 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.
- Advise patient of importance of adequate intake of calcium and vitamin D
 - All patients should be advised to take supplemental vitamin D 20-25 micrograms (800–1,000 Units) daily; brought over the counter (OTC) from pharmacies, supermarkets or health food shops.
 - If dietary intake of calcium is low, ask GP to prescribe combined calcium and vitamin D preparation instead
 - Include in GP letter whether calcium and vitamin D needs to be prescribed or patient has been advised to buy vitamin D.
- Discuss potential side effects with patient including:

Osteonecrosis of the jaw (MHRA warning):

- Patients should be advised to have a dental examination with appropriate preventative dentistry prior to treatment with bisphosphonates.
- During bisphosphonate treatment, patients should maintain good oral hygiene, receive routine dental check-ups, and report any oral symptoms such as dental mobility, pain, or swelling.

Atypical femoral fractures (MHRA warning):

- During bisphosphonate treatment, patients should be advised to report any thigh, hip, or groin pain. Any patient who presents with such symptoms should be evaluated for an incomplete femur fracture.

Very rare reports of osteonecrosis of the external auditory canal (MHRA warning):

- Patients should be advised to report any ear pain, discharge from the ear, or an ear infection during bisphosphonate treatment.

Adverse effects on renal function with IV Zoledronic Acid (MHRA warning):

- Patients should be warned about the risk of renal toxicity and renal failure with IV bisphosphonates
- Inform patient that renal function will be measured before each dose, and patients should be adequately hydrated before treatment

Oesophageal reactions with oral Ibandronic Acid (MHRA warning):

- Patients should be advised to stop taking the tablets and to seek medical attention if they develop any symptoms of oesophageal irritation such as difficulty or pain upon swallowing, chest pain, or new or worsening heartburn.
- See above regarding importance of dosing instructions.

4. Responsibilities of GP

- Issue on-going prescriptions for ibandronic acid 50mg daily for length of time specified by hospital specialist
- Ensure patient is taking Vitamin D supplementation and has adequate dietary calcium intake, otherwise co-prescribe Calcium and Vitamin D supplement
- Ensure other bisphosphonates are stopped during this period.
- For patients taking a regular NSAID review and consider whether this can be discontinued.
- Annual review including:
 - Blood tests: renal function and serum calcium:
 - Medication review: to check for compliance; side effects and tolerability; ensure patient and/or carer understands how to administer tablets; check oral hygiene advice is being followed.

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 vitamin D 20-25 micrograms (800–1,000 Units) daily (brought from pharmacies, supermarkets or health food shops) and maintain dietary intake of calcium. Alternatively they may be prescribed a Calcium and Vitamin D supplement
- 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.
- Patients should be advised to report any ear pain, discharge from the ear or an ear infection during treatment with a bisphosphonate.
- Patients should be advised to report any thigh, hip, or groin pain during treatment with a bisphosphonate.

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.

7. Audit

It is proposed that the uptake of this pathway be audited at 2 years post-implementation. The audit should include the numbers of patients referred back in from primary care for ongoing zoledronic acid due to intolerance to ibandronic Acid and the impact on the Day treatment unit.