NHS
Northern Lincolnshire
Area Prescribing Committee

HERPC
Hull & East Riding Prescribing Committee

Prescribing Framework for Ibandronate (oral bisphosphonate) for metastatic bone disease

Patients Name:…… Unit Number: ……

Patients Address:……(Use addressograph sticker)

G.P's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:……

Where prescriber is <u>not</u> a consultant:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……..... ……. Date:……

GP's Signature:…… Date:……

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.

The patient's GP should sign and **send back to specialist**, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **<u>unwilling</u>** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

1. Background

Metastatic bone disease is a common complication of breast cancer. Bisphosphonates act to reduce the osteoclast activity within bone and thus help prevent skeletal events. Intravenous bisphosphonates have been the standard of care for patients with metastatic bone disease. Ibandronate is a highly potent bisphosphonate, with an oral formulation available allowing self-administration at home.

This document should be read in conjunction with the guidance "Responsibility for prescribing between Primary & Secondary/Tertiary Care" https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

2. Indication

Ibandronate is indicated for the prevention of skeletal events in patients with breast cancer and bone metastases.

3. Dose

The recommended dose is one 50mg film-coated tablet daily.
Ibandronate tablets contain lactose and should not be administered to patients with lactose intolerance.

Additional medication to be prescribed by the GP

Calcium and Vitamin D supplementation may be required and will be initiated by the consultant. Evacal D3 or Calceos(or equivalent), One tablet Twice Daily is recommended

Dose Adjustment

- Elderly population (> 65 years): No dose adjustment is necessary[4]
- Patients with hepatic impairment: No dose adjustment is required[4]
- Patients with renal impairment[4]
    - For patients with mild renal impairment (eGFR/CrCl ≥ 50 and < 80 mL/min), no dose adjustment is necessary
    - For patients with moderate renal impairment (eGFR/CrCl ≥ 30 and < 50 mL/min) a dose adjustment to one 50mg tablet every second day is recommended

NOTE: Many laboratory results are expressed as eGFR. While it is likely that in many cases the eGFR and the CrCl will be very similar, beware that differences could occur in people at extremes of body size.

4. Duration of treatment

Until disease progression or unacceptable toxicity

5. Adverse effects

Oral bisphosphonates have been associated with:

- Dysphagia
- Oesophagitis
- Oesophageal or gastric ulcers.

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.

Oesophageal reactions (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.

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.
- 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.

Contraindications: Hypocalcaemia, inability to stand or sit upright for at least 60 minutes, abnormalities of the oesophagus which delay oesophageal emptying such as stricture or achalasia and hypersensitivity to the active substance or to any of the excipients (e.g. lactose intolerance).

6. Interactions

There are no significant drug interactions.

Products containing calcium and other multivalent cations (such as aluminium, magnesium, iron), including milk and food, are likely to interfere with absorption of ibandronic acid.

7. Monitoring

LFT's U&E's, creatinine, serum calcium, phosphate and magnesium, creatinine clearance every 3 months

8. Information to patient

Take tablet first thing in the morning after an overnight fast and before the first food or drink of the day and do not eat or take other medicines for 30minutes to 1 hour after taking the tablet.
− The tablet should be swallowed whole with a full glass of plain water while standing or sitting in an upright position.
− Patients should not lie down for 60 minutes after taking ibandronate.
− Patients should not chew or suck the tablet because of a potential for oropharyngeal ulceration.

− Plain water is the only drink that should be taken with ibandronate. Please note that some mineral waters may have a higher concentration of calcium and therefore should not be used.

- 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.
- Patients should be advised to contact their GP if they have any concerns with the medication.

9. Responsibilities of clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	Assessing the patient and establishing a need for bisphosphonate treatment. Establishing that the patient has adequate renal function (estimated creatinine clearance greater than 30ml/min) Ensuring that there are no contra-indications to therapy with ibandronate. Providing information for the patient, including adverse effects, obtaining consent and initiating treatment. Contacting the GP to invite shared care for the patient. Stop any other bisphosphonates Prescribe initial 28 days' supply	
Maintenance	Assessing the continued appropriateness for ibandronate on a 3 monthly basis. Reviewing any concerns regarding disease progression from the GP within 2 weeks. Monitoring toxicity and reporting adverse events Ensuring that all other medical professionals in the shared care team are kept informed of any changes in the patient's circumstances.	Provision of general care and advice to the patient and her family/carers. Assessment of continued well being of the patient. No routine monitoring of toxicity is required, however referral to secondary care is necessary if the patient presents with signs of hypo or hypercalcemia, clinical deterioration or reduced renal function: a) If normal at baseline then reduction to <50mL/min b) If below normal at baseline and on appropriately modified dose (see page 2) then reduction of >10mL/min form baseline (i.e.if drops from 38 to 28mL/min). Monitor LFT's U&E's, creatinine, serum calcium, phosphate and magnesium, creatinine clearance every three months. Monitoring toxicity and reporting adverse events.

		Report any serious adverse reaction to the MHRA and the referring consultant. Providing the patient with repeat prescriptions for ibandronate and calcium supplementation as appropriate Referring for review if there are signs of disease progression. Individual patients who require additional serum creatinine and calcium levels monitoring may be identified by the consultant. Stop any repeat prescriptions for other bisphosphonates.

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APPROVAL PROCESS

Written by:	**Marian Opuku-Fofie; updated Jane Morgan Interface Pharmacist**
Consultation process:	**Breast Cancer Network Site Specific Group**
Approved by:	**MMIG Feb 2010**
Ratified by:	**HERPC March 2010 Updated June 2018; July 21 NLAPC**
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