Title SHARED CARE PROTOCOL for IBANDRONATE (BONDRONAT®) in metastatic breast cancer		**Unique Identifier**
Scope Ibandronate may be considered for shared care arrangements for the treatment of skeletal events in patients with breast cancer and bone metastases.		**Classification SHARED CARE PROTOCOL**
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To be read in conjunction with the following documents: The Summary of Product Characteristics (SPC)		
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1.0 Introduction

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.

2.0 Purpose

These guidelines will now go on to look at the shared care management of skeletal events in patients with advanced breast cancer and bone metastases treated with ibandronate.

3.0 Scope

Ibandronate may be considered for shared care arrangements for the treatment of skeletal events in patients with breast cancer and bone metastases.

4.0 Review

2 years

5.0 Shared Care Protocol

5.1 Clinical Details

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

Clinical studies have not shown any evidence of deterioration in renal function with long term ibandronate therapy.

5.2 Product Information

The recommended dose is one 50mg film-coated tablet daily.

Ibandronate tablets contain lactose and should not be administered to patients with lactose intolerance.

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. Therefore, with such products, including food, intake must be delayed at least 30 minutes following oral administration.

It is recommended that the tablets should be taken after an overnight fast (at least 6 hours) and before the first food or drink of the day. Fasting should continue for at least 30 minutes after the dose has been taken.
The patient should swallow the tablet whole with a full glass of water and remain upright in a sitting or standing position.
The patient should not lie down for 60 minutes after taking the tablet.

There are no significant drug interactions.

5.3 Ancillary products/apparatus which may need to be prescribed by a GP

Calcium carbonate (1.25g to 1.5g) with 400 units colecalciferol (or equivalent): TWO tablets to be taken daily as Calcichew D³ Forte or Adcal-D³ (most cost effective) respectively.

5.4 Possible side effects of treatment

Oral bisphosphonates have been associated with dysphagia, oesophagitis, and oesophageal or gastric ulcers.

5.5 Aspects of care for which the consultant is responsible

Assessing the patient and establishing a need for bisphosphonate treatment.
Establishing that the patient has adequate renal function (calculated 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.
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.

5.6 Conditions of assuming responsibility by the GP

	Consultant	**Usual GP**
Renal function	Every 3 months	Not required routinely
Serum calcium, phosphate, magnesium	Every 3 months	Not required routinely

5.7 Aspects of care for which the GP is responsible

Initial referral to a consultant on suspicion of breast cancer.
Provision of general care and advice to the patient and her family/carers.
Assessment of continued well being of the patient.
Monitoring toxicity and reporting adverse events to the consultant.
Providing the patient with repeat prescriptions for ibandronate and calcium supplementation as appropriate.
Referring for review if there are signs of disease progression.
Ensuring that all other medical professionals in the shared care team are kept informed of any changes in the patient's circumstances.

5.8 Individual consideration of each case between consultant and GP

Individual patients may require serum creatinine and calcium levels monitoring after initiating therapy, with parameters for referring back to the consultant established on a patient specific basis.

5.9 Product Patient Information Leaflet

See attached leaflet

5.10 Roche Customer Care Team

Community pharmacies have reported difficultly in obtaining ibandronate. Ibandronate can be obtained directly from Roche. For stock enquiries, orders and emergency supply please contact the Roche customer care team – Tel 0800 731 5711

5.11 References

Body JJ, Diel IJ, Lichinitzer M et al
Oral Ibandronate reduces the risk of skeletal complications in breast cancer patients with metastatic bone disease: results from two randomized, placebo controlled phase III studies. British Journal of Cancer 2004, 90: 1133-1137

6.0 Back up details available from hospital to General Practitioner and patient e.g. contact name and number, especially for out of hours problems

7.0 Statement of Agreement.

Shared care is an agreement between the GP and the Consultant. This form is a request by the consultant to share the suggested care pathway of your patient. If you are unable to agree to the sharing of care and initiating the suggested medication, please make this known to the consultant within 14 days, ideally stating the nature of your concern