BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Ibandronic Acid
Amber ***three months***	
Indication	Adjuvant therapy for postmenopausal patients with early breast cancer with an intermediate or high risk of recurrence. Bisphosphonates have been shown to reduce the rate of breast cancer recurrence in the bone and improve breast cancer survival; definite benefit has been demonstrated only in postmenopausal women. Bisphosphonates are not licensed for preventing recurrence or improving survival in people with early breast cancer, and use for this indication is off-label.

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	Ibandronic acid - One 50mg tablet each morning. An oral supplement of Calcium and vitamin D is recommended if dietary intake is inadequate. Treatment will be initiated after specialist review and evaluation of biochemical function including creatinine clearance. Full dose will be prescribed if calculated creatinine clearance ≥ 50ml/min. For patients with moderate renal impairment (≥30 and <50 mL/min) a dosage adjustment to one 50 mg film-coated tablet every second day is recommended. For severe renal impairment (CrCl <30ml/min) the recommended dose is 50mg once weekly.
Route and formulation	Oral, tablets
Duration of treatment	Ibandronic acid should be used for a total of 3 years (initially patients may be treated with IV zolendronic acid whilst on concurrent systemic anticancer therapy). Finish dates should be specified where appropriate.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Treatment will be initiated after specialist review and evaluation of biochemical function including creatinine clearance (See section 2 for dosing).

Baseline blood tests to include FBC, U&E, LFT, Calcium, Phosphate and Vitamin D levels. Ensure Calcium and vitamin D are replete.

Dental review is recommended to reduce risk of osteonecrosis of the jaw (ONJ)

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	Frequency	Who by	Action/management
FBC, U&E, Magnesium, Ca, Phosphate	After 2-3 months	Secondary Care	Amend dose if renal function deteriorates <50ml/min. Give calcium supplement if calcium decreases below lower limit of normal.
FBC, U&E, Magnesium, Ca, Phosphate	Then annually	Primary Care (GPs)	Amend dose if renal function deteriorates <50ml/min as per BNF. Give calcium supplement if calcium decreases below lower limit of normal.

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency/severity	Action/management
Hypocalcaemia	Common/usually asymptomatic	Check compliance if on calcium tablet. Prescribe or increase dose.
Oesophageal reactions (oesophagitis, dysphagia, odynophagia, retrosternal pain, new or worsening heartburn)	Discontinue and seek medical attention. Post marketing reports of gastric and duodenal ulcers.	Seek medical attention
Osteonecrosis of the jaw (ONJ)	Reported rarely in post marketing setting.	Postpone/delay treatment until investigated
Osteonecrosis of the external auditory canal	Osteonecrosis of the external auditory canal has been reported with bisphosphonates, mainly in association with long-term therapy. Possible risk	Postpone/delay treatment until investigated

		factors for osteonecrosis of the external auditory canal include steroid use and chemotherapy and/or local risk factors such as infection or trauma. The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving bisphosphonates who present with ear symptoms including chronic ear infections.	
Referral back to specialist	Click here to enter details		

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues	Ibandronic acid should not be prescribed in pregnancy. Caution is indicated in patients with hypersensitivity to bisphosphonates, breast feeding women, aspirin sensitive asthma, renal and hepatic impairment, hypocalcaemia and cardiac disease. 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 tablets. Since Acetylsalicylic acid, Nonsteroidal Anti-Inflammatory medicinal products (NSAIDs) and bisphosphonates are associated with gastrointestinal irritation, caution should be taken during concomitant administration.
Reminder to ask patient about specific problems	Click here to enter details

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

Ibandronic acid tablets should be taken after an overnight fast (at least 6 hours) and before the first food or drink of the day. Medicinal products and supplements (including calcium) should similarly be avoided prior to taking ibandronic acid tablets. Fasting should be continued for at least 30 minutes after taking the tablet. Water may be taken at any time during the course of ibandronic acid treatment. Water with a high concentration of calcium should not be used. If there is concern regarding potentially high levels of calcium in the tap water (hard water), it is advised to use bottled water with a low mineral content. - The tablets should be swallowed whole with a full glass of water (180 to 240 ml) while the patient is standing or sitting in an upright position.

- Patients should not lie down for 60 minutes after taking ibandronic acid.

- Patients should not chew, suck or crush the tablet because of a potential for oropharyngeal ulceration.

- Water is the only drink that should be taken with ibandronic acid.

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 10: Contact Details

Name	Organisation	Telephone Number	E mail address
Dr Vivek Mohan	Bristol Haematology and Oncology Centre	01179230000 via switch	Vivek.mohan@UHBristol.nhs.uk
Eve Blackmore	Bristol Haematology and Oncology Centre	01173422349	Eve.Blackmore@UHBristol.nhs.uk
Jeremy Braybrooke	Bristol Haematology and Oncology Centre	01173426295	Jeremy.braybrooke@uhbw.nhs.uk

Section 11: Document Details

Date prepared	15/01/2020

Prepared by	Eve Blackmore Dr Vivek Mohan
Date approved by JFG	June 2020
Date of review	June 2022
Document Identification: Version	SCP Ibandronic Acid Feb 2020 Final.docx

Section 12: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Originally reviewed by North Bristol Trust and WAHT Feb 2017

Section 13: References

Please list references

1. Early breast Cancer Trialists Collaborative Group. Adjuvant bisphosphonate treatment in early breast cancer:meta-analysis of individual patient data from randomised trials. Lancet. 2015. 386: 1353-61
2. Ibandronic Acid. Consilient Health Ltd. Summary of Product Characteristics [Internet]. Last reviewed 15th Jul 2019. Available at URL https://www.medicines.org.uk/emc/product/1984/smpc
3. NICE. Early breast cancer (preventing recurrence and improving survival): adjuvant bisphosphonates. July 2017. Available at URL https://www.nice.org.uk/advice/es15/chapter/Introduction-and-current-guidance
4. BNSSG Adult Guidelines for Vitamin D Deficiency. [Internet] Last reviewed April 2019. Available at https://remedy.bnssgccg.nhs.uk/media/3244/ssg-adult-vitamin-d-prescribing-guidance.pdf