West Yorkshire
Health and Care Partnership

SPECIALIST INITIATION GUIDANCE
With additional information

Bezafibrate oral for treatment of Primary Biliary Cholangitis in adult services

WY ICS definition for specialist initiation:

Items initiated by a specialist that offer a valuable alternative/addition to the patients' treatment. These are considered suitable for GP prescribing following specialist initiation, including initial titration of dose and assessment of efficacy (where appropriate). The specialist will highlight if there is any need for any further titration. Some standard/routine monitoring may be required. Dosing will be in line with the BNF/SPC or outlined in the letter from the specialist. A brief prescribing document may be available otherwise this will just link to a standard document that outlines the responsibilities of the specialist primary care prescriber and patient. All patients on these should still be regularly reviewed in primary care regarding their treatment.

We have started your patient on bezafibrate for treatment of Primary Biliary Cholangitis. We will continue to see the patient and prescribe bezafibrate for (minimum period of 3 months). After this period the General Practitioner (GP)/Primary Care Prescriber will be asked to take over prescribing and monitoring. Patients will not be discharged from this service and will continue to be discussed/monitored with the option for immediate access should they need it.

Unless otherwise specified within this guidance, this drug must be initiated by a specialist who must be a prescriber with relevant expertise. Specialist may include consultants, registrars, GPs with special interest or independent non-medical prescribers with relevant experience/expertise. Subsequent changes in drug treatment may be recommended by non-prescribers with the relevant competency working with the specialist MDT in accordance with clinical guidelines and best practice

Indications **(Please state whether licensed or unlicensed or unlicensed use of a licensed product)**	Primary Biliary Cholangitis Unlicensed use of a licensed medicine	
Initiation and ongoing dose regime	Use modified-release tablet if creatinine clearance over 60mL/minute • 400mg once daily Use immediate-release tablet if creatinine clearance less than 60ml/minute: • 400 mg daily if creatinine clearance 40–60 mL/minute. • 200 mg every 1–2 days if creatinine clearance 15–40 mL/minute. • Avoid bezafibrate if creatinine clearance less than 15mL/minute	
	Route of administration:	Oral

Pharmaceutical aspects If a medicine needs to be prescribed by brand /formulation information will be included in this section.	Other important information:	Formulation: 400mg MR tablets or 200mg tablets
Baseline investigations, routine tests/monitoring and follow up	**Baseline investigations:** Monitoring at baseline is the responsibility of the specialist. LFTs, U+Es, CK - at baseline and at 3 months (this will be done by the hospital specialists) **Routine tests/ monitoring:** LFTs, U+Es, CK - 6 monthly (this will be the responsibility of primary care). LTHT will provide the forms for these and follow up results. Beyond this time period, only routine disease monitoring is needed. Stop therapy and refer to hospital specialist if any of these blood results are significantly deranged (serum bilirubin and/or ALT >2 x raised from baseline value, develops AKI (Any concerns over renal function should be flagged to secondary care and rediscussed with the secondary care team who will advise), significantly raised CK (3 x ULN)) **Follow up:** Patients would receive ongoing review at the autoimmune liver disease outpatient clinic and would be regularly discussed at the PBC second-line treatment MDT.	
Consult the BNF, BNFC and SPC for full and current prescribing information. *The following information has been added only if it differs from the BNF, BNFC and SPC or supports that information.*		
Specialist contact information	See letter from Specialist leedsth-tr.ihepnurseteam@nhs.net	
Specialist responsibilities	• Ensure current diagnosis of condition and the treatment options have been discussed and understood by the patient (and their carers where appropriate). • To assess the suitability of the patient for this treatment. • To discuss the benefits and side effects of treatment with the patient/carer and where applicable the need for long term monitoring. • Checking for allergies, interactions and contra-indications. • To perform baseline tests. • To initiate treatment in agreement with the patient/carer. • To assess and monitor the patient's response to treatment (as appropriate) and when safe to do so transfer prescribing to the GP/Primary Care Prescriber. • Liaise with the patient's GP/Primary Care Prescriber whether they are willing to take over the prescribing and monitoring responsibilities under this specialist initiation guidance. • To advise on the dose to be prescribed • To advise GP/Primary Care Prescriber what routine monitoring will be completed by the specialist and what monitoring the GP/Primary Care Prescriber will be responsible for.	

	• Depending on renal function the preparation and dose of bezafibrate may need to be changed (see pharmaceutical aspects section on p2) • To forward results of monitoring to GP/Primary Care Prescriber. • Advise when therapy may be reduced and stopped assuming no relapse in patient's condition. Review periods to be agreed. • Ensure this is also known, understood and agreed with the patient (and where appropriate their carers). • Responding to issues raised by GP/Primary Care Prescriber and informing the patient (and carers) of any changes. • To monitor the patient for adverse events/side effects and report to the GP/Primary Care Prescriber and where appropriate Commission on Human Medicines/MHRA (Yellow card scheme). • Discuss with the patient their responsibilities outlined below, confirm understanding and confirm that the patient is happy to adhere to them.
Primary Care prescriber responsibilities	• Checking for allergies, interactions and contra-indications when taking over prescribing and when changing treatment or initiating new treatments. • To prescribe bezafibrate and adjust the dose as recommended by the specialist following initiation and stabilisation by the specialist. • Monitoring the patient's overall health and wellbeing, observing patient for evidence of ADRs and liaising with specialist clinician if necessary and where appropriate report to Commission on Human Medicines/MHRA (Yellow card scheme). • Routine disease or condition monitoring should continue. • When patient attends for review of treatment confirm, in line with the information already provided, by the specialist (or other specialist acting on their behalf) the circumstances under which the medicines should be immediately stopped and what actions the patient is to take. • To ensure that there is an agreed process in place for accessing the ongoing supply of the medicines that is not placing any unnecessary burden or workload on the patient or their carers. Prescriptions should be issued and dispensed following usual processes. • Ensure advice is sought from the responsible specialist clinician if there is any significant change in the patient's physical or mental health status that may affect prescribing or appropriateness of the medicine, or any information relevant to their care that becomes available that was not made available at the time of the specialist diagnosis and treatment option agreement. • Take reasonable steps to ensure that the patient is using their medicines as prescribed and intended. • Reducing/stopping treatment in line with specialist clinician's original request • Encourage the patient at medication review appointments to ask questions and raise any concerns they have about their treatment, particularly anything that may be affecting their adherence to treatment. Use the Me & My Medicines Charter - https://meandmymedicines.org.uk/the-charter/.

Patient/carer responsibilities	• To agree and accept responsibility for taking bezafibrate as prescribed. • To understand how to take this medicine safely. • To understand the most common adverse events/side effects and inform the Specialist/ GP/Primary Care Prescriber as soon as reasonably possible should they occur and significantly affect the use of the medicines. • To understand the circumstances under which the medicines should be immediately stopped and what action to take. • The duration of treatment prescribed initially by the hospital specialist should be understood. • To attend for blood tests/disease monitoring on time. • To check with the community pharmacist that there are no interactions with this medication, and other medications taken including other prescribed medications, medicines bought over the counter and herbal/homoeopathic products. • To check with dentists or other specialists who may prescribe medicines that there are no interactions with this drug. • To understand contents of written information provided by the Specialist and in the patient information leaflet supplied with the medicines and to seek clarification if required. • To contact the GP/Primary Care Prescriber, Specialist or Medicines Information patient helpline if further information or advice is needed about this medication or if there is anything they do not understand. More information on asking about medication can be found in the Me & My Medicines Charter https://meandmymedicines.org.uk/the-charter/. The NHS website information on health link and medicines link Bradford District Care NHS Foundation Trust *www.choiceandmedication.org/bradford*

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