

Primary Care Prescribing Support Factsheet Prescribing and Supply of Bezafibrate

| Document control | | |
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| Version | 1.0 | |
| Produced by | Hepatology Pharmacy Team (Barts Health NHS Trust, BHRUT NHS Trust) | |
| Approved by | NEL Formulary and Pathways Group | |
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1. What is Bezafibrate?

Bezafibrate belongs to a class of drugs called fibrates, and acts as a peroxisome proliferator-activated receptor alpha (PPAR- α) agonist, which helps regulate lipid metabolism in the liver and other tissues.

It is used off-label as a second line therapy for management of PBC (primary biliary cholangitis) as combination therapy with other agents (such as ursodeoxycholic acid) or as monotherapy. National guidelines recommending its use in these conditions is listed below. It is also used for control of itch/pruritus in PBC and in other cholestatic liver diseases such as PSC (primary sclerosing cholangitis).

2. Indication: Primary Biliary Cholangitis (PBC), Pruritus in Primary Sclerosing Cholangitis (PSC)

Not applicable for obstetric cholestasis

3. Formulary and Pathway Group (FPG) approval

| NEL Formulary status | Amber (Specialist initiation) |
|----------------------|-------------------------------|
| Date approved | 15 th July 2025 |

4. National approval e.g. NICE

European Association for the Study of the Liver (EASL) PBC clinical guidelines: https://easl.eu/publication/the-diagnosis-and-management-of-patients-with-primary-biliary-cholangitis/

British Society of Gastroenterology (BSG) and UK-PBC clinical guidelines: https://www.bsg.org.uk/clinical-resource/bsg-and-ukpbc-pbc-guidelines

EASL clinical guidelines: https://www.journal-of-hepatology.eu/article/S0168-8278(22)00326-9/fulltext



5. Prescribing and Supply Information

| Dose | Standard dose and preparation | |
|----------------------------|---|--|
| | 400 mg OD (MR preparation) [£7.63 for 30 tablet pack] | |
| | In renal impairment: | |
| | 200 mg BD or 200 mg OD (immediate release preparation)— see below. [£8.63 for 100 tablet pack] | |
| Duration | Lifelong | |
| Supply | Following specialist initiation or preparation change, 1 month supply issued from hospital. Then ongoing supply to be issued from GP on repeat prescription. | |
| | Dose adjustments and monitoring will be done as part of Hepatology clinic, but for prescriber information: | |
| | The modified release preparation is not appropriate in patients with renal impairment | |
| Renal impairment | CrCl: 40-60 ml/min – switch to immediate release prep and dose as 200 mg BD | |
| | CrCI: 15-40 ml/min – reduce dose to 200 mg OD (immediate release prep) | |
| | CrCl: <15 ml/min – Stop | |
| | Monitor Creatinine Kinase or for signs of myotoxicity | |
| Hepatic impairment | Monitoring will be done as part of hepatology clinic | |
| Monitoring | No additional monitoring requirement for the GP, this will be done as part of Hepatology clinic follow up | |
| | PBC and PSC patients are followed up between 2-4 times per year in the hepatology outpatient clinics. | |
| Criteria for referral back | Queries regarding interactions with other medications (i.e. statins) | |
| to Parent Team | Patients lost to follow up | |
| | Medical emergencies such as development of rhabdomyolysis or decompensated liver cirrhosis should be handled as such and should not wait for referral back to hepatology outpatients. | |



This is not a full list of potential interactions – please see resources such as the BNF, or Stockley's drug interactions for a complete list.

PBC patients can have a raised cholesterol level. If their cardiovascular risk factors indicate that they require a statin this can be prescribed, but they require closer monitoring for rhabdomyolysis in primary care due to the interaction with bezafibrate, as there is an increased risk. Consider checking routine bloods 2-4 weeks after statin initiation (and include creatinine kinase). For information on monitoring please see the information from the Specialist Pharmacy Service here: https://www.sps.nhs.uk/monitorings/statins-monitoring/

Interactions

Patients require counselling on adverse events / myotoxicity and should be prescribed the lowest effective statin dose. Each statin has different advice with regard to the potential interaction with fibrates, so please also be aware of this.

For further information on prescribing statins in liver disease, please see the NEL position statement linked here.

https://primarycare.northeastlondon.icb.nhs.uk/wp-content/uploads/2025/06/Position-statement-Initiation-of-statins-for-primary-prevention-of-cardiovascular-disease-in-patients-with-Liver-disease.pdf

Other lipid lowering agents such as Acipimox or ezetimibe – may increase risk of myotoxicity / rhabdomyolysis

6. Prescribing Support

Referrals and enquiries sent via email are to be answered within **10 working days** of receipt.

| Team | Email Address | | |
|--|---|--|--|
| Barts Health | | | |
| Hepatology Team | bartshealth.hepatology.services@nhs.net | | |
| Homerton | | | |
| Hepatology Team | huh.tr-gastrosecs@nhs.net | | |
| Barking, Havering and Redbridge University Hospitals | | | |
| Hepatology Team | Bhrut.liverteam@nhs.net | | |