**Second-Line Therapy Options in Primary Biliary Cholangitis**

Updated **8th September 2024**

The standard approach to treating in PBC is to use ursodeoxycholic acid (UDCA) as first line therapy at a dose of 13-15mg/Kg. Response to UDCA is assessed at 12 months and in people thought to have an inadequate response second-line therapy is started.

There are a number of options for second-line therapy.

Which of these therapies can be used in which country is varying all the time as they go through the approvals process. This guide, which will be updated as any changes occur, is designed to summarise what treatments can be used in which jurisdictions.

The information here is not intended to recommend that second-line therapy be used, or which agent to choose. These are decisions for individual patients and their doctors. It is designed to show you which treatments might be available to you depending on where you live.

**USA**

| | |
|---|---|
| *Licensed for use in PBC:* | Obeticholic acid, elafibranor, seladelpar |
| *Available but not licensed for use in PBC:* | Fenofibrate |

**UK**

| | |
|---|---|
| *Licensed for use in PBC:* | Obeticholic acid |
| *Available but not licensed for use in PBC:* | Fenofibrate, bezafibrate |

***EU***

| | |
|---|---|
| *Licensed for use in PBC:* | Obeticholic acid*, elafibranor |
| *Available but not licensed for use in PBC:* | Fenofibrate, bezafibrate |

**Australia**

| | |
|---|---|
| *Licensed for use in PBC:* | Obeticholic acid |
| *Available but not licensed for use in PBC:* | Fenofibrate |

**Canada**

| | |
|---|---|
| *Licensed for use in PBC:* | Obeticholic acid |
| *Available but not licensed for use in PBC:* | Fenofibrate, bezafibrate |

***Obeticholic Acid Status in the EU:** In September 2024 the EU decided to revoke the licence for OCA in the EU 27 countries. This decision was based on confidence in the extent of clinical benefit, not safety. This revocation was then suspended as a result of court action meaning that OCA remains available and licensed in the EU27 countries. This document will be updated if and when this status changes again.