

17 December 2009

Proposal to widen access to ursodeoxycholic acid for cholestasis of pregnancy

PHARMAC is seeking feedback on a proposal to amend the current ursodeoxycholic acid Special Authority restriction to widen access to patients with cholestasis of pregnancy.

Ursodeoxycholic acid is indicated for chronic intrahepatic cholestatic diseases, however the Medsafe data sheet states that there have been no adequate and well-controlled studies of ursodeoxycholic acid in pregnant women; hence it is not recommended for use during pregnancy.

However, ursodeoxycholic acid is currently recognised by clinicians as the most appropriate treatment for the management of cholestasis of pregnancy and its use reflects current clinical practice.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Monday, 26 January 2010** to:

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| Mike Bignall | Email: mike.bignall@pharmac.govt.nz |
| Therapeutic Group Manager | Fax: 04 460 4995 |
| PHARMAC | Post: PO Box 10 254, Wellington 6143 |

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

PHARMAC proposes to amend the Special Authority restriction for ursodeoxycholic acid in Section B of the Pharmaceutical Schedule to include funded access for cholestasis of pregnancy. The proposed Special Authority criteria would be (changes in bold, deletions in strikethrough) as follows:

Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either

- 1. Patient diagnosed with cholestasis of pregnancy; or**
2. Both:

2.1. Primary biliary cirrhosis confirmed by antimitochondrial antibody titre (AMA) > 1:80, and raised cholestatic liver enzymes with or without raised serum IgM or, if AMA is negative, by

liver biopsy; and

2.2. Patient not requiring a liver transplant (bilirubin > 170umol/l; decompensated cirrhosis).

Note: Liver biopsy is not usually required for diagnosis but is helpful to stage the disease.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Note: **Ursodeoxycholic acid Actigall** is not an appropriate therapy for patients requiring a liver transplant (bilirubin > 170 micromol/l; decompensated cirrhosis). These patients should be referred to an appropriate transplant centre. Treatment failure - doubling of serum bilirubin levels, absence of a significant decrease in ALP or ALT and AST, development of varices, ascites or encephalopathy, marked worsening of pruritus or fatigue, histological progression by two stages, or to cirrhosis, need for transplantation.

Background

Ursodeoxycholic acid is currently funded for patients with primary biliary cirrhosis who meet Special Authority criteria. The Pharmacology and Therapeutics Advisory Committee (PTAC) has reviewed the Special Authority criteria on various occasions and recommended against any changes to the restriction noting that there would be potential use in gallstones, fatty liver, primary sclerosing cholangitis, and biliary atresia.

PHARMAC receives a number of Hospital Exceptional Circumstances (HEC) applications for ursodeoxycholic acid for cholestasis of pregnancy and we note that applicants consider that ursodeoxycholic acid is the most appropriate treatment for this indication.

In June 2008, the ad-hoc Gastrointestinal Subcommittee of PTAC recommended listing ursodeoxycholic acid on the Discretionary Community Supply (DCS) list for cholestasis of pregnancy. The Subcommittee noted that cholestasis leads to pre-term delivery in a large number of cases.

PHARMAC staff consider it may be more appropriate to fund this indication in Section B of the Pharmaceutical Schedule as its use for this indication is essentially a community treatment.

At its November 2009 meeting, PTAC considered it appropriate to amend the ursodeoxycholic acid Special Authority criteria to include cholestasis of pregnancy. The Hospital Pharmaceutical Advisory Committee also considered that this should be funded in the community via Section B of the Pharmaceutical Schedule.