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Your questions to the PBAC

Bisphosphonates

A recent case highlighted the problems with authority prescriptions for bisphosphonates. A man with steroid-induced osteoporosis is at risk of fractures, but is unable to be prescribed bisphosphonates under the current conditions of the Pharmaceutical Benefits Scheme (PBS). In this case bone densitometry showed clearly that the patient had very low bone density.

The consultant has decided to use alendronate to improve this patient's prognosis. My question to the Pharmaceutical Benefits Advisory Committee is why is it necessary to wait until the patient inevitably cracks some bones before therapy can commence. A private prescription is quite expensive – about $90 for one month of treatment with alendronate 10 mg.

I was informed by the PBS Hotline that alendronate is not subsidised for male patients, however calcium/etidronate or calcitriol are available. Nevertheless the authority conditions for these drugs require the patient to have had a fracture.

It seems to me that on one hand the PBS is moving in the right direction in terms of preventative medicine. We now have few restrictions on COX-2 inhibitors which should reduce the gut ulceration caused by non-steroidal anti-inflammatory drugs. Yet we are not moving as fast with the bisphosphonates.

Phil Day

Pharmacist

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PBAC response:

Under current legislation, the PBAC can only recommend that a preparation be listed as a pharmaceutical benefit for those conditions in which use has been shown to be effective, safe and of reasonable cost-effectiveness. This ensures that the money the community spends in subsidising the PBS represents good value.

The subsidy of drugs used for the treatment of osteoporosis, such as alendronate sodium, disodium etidronate/calcium carbonate, calcitriol, and raloxifene, is limited to patients with osteoporosis who have experienced a fracture due to minimal trauma. This is because this is the only patient group in which cost-effectiveness has been demonstrated. To date, no manufacturer or other applicant has presented data to substantiate that these drugs are cost-effective in preventing osteoporotic fractures. Since the PBAC's decisions are evidence based, it cannot recommend a change to listing in the absence of the necessary supporting cost-effectiveness data.

Furthermore, the PBAC is aware of the importance of prevention of disease. It takes into account many factors in assessing the cost-effectiveness of a medication proposed for PBS listing. These include costs of hospitalisation or other medical treatments that may be required if the medication is not available, as well as less tangible factors such as patients' quality of life. If these preparations were to be listed for the primary prevention of fractures, the PBAC has decided (based on the evidence presented) that the benefits would be relatively small compared to the considerable cost of therapy.

Under the legislation on which the PBS is based, there is no provision for exceptions to be made to suit individual circumstances, even when the use of the drug may be beneficial, or where significant financial hardship is being incurred.

While I appreciate that this means the cost of alendronate will need to be borne as a private prescription, the Commonwealth Government has no control over the prices of non-PBS medicines.