Access to high cost drugs in Australia

Risk sharing scheme may set a new paradigm

The Australian pharmaceutical benefits scheme provides universal subsidised access to a wide range of medicines (www.health.gov.au/pbs/). Consumers make a co-payment of $A23.70 (£8.90; €13.50) per prescription ($A3.80 for patients who get concessions) for medicines that cost the government more than this amount (and pay in full for medicines that cost less than $A23.70). Prescription medicines are assessed by the Pharmaceutical Benefits Advisory Committee, which evaluates incremental cost effectiveness (including quality adjusted life years) of the prod-

Competing interests appear on bmj.com
uct compared with other treatments that the new treatment could replace. Expenditure of the pharmaceutical benefits scheme has been rising at some 10% per year, a rate greater than any other federal health programme, and this situation is considered by many to be economically and politically unsustainable. Recent listings of costly medicines used for relatively common conditions, underestimates of prescribing rates for drugs such as celecoxib and omeprazole, and prescribing beyond the approved restrictions have contributed to the increased expenditure.

Payers in the public and private health systems face the challenge of increasing demands for effective but expensive medicines. One approach has been to target a subset of individuals in whom acceptable cost effectiveness has been shown. The recent listing of etanercept for the treatment of rheumatoid arthritis illustrates an attempt to balance competing health, economic, societal, and ethical demands.

The listing of etanercept in the pharmaceutical benefits scheme costs government $A1888 per month per patient. It emerged from a unique collaboration between the key stakeholders—the Pharmaceutical Benefits Advisory Committee, the sponsor (Wyeth), rheumatologists, and consumers (Arthritis Foundation of Australia and Arthritis Research TaskForce). These stakeholders addressed issues of efficacy, cost effectiveness, and possible arrangements for access. They agreed on eligibility criteria for the initial prescription and for continuation of treatment beyond three months. Prescribing rights were limited to rheumatologists and evidence was required that patients agreed to abide by a decision to stop treatment at three months if response criteria were not met. The Pharmaceutical Benefits Advisory Committee felt that etanercept would achieve acceptable cost effectiveness if listed under these restrictions.

The annual expenditure for the pharmaceutical benefits scheme from this endeavour was predicted to be up to $A140m by the government. Wyeth believed that outlays would “not exceed $A100m” and agreed to pay for expenditure above this figure. This risk sharing agreement provided incentives to the sponsor to promote the drug in accordance with the restrictions and to prescribers and consumer organisations, to avoid leakage to individuals outside the restrictions. Other risk sharing arrangements have been adopted elsewhere—for example, in the United Kingdom for access to interferon beta and glatiramer acetate for multiple sclerosis.

Several questions emerge as this novel programme of access evolves. Will the collaboration of stakeholders remain intact as the programme is implemented? Will the agreement process for patients be acceptable and effective? How concordant was the prediction with actual usage of the drug and the number of eligible patients according to the criteria? How effective will be the risk sharing agreement in containing costs but achieving desired patient health outcomes? How does the system manage patients who received the drug as part of a clinical trial or an early access programme and who have shown a benefit but do not meet the eligibility criteria for subsidy?

The key to evaluation will be accurate and timely data. National datasets will provide information on prescription rates, but these are not linked currently to information on health outcomes in individual patients.

The Australian Rheumatology Association has recently established a national database to track patient outcomes over the long term. These data will allow the stakeholders to determine whether the restrictions are achieving the desired clinical responses.

Arrangements for access will need revision as new data emerge and other drugs in the group are listed. The importance of the rheumatoid factor status as a modifier of the treatment effect and the decision to exclude patients who are negative for rheumatoid factor has been contentious. Broadening access criteria will depend on the government’s confidence that predictions of usage are accurate, and that all stakeholders, including those at the grass roots, embrace criteria for starting and stopping etanercept. The unique consultation process that achieved a consensus on access to etanercept in Australia may set a new paradigm for ensuring equitable distribution of limited resources based on evidence and ethical practice. It may thus allow sustainability of publicly subsidised access to effective but expensive treatments. Whether the collaboration is durable as the programme unfolds and the lessons learned used to improve the system will have far reaching consequences for publicly funded formularies such as the pharmaceutical benefits scheme.

Christine Y Lu postgraduate student
(L Christine.lui@student.unsw.edu.au)

Ken Williams deputy director

Ric Day director
Therapeutics Centre, Xavier Level 2, St Vincent’s Hospital, Darlinghurst, NSW 2010, Australia

Lyn March associate professor
University of Sydney, Institute of Bone and Joint Research, Department of Rheumatology, Royal North Shore Hospital, St Leonards, NSW 2065, Australia

Lloyd Sansom chair
Pharmaceutical Benefits Advisory Committee, 39 Burnbank Grove, Athelstone, SA 5076, Australia

James Bertouch head
Department of Rheumatology, Prince of Wales Hospital, Randwick, NSW 2031, Australia

Competing interests: See bmj.com


