

## Remicade<sup>®</sup> presents cost quandary for members and plan sponsors



Remicade<sup>®</sup>, one of the newest prescription drugs available in the marketplace, is presenting challenges to health insurers, plan sponsors and administrators as well as provincial governments.

This monoclonal antibody was originally designed for the treatment of severe active Crohn's disease and fistulising Crohn's disease. In mid-2001, it also received approval for the treatment of rheumatoid arthritis. In our bulletin of December 2001, we reported that annual costs for this new drug range in the area of \$15,000.

### Developments in Ontario

In the initial months following its approval for sale in June 2001, Remicade<sup>®</sup> was used primarily for in-hospital treatment, with

prescription costs borne by the hospitals and the provincial health care plans.

We conducted research and have learned that since late August 2001, **hospitals in Ontario are no longer able to bill the cost of Remicade<sup>®</sup> to the province.** As a result, there is now a potential liability for benefit plans providing drug coverage.

Our research indicates that Remicade<sup>®</sup> will likely be added to the list of eligible drugs in the Ontario Drug Benefit plan formulary. The formulary provides for government reimbursement to seniors (those over age 65) as well as individuals on social assistance who rely on the ODB to help meet their prescription drug costs. Individuals who are members of benefit plans usually are not eligible for reimbursement of drugs under Ontario government programs. However, they may apply

for funding under the Trillium Drug Program if their plan does not cover 100 per cent of their drug expenses or if a particular drug, such as Remicade<sup>®</sup>, is excluded. The Trillium Program is income-based; however, it could provide some financial support to some residents under certain circumstances.

According to Regulation 552 of the Ontario Health Act, hospitals may charge the cost of drugs like Remicade<sup>®</sup> directly to patients when they make out-patient visits solely for the administration of the drug. As a result, the cost of Remicade<sup>®</sup> will now be passed back to the patient and may ultimately be claimed as an eligible drug under the drug benefit plans administered by Coughlin & Associates Ltd.

### Western provinces reflect varied approaches

Canada's four western provinces each have their own position on the issue.

In Manitoba, a patient can have Remicade<sup>®</sup> costs covered by the provincial health care plan if he/she has Exception Drug Status under Part III under that province's Pharmacare program. The physician must contact Pharmacare and provide medical information and other data including patients' specific circumstances, etc. Once coverage is approved, the medication costs will be covered for a one year period. The physician must re-apply every year to maintain the coverage.

Alberta and British Columbia are still in the process of reviewing the drug.

However, in British Columbia, patients on the Special Access Program, available through Health Canada and Schering Canada, were covered on a temporary basis until January 31, 2002. The Pharmacare program plans to finish its formal review as soon as possible after that date.

Saskatchewan's position is similar to that of Manitoba; the physician must apply for Exception Drug Status before the province will pay for a Remicade<sup>®</sup> treatment. Coverage is limited to one year once approved.

### **Quebec: treatment restricted to Crohn's disease**

In Quebec, Remicade<sup>®</sup> has been placed on the list of exception drugs administered by the Régie de l'assurance maladie du Québec (RAMQ) and requires prior approval from RAMQ before it may be prescribed by a doctor. As well, it is accepted only for the treatment of Crohn's disease and must meet very specific criteria for such use.

### **Atlantic provinces: coverage ineligible**

In the Atlantic provinces, it appears that the drug will see limited, if any, support in the near future.

In New Brunswick, Remicade<sup>®</sup> remains ineligible for reimbursement. However, a provincial spokesperson indicated that all clinical and economic data will be reviewed as the province considers future funding of Remicade<sup>®</sup> and other biologic therapies.

Nova Scotia has indicated that the drug is under review for possible coverage under that province's Seniors' Pharmacare Program and

Community Service Program. However, it has no plans to cover the drug universally through the acute care system.

Prince Edward Island will not cover Remicade<sup>®</sup> under any circumstances until it is reviewed by the Atlantic Common Drug Review Expert Advisory Committee. It does not expect to hear from that group until April 2002 at the earliest.

We are still waiting to hear from health authorities in the province of Newfoundland and Labrador.

### **Mixed signals from insurers**

Adding to the confusion are the inconsistencies of insurers when dealing with the eligibility of Remicade<sup>®</sup> under employee benefit plans. While most insurers have introduced pre-authorization or other monitoring processes to ensure Remicade<sup>®</sup> is prescribed only when needed, some are covering Remicade<sup>®</sup> while others are not.

Our research indicates that Sun Life, Clarica Life and Great-West Life are reimbursing Remicade<sup>®</sup> claims, subject to the appropriate documentation, while Manulife Financial and Maritime Life are not prepared to cover it if it is administered in a hospital (however, the latter two companies will cover the drug, subject to prior authorization and providing it is administered in private settings such as doctors' offices or in private clinics). The Canadian Life and Health Insurance Association (CLHIA) is still studying this issue and has yet to develop an industry-wide position on it.

### **The Coughlin & Associates Ltd. position**

We believe Remicade<sup>®</sup> is an eligible drug and there is no basis for not covering it, if it is prescribed responsibly. This can be achieved through appropriate pre-authorization

and monitoring processes to ensure that Remicade<sup>®</sup> claims are properly adjudicated. However, for adjudication purposes, plan sponsors and their members should also note that, where applicable, Coughlin & Associates Ltd. will follow the guidelines provided by insurers and provincial regulators.

Plan sponsors of self-insured programs should be aware of the increased claims risk associated with Remicade<sup>®</sup> and the potential impact it could have on plan reserves over the mid to long term. Increasing reserves, reviewing the benefit plan formulary or introducing plan or per drug maximums or deductibles may be options for these groups to consider.

Your Coughlin & Associates Ltd. consultant can help plan sponsors review alternatives and develop appropriate strategies.

### **Is Remicade<sup>®</sup> just the beginning?**

In researching Remicade<sup>®</sup>, we spoke to provincial government authorities, pharmacists and hospital personnel. It appears that Remicade<sup>®</sup> is the first of many new drugs that will reach the marketplace in the coming months and years. Many of these new drugs will carry significant costs that will ultimately strain claims utilization of client benefit plans. Furthermore, in the not-too-distant future, *genomics*, the mapping of human genes, will likely lead to the development of some drugs being used for *preventive purposes* **before** an individual is actually struck with a serious illness. The genomics issue and its implications will be researched in detail in the near future. We will provide more information to our clients as it becomes available.

Plan sponsors should be prepared for increased drug plan costs in the future. Serious consideration may have to be given to solutions that restrict the cost and liability of drug benefits.