

**Submission to the
Ontario Drug Strategy Review**

**Multiple Sclerosis Society of Canada
Ontario Division**

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INTRODUCTION

The Multiple Sclerosis Society of Canada is actively involved with Canada's federal and provincial governments across a wide range of concerns affecting people with multiple sclerosis and their families and caregivers. These concerns include the adequacy and fair administration of income security programs, taxation policies affecting people with disabilities, access to community-based services such as home and community care and accessible housing, prompt access to diagnostic services and access to approved drug therapies and medical devices.

The Ontario Division of the MS Society of Canada is pleased to participate in the Government of Ontario's drug strategy review. There are a number of areas where we feel improvements can be made easily that will save money, improve efficiency and improve the timely access to drug therapies for people with MS. These are outlined below.

MULTIPLE SCLEROSIS: A PROGRESSIVE, SEVERE AND CHRONIC DISEASE

MS is a chronic disease of the central nervous system that unfortunately often leads to severe disability. MS attacks the protective myelin covering of the nerves, causing inflammation and often the destruction of the myelin in patches. This interrupts the normal flow of nerve impulses. The results often include vision problems, numbness, loss of balance, extreme fatigue and even paralysis.

MS is one of many chronic conditions affecting Canadians. According to the National Population Health Survey, in 1998-99, more than half of all Canadians reported having a chronic condition. As the leading cause of disability, loss of productivity, and deterioration in the quality of life, chronic non-communicable diseases are the major health burden today in developed countries.¹ Although the cause and the cure are so far unknown, four drugs are now in use for the treatment of MS and can reduce the frequency and severity of attacks and slow the progression of disability. Other medications and therapy can help many MS symptoms.

Epidemiological studies indicate that Canada has one of the highest rates of MS in the world. An estimated 50,000 Canadians have this all too frequently disabling disease. Usually diagnosed between the ages of 20 and 40, MS is the most common disease of the central nervous system affecting young adults in Canada. Women are affected almost twice as often as men. Periods of spontaneous recovery are interrupted by unpredictable attacks that over time result in most

¹ Dr. David MacLean, Addressing the Burden of Chronic Disease in Canada, Brief to the Senate Committee on Social Affairs, Science and Technology, 3 April 2001, p.1.

people with MS becoming disabled. The result: young Canadians face a progressive and unpredictable disease that cannot be prevented, and that they must live with for 40 or more years.

Most people with MS are eventually unable to work full-time and many experience total disability. In 1991, 44% of adults with disabilities (aged 15-44) were not part of the labour force. With MS, however, this is significantly higher. Seventy per cent of people with MS are not working 5-10 years after they are diagnosed.

RESPONSE TO STEERING COMMITTEE ISSUES FOR DISCUSSION

1. ACHIEVING MORE PATIENT-CENTRED PHARMACEUTICAL CARE

Reducing bureaucracy in the Section 8 mechanism

There is agreement among clinicians that people with MS benefit from early treatment with drugs that can reduce the frequency and severity of attacks and slow the progression of disability. In Ontario, the four drugs most commonly used are not on the Drug Benefit Plan Formulary. Rather, they are available under the Section 8 mechanism.

Our understanding of the Section 8 mechanism is that it was designed to accommodate drug therapies that are effective for some patients but which either involve side-effects that warrant close control of their prescribing or are very expensive and, therefore, should be used only if less expensive alternatives are not effective. These circumstances seem reasonable.

However, in recent years, our interpretation is that Section 8 has become used increasingly as a cost-constraint mechanism — in other words, putting products in this category limits their use because each prescription requires case-by case scrutiny and delays before the patient can receive the drug prescribed by the physician.

More than 96,000 Section 8 requests were processed in 2002, an average of almost 400 per working day. Roughly three-quarters were considered to be urgent. Right now, it takes approximately 10 weeks to process a “non-urgent” request. According to ODB figures, the volume of Section 8 requests more than tripled between 1997/98 and 2000/01, yet the overall approval rate of requests remained steady at more than two-thirds.

Many of the drugs approved under Section 8 achieve very high rates of approval. Indeed, the 10 most frequently requested drugs under Section 8 are approved at rates that vary from 81-97%. The most frequently requested drug, Plavix (indicated for the secondary prevention of heart attack or stroke in patients with underlying atherosclerosis) accounted for fully 38% of the total volume of requests in 2001 and yet 97% of the requests for Plavix were approved. Among MS-specific

therapies in 2000 (the last year in which statistics were available) two of these therapies, Copaxone (glatiramer acetate) and Rebif (interferon beta-1a) were approved in 84% of requests.

It does not make sense to us that drugs that are approved more than 80% of the time despite individual assessment of the prescriptions should be subject to a bureaucratic mechanism designed to limit such prescriptions to appropriate cases. Surely, the evidence lies in the results. The disease modifying therapies are being appropriately prescribed.

One of the consequences of using the Section 8 mechanism is that prescriptions are delayed. According to the ODB Plan, 88% of prescription requests are assessed within three weeks. However, for patients in the 12% minority, delays can be quite substantial.

Most people with MS have difficulty finding family physicians with the specialized knowledge necessary to treat a complex disease like MS. They receive much better and more expert treatment from neurologists – especially those working in MS Clinics. Given the delays in filling a Section 8 prescription, people with MS often find it hard to accommodate the cycle of neurological consultation/prescription/evaluation of effects/follow-up examination by the neurologist in a timely way. In far too many cases, by the time the effect of a drug therapy can be assessed, it is already past time to see the neurologist again, given the time it takes to get an appointment and then have the prescription renewal processed.

This can be harmful to people with MS as prompt treatment can mitigate the severity of symptoms. Moreover, given that fatigue and limited mobility are among the most common symptoms, the difficulties of getting to the doctor for a renewal and delays in getting a prescription renewed can result in cumulative problems.

As one MS Clinic coordinator notes,

“The current requirement is that the patient secures an appointment for neurological consultation and examination within 1-3 months of the expiry date of the previous funding approval date. This is a challenge in a busy clinic where every effort is made to accommodate patients with MS, but it is not always possible to arrange for a timely consultation. ...

“There are often lapses of funding between approval periods, when Section 8 letters are submitted less than two months in advance. There have also been instances when request letters have been submitted and approval granted several weeks after a previous prescription’s expiry date, leaving patients vulnerable.”

MS Clinic coordinators report that it takes far too long to receive a response on requests for new drugs used for MS symptom relief. As one coordinator reports,

“It takes 8 – 10 weeks to receive a response on requests for Section 8 approval for Alertec (for fatigue); Neurontin (for severe pain) and Zanaflex (for spasticity). In addition, often the approval for these drugs is only for three months which means you have to start the reapplication process right away because it takes 8 – 10 weeks (for the Section 8 to be processed) before you have had a chance to assess how the patient is doing on the drug.”

A nurse in Ottawa who handles Section 8 requests also notes problems with approval times for MS-related drugs such as Neurontin, Alertec and Zanaflex:

“It takes eight weeks for approval of requests for these drugs, but in Quebec requests can be processed within 48 hours to a week. In Quebec, they have hired pharmacists to review the requests and not external consultants.”

Some of this backlog and delay could be eliminated by transferring drugs that over time are approved in the overwhelming majority of cases either to Limited Use listing (eliminating the need for case-by-case assessment of prescriptions) or to unrestricted listing on the formulary. The rationale for Section 8 listing in these cases seems to us to be rebutted by prescribing experience and, by removing these drugs from the Section 8 process, resources would be freed up that might well allow the roughly 6,000 cases per year that experience multi-week processing to be dealt with more efficiently. Patients, ODB Program administration and taxpayers would benefit.

The MS Society is also concerned that the increased use of the Section 8 process undercuts the clinical expertise of the physician who is treating the patient, knows that individual best and what treatment is most likely to work for him or her. A patient-centred approach would respect the physician-patient relationship and also allow for the patient to be more actively involved in the process, leading to better understanding and compliance.

Harmonizing Criteria for most commonly prescribed drugs for people with MS

It would be more beneficial to people with MS if the same prescribing and reimbursement criteria were used for all four disease modifying therapies for MS (Avonex, Betaseron, Copaxone and Rebif) where Health Canada approved indications allow. This would make it easier to switch people from one therapy to another, which is sometimes necessary because of how individuals respond to particular drugs or if they have problems with side-effects.

Recommendations

- Transfer drugs with very high rates of request approvals from Section 8 to either Limited Use or unrestricted formulary listing.
- If MS drugs remain available through the Section 8 mechanism or if they are moved to Limited Use listing, the criteria for the four current disease-modifying therapies for people with MS should be harmonized where appropriate.
- If separate criteria for the four current disease-modifying therapies are maintained, the criteria should be easily available to prescribers and the public on the Ministry of Health web site and prescribers should have easy access to MS drug templates which include the current criteria.

2. IMPROVING ODB PROCESSES

MS Clinic coordinators and people with MS report that a lack of administrative transparency leads to problems. According to one clinic coordinator,

“One patient was turned down after a wait of 10 weeks because the rules had been changed and we weren’t notified of that change. We re-applied supplying more information and still had to wait another 10 weeks for a response. It is vital that the Ontario Drug Programs Branch communicate clearly to physicians about the criteria for both Limited Use and Section 8. If this information could be posted on the Drug Programs Branch web site, it would be helpful to health care professionals.

“Physicians who don’t treat a lot of MS (unlike those at the MS clinics) often have Section 8 applications rejected because they are not familiar with the required EDSS scores and other information. For these physicians, they find it far too complicated and many of their applications on behalf of patients are turned down.”

Personal Story: Barbara

Barbara was diagnosed with MS in 1982. She recovered well from her first attacks and had no major MS attacks until 1998. At that time she had a major attack which affected her physically as well as her memory and cognitive processes. Her doctor prescribed the high dose of Rebif (interferon beta-1a).

Her doctor did the paperwork for the Section 8 but unfortunately because of a misunderstanding it was approved for the low dose (22 mL). This did

not match the paperwork done for the Trillium Drug Program and the reimbursement was refused. She was desperate to start treatment so she started to pay for the drug herself even though she had virtually no money.

She found the entire process very confusing especially at a time when MS was affecting her ability to think and her memory. She found the lack of cooperation between the Section 8 process and the Trillium Drug Program difficult and did not feel that she received clear information from staff responsible for either program.

Personal Story: Lisa

Lisa has been on Betaseron (interferon beta-1b) for almost six years. She credits the treatment for slowing the worsening of her disability. She can still walk although for long distances she uses a scooter.

Because she is considered on “the edge” of the eligibility criteria for the drug, her doctor’s Section 8 requests for her to continue on treatment have been turned down several times. On appeal, she has been able to have them approved. This has caused her much stress and on occasion she has been very close to running out of medication.

“This is not a fluid way to help people with MS who don’t need extra stresses in their lives,” she explains. “I’m grateful that I qualify for financial assistance (she now receives benefits from the Ontario Disability Support Program) because otherwise I couldn’t afford this treatment which is keeping me from becoming more disabled.”

Recommendations

- Improve the transparency of the process to both prescribers and the public.
- Although we feel the best solution is to transfer the MS disease-modifying therapies and other frequently used and approved therapies from Section 8 to either Limited Use or unrestricted formulary listings, in all cases communication with prescribers about Section 8 and Limited Use criteria should be improved. Information on program criteria and administrative requirements should be posted on the Ministry of Health web site, including recent changes, so that prescribers can ensure that they are responding to current requirements.
- The amount of time given for a Section 8 approval should be increased to six months at a minimum.

- Section 8 requests for people with severe, chronic diseases should be fast-tracked (e.g., processed within two to seven days as is the case in Quebec).

3. TRILLIUM DRUG PLAN

The MS Society of Canada, Ontario Division, has received many complaints from people attempting to gain reimbursement through the Trillium Drug Plan.

For example, an MS Clinic director in eastern Ontario reports as follows:

“I hear mostly complaints from patients about the cumbersome deductible provisions, especially the quarterly application. More patients have gone to their MPP over this than any other issue I can recall. I would suggest that the interface to the patients undergo a full examination with a view to improving the patient friendliness of the program.

“Some patients have just given up trying to get reimbursement from Trillium even though they are entitled to it. If this were solved, I would tolerate all the Section 8 problems!”

An MS Clinic coordinator in southern Ontario reports issues regarding response times:

“It takes far too long to receive a response from the Trillium Drug Program and it is not well coordinated with the Section 8 process. We warn patients not to fill their prescriptions until they get the notice from Trillium that they are approved otherwise they would have to pay the whole cost of these expensive drugs. This is very frustrating for patients and for us as health care professionals since we know that it is best to start the disease modifying therapies as early as possible. It should be a goal for the Trillium Drug Program to have a maximum turn around time of 4 weeks.

“The deductible for Trillium is still too high for many patients. Even if they have high family incomes, paying \$4,000 out of pocket can be very difficult.”

Personal Story: Lynette

Lynette has had MS for five years. Shortly after she was diagnosed, her doctor prescribed Rebif (interferon beta-1a) and she has responded well to treatment. The Section 8 process has worked well for the most part and approvals for renewal usually come through in two to three weeks. Her

Section 8 applications are handled through the local MS Clinic which is very experienced and knowledgeable about the procedures to be followed.

However, her experience with the Trillium Drug Program has not been as smooth, and she has been off medication for the past six weeks because she has not been able to afford it. She is beginning to experience MS symptoms that have not presented for some time.

There has been ongoing difficulty in coordinating the Trillium Plan with the private insurance she has through her husband's employer. Trillium is consistently 8-12 weeks behind in the money owed to the family which several times has caused them considerable financial hardship. At one point her husband took a second job to help pay for the medication but then learned this put the family in a higher category for the deductible under the Trillium Drug Program.

She and her husband are extremely frustrated with the lack of information from staff at the Trillium Drug Program. They say that no one ever returns their calls, they are never able to talk to the same person more than once and at times, staff members' command of English is not good.

Lynette's husband points out that this is doubly frustrating because their private insurance saves the Government of Ontario 80% of the cost of the medication.

Recommendations

- Improve communications about the Trillium Drug Program and how people can apply. This could be done in part by better use of the expertise of pharmacists in letting people know about the program and how to apply to it.
- Ensure that Trillium Drug Program staff are well trained in working with the public and that their communication skills are of a high quality.
- Ensure that the interface between the Trillium Drug Program and private insurers is seamless.
- Ensure that people receive reimbursement payments from the Trillium Drug Program in a timely manner – eight to 12 weeks is far too long for most people.

- Investigate the use of a simple electronic card that Trillium Drug Program recipients can use at pharmacies that would allow them to know how much they need to pay and what the TDP will be paying.

4. DECREASED ACCESS TO APPROVED THERAPIES IN ONTARIO

The MS Society of Canada, Ontario Division, is concerned that recent trends in formulary approvals indicate trends toward decreased access to approved drug therapies. According to ODB figures, in recent years,

- Ontario has approved fewer single-source drug products for formulary listing than Quebec, Alberta and British Columbia
- Ontario has by far the lowest number of full listings and the highest number of partial listings among these four provinces
- Ontario takes longer to list drugs than Alberta, Quebec or British Columbia

Recommendation

- Ontario should strive to improve its listing time for adding new drugs to the formulary and increase the number of drugs receiving full listing to match those of the three leading provinces. This will greatly improve access to people who must rely on drug therapies.

5. COMMON DRUG REVIEW

The MS Society is also concerned that recent steps toward participation in the Common Drug Review (CDR) initiative could add to current delays and add additional layers of decision-making and potential bottlenecks in getting timely listing of new therapies to the Ontario Drug Benefit formulary.

Recommendation

- We urge that the Government of Ontario ensure that its participation in the Common Drug Review does not lead to longer approval times or add to current delays, and that it uses its influence with the other CDR partners to ensure that this principle is accepted across Canada.

CONCLUSION

Our discussions with staff, volunteers, physicians and other health care workers and many, many people with MS indicate that Ontarians with MS are appreciative of the Section 8 process and the Trillium Drug Program. Their experience leads them to hope that the Government of Ontario will make the needed changes in its drug programs to improve transparency, communication with prescribers and potential beneficiaries, speed of response and as uncomplicated a system as possible.

We hope our suggestions are helpful. We think the current consultative process is useful and urge the government to continue to solicit input from consumers or consumer groups on a regular basis to ensure that its drug programs meet the needs of people in Ontario. We would support and be pleased to participate in a consumer advisory group that could work with and perhaps report to the Drug Quality and Therapeutics Committee.