

**Better Health for All: Improving Health
Outcomes in Ontario**

**Submission to the
Ontario Drug System Secretariat**

**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 review of government drug programs. There are a number of areas where we feel improvements can be made easily that will save money, improve efficiency, increase the timely access to drug therapies for people with MS and improve the health outcomes for Ontarians. These are outlined below.

KEY CHALLENGES AND CONCERNS

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 disease-modifying 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 143,000 Section 8 requests were processed in 2004, an average of about 550 per working day. According to ODB figures, the volume of Section 8 requests has

increased by more than 400% between 1998 and 2004, yet the overall approval rate of requests has remained steady at about 70%.

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 an average rate of 76%. The most frequently requested drug, Plavix (indicated for the secondary prevention of heart attack or stroke in patients with underlying atherosclerosis) accounted for fully 33% of the total volume of requests in 2004 and yet 86% 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 starting patients on therapy is delayed. In 2004, 71% of prescription requests are assessed within three weeks. Although this is an improvement over the most recent previous years (2003: 56%, 2002: 53%, 2001: 67%), we note that in 1999, 87% of claims were assessed within three weeks, and the figure for 2000 was 88%. Further, for those patients among the 29% whose claims took more than three weeks, delays can be quite substantial.

Multiple Sclerosis Therapies

Turning specifically to MS therapies, it may be helpful to consider them in two categories: disease-modifying drugs and drugs for symptom relief.

Disease-Modifying Drugs

As mentioned above, the four disease-modifying drugs (Avonex [interferon beta-1a], Betaseron [interferon beta-1b], Copaxone [glatiramer acetate], and Rebif [interferon beta-1a]) are available only under the Section 8 process for people who need to access the Trillium Drug Program. Since these drugs are quite expensive (\$16,000 to \$22,000 per year), even people with extended health benefits often go through the Section 8 process to access the Trillium Drug Program for assistance with the cost.

Another complication is that while some people have local neurologists and family physicians who are comfortable treating a complex disease like MS, many refer their patients to the seven MS clinics located in Ontario teaching hospitals. 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.

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.”

The MS Society suggests these issues could be addressed creatively in a number of ways. 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 general (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 40,000 cases per year that experience more than three weeks of 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

It would be 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.

In addition, the Ministry of Health should recognize the new international standard for diagnosing MS (known as the McDonald criteria) which incorporates MRI scanning outcomes as an integral part of the diagnostic process. Currently, the Section 8 requirement for eligibility is two attacks in two years, which according to accepted international standards is very late to initiate treatment with one of the disease-modifying therapies.

Alternatives to Section 8

Some provinces (e.g., Nova Scotia, British Columbia, Manitoba) have delegated decision making vis-à-vis the eligibility for receiving disease-modifying MS therapies under the publicly paid program to the specialized MS clinics in these areas. While this has the advantage in ensuring people with MS are seen by MS expert neurologists, there are also a number of negatives. Requiring newly diagnosed with MS to travel a long distance to a specialty clinic can be a physical and financial hardship. This is especially the case for people living in northern Ontario or in remote rural areas. It could put an increased strain on the staffing and other resources at the existing MS clinics, and it has the potential to loosen the connection of a patient to his/her local neurologist or family physician who has the responsibility for other components of the patient's care.

A compromise might be to recognize the higher expertise of the neurologists, nurses and other health care professionals at the MS clinics and develop a streamlined process for Section 8 applications, if this process is maintained. This would be beneficial for the clinics in freeing up time spent on paper work, positively impact their patients and remove a large number of applications from the "normal" Section 8 stream.

Therapies for MS Symptoms

Symptom management is also vital for people with MS. A wide variety of medications are used to manage pain, depression, fatigue, spasticity and bladder problems. We are pleased that MS clinic coordinators generally report that approvals of Section 8 requests are now received within two to four weeks. This is a major improvement from two years ago, and we commend the Ministry of Health for this progress.

However, drug therapies are not the entire answer. For people with MS who have severe spasticity that cannot be treated by usual medication, often the only answer is to implant a pump to deliver the spasticity drug Baclofen. While the surgical procedure and the drug itself are covered, the pump itself is not. At \$10,000, this is a major expense that few people with MS can afford, but yet it can provide them the relief they need from painful muscle spasms. As well, consideration should be given for the cost of stimulators, used infrequently but successfully for the treatment of unbearable tremors.

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.
- Provide MS clinics with streamlined access to the Section 8 process in recognition of the expertise of clinic neurologists, nurses and related health care professionals.
- Include the cost of pumps to deliver Baclofen and stimulators to treat tremors under the Ontario Drug Benefit Program to increase access.

2. IMPROVING ODB PROCESSES

MS Clinic coordinators and people with MS report that a lack of administrative transparency leads to problems.

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.

One way to solve these type of problems is to enhance communications and cooperation within the Ontario Drug Benefits Program. As one MS clinic coordinator said:

“It would be nice to see increased cooperation between ODB and MS clinic staff so that administrative issues can be worked out with the least amount of hassle and in the least amount of time. Perhaps staff at ODB can be assigned a geographical area to deal with, so we can develop rapport with each other.”

We note that the Ministry has added fact sheets on the Limited Use and Section 8 mechanisms and the relevant forms to its web site. This is a step forward for patients and prescribers, and we laud the Ministry for this improvement.

Recommendations

- 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. If Section 8 is maintained, we suggest the following;
- The amount of time given for a Section 8 approval should be increased to two years as a minimum.
- Priority should be given within the Ontario Drug Benefits Program to provide excellent and timely service to the health care professionals with whom they interact.

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.

An MS clinic coordinator in southern Ontario notes several frustrations:

“Trillium Drug Program should ensure that their staff is well trained in working the public and that their communication skills are of a high quality. Also, it is very difficult to speak with a real person at Trillium. The phone tree is frustrating, especially if you have a

specific problem that needs to be addressed. I tried to do some trouble-shooting for a patient today and waited on the Trillium phone line for 30 minutes before finally hanging up. I had to listen to 'Your call is important to us' many times. "

Another clinic coordinator 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.

We note that Trillium program processing time has been slipping. Between 1999 and 2002, processing times declined steadily, reaching 17 days in 2002. However in 2003 and 2004, it increased to between 22 and 23 days, on average. For some people with MS, the wait can be between six and eight weeks. This makes the process of getting started on a disease-modifying drug very long.

Recommendations

- 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 approvals and reimbursement payments from the Trillium Drug Program in a timely fashion.
- 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. COMMON DRUG REVIEW AND DECREASED ACCESS TO APPROVED THERAPIES IN ONTARIO

The MS Society of Canada, Ontario Division, is concerned about the impact that the Common Drug Review (CDR) is having on Ontario's decisions to make available drugs that have been approved by Health Canada as being safe and effective. A former highly placed Ontario politician several years ago summarized what CDR recommendations meant in Ontario as, "no" means "no", but "yes" means "maybe". We certainly hope that

is not how CDR recommendations are currently being viewed within the Ministry of Health and Long-Term Care. A look at some current statistics is not encouraging. Despite improvements in the timelines for review of multiple source drugs, the timelines for review of single-source drugs – which is what patients with MS rely on have shown little or no improvement. According to ODB figures,

- In 2004, the average time from initial submission to formulary listing for single-source drugs was 494 days. Assuming this means working days, the average length of time required is almost two years.
- The comparable figures for the preceding three years are 2003: 489, 2002: 530, 2001: 416.
- While even these numbers represent an improvement from the timelines experienced a decade ago, they are still high and review times have deteriorated substantially from the 253 day average recorded in 2000 and even the 416 day average in 2001

In addition, the MS Society of Canada shares the general concern about the CDR process which does not include input from patients/consumers with “real world” experience – the people whom CDR recommendations effect the most. We recognize the Ontario Ministry of Health does not operate CDR, but we urge that the Ontario government use its influence to make the process more accessible to serve and benefit people with severe and chronic illnesses and diseases.

Recommendation

- Ontario should strive to improve its listing time for adding new single-source drugs to the formulary. This will greatly improve access.
- Ontario should use its influence to improve the Common Drug Review process to allow more input by consumers throughout the various stages of deliberations.

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 and speed of response and achieve as uncomplicated a system as possible.

Achieving optimum health requires a complex interplay of many systems and players. One concern we have is that a review of the drug system only will not capture the other

vital parts of the health care system. We urge the Drug System Secretariat in its review to look at how the other parts interact with the Ontario Drug System and that this review not be a cost reduction exercise. A frequently quoted statistic is that in 2003, Canadians spent \$16 billion on out-of-hospital prescription drugs, making this expenditure the second-largest cost component of the health care system.¹ What is seldom captured is how expenditures on drugs are keeping Canadians out of hospitals, shortening hospital stays, allowing people to remain or return to work and decreasing home care costs. We urge the Drug Systems Secretariat to break down expenditure silos when recommending how the Ontario drug system can be improved to benefit health outcomes for all Ontarians.

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 would support the work of the Drug System Secretariat.

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¹ Canadian Institute for Health Information. 2003. National Health Expenditure Trends. 1975-2003.

APPENDIX

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.² 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 15 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 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. Nearly 80 percent of people with multiple sclerosis are eventually unable to work full time because of the severity and unpredictability of their MS symptoms. The change in work force attachment comes fairly soon after diagnosis: 25 percent have a change in their employment status within five years of diagnosis; 50 percent within 10 years and 80 percent within 20 years.

² 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.