

MEDICAL UPDATE MEMO
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**HEALTH CANADA EXTENDS AVONEX LABELLING
TO INCLUDE FIRST ATTACK AND SUPPORTING MRI DATA**

Health Canada has extended the labelling of Avonex® (interferon beta-1a) to include people who experience their first clinical episode and have supporting MRI-detected brain lesions consistent with multiple sclerosis. The approval was based on the “CHAMPS” study, published in 2000, which involved 383 participants who had a single attack and MRI lesions consistent with MS. People in this group would be considered at high risk of developing clinically definite MS. The study showed that Avonex can delay the onset of a second attack, which would then be considered clinically definite MS. It is expected that provincial governments and third-party insurers will use the expanded labelling decision in considering whether to reimburse the cost of Avonex for people with one attack and supporting MRI data. Quebec is the only province to reimburse on the basis of one attack and MRI-related brain lesions. It reimburses for both Avonex and Rebif, another interferon beta-1a.

Background

Health Canada has extended the labelling of Avonex® (interferon beta-1a) to include people who experience their first clinical episode and have supporting MRI-detected brain lesions consistent with multiple sclerosis. The approval was based on the “CHAMPS” study, (Controlled High Risk Subjects Avonex Multiple Sclerosis Prevention Study) published in the *New England Journal of Medicine* in September 2000. The study involved 383 participants considered to be “high risk” in developing clinically definite MS. The study took place at 50 MS research clinics in Canada and the United States. Participants had one neurological sign – such as optic neuritis – plus multiple clinically silent brain lesions as shown on MRI. Participants were treated with standard steroid drugs and then randomized to receive active treatment or placebo. Active treatment was the usual, once-a-week dose of Avonex injected into the muscle. (Avonex was approved in Canada in 1998 for the treatment of relapsing-remitting MS.)

After two years, the original three-year CHAMPS study was stopped with the treated group having a slower progression to clinically definite MS (the development of a second neurological sign). The conversion to clinically definite MS was reduced by 44% in the treated group compared to placebo. In addition, treated participants had fewer new and enlarging brain lesions as seen on MRI scans.

The diagnosis of clinically definite MS requires two neurological events (attacks) suggesting loss of myelin in the brain and spinal cord separated in time and location. Studies have shown that people who have had a single sign or symptom suggestive of demyelination **and** MRI-detected brain lesions are at high risk of developing MS within several years. People with similar neurological events **but no** evidence of MRI-detected brain lesions are at relatively low risk for developing clinically definite MS over the same time period.

It is expected that provincial governments and third-party insurers will use the expanded labelling decision in considering whether to reimburse the cost of Avonex for people with one attack and supporting MRI data. At this time, Quebec is the only province to reimburse on the basis of one attack and MRI-related brain lesions. It reimburses for both Avonex and Rebif, another interferon beta-1a. Health Canada has not extended the labelling for Rebif.

Data from a study of Rebif® (interferon beta-1a) called ETOMS (**E**arly **T**reatment of **M**ultiple Sclerosis) was reported in 2000, at an American Academy of Neurology meeting. The study involved 308 people with one neurological event and MRI brain lesions suggestive of MS. They received active treatment (the lower 22mcg dose of Rebif every other day injected under the skin) or placebo for two years. The treated group had a slower progression to clinically definite MS, with the conversion reduced by 24%. In addition, treated participants had fewer new and enlarging brain lesions.

The Health Canada decision on expanded labelling for Avonex is supportive of a growing body of evidence that early treatment has a positive impact in delaying a second MS attack. In addition, many MS specialists believe early treatment may reduce or even prevent the development of permanent clinical disabilities.

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