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1st MS pill approved in Canada

CBC News

Posted: Mar 10, 2011 5:01 PM ET

Last Updated: Mar 11, 2011 11:48 AM ET



An infusion treatment for multiple sclerosis. An oral drug is now an option for some Canadians with MS who aren't improving with injection and infusion medications. (M. Spencer Green/Associated Press)

An oral drug for multiple sclerosis has been approved for some MS patients in Canada.

Until Thursday's announcement, drug treatment options for MS patients in this country were limited to medications taken regularly by injection or infusion.

Gilenya, also called fingolimod, is a capsule taken once a day for people with the relapsing-remitting form of MS. These patients have relapses that continue to worsen in severity, disability level, or who are unable to tolerate injections.

"It's a very long awaited type of medication for our patients," said Dr. Heather MacLean, a neurologist at the Ottawa Hospital who specializes in MS.

Needle injections under the skin are painful and are associated with itching and lumpy skin reactions, and the weekly intramuscular medication can also cause muscle pain, noted MacLean, who has treated patients with the new drug as part of early clinical trials.

From her experience, MacLean estimated that 10 to 20 per cent of relapsing-remitting MS patients currently on treatment stand to benefit from Gilenya.

"It always surprises me how patients really require different modalities of treatment based on their own personal disease course and their own treatment goals. To have another available option for them, I think they'll be thrilled."

Gilenya's manufacturer, Novartis, submitted clinical trial data to Health Canada to get the approval.

"Following a rigorous assessment process to ensure that the benefits of drugs sold in Canada outweigh their potential health risks, as of March 9, 2011, Gilenya is authorized for sale in Canada," Health Canada said in an email to CBC News.

Side-effects and cost

The medication will be available in Canadian pharmacies by April 1. Novartis has applied for it to be covered in all provinces. The reviews can take from eight to 24 months, the Multiple Sclerosis Society of Canada said.

The company's published trials suggested the drug reduced relapses by about half compared with a placebo — an annual relapse rate of 0.18 on the drug compared with 0.40 for the placebo.

Gilenya also improved disability progression by about a third or 0.30 times compared with the placebo in the two-year trial, Novartis said.

In another study that lasted a year comparing Gilenya with Avonex, a gold-standard MS drug, the pill reduced relapses by about half.

The main side-effect associated with the drug was a drop in heart rate, which means patients taking it will need to be monitored for about six hours the first time they take it, MacLean said.

Gilenya also lowers the number of white blood cells and may therefore increase the risk of infections.

The MS Society warned of other side-effects associated with Gilenya, including head colds, headaches and fatigue. It also noted that some studies have linked the drug to skin cancer, according to the society's website.

Novartis expects the drug will be priced "competitively" to similar MS medications at about \$30,000 per year.

Gilenya is a new class of medication called a sphingosine 1-phosphate receptor modulator. The drug is thought to act by keeping lymphocytes or white blood cells in lymph nodes instead of circulating in the central nervous system where they could potentially attack myelin, MacLean said.

Myelin is a fatty substance insulating nerves that is damaged in people with MS.

The neurological disease affects vision, hearing, balance and mobility. It's usually diagnosed in young adults, mostly women, but can also affect children.