

PRESS RELEASE

AbbVie's HOLKIRA™ PAK Now Reimbursed in all Four Atlantic Provinces

- *HOLKIRA PAK now reimbursed in Nova Scotia, New Brunswick and Newfoundland and Labrador for patients with genotype 1 hepatitis C virus infection*
- *Prince Edward Island was the first province in Canada to reimburse HOLKIRA PAK*
- *In Phase 3 clinical trials, HOLKIRA PAK (with or without ribavirin) cured an overall 97 percent of genotype 1 HCV patients; additionally, 98 percent of patients completed treatment*

MONTREAL, CANADA, OCTOBER 21, 2015 – AbbVie's HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film-coated tablets) will now be reimbursed in Nova Scotia, New Brunswick and Newfoundland and Labrador. HOLKIRA PAK is an all-oral, short-course (12 weeks for the majority of patients), interferon-free treatment, with or without ribavirin (RBV), for the treatment of patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, including those with compensated cirrhosis.

“With the hepatitis C treatment revolution over the last few years, there is an amazing shift in how we approach our patients. We can now offer them options and hope,” explains Dr. Lisa Barrett, Clinician Scientist, Division of Infectious Diseases, Nova Scotia Health Authority and Dalhousie Medical School. “Now, we want to eliminate HCV by treating and curing everyone, in order to prevent the devastating long-term effects the disease has on the liver. I am excited that providers have another tool to treat hepatitis C. In the long-term, this benefits not only people living with this disease, but also our health care system as a whole.”

In the Atlantic Provinces, HOLKIRA PAK will be reimbursed for treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis) according to specific criteria. Prince Edward Island's HCV strategy, including access to HOLKIRA PAK, was announced on February 12¹. HOLKIRA PAK was listed on the Newfoundland and Labrador Prescription Drug Program², effective August 1. The listing by Nova Scotia Pharmacare³ was announced on August 13 but became effective on Tuesday, September 1.

“It is wonderful to see the new hepatitis C treatments, such as HOLKIRA PAK, become available in Nova Scotia. This treatment, that has an extremely high cure rate, manageable side effects, and short treatment course, offers hope to many Nova Scotians who have been living with hepatitis for years as well as those who are newly diagnosed. This is what we have been waiting for; it's a life saver,” says Carla Denmore MS, executive director, Hepatitis Outreach Society of Nova Scotia.

In New Brunswick⁴, the listing on the Drug Plans Formulary became effective on October 14. “It is a truly exciting time to have well tolerated and curative treatments for a disease that is a leading cause of liver failure and liver cancer in New Brunswick. With these drugs New Brunswick physicians are dramatically improving models of care for patients living with this disease,” states Dr. Daniel Smyth, assistant



professor, Dalhousie University, Division of Infectious Diseases. "Research programs initiated in New Brunswick will show that using these drugs correctly saves money in the long term by preventing new infections and preventing costly complications of untreated disease. I recommend that all persons born between the years 1945 and 1975 be screened for hepatitis C infection, as well as others who may have been exposed through high risk activities including injecting drugs and self-tattooing. Please ask your family physician about hepatitis C testing, and referral if needed."

HOLKIRA PAK combines three direct-acting antivirals to attack the virus at three separate stages of its replication process. In Phase 3 clinical trials, HOLKIRA PAK (with or without ribavirin) cured an overall 97 percent of GT1 HCV patients, and 98 percent of patients completed treatment.

"Since the launch of HOLKIRA PAK in December 2014, we committed to a collaborative approach with governments, medical and patient organizations to bring our best-in-class treatment to Canadians living with genotype 1 hepatitis C. Today, we are proud to say that we made good on our promise because HOLKIRA PAK is now reimbursed across Canada," says Stéphane Lassignardie, general manager, AbbVie Canada. "And with HOLKIRA PAK, AbbVie is offering its support program AbbVie Care, designed to provide a wide range of customized services throughout the treatment and beyond."

HOLKIRA PAK was approved by Health Canada on December 22, 2014. The approval of HOLKIRA PAK was supported by a robust clinical development program that was designed to study the safety and efficacy of the regimen in six pivotal Phase 3 studies with more than 2,300 patients across 25 countries, including one trial exclusively in subjects with cirrhosis.

About HOLKIRA PAK

HOLKIRA PAK consists of the fixed-dose combination of ombitasvir/paritaprevir/ritonavir, taken once daily, and dasabuvir taken twice daily. HOLKIRA PAK is administered with or without ribavirin, depending on the type of hepatitis C virus in cause, the treatment history of the patient and the presence/absence of cirrhosis. The combination of three different mechanisms of action interrupts the hepatitis C virus replication process with the goal of optimizing sustained virologic response across different patient populations.

The complete HOLKIRA PAK Product Monograph is available on the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

Additional information about AbbVie's chronic hepatitis C clinical program can be found on www.clinicaltrials.gov.

Important Safety Information⁵

To help avoid possible side effects and ensure proper use, talk to your health care professional before you take HOLKIRA PAK. Talk about any health conditions or problems you may have, including if you:

- are using a medicine containing ethinyl estradiol for contraception or for other reasons. You must not use medicines that contain ethinyl estradiol while taking HOLKIRA PAK. Your doctor will ask you to stop or consider changing to a different type of contraceptive medicine during your treatment.



- have liver problems other than hepatitis C infection.
- have any other medical condition.
- have had a liver transplant.
- are breastfeeding or plan to breastfeed. It is not known if HOLKIRA PAK passes into your breast milk. You and your health care provider should decide if you will take HOLKIRA PAK or breastfeed. You should not do both.
- You or your partner should not become pregnant while taking HOLKIRA PAK with ribavirin and for six months after treatment is over.

Other warnings you should know about:

Let your health care provider know if you develop nausea, vomiting, loss of appetite, yellowing of your skin or eyes, or darkening of your urine while on treatment with HOLKIRA PAK.

If HOLKIRA PAK is administered with ribavirin, the warnings and precautions for ribavirin also apply to this combination regimen. Refer to the ribavirin Patient Medication Information for a full list of the warnings and precautions for ribavirin.

It is not known if taking HOLKIRA PAK is safe and effective in children under 18 years of age.

Your doctor may do blood tests before you start your treatment and regularly during your treatment. These blood tests are done to help your doctor to check if the treatment is working for you.

Tell your health care professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

HOLKIRA PAK should not be administered with other ritonavir-containing medicines (NORVIR[®], KALETRA[®]). When co-administered with HOLKIRA PAK, atazanavir or darunavir should be taken without ritonavir.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharamcyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.ca and www.abbvie.com. Follow [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](#) or [LinkedIn](#) page.

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¹The Government of Prince Edward Island.

<http://www.gov.pe.ca/newsroom/index.php?number=news&dept=&newsnumber=10059&lang=E>

Accessed on October 20, 2015



² Government of Newfoundland and Labrador.

http://www.health.gov.nl.ca/health/forms/pdf/Holkira_Pak_Request.pdf

Accessed on October 20, 2015

³ Nova Scotia Pharmacare News Bulletin.

http://www.novascotia.ca/dhw/pharmacare/physicians_bulletins/physicians_bulletin_september_15-05.pdf

Accessed on October 20, 2015

⁴ New Brunswick Drug Plans.

<http://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/formularyupdates/NBDrugPlansBulletin914.pdf>

Accessed on October 20, 2015

⁵ HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film coated tablets) Product Monograph. Date of Revision: October 14, 2015

http://www.abbvie.ca/content/dam/abbviecorp/ca/english/docs/HOLKIRA_PAK_PM_EN.pdf

Accessed on October 20, 2015

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