APRIL 2022

COVID-19 vaccine and drug pipeline

Considerations for employer benefit plans

ALBERTA BLUE CROSS®

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EXECUTIVE SUMMARY

COVID-19, or the coronavirus disease, is an infectious disease caused by the virus SARS-CoV-2. Due to its contagious nature and risk of severe illness and death, efforts to contain the pandemic initially focused on the rapid development, approval and uptake of COVID-19 vaccines. However, as variants of the virus emerge, where vaccine efficacy or uptake is not as high, COVID-19 prevention and treatment options serve as another means to temper the effects of the pandemic.

To date, prevention and treatment options administered in hospital or in the community have been entirely funded and supplied by government bodies. In the future, private payers may play a role in providing coverage of these drugs should public funding priorities shift, particularly for outpatient community based treatments. This document summarizes which COVID-19 vaccines and drugs are available in Canada, as well as those currently under review by Health Canada.

COVID-19 VACCINES

APPROVED COVID-19 VACCINES

Vaccines are a cost-effective option to lessen the burden of COVID-19 on the public health care system, and to date, have been funded by government bodies. Should funding for COVID-19 vaccines mirror the funding model of influenza vaccines, one would anticipate that COVID-19 vaccines will likely remain publicly funded for the foreseeable future.

The first four Health Canada approved COVID-19 vaccines are two different types of vaccines: mRNA and viral vector-based. Both types of vaccines use novel technologies to elicit an immune response and have been proven effective in decreasing COVID-19 infections and severity of symptoms.

More recently, Health Canada approved two additional types of COVID-19 vaccines:

- Nuvaxovid—protein subunit vaccine, a proven vaccine technology already in widespread use (such as Hepatitis B vaccine, Pertussis vaccine).
- Covifenz—first-in-class plant-based vaccine, the first to be approved for human use.

At the time of writing, only the first five COVID-19 vaccines listed in the table below are publicly funded. The last vaccine, Covifenz, was approved February 2022, but funding and supply for Canadians is yet to be determined.

VACCINE NAME	MANUFACTURER	TYPE OF VACCINE	DOSING*	AGE
Comirnaty	Pfizer-BioNTech	mRNA	2 doses	5 and older
Spikevax	Moderna	mRNA	2 doses	6 months and older
Janssen COVID-19 vaccine	Johnson & Johnson	Viral vector-based	1 dose	18 and older
Vaxzevria	AstraZeneca	Viral vector-based	2 doses	18 and older
Nuvaxovid	Novavax	Protein subunit	2 doses	18 and older
Covifenz	Medicago Inc./ GSK	Plant-based Coronavirus-like particle	2 doses	18 to 64

**Booster doses of COVID-19 vaccines may be recommended to provide increased protection.*

COVID-19 VACCINES UNDER REVIEW

Health Canada is currently reviewing another protein subunit vaccine, as well as another viral vector-based vaccine. These new vaccines are touted to be more effective than existing vaccines against the original COVID-19 virus and its variants. In addition, two of the already approved vaccines have submitted to Health Canada for expansion of their approved indications.

COVID-19 vaccines under review by Health Canada are outlined below.

VACCINE NAME	MANUFACTURER	TYPE OF VACCINE	INDICATION UNDER REVIEW	DATE SUBMITTED TO HEALTH CANADA
New vaccines under review				
Vidprevtyn*	Sanofi-GSK	Protein subunit with adjuvant	2 dose vaccine and booster dose	July 21, 2021
Covaxin	Vaccigen Ltd.	Viral vector-based	2 dose vaccine	June 30, 2021
Approved vaccines—new indications under review				
Spikevax	Moderna	mRNA	Booster Doses	March 16 and April 1, 2022
Comirnaty	Pfizer-BioNTech	mRNA	Booster dose for ages 5 to 11 Pediatric dose vaccine for children aged 6 months to 5 years old	May 27, 2022 June 23, 2022
Nuvaxovid	Novavax	Protein subunit	Adolescent vaccine dose Booster dose	June 21, 2022 July 22, 2022

**drug name in other jurisdictions.*

COVID-19 VACCINES AND VARIANTS OF CONCERN

New variants of the COVID-19 virus are constantly discovered. If these variants are highly transmissible or capable of causing more severe illness, they are closely monitored as variants of concern. The two main variants of concern have been the Delta and Omicron variants, both of which are more transmissible than the original COVID-19 strain.

Immune response from existing COVID-19 vaccines has waned in vaccinated individuals and when coupled with pandemic fatigue, the rapid global spread of the highly transmissible Omicron variant occurred in both vaccinated and unvaccinated individuals. Research shows existing COVID-19 vaccines provide adequate protection against the Omicron variant in preventing severe disease, hospitalization and death, but still leave vaccinated individuals at risk of infection.

As the effect of emerging variants of concern is unpredictable, vaccine efficacy against these variants can play a crucial role in controlling the pandemic. Vaccine manufacturers are investing in the research and development of new vaccines that either:

- target specific variants of concern,
- target multiple variants of concern (bivalent or multivalent); or
- broadly protect recipients against all strains of the COVID-19 virus.

The table below outlines booster vaccines submitted to Health Canada that target new variants of the COVID-19 virus.

VACCINE NAME	MANUFACTURER	INDICATION UNDER REVIEW	DATE SUBMITTED TO HEALTH CANADA
Spikevax	Moderna	Bivalent vaccine booster	June 30, 2022
Comirnaty	Pfizer-BioNTech	Bivalent vaccine booster	July 25, 2022

COVID-19 TREATMENTS

APPROVED HOSPITAL COVID-19 TREATMENTS

Research and development of COVID-19 treatments have been underway since the beginning of the pandemic. The earliest treatments approved by Health Canada were limited to injectable therapies administered at the hospital. A summary of the approved hospital based COVID-19 treatments are outlined below.

DRUG NAME	INDICATION	HEALTH CANADA STATUS
Remdesivir *Gilead Sciences Canada Inc*	Treatment of COVID-19 infection in patients (12 years of age and older) with pneumonia requiring supplemental oxygen	Approved July 2020
Bamlanivimab *Eli Lilly Canada Inc.*	Treatment of mild to moderate COVID-19 infection in patients (12 years of age and older) at high risk of severe illness	Approved November 2020
Casirivimab and imdevimab *Hoffmann-La Roche Limited*	Treatment of mild to moderate COVID-19 infection in patients (12 years of age and older) at high risk of severe illness	Approved June 2021

APPROVED OUTPATIENT COMMUNITY BASED COVID-19 TREATMENTS

Health Canada has now approved three COVID-19 treatments that can be administered in an outpatient setting. These treatments are indicated for mild to moderately infected individuals who are at high risk for severe outcomes, including hospitalization and death. The goal of these treatments is to help prevent hospitalizations so that hospital resources and capacity can be prioritized for those in need of urgent care.

Currently, all approved outpatient therapies are:

- indicated for individuals with lab-confirmed COVID-19 infection;
- to be given early in the course of illness, within five to seven days (dependent on therapy) of symptom onset; and
- for those at high risk of severe illness. The list of those who are considered high risk is extensive and includes:
  - unvaccinated or not fully vaccinated individuals who are:
    - advanced age;
    - pregnant; or
    - have a pre-existing health condition (including but not limited to diabetes, obesity, chronic obstructive pulmonary disease, asthma, and congestive heart failure).
  - immunocompromised individuals regardless of vaccination status.

While all therapies can be administered outside of a hospital, additional considerations may limit utilization in eligible patients. These considerations are outlined below for each treatment.

- Paxlovid
  - While convenient to administer as a combination of two oral antivirals, Paxlovid has numerous significant drug interactions that may restrict its use in eligible patients.

- Sotrovimab
  - A monoclonal antibody infused intravenously by trained health care individuals at a clinic, or by a mobile health care unit, can take up to three hours to administer.

- Remdesivir
  - An antiviral drug given intravenously by trained health care individuals at a clinic, or by a mobile health care unit. Each dose of Remdesivir takes up to 1.5 hours to administer and the treatment course is one dose a day for three days.

Despite the limitations of these approved treatments, the high infection rates of the COVID-19 variants still leave significant portions of the population eligible for outpatient treatment, which could lead to high utilization. In addition, these approved treatments for COVID-19 infection come with substantially higher price tags than other common infectious disease treatments; these therapies cost in excess of $530 USD per treatment course (see table below).

High utilization and expensive price points make coverage of COVID-19 outpatient treatments a significant financial commitment for any payer, public or private. To date, all outpatient treatment options have been publicly funded. Throughout the course of this pandemic, the federal government has made agreements to purchase limited quantities of COVID-19 drugs directly from manufacturers. So far, the Canadian government has agreed to purchase one million courses of Paxlovid, 30,000 courses of Sotrovimab and 150,000 vials of Remdesivir (for use in both hospital and outpatient settings), available to eligible Canadians free of charge.

Funding for COVID-19 treatments has not impacted private payers so far. Should public funding priorities shift and given the current private plan funding model for treatments for other infectious diseases, private plans may be called upon to cover these costly COVID-19 outpatient treatments in the future. This would represent a significant cost for private plans if high infection rates continue.

The table below outlines the three available outpatient treatments, with their pricing from other jurisdictions:

DRUG NAME	INDICATION	HEALTH CANADA STATUS	ESTIMATED PRICING
Paxlovid *Pfizer Canada*	Oral antiviral treatment of mild to moderate COVID-19 infection in adult patients at high risk of severe illness	Approved Jan 2022	$530 USD per five-day treatment course (30 tablets)[1]
Sotrovimab *GlaxoSmithKline Inc*	One-time IV immunosuppressant infusion treatment of mild to moderate COVID-19 infection in patients (12 years of age and older) at high risk of severe illness	Approved July 2021	$2,100 USD per treatment course (one-time IV infusion)[2]
Veklury *Gilead Sciences Canada Inc*	Antiviral given intravenously for treatment of COVID-19 infection in individuals who are at high risk of severe illness	Approved April 2022	$1,900 USD per three-day treatment course (3 doses of IV infusion)[3]

COVID-19 TREATMENTS UNDER REVIEW

Health Canada is reviewing other treatments for active COVID-19 infection, ranging in price from $52 USD to $1,828 CAD per treatment course. As funding has not been announced for any of the following drugs, private payers may be responsible for coverage of these therapies if they are approved by Health Canada.

The following table outlines COVID-19 treatments currently under review by Health Canada. Where Canadian pricing is not available, pricing in other jurisdictions have been provided.

DRUG NAME	INDICATION	DATE SUBMITTED TO HEALTH CANADA	ESTIMATED PRICING
Baricitinib (Olumiant) *Eli Lilly Canada Inc.*	Oral antiviral for moderately to critically ill COVID-19 patients *Already approved for treatment of rheumatoid arthritis	May 13, 2021	$1,425 per treatment course[4]
Molnupiravir *Merck Canada Inc*	Oral antiviral for treatment of mild to moderate COVID-19 infection in those at high risk of severe illness *not indicated for patients requiring hospitalization for treatment of COVID-19	August 13, 2021	$700 USD per treatment course[5]
Tocilizumab (Actemra) *Hoffmann-La Roche Limited*	One-time IV immunosuppressant infusion for treatment of severe COVID-19 disease in hospitalized patients *Already approved for inflammatory conditions (such as rheumatoid arthritis, PJIA)	February 4, 2022	Up to $1828 per treatment course[6]
Regdanvimab (Regkirona) *Celltrion HealthCare Co Ltd*	One-time IV immunosuppressant infusion for treatment of mild to moderate COVID-19 infection in those at high risk of severe illness	May 21, 2021	$425 per treatment course[7]
Bamlanivimab and Etesevimab *Eli Lilly Canada Inc*	One-time IV immunosuppressant infusion for treatment of mild-moderate COVID-19 infection in patients (12 years of age and older) at high risk of severe illness *not indicated for patients requiring hospitalization for treatment of COVID-19	February 16, 2021	$1,250 USD per treatment course[8]

COVID-19 PREVENTATIVE THERAPIES

In addition to seeking approval for therapies to treat active COVID-19 infection, manufacturers are also developing COVID-19 drugs to be used as preventative or prophylactic therapy. At the time of writing, Evusheld is the first and only drug therapy to be approved by Health Canada for pre-exposure prophylaxis of COVID-19. Evusheld is an antibody therapy for high-risk individuals who either cannot receive vaccinations or cannot develop a sufficient immune response after vaccination. The federal government has purchased 100,000 doses for Canadians. However, similar to the other manufacturer agreements, the funding model for Evusheld after depletion of these doses is unknown at this time.

In addition to pre-exposure preventative therapies, further research is being conducted on prophylactic treatment for those who have been exposed to COVID-19. A research trial is currently underway to study the efficacy of Paxlovid when used as a preventative measure for individuals exposed to COVID-19 who are at high risk for severe illness. The funding model for Paxlovid as a prophylactic therapy has not been announced, and therefore, if approved, coverage again could potentially fall on private payers.

The table below outlines additional details on the approved COVID-19 preventative drug therapy.

DRUG NAME	INDICATION	HEALTH CANADA STATUS	PRICING IN OTHER JURISDICTIONS
Cilgavimab and tixagevimab (Evusheld) *AstraZeneca Canada Inc*	Intramuscular immunosuppressant injection for pre-exposure prophylaxis of COVID-19 in ages 12 and older who cannot be vaccinated against COVID-19 due to severe allergy, or will not benefit from vaccination due to being immune compromised	Approved April 14, 2022	Pricing unavailable

WHAT'S NEXT

As COVID-19 vaccines and treatments have been publicly funded and supplied to date, the future cost impact of COVID-19 pharmaceuticals on private payers is currently unknown. Should government funding stop for these therapies, Alberta Blue Cross's Drug Review Committee will review these drugs in a manner consistent with all other drug reviews prior to listing on our formularies.

BENEFIT PLAN MANAGEMENT

Alberta Blue Cross's benefit plan management team, comprised of industry experts, is dedicated to helping our customers make knowledgeable decisions on their benefit plans. Our in-house team closely monitors the drug landscape, including COVID-19 related treatments and vaccines, and its impact on drug benefit plans. We are committed to helping our customers navigate this changing landscape while always prioritizing the health of plan members and the sustainability of drug plans.

REFERENCES

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QUESTIONS?

To learn how the benefit plan management team can help your organization, contact your Alberta Blue Cross representative today.