

Idaho's Approach to the Distribution of Pharmaceuticals for the Prevention and Treatment of COVID-19 in Non-Hospitalized Patients

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Overview

This document provides an overview of Idaho's approach for coordinating the distribution of federally-purchased pharmaceuticals for the prevention and treatment of COVID-19 for non-hospitalized patients. Specifically, this document describes Idaho's approach to the distribution of:

- oral antiviral medications for treatment of COVID-19
- monoclonal antibodies for treatment of COVID-19
- monoclonal antibodies for pre-exposure prophylaxis (prevention) of COVID-19

This document addresses the distribution of COVID-19 therapeutics that have been purchased by the U.S. government and are distributed through a state/territory-coordinated system. This document does not address commercially available therapeutics.

The Idaho Division of Public Health (DPH) is coordinating with local public health districts and federal partners to ensure Idahoans have access to therapeutics as they become available. DPH staff participate in multiple calls weekly with federal partners to ensure we are receiving the latest information and utilizing our allocated medications appropriately.

Limited supply continues to be a significant constraint in offering these therapies to Idahoans.

Antivirals are allocated every two weeks. Idaho's two-week allocation of antivirals for the timeframe including the weeks of February 7th and February 14th was enough to treat the following numbers of patients:

Molnupiravir (oral antiviral)	Paxlovid (oral antiviral)
1608	400

Monoclonal antibodies are allocated weekly. Idaho's weekly allocation of monoclonal antibodies for the week of February 14th was enough to treat or provide prevention to the following numbers of patients:

Sotrovimab (monoclonal antibody for treatment)	Bebtelovimab (monoclonal antibody for treatment)	EVUSHELD (long-acting monoclonal antibody for pre-exposure prophylaxis)
336	360	240

Allocations of therapeutics to Idaho healthcare providers and treatment sites are made by DPH weekly (monoclonal antibodies) or every other week (oral antivirals) based on requests, geographic distribution, and demonstrated use/on-hand inventory as reported by the requesting providers or pharmacies. These therapies are currently prioritized for high-risk patients as defined in this document. The general approach to distribution in the state is:

- Oral antiviral medications are allocated to pharmacies, as these are medications that can be prescribed for use at home
- Treatment monoclonal antibodies are allocated to providers such as clinics, hospitals, and healthcare systems able to provide outpatient intravenous infusions to high-risk populations
- Preventive monoclonal antibodies were initially allocated to cancer treatment centers and are now also being allocated to clinics serving patients taking immunosuppressive medications

Sites receiving these therapeutics have been encouraged to work with other providers in their communities to allow referrals of patients meeting the criteria established for receipt of the therapeutics.

Oral Antiviral Medications

Two recently authorized oral antiviral medications are being allocated to Idaho for use in persons at high risk of severe disease as outlined in the following Emergency Use Authorization Fact Sheets:

• Molnupiravir: https://www.fda.gov/media/155054/download

Paxlovid: https://www.fda.gov/media/155050/download

To date, doses of these two antivirals have been allocated to pharmacies that are part of the federal retail pharmacy partnership program, as per federal recommendations, and include at least one pharmacy in each of the local public health districts. A list of pharmacies receiving oral antivirals has been made available and sent to prescribing healthcare providers statewide via our Health Alert Network (HAN) messaging system. As additional supplies of oral antivirals arrive in Idaho, we will expand sites receiving the medications and send updates to providers via the HAN messaging system with an updated list of pharmacy locations and instructions on how to work with receiving pharmacies to confirm availability. Supply as of this date remains limited.

Of note, the FDA approved remdesivir for outpatient use on January 21st. DPH is not involved in distributing this medication as it is commercially available.

• Remdesivir for outpatients: https://www.fda.gov/news-events/press-announcements/fda-takes-actions-expand-use-treatment-outpatients-mild-moderate-covid-19

Several healthcare systems are utilizing remdesivir in the outpatient setting.

Monoclonal Antibodies for Treatment

Currently, patients who are diagnosed with mild-to-moderate COVID-19 and are at high risk of severe outcomes are eligible for one of two monoclonal antibody products. sotrovimab or bebtelovimab, at various clinics and treatment centers throughout the state.

- Sotrovimab: https://www.fda.gov/media/149534/download
- Bebtelovimab: https://www.fda.gov/media/156152/download

Sotrovimab and bebtelovimab are in short supply. DPH has allocated all doses of sotrovimab made available to Idaho and is beginning to allocate bebtelovimab as of the week of 2/14/2022. DPH has allocated the doses to clinics and healthcare systems in each of the seven local public health districts to try to maximize geographic equity.

Receiving providers have also been recommended to review and take into consideration the NIH COVID-19 Treatment Guidelines Panel's Statement on prioritization when there are logistical or supply constraints. These guidelines include a link to the CDC webpage which lists patient characteristics with a higher risk of severe outcome, which include:

- age ≥65y
- cancer
- obesity with BMI >30 kg/m2
- cardiovascular disease
- pregnancy
- diabetes
- significantly reduced kidney function
- chronic lung disease
- chronic liver disease
- smoking

Monoclonal antibodies for pre-exposure prophylaxis

A long-acting monoclonal antibody combination product, EVUSHELD, is now available in limited supply for pre-exposure prophylaxis in certain patients.

EVUSHELD is indicated for persons:

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2, and either:
 - have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination, or
 - vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Given the severely constrained supply, EVUSHELD was initially prioritized for highly immunocompromised individuals, and initial allocations were entirely distributed to cancer treatment centers. These cancer centers were asked to also administer EVUSHELD to other

highly immunocompromised individuals, such as organ transplant patients, upon referral from a provider. As cancer centers have begun to meet their needs, other immunocompromised patients such as those on immunosuppressive medications have been prioritized, and providers serving those patients are being offered supplies of EVUSHELD.

Communication with Healthcare Providers and the Public

In light of the limited supply, it is challenging to communicate clearly to providers and the public about where to locate these therapeutics; providers and pharmacies may have some available at certain times but may then quickly use up their allotment prior to receiving additional doses. Providers need reliable information on where their patients can receive monoclonal antibodies and which pharmacies carry the oral antivirals.

The HHS COVID-19 Therapeutics Locator website provides data on allotted and available courses of some therapeutics https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/ and lists locations that have received molnupiravir, Paxlovid, or EVUSHELD. However, this site is not yet tracking allocated or available courses of sotrovimab or bebtelovimab. DPH sent a HAN message to Idaho healthcare providers the week of January 3, 2022 on how to access the oral antivirals and is planning an additional release for the week of February 21st to highlight changes in availability and distribution of therapeutics in the state.

More recently, the state https://coronavirus.idaho.gov/ website has been updated with information for providers and the general public.

Links on the site include a link to this document and:

- Idaho Department of Health and Welfare, Side-by-Side Overview of Therapeutics Authorized for Non-Hospitalized Patients, January 13, 2022, available at https://coronavirus.idaho.gov/wp-content/uploads/2022/01/COVID-19 Therapeutics-Overview Providers 20220113 FINAL.pdf
- U.S. Centers for Disease Control and Prevention, What Clinicians Need to Know About the New Oral Antiviral Medications for COVID, Clinician Outreach and Communication Activity (COCA) Call, January 12, 2022, available at https://coronavirus.idaho.gov/wp-content/uploads/2022/01/What-Clinicians-Need-to-Know-about-the-New-Oral-Antiviral-Medications-for-COVID-19.pdf
- U.S. Department of Health and Human Services (HHS) COVID-19 Therapeutics Locator, available at https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/

DPH will prioritize the equitable distribution of and access to COVID-19 therapeutics throughout the state and will help ensure these limited resources reach vulnerable and hard-hit communities. We are working with our local public health departments, infusion centers, cancer centers, hospitals and clinics to allocate therapeutics fairly across the state. We are committed to maintaining transparency throughout the process.