

## **Paxlovid Allocation Methodology**

**Updated: 12/27/2021**

### **Introduction**

COVID-19 has had disproportionate impact on communities of color, and tribal communities across the state and the nation. The same social inequities that have affected healthcare access and treatment before the pandemic continue to have a disproportionate effect on these communities. Equitable selection of sites for allocation and distribution of effective COVID-19 therapies can help mitigate COVID-19's disproportionate impacts on these populations.

### **Ethical Goals of Allocation Framework for Emerging COVID-19 Treatments**

The distribution and use of emerging medical countermeasures must take into consideration the historical consequences for people of color and individuals with disabilities who have been affected by lack of disclosure related to experimental drugs, procedures, and testing. The distribution and use of these therapies must be done equitably<sup>[1]</sup> and take current and historical experiences into consideration.

#### **Treatment decisions should NOT consider or be based upon:**

- Race, ethnicity, gender, gender identity, sexual orientation or preference, religion, citizenship or immigration status, or socioeconomic status;
- Ability to pay;
- Age as a criterion in and of itself;
- Disability status or comorbid condition(s) as a criterion in and of itself;
- Predictions about baseline life expectancy beyond the current episode of care (i.e., life expectancy if the patient were not facing the current crisis)
- Judgments that some people have greater “quality of life” than others;
- Judgments that some people have greater “social value” than others.

<sup>[1]</sup> Oregon Health Authority's definition of health equity: Oregon will have established a health system that creates health equity when all people can reach their full health potential and well-being and are not disadvantaged by their race, ethnicity, language, disability, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances.

Achieving health equity requires the ongoing collaboration of all regions and sectors of the state, including tribal governments, to address:

- The equitable distribution or redistributing of resources and power; and
- Recognizing, reconciling, and rectifying historical and contemporary injustices.

### **Product specifics and eligibility**

**Paxlovid** is manufactured by **Pfizer-BioNTech**. It is an oral antiviral combination of 2 drugs, new antiviral called Nirmatrelvir co-packed with the older antiviral and Ritonavir; that is taken as tablets twice a day for 5 days.

FDA issued an EUA for the product on December 22, 2021. Use was authorized for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19). Eligibility criteria are listed below.

#### ***Eligibility***

This product is intended for treatment of mild-to-moderate COVID-19 disease in adults and pediatric patients 12 years and older weighing at least 88 lbs. (40 kg).

1. **Paxlovid** (nirmatrelvir/ritonavir) is authorized for **treatment** of mild-to-moderate COVID-19 disease in those with positive results of direct COVID-19 viral testing, and who are at high risk, due to an underlying medical condition, as described by CDC, for progression to severe COVID-19.
2. The product is authorized for the treatment of patients hospitalized for conditions other than COVID-19, provided the terms of the authorization are otherwise met. It is also authorized for patients who require hospitalization due to severe or critical COVID-19 after starting treatment.

#### ***Limitations***

Paxlovid is not authorized for:

- Initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19

- Use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19
- Use longer than 5 consecutive days

**Paxlovid** may only be prescribed by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe anti-infectives. Product must be dispensed by a pharmacy.

### **Product Availability**

Initial demand for **Paxlovid** will likely exceed supply. The federal government has purchased 10 million courses. Product will be limited at first and will ramp up significantly in the coming months. An initial 65,000 courses of Paxlovid will be made available for shipment to states and territories, and select HRSA funded health clinics, and will begin arriving in states and territories during the first week of January. Initial allocations of Paxlovid will be provided for free. **First state allocation for Oregon is 680 courses for a period of two weeks.**

### **Methodology**

Allocation of **Paxlovid** will prioritize areas of Oregon with the largest burden of COVID-19 disease. Focus will go to racial and ethnic disparities for initial allocation and will not yet consider regional spread, with consideration given to rural versus metro areas. Allocation strategies currently include:

#### ***Tier 1:***

- Due to limited supply, product will not, initially, be made available to all facilities. Initial survey outreach will target all federally qualified health centers (FQHC) with pharmacy partnership and regional coordinating hospitals. In addition will be Harney and Asante Three Rivers as well as tribes not on Indian Health Service.
- Based on discussions with the survey opportunity will be sent to 4 pre-specified pharmacies in Douglas County Public Health Director, the Therapeutic Operations Team recommends distributing a small amount from Oregon's initial allocation to four pharmacies in that county, who will work with the Douglas County Public Health Network and healthcare providers to distribute to those at highest risk as a pilot of this potential model for distribution.
- Further determination of sites to depend on the following:
  - population size
  - disease and hospitalization rates

- regional availability and spread

***Prioritization:***

Initial survey outreach will give priority sites and areas the opportunity to request product. Distribution will be determined based on survey data paired with population matches.

- The survey will be sent to five strategic regional coordinating hospitals, including Salem hospital, Peace Health River Bend, Asante Rouge, St. Charles, and Grand Ronde

***Rationale:***

- COVID-19 cases and hospitalizations remain elevated in communities of color
- FQHCs often serve communities disproportionately affected by severe COVID-19 and are often in high CCVI (COVID community vulnerability index) communities
- Hospital emergency rooms are often the primary resource for health care among the medically disenfranchised
- Use of a pilot to explore the potential for Public Health/Pharmacy/Clinician partnership in providing access to medical countermeasures for those most in need will inform subsequent product allocation efforts

The ability to dispense this product requires a pharmacy partnership. Further, it is necessary to allocate and distribute among FQHCs and regional hospitals, with the following goals here:

- Provide access to residents of remote geographic location expanding services to remote areas
- Make easier access available to care for vulnerable communities
- Potential product adverse effects and drug interactions require detailed patient counseling and review of existing medications, which pharmacists can facilitate provider information of the product

Distribution based on the regional spread is not achievable at the moment due to limited initial reduced product state allocations.

***Data Pull:***

- Results from surveys to determine qualified provider sites.

- Assess the available data in disadvantaged communities and their accessibility to Paxlovid.
- Support from stakeholders and health systems who can potentially provide other relevant data to guide allocation decisions that can retrieve.

It is not yet possible to expand prioritization plans to second and third tiers due concise criteria and manufacturing constraints and absent no timeline for expansion. **Tiers 2 and 3 pending supplies.**

## **Distribution:**

### **Tier 1:**

**Week 1-4:** Select federally qualified health centers and regional hospitals as well as a small number of specified facilities above will have received the opportunity to order product via survey outreach. 70% of initial courses will go to FQHCs and 25% will go to regional hospitals for distribution to hospital emergency rooms. Five percent of the initial allocation would go to the Douglas County pharmacies working with the Douglas Co.PH Network to pilot this model of distribution. Further determination of exact number of courses will be made once survey results and population metrics are analyzed. Distribution will take place in 2-week cycles.

**Week 5+:** Need to utilize provider feedback via Smartsheet for ongoing allocations and expand outreach and allocation to broader list of sites as needed. Will be guided by “inventory on hand” and ongoing supply estimates from HHS. Expansion to Tier 2 and 3 and subsequent allocation will be based on product supply. Timeline will be determined by supply as well.

### **Tier 2**

As product becomes more available, additional allocations would be made to FQHCs, Tribal and Urban Indian clinics, and hospital emergency rooms that have not yet received Paxlovid. Distribution would also be widened to promote availability to corrections facilities and long-term care facilities and other facilities that serve disproportionate numbers of high-risk patients.

### **Tier 3**

When limitations no longer exist on supply, we would likely move to a model that includes broader distribution to pharmacists to make product available to those in the general population who, based on clinical evaluation, are eligible to receive it.