



March 10, 2020

TO: NASTAD Members
FR: Stephen Lee, MD; Amy Killelea; and Tim Horn
RE: COVID-19

NASTAD continues to closely monitor the community outbreaks of coronavirus disease (COVID-19) in the United States and the rapidly evolving public health responses to contain and mitigate the infection. We are committed to providing NASTAD members with potentially useful information, as it becomes available, to help ensure the continuity of essential programming and the protection of people living with and vulnerable to HIV infection and viral hepatitis. NASTAD is monitoring guidance from our federal partners, including HRSA/HAB (who released guidance to RWHAP grantees last week) and CDC (who is continually [updating resources and guidance](#) on COVID-19).

Antiretroviral (ARV) and Direct Acting Antiviral (DAA) Shortages

The COVID-19 outbreak in China is expected to impact the medical, pharmaceutical, and biologics supply chain, including [potential disruptions](#) to supply critical medical and pharmaceutical products in the U.S. NASTAD remains in contact with the major manufacturers of brand-name ARVs and DAAs, as many of these products rely on active pharmaceutical ingredients (APIs) and feedstock required for the synthesis of APIs produced in China. The following ARV and DAA manufacturers are reporting no manufacturing concerns or supply shortages:

- Gilead Sciences
- ViiV Healthcare
- Janssen Pharmaceuticals
- Merck

NASTAD has learned of a Florida clinic experiencing difficulty procuring Kaletra (lopinavir/ritonavir) for their HIV-positive pediatric patients. AbbVie is not reporting shortages. However, it is controlling Kaletra orders to prevent stockpiling for use against COVID-19. AbbVie has sent a large volume of Kaletra to China for the experimental treatment of COVID-19-related pneumonia.

NASTAD will continue to track actual or potential medical supply chain disruptions of significance to HIV and viral hepatitis programs. NASTAD members are strongly encouraged to contact Tim Horn regarding any supply chain disruptions or shortages.

Repurposing ARVs for COVID-19 Treatment

A few members have inquired about the potential for ARVs to be used to treat COVID-19 and potentially prevent or mitigate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among people living with HIV. HIV protease inhibitors, notably Kaletra, are being evaluated for potential activity against SARS-CoV-2 and efficacy as a treatment for COVID-19-related pneumonia. While there is some evidence that HIV protease inhibitors might work based on data from a [2004 study](#) demonstrating “substantial clinical benefit” when given to patients with SARS and emerging anecdotal reports from COVID-19 outbreaks, no data are yet available from randomized controlled trials to support off-label use of these drugs to treat or prevention COVID-19 in any individuals.

In the absence of U.S. Food and Drug Administration (FDA) or other regulatory guidance recommending the use of any ARV drug product to treat or prevent COVID-19 in people living with HIV, NASTAD encourages its members to dissuade clinicians from switching patients to a Kaletra- or other protease inhibitor-based regimen until such evidence-based guidance becomes available, to safeguard against supply chain disruptions for adults and children currently using these regimens for the management of their HIV. NASTAD will continue to track the COVID-19 treatment pipeline, including the repurposing of ARVs.

Maintaining Access to Medications

AIDS Drug Assistance Programs (ADAPs) are relying on existing policies and procedures in place to ensure continued access to medications during disruptive events. NASTAD published the following [emergency preparedness guide](#) several years ago, which may be useful as programs prepare for clients who may have restricted access to pharmacies or non-emergency healthcare access. NASTAD has been in touch with PBMs working closely with ADAPs who are ready to put in place relaxed dispensing limit and network restrictions for jurisdictions experiencing disruptions in access to pharmacies. Please let NASTAD know if your jurisdiction is anticipating new ADAP policies to respond to COVID-19 or is encountering any challenges.

Legislative and Regulatory Responses

As health department responses to community outbreaks of COVID-19 continue to expand and evolve rapidly, federal and state policies are being updated to maximize the impact of disease containment and mitigation strategies.

- *Emergency Funding*
Congress passed an emergency funding bill that was signed into law on March 6, providing \$8.3 billion for COVID-19 response activities, including investments public health response activities, research (including vaccine and treatment development), testing capabilities, and medical supply medication procurement. The \$800,000 that had been reprogrammed from NCHHSTP last month was returned in this bill.
- *Federal Public and Private Insurance Coverage Actions*
[CMS has released a number of fact sheets and guidance](#) to instruct Medicaid, Medicare, and individual and small group coverage with regard to provision of a range of services associated with the COVID-19 outbreak. This includes information to healthcare facilities regarding increased and focused inspections, resources for billing for diagnostic testing (including release of new billing codes), and fact sheets and information regarding coverage and cost-sharing requirements for preventive services.
- *State insurance regulatory actions*
Several states departments of insurance have issued regulations and orders to ensure that individuals have access to COVID-19 testing and easy access to necessary medications should there be more aggressive containment measures in jurisdictions that prevent travel to pharmacies. These measures – adopted now in [California](#), [Washington](#), and [New York](#) – include consumer protections like waiving cost sharing associated with COVID-19 testing; allowing early refills for prescriptions; suspending prior authorization for testing or treatment for COVID-19; providing easier access to telehealth medical advice and treatment; and allowing individuals to seek COVID-19 related services outside of their provider network. Additionally, many major [commercial insurance plans](#) have put in place similar policies that apply in states even without regulatory action.

Health Department Staffing Impact

NASTAD is aware that many HIV and hepatitis health department staff are being detailed to state and local COVID-19 efforts, putting an additional strain on already lean programs. Federal HIV and hepatitis partners – particularly those at CDC – are also being detailed away from their HIV and hepatitis posts. We are aware that a

communication went out to CDC health department grantees from the Center for State, Tribal, Local, and Territorial Support (CSTLTS) entitled “Guidance for The Temporary Reassignment of State, Tribal, and Local Personnel During a Declared Federal Public Health Emergency.” The guidance details the process by which public health staff can be reassigned for emergency response and references additional CDC resources ([available here](#)). Please keep NASTAD posted of challenges you are experiencing related to COVID-19 re-assignments and how we can support you and your staff during this time. We are also aware that many jurisdictions have issued restrictions on non-essential out-of-state travel during this time. Please keep NASTAD updated on the policies in place in your jurisdiction.

NASTAD Operations Impact

NASTAD is closely monitoring the impact of COVID-19 community outbreaks on our operations and staff. At this time, we are open for business. However, we are making some changes to our operations to take additional precautions to keep our staff, our members, and vulnerable populations in our communities safe. We are relaxing our remote employment policies for any staff that chooses to work from home. Given our extended office closure last year, all staff are equipped to work remotely and are able to remain efficient and productive. We are monitoring our remote policies closely and may make additional changes as events unfold. We are currently reviewing all NASTAD travel and meetings, making decisions to cancel, postpone, or move meetings to virtual platforms when possible through April. We will also communicate any changes to NASTAD’s annual meeting over the coming days as we weigh whether to postpone. The health and safety of NASTAD staff and our members are of utmost importance to us. We will be in close communication over the coming weeks as we learn more.

NASTAD encourages its members to keep us informed of any emerging issues pertaining to COVID-19 and its actual or potential impact on jurisdictional HIV and hepatitis programming, including staffing and resource strains.

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