To: BILH Clinicians and Managers

From: Richard Nesto, MD
Chief Medical Officer, BILH

Subject: **Update: BILH COVID-19 Ambulatory Therapeutics**

I am writing to share an update on the significant ongoing changes to our ambulatory COVID-19 therapeutics based on the rapidly increasing rate of the Omicron variant in New England as well as three new FDA Emergency Use Authorizations (EUAs).

BILH COVID-19 Monoclonal Antibody Therapy Clinics

BILH has expanded access for COVID-19 monoclonal antibody therapy (mAb) and is now offering treatment at Beth Israel Deaconess Medical Center, Lahey Hospital & Medical Center, Mount Auburn Hospital and Winchester Hospital. As a reminder, all COVID-19 mAb treatment referrals are reviewed centrally and then distributed to treatment sites based on available access. Information about the mAb program is posted on the BILH COVID-19 staff website, under "Monoclonal Antibody Therapy."

Despite expansion of this program, at this time, referrals for monoclonal antibody therapy continue to far exceed our capacity for treatment. We will continue to prioritize those patients at highest risk of severe illness including those who are unvaccinated or immunocompromised.

As of Monday, Dec. 27, the state will no longer be distributing allocations of two of the three FDA EUA-approved COVID-19 monoclonal antibody therapy (Bamlanivimab plus Etesevimab and Casirivimab plus Imdevimab) due to concern for lack of efficacy against the Omicron variant. At this time, we are able to maintain our current capacity for treatment with our allocation of the third FDA approved monoclonal antibody, sotrovimab, which is expected to retain efficacy against the Omicron variant. We are carefully monitoring our supply and will provide updates as the situation continues to evolve. Please note that sotrovimab is not authorized for use in post-exposure prophylaxis thus no current option for this indication is available.

COVID-19 Monoclonal Antibody Therapy - Pre-Exposure Prophylaxis

On Wednesday, Dec. 8, the FDA issued an EUA for tixagevimab and cilgavimab (Evusheld) for pre-exposure prophylaxis for COVID-19 in individuals with moderate-severe immunosuppression who may not mount an adequate response to vaccination or have a history of severe adverse reaction to COVID-19 vaccine. As is the case across the state, we expect to begin to receive an extremely limited supply of this therapy over the next two weeks. More details will be forthcoming as we gain details on allocation, initial available supply, and logistics for administration. Please do not contact the COVID-19 Monoclonal Antibody Treatment locations with questions on this agent as it is not currently available.

COVID-19 Oral Antiviral Medications

Within the last week (Dec. 22-23), the FDA issued two EUAs for oral drugs: one for the combination of nirmatrelvir and ritonavir (Paxlovid) for the treatment of mild-moderate COVID-19 infection in individuals at high risk for progression to severe disease and a more restrictive EUA for molnupiravir (Lagevrio) in limited situations where alternate treatment options are not available. These agents are not yet available, and we are awaiting details on distribution plans

from the Massachusetts Department of Public Health. More information will be forthcoming as we gain details on allocation, initial available supply, and logistics for administration.

Ambulatory Use of Remdesivir

On Thursday, Dec. 23, the NIH COVID-19 Treatment Guidelines were updated to include the recommendation for use of intravenous remdesivir as an option for the treatment of COVID-19 in non-hospitalized patients who are at high risk of clinical progression. The need for three consecutive daily intravenous infusions is expected to cause significant logistical constraints and is not yet available at our COVID-19 treatment sites; however, this option is also being actively reviewed for BILH.

As these emerging therapies become available in initial quantities insufficient to meet the needs of all eligible patients, BILH is activating a BILH Drug Shortage Task Force for COVID-19 Therapeutics, reporting into the BILH Pharmacy and Therapeutics Committee, to establish and operationalize prioritization schemes to ensure that the (initially) limited supply of these treatments are equitably allocated to those at highest risk of COVID-19 complications.

We will continue to keep you updated as the options for ambulatory COVID-19 therapeutics continue to evolve.