March 31: FDA Authorizes Second Booster, BA.2 Omicron Subvariant Update, Transition to Bebtelovimab for Monoclonal Antibody Treatment

Today's issue features information from the U.S. Food and Drug Administration (FDA) regarding the authorization of a second booster and an update on the BA.2 omicron subvariant from Egon A. Ozer, MD, PhD, director, Center for Pathogen Genomics and Microbial Evolution, Institute for Global Health. It also includes information about a new medication for monoclonal antibody treatment for patients at high risk for hospitalization from COVID-19.

FDA AUTHORIZES SECOND BOOSTER

On March 29, the FDA **authorized** a second booster dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine for people age 50 or older, as well as certain immunocompromised individuals.

The FDA reports that current evidence suggests some waning of protection over time against serious outcomes from COVID-19 in older and immunocompromised individuals. Based on an analysis of emerging data, a second booster dose could help increase protection for these higher-risk individuals. Emerging evidence also suggests that a second booster dose of an mRNA COVID-19 vaccine is not associated with any new safety concerns.

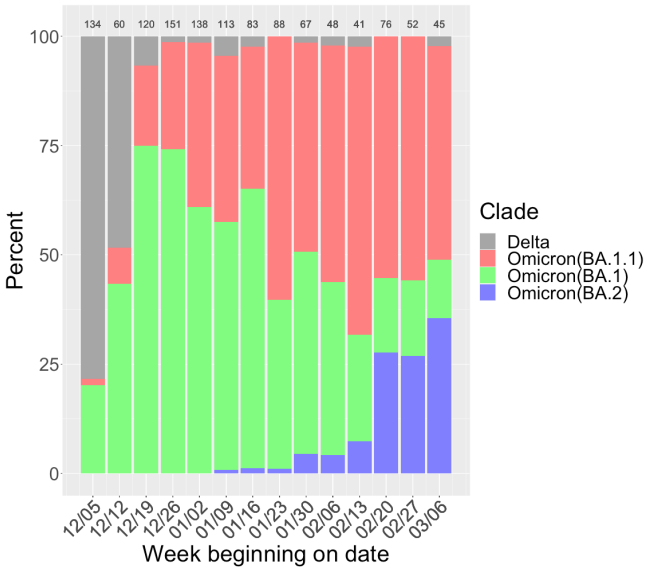
The agency amended the Emergency Use Authorizations as follows:

- A second booster dose of the Pfizer or Moderna vaccine may be administered to individuals 50 years of age and older at least four months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- A second booster dose of the Pfizer vaccine may be administered to immunocompromised individuals 12 years of age and older at least four months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- A second booster dose of the Moderna vaccine may be administered at least four months after the first booster dose of any authorized or approved COVID-19 vaccine to individuals 18 years of age and older who are immunocompromised.

For more information, please the **announcement** on the FDA website. For vaccination locations, visit **COVID-19 Vaccines for People Age 12 and Older** on nm.org.

BA.2 OMICRON SUBVARIANT UPDATE

NM testing confirmed the health system's first case of the BA.2 omicron subvariant during the week of January 9. Prevalence of BA.2 remained low across NM through January and early February, representing less than 4% of sequenced cases. Since mid-February, as the overall number of cases continued to decline, the rate of omicron BA.2 grew, increasing from 7% in the third week of February to 35% in the second week of March. The proportion of BA.2 cases observed at NM closely aligns with CDC **data** across the Midwest.



The graphic above represents sequencing data from NM and Ann & Robert H. Lurie Children's Hospital of Chicago performed by the **Northwestern Center for Pathogen Genomics and Microbial Evolution**. Each bar shows the proportions of each lineage sequenced in the given week, and the number at the top of each bar is the total number of cases sequenced that week.

While the city of Chicago is now **reporting** increasing COVID-19 cases, it is not yet clear if the increase is being driven by the BA.2 subvariant specifically or by other factors, such as the lifting of mask mandates and vaccination requirements across the state. For more information about the proportion of COVID-19 cases caused by the BA.2 subvariant, visit the **Variant Proportions page** on the CDC website.

TRANSITION TO BEBTELOVIMAB FOR MONOCLONAL ANTIBODY TREATMENT

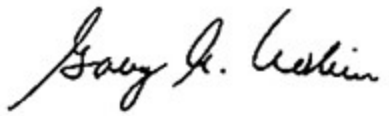
In accordance with recommendations based on the growing prevalence of the BA.2 omicron subvariant in the region, NM is changing its monoclonal antibody (mAb) product. Since sotrovimab has very little efficacy against BA.2, bebtelovimab now replaces sotrovimab for the treatment of mild to moderate COVID-19 disease in patients who are at high risk for hospitalization.

The Emergency Use Authorization criteria and NM requirement for use remain unchanged. Patients should be scheduled for mAb treatment within seven days of symptom onset. Bebtelovimab is administered via slow IV push, as opposed to infusion, which will likely shorten the current three-hour scheduling timeframe for mAb treatment in the near future. Additional information will be shared as it becomes available.

For more information about bebtelovimab, view the **Bebtelovimab Administration Tip Sheet**. To learn more about placing an mAb referral order, please view the **Order the Monoclonal Antibody (mAb) for COVID-19** Epic tip sheet.

With cases of the BA.2 omicron subvariant increasing across the region, please encourage patients and colleagues to protect themselves from COVID-19 by getting vaccinated and keeping up to date on recommended boosters. This is particularly true for older individuals and those who are immunocompromised.

As always, thank you for your continued perseverance, courage and compassion in providing exceptional care to the patients and communities we are privileged to serve, and thank you for choosing to practice medicine at NM. It is an honor to work alongside each of you.



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