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November 25, 2020 Time 1400 (2:00 PM EDT)
NH-HAN 20201125

NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs *for all*
Department of Health and Human Services

Coronavirus Disease 2019 (COVID-19) Outbreak, Update # 26

Regeneron's monoclonal antibodies casirivimab and imdevimab

Key Points and Recommendations:

- The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for casirivimab and imdevimab to be administered together for treatment of mild to moderate COVID-19. Medication has been purchased by the federal government and will be distributed proportionally to NH hospital pharmacies (based on COVID-19 hospitalization numbers) through AmerisourceBergen.
- Casirivimab and imdevimab are investigational recombinant monoclonal antibodies that target the receptor binding domain of the spike protein of SARS-CoV-2; use and indications are similar to the monoclonal antibody bamlanivimab that received FDA EUA earlier this month (see HAN Update #24).
    - Casirivimab and imdevimab are administered together as a single intravenous infusion as soon as possible after a positive SARS-CoV-2 test result and within 10 days of symptom onset.
    - Limited study data shows that a lower proportion of casirivimab/imdevimab treated patients with mild to moderate COVID-19 progressed to hospitalization or emergency room visits when compared to placebo, and benefit was greater in patients at higher risk for severe disease and hospitalization.
- Providers should familiarize themselves with indications for use of therapeutics that have received FDA EUA, and review medical treatment guideline recommendations on use of these new investigational therapeutics, including:
    - National Institutes of Health (NIH) COVID-19 Treatment Guidelines
    - Infectious Disease Society of America (IDSA) COVID-19 Practice Guidelines
- The FDA EUA permits the use of casirivimab and imdevimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive viral SARS-CoV-2 test results, and all the following criteria must apply. Patient must be:
    - 12 years of age and older,
    - Weighing at least 40 kg, and
    - High risk for progressing to severe COVID-19 and/or hospitalization (see FDA Fact Sheet for Health Care Providers for definition of "high risk")
- Casirivimab and imdevimab are NOT authorized for use in the following patients:
    - Adults or pediatric patients hospitalized due to COVID-19.
    - Adult or pediatric patients who require oxygen therapy due to COVID-19.
    - Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in patients on chronic oxygen therapy due to an underlying non-COVID-19 related comorbidity.

- Clinicians managing patients for whom casirivimab and imdevimab are appropriate under the FDA EUA, and who have access to casirivimab and imdevimab through their hospital pharmacies, must review the following information and requirements before treating patients:
    - FDA EUA for casirivimab and imdevimab
    - Frequently Asked Questions on the EUA of Casirivimab + Imdevimab
    - Fact Sheet for Health Care Providers
    - Fact Sheet for Patients, Parents and Caregivers (English)
    - Fact Sheet for Patients, Parents and Caregivers (Spanish)
- The Fact Sheet for Health Care Providers contains important information about who may receive casirivimab and imdevimab under the FDA EUA, preparation and storage information, dosing and administration instructions, and other specific instructions for health care providers and mandatory requirements for administration.

- For any questions regarding this notification, please call the NH DHHS, DPHS, Bureau of Infectious Disease Control at (603) 271-4496 during business hours (8:00 a.m. – 4:30 p.m.).
- If you are calling after hours or on the weekend, please call the New Hampshire Hospital switchboard at (603) 271-5300 and request the Public Health Professional on-call.
- To change your contact information in the NH Health Alert Network, please send an email to DHHS.Health.Alert@dhhs.nh.gov.

Status:	Actual
Message Type:	Alert
Severity:	Moderate
Sensitivity:	Not Sensitive
Message Identifier:	NH-HAN 20201125 COVID-19, Update 26
Delivery Time:	12 hours
Acknowledgement:	No
Distribution Method:	Email, Fax
Distributed to:	Physicians, Physician Assistants, Practice Managers, Infection Control Practitioners, Infectious Disease Specialists, Community Health Centers, Hospitals, Hospital CEOs, Hospital Emergency Departments, EMS, Nurses, NHHA, Pharmacists, Laboratory Response Network, Manchester Health Department, Nashua Health Department, Public Health Networks, DHHS Outbreak Team, DPHS Investigation Team, DPHS Management Team, Northeast State Epidemiologists, Zoonotic Alert Team, Health Officers, Deputy Health Officers, MRC, NH Schools, EWIDS, Dialysis & Transplant Clinics, STD Clinics, Immunization Practices, Travel Centers, Influenza Sentinels, Urgent Care Centers, Ambulatory Surgical Centers, Walk-in Clinics, Poison Center, Alcohol and Other Drug Treatment Centers, Long-Term Care Facilities, Community Mental Health Centers, Health Departments, Internal Medicine, Occupational Health, Gastroenterology, Schools and Daycare Providers, Regional Public Health Networks, Environmental Services, Family Planning Programs, Department of Corrections, Home Care Providers, Local and State Partners, Area Agencies
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Originating Agency:	NH Department of Health and Human Services, Division of Public Health Services

Attachments: None