The Long-Term-Care Infusion Support Activity (LISA)

An Open Invitation for Local Medical Reserve Corps Units to Support Monoclonal Antibody Infusions in Long-term Care Facilities and Protect America's Seniors Against COVID-19

Background: The COVID-19 pandemic has disproportionately impacted nursing homes and seniors. Although residents of nursing homes and other long-term care (LTC) facilities account for less than 1% of the U.S. population, almost 40% of COVID-19 deaths have occurred in these settings.¹

COVID-19 vaccines are a critical tool for protecting LTC residents, but the vaccines are not 100% effective and that effectiveness may decrease with some variants. Further, LTC facilities admit new residents on an ongoing basis, many of whom may not have been vaccinated in their communities.

An important bridge for protecting America's seniors is COVID-19 monoclonal antibody (CmAb) therapies, which have been available via Emergency Use Authorization (EUA) since November 2020. These outpatient infusions, if given early in the course of illness to high-risk patients, can interrupt disease progression and prevent hospitalizations.^{2,3}

The U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response recently established a program called <u>SPEED (Special Projects for Equitable and Efficient Distribution)</u> to provide CmAbs directly to pharmacies serving LTC facilities. However, even with ready access to CmAbs, many nursing homes and assisted living communities are unable to administer these potentially life-saving treatments due to limited availability of qualified staff and overwhelming clinical demands.

Objectives:

- 1. In partnership with 6 national associations, **create a pathway for MRC volunteers** to be trained and deployable to administer CmAb infusions in local nursing homes and other LTC facilities
- 2. Empower communities to accelerate the use of CmAbs nationwide among high-risk seniors in order to save lives and reduce burden on the U.S. Healthcare System
- 3. Leverage America's volunteerism spirit, promote community resiliency, and harness the potential of neighbors helping neighbors during crises

Description: The Long-Term-Care Infusion Support Activity (LISA) is a grass-roots initiative and pathway designed and supported by **the Coalition to Advance Community-Based Solutions for COVID-19** (hereafter referred to as "the Coalition"). The Coalition is comprised of 6 national associations representing long-term care facilities (both nursing homes and assisted living), senior housing, and infusion centers.

- American Health Care Association/National Center for Assisted Living
- <u>LeadingAge</u>
- Argentum
- American Seniors Housing Association
- AMDA The Society for Post-Acute and Long-Term Care Medicine
- National Infusion Center Association

Together, the Coalition invites interested and qualified volunteers from local MRC units to sign up for LISA and, upon request, provide critical infusion support services in their communities. The MRC was created after the 9/11 terrorist attacks as a way to organize, credential, and activate volunteer responders for community and national public health emergencies. Currently, the MRC network comprises approximately 200,000 volunteers in roughly 800 community-based units throughout the United States and its territories.

Local MRC units are not required to participate in LISA. LISA is simply a new opportunity, born from the immense challenges of the COVID-19 pandemic, for qualified MRC volunteers to give back to their communities and support local LTC facilities. Unique characteristics of LISA include: 1) Training and service can be conducted entirely within their local communities. 2) Volunteer service can be done on an ad hoc or part-time basis (minimum service time is approximately 2 hours for administering one CmAb infusion, including prep and post-infusion observation time). 3) Ample opportunities exist to provide LISA service outside of local communities, if desired.

Steps for Activating the LISA Pathway

<u>STEP 1</u>: On March 2, 2021, the Coalition will announce the launch of the LISA pathway and invite volunteers from local MRC units to participate.

The Coalition will share information about LISA directly with MRC Unit Directors using publicly available email addresses. MRC Unit Directors are encouraged to share LISA communications with their members. In most cases, potential LISA volunteers will be nurses with active state licenses. LISA may also be of interest to other healthcare professionals experienced in IV infusions, such as physicians, nurse practitioners, and physician assistants. In some states, infusions are within the scope of practice for advanced emergency medical technicians (EMTs), paramedics, and other professions.

<u>STEP 2</u>: LTC facilities interested in LISA should contact their local MRC Unit Director(s) using the <u>"Find MRC Unit" tool</u> (select a state, then click map location(s) for phone/email) and request LISA support.

At the time of launch, the Coalition will also disseminate the LISA announcement and step-by-step instructions broadly to LTC facilities nationwide in cooperation with 5 LTC associations and their respective state chapters. These 5 associations are the 4 primary LTC trade associations—the American Health Care Association/National Center for Assisted Living, LeadingAge, Argentum, and the American Seniors Housing Association; plus AMDA — The Society for Post-Acute and Long-Term Care Medicine, which is the association representing nursing home medical directors and other clinical staff. If MRC Unit Directors are unaware of LISA, LTC facilities are encouraged to share LISA communications with them. It should be noted that local MRC units vary widely in terms of capacity, capabilities, and competing priorities; MRC units might or might not be able to satisfy requests for LISA support.

<u>STEP 3</u>: MRC Unit Director(s) are encouraged to share local requests for LISA support with their members and identify potential qualified and interested LISA volunteers.

Ideally, at this step, MRC Unit Directors will confirm and record the status of potential LISA volunteers' background checks, licensure, and other readiness measures.

<u>STEP 4</u>: Interested MRC volunteers should sign up for LISA <u>here</u> and complete 4 required, open-access online training modules:

- Module 1—Infection prevention for LTC facilities [30 minutes total]
 - a. Keep COVID-19 OUT!
 - b. PPE
 - c. Clean Hands
 - d. Successfully complete quiz with at least 80% correct (3 attempts)
- Module 2—General LTC/nursing home orientation [60 minutes total]
 - a. The 4 types of LTC facilities
 - b. Residents and common diagnoses
 - c. LTC facility mandatory abuse/neglect reporting requirements
 - d. Safety in LTC
 - e. Communication practices for engaging residents
 - f. COVID-19 and infection control
 - g. LTC facility regulations (42 CFR 483 and CMS State Operations Manual, Appendix PP)
 - h. Assisted living regulatory environment
 - i. Successfully complete quiz with at least 80% correct (3 attempts)
- Module 3—Resources/links for CmAb therapies issued EUAs (as of 2/9/21, n=3 CmAb therapies) [60 minutes total]
 - a. Bamlanivimab (Eli Lilly and Company)
 - b. Casirivimab/Imdevimab (Regeneron Pharmaceuticals, Inc.)
 - c. Bamlanivimab/Etesevimab (Eli Lilly and Company) [Note: Resource page being developed; as of 3/2/21, U.S. Government not yet distributing etesevimab]
 - d. COVID-19 Therapeutics: Monoclonal Antibody Playbook
 - e. Successfully complete quiz with at least 80% correct (3 attempts)
- Module 4—Infusion therapy refresher training [60 minutes total]
 - a. Peripheral vascular access
 - b. Preparation of parenteral medications
 - c. Infusion reaction identification and management
 - d. Vascular access device complications
 - e. Successfully complete quiz with at least 80% correct (3 attempts)
- Receive a certificate of completion after successfully completing all 4 modules

<u>STEP 5</u>: The MRC Unit Director will reach out to the Human Resources Director of a nearby infusion center using the <u>National Infusion Center Association (NICA) locator tool</u> and inquire about the availability of hands-on training for LISA volunteers in the following core topics:

- 1. IV access
- 2. Preparation of parenteral medications/aseptic technique
- 3. Administering CmAb infusions (both via IV pump and gravity infusion)
- 4. Monitoring and responding to potential infusion reactions, including anaphylaxis

At the time of LISA launch, NICA will communicate with their member organizations about the opportunity to volunteer as a local infusion training site, if contacted by a MRC Unit Director. In most cases, this training will be a just-in-time refresher since most LISA volunteers should have prior

experience and competence with IV infusions. This hands-on LISA training is recommended, but not required, pending local availability. NICA is a trade association representing approximately 4,000 community non-oncology infusion centers.

<u>STEP 6</u>: The trained LISA volunteer(s) will coordinate with the LTC facility about logistics and any additional pre-requisites, including:

- State or facility-specific regulations or requirements
- COVID-19 testing requirements
- Documentation of active state license, valid background check, completion of LISA training
- Additional trainings (e.g., HIPAA, electronic medical record)
- Details for infusion support, including:
 - a. Number of anticipated infusions and service date(s)
 - b. Specific services requested (e.g., IV access, parenteral medication preparation, and/or infusion support)
 - c. Medical orders (for CmAbs and medications to address infusion reactions, if needed)
 - d. Ancillary support
 - e. Emergency SOPs and POC
 - f. Primary POC

Background Checks and Licensing: Maintenance of valid background checks for MRC members varies by MRC unit and according to state regulations. Almost all MRC members who serve in clinical roles should have active state licenses. LTC facilities can request documentation of LISA volunteers' background checks and licensure from MRC Unit Directors.

If LISA volunteers do not have a valid or adequate background check, LTC facilities are encouraged to conduct their own background checks, if required by state regulations or if background checks are used to satisfy federal requirements to not employ or engage with individuals who have been found guilty of abuse, neglect, or exploitation [42 CFR 483.12 (a)(3) (i-iii)]. CMS administers a National Background Check Program to assist states with identifying efficient, effective, and economical procedures for conducting background checks.

Liability: 1) For MRC units—Participating MRC units should ensure they have sufficient liability coverage addressing the proposed clinical activities of their LISA volunteers. **2) For LTC facilities**—Potential liability related to the use of emergency countermeasures, such as COVID-19 CmAbs, is mitigated through the <u>Public Readiness and Emergency Preparedness (PREP) Act</u>, which provides immunity from liability (except for willful misconduct) for specified claims. The U.S. Government-funded <u>Countermeasures Injury Compensation Program</u> offers additional protection.

Billing for CmAb Infusions: Since the U.S. Government has purchased the initial supply of CmAbs from manufacturers, there is no cost to facilities or providers for these drugs. CMS has established a Medicare CmAb administration reimbursement rate (approximately \$310) that applies in all healthcare settings. For patients covered by Medicaid and/or commercial payers, reimbursement for administration might vary (see CMS infographic) and should be discussed with each payer.

As volunteer organizations, local MRC units and their volunteers will not request payment for their services and will not bill to collect reimbursement for CmAb administration. LTC facilities and their providers can bill for administration as long as there is a medical order in the patient's record. It should be noted that CMS currently classifies CmAb therapies as a "type of vaccine", which in part, allows for CmAbs to be administered and billed for in nursing homes above the daily bundled nursing home rate.

LISA 2.0: If LISA is successful, trained volunteers can potentially administer infusions in other settings (e.g., correctional facilities, federally qualified health centers, home infusion) that also serve high-risk populations and face similar staffing limitations. If needed, setting-specific training (akin to Module 2 of the LISA curriculum) can be developed in partnership with relevant associations. LISA may also be a viable pathway for non-MRC clinical volunteers.

Contact: If you have questions or comments about LISA, please email educate@ahca.org.

References

- 1. More than 100,000 U.S. deaths are linked to nursing homes. *New York Times*. December 4, 2020. Accessed January 4, 2021. https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html
- 2. Chen P, et al, for the BLAZE-1 Investigators. SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19. *N Engl J Med*. October 28, 2020. DOI:10.1056/NEJMoa2029849.
- 3. Weinreich DM, et al, for the Trial Investigators. REGN-COV2, a Neutralizing Antibody Cocktail, in Outpatients with Covid-19. *N Engl J Med*. December 17, 2020. DOI:10.1056/NEJMoa2035002.