ASPR TRACIE Technical Assistance Request

Request Receipt Date (by ASPR TRACIE): 21 June 2024
Response Date: 27 June 2024
Type of TA Request: Standard

Request:

The requestor asked for resources related to the availability of intravenous (IV) infusions for the prophylaxis/treatment of COVID-19 and potentially other special pathogens. They would like resources such as sample memorandum of understanding (MOUs) between counties and medical providers to arrange services, state or regional templates, and other materials identifying lessons learned.

Response:

ASPR TRACIE conducted an online search for relevant resources, including those in the ASPR TRACIE Coronaviruses, Mass Distribution and Dispensing/Administration of Medical Countermeasures, and Pharmacy Topic Collections. Section I of this document provides sample MOUs, Section II includes guidance documents, Section III provides resources with lessons learned, and Section IV contains additional relevant materials.

I. Sample Memorandum of Understanding

California Department of Public Health. (2008). Government-Authorized Alternate Care Site Operational Tools Manual.

This resource includes templates and checklists to support the operation of an Alternate Care Site (ACS). **NOTE**: A sample MOU template begins on page 104. Although this document is specific to ACSs, the sample MOU can be modified for use when establishing an infusion site.

Franklin County Public Health. (n.d.). Memorandum of Understanding. (Accessed 6/27/2024.)

This template MOU is for organizations who may work with Franklin County Public Health (OH) to provide emergency public health services to affected populations. The document outlines liability, provider responsibilities, Franklin County Public Health responsibilities, terms and implementation. **NOTE**: This document does not address IV infusions specifically but may be tailored to the department's needs.

PACER (Preparedness and Catastrophic Event Response). (2009). Model Memorandum of Understanding Between Hospitals during Declared Emergencies.

This document is a model MOU developed by PACER for hospitals and potentially other healthcare entities to consider within a specified healthcare system. **NOTE**: This document is intended for hospitals, but information can be used and tailored to the needs of a local public health department.

II. Guidance Documents

ASPR. (2024). Federal Response to COVID-19: Therapeutics Clinical Implementation Guide.

While portions of this presentation are no longer relevant, some of the content may be modified for future planning. Slides 47 and 59 offer examples of patient flows and Appendix A has outpatient infusion site resource recommendations.

ASPR. (2021). NDMS Monoclonal Antibody Infusion Material.

While this training presentation was developed in early 2021, some of the content may be informative when establishing a future infusion site.

ASPR. (2024). Sunsetting the U.S. Government COVID-19 Therapeutics Distribution Program.

This webpage provides information to healthcare providers and jurisdictions about the transition of COVID-19 treatments to the commercial market. It includes information about programs established by manufacturers to provide access to these treatments for uninsured and underinsured individuals.

COVID-19 Healthcare Resilience Working Group. (2020). Monoclonal Antibody Infusion Center Model (15 Bed).

While portions of this document are outdated, the staffing, facility layout, supplies, and criteria and protocols information can help healthcare staff at the state, tribal, local, and territorial levels prepare to and deliver therapeutic monoclonal infusions against COVID-19 in an outpatient setting.

Eli Lilly and Company. (2020). Lilly Bamlanivimab Antibody Playbook.

While bamlanivimab is no longer authorized for use, Sections 4, 5, and 6 and Appendix B of this Playbook offer considerations that may be applicable when establishing infusion sites for other therapeutics.

III. Lessons Learned Resources

ASPR TRACIE. (2021). Methods for Monoclonal Antibody (mAb) Therapy.

In this speaker series, Dr. William Fales, MD, FACEP, FAEMS, Medical Director, Michigan Department of Health & Human Services, Division of EMS and Trauma and Professor and Chief, Division of EMS and Disaster Medicine, Western Michigan University describes the statewide approach and support of monoclonal antibody therapy in various healthcare settings.

Çaglayan, Ç., Thornhill, J., Stewart, M., et al. (2021). Staffing and Capacity Planning for SARS-CoV-2 Monoclonal Antibody Infusion Facilities: A Performance Estimation Calculator Based on Discrete-Event Simulations. Frontiers in Public Health. 9:770039.

The authors evaluated 162,000 scenarios to understand the optimal resource allocation at facilities administering monoclonal antibody infusions for COVID-19. They conclude that "physical capacity, check-in staff, and infusion time were as important as nurses for [monoclonal antibody] sites," and that simulations can be an important tool for planning optimal resource allocation for COVID-19 patients receiving monoclonal antibody infusions and other resource optimization.

Lambrou, A.S., Redd, J.T., Steward, M.A., et al. (2022). Implementation of SARS-CoV-2 Monoclonal Antibody Infusion Sites at Three Medical Centers in the United States: Strengths and Challenges Assessment to Inform COVID-19 Pandemic and Future Public Health Emergency Use. Disaster Medicine and Public Health Preparedness. 14;1-32.

The authors of this article conducted a descriptive analysis from three sites at medical centers in the U.S. supported by the National Disaster Medical System to examine the monoclonal antibody infusion site process during the COVID-19 pandemic. The authors discuss several successes and challenges in implementing these sites.

Nelsen, G., Pigott, H., Hopkinson, C., and Formea, C. (2020). Considerations for Development of Pharmacy Support Models for COVID-19 Alternate Care Sites. American Journal of Health-System Pharmacy.

This article describes the planning considerations of one health system's pharmacy department to support pharmacy operations at an alternate care site (ACS). Building upon the Federal Healthcare Resilience Task Force ACS Toolkit, U.S. Army Corps of Engineers ACS guidance web page, and crisis standards of care concepts, the pharmacy team developed resource lists to meet the needs of their expected patient population. Included in appendices and tables are: key assumptions and issues in medication list planning for an ACS, key medication-related and staffing questions to consider in alternate site care planning, and considerations and options for IV infusion pump use, staffing, and transitions of care at an ACS.

IV. Other Relevant Resources

ASPR TRACIE. (2021). Monoclonals and More – Allocation and Distribution of Outpatient COVID-19 Treatments (Supplemental Resource).

This resource with information to supplement a webinar conducted in November 2021 is outdated; however the Issues for Allocation and Resources sections may be helpful to inform future planning.

ASPR TRACIE. (2021). Planning Considerations for Monoclonal Antibody Administration.

This tip sheet describes monoclonal antibody therapy for COVID-19 patients and highlights considerations for providers and planning and allocation. The introductory and background information are outdated, but the provider, planning, and allocation considerations may be useful when preparing for future emergencies.