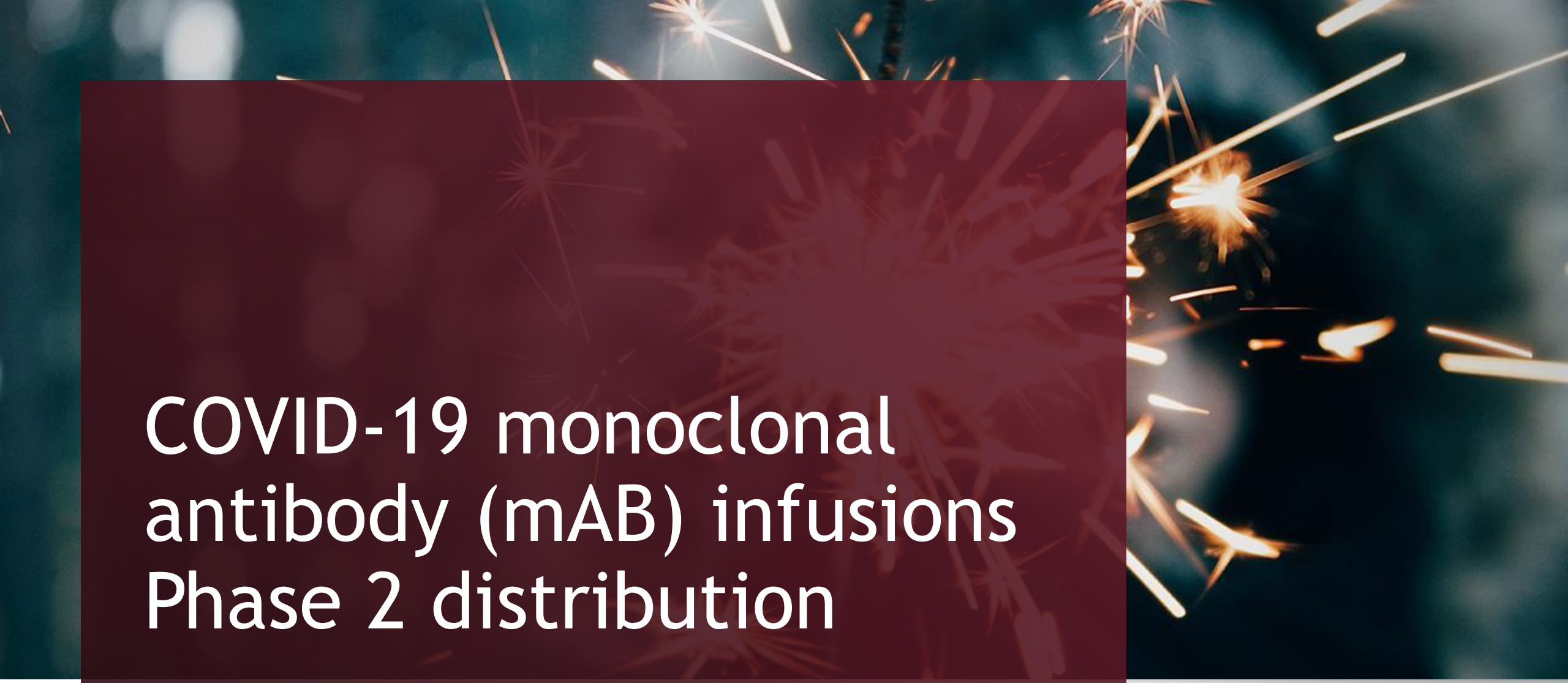


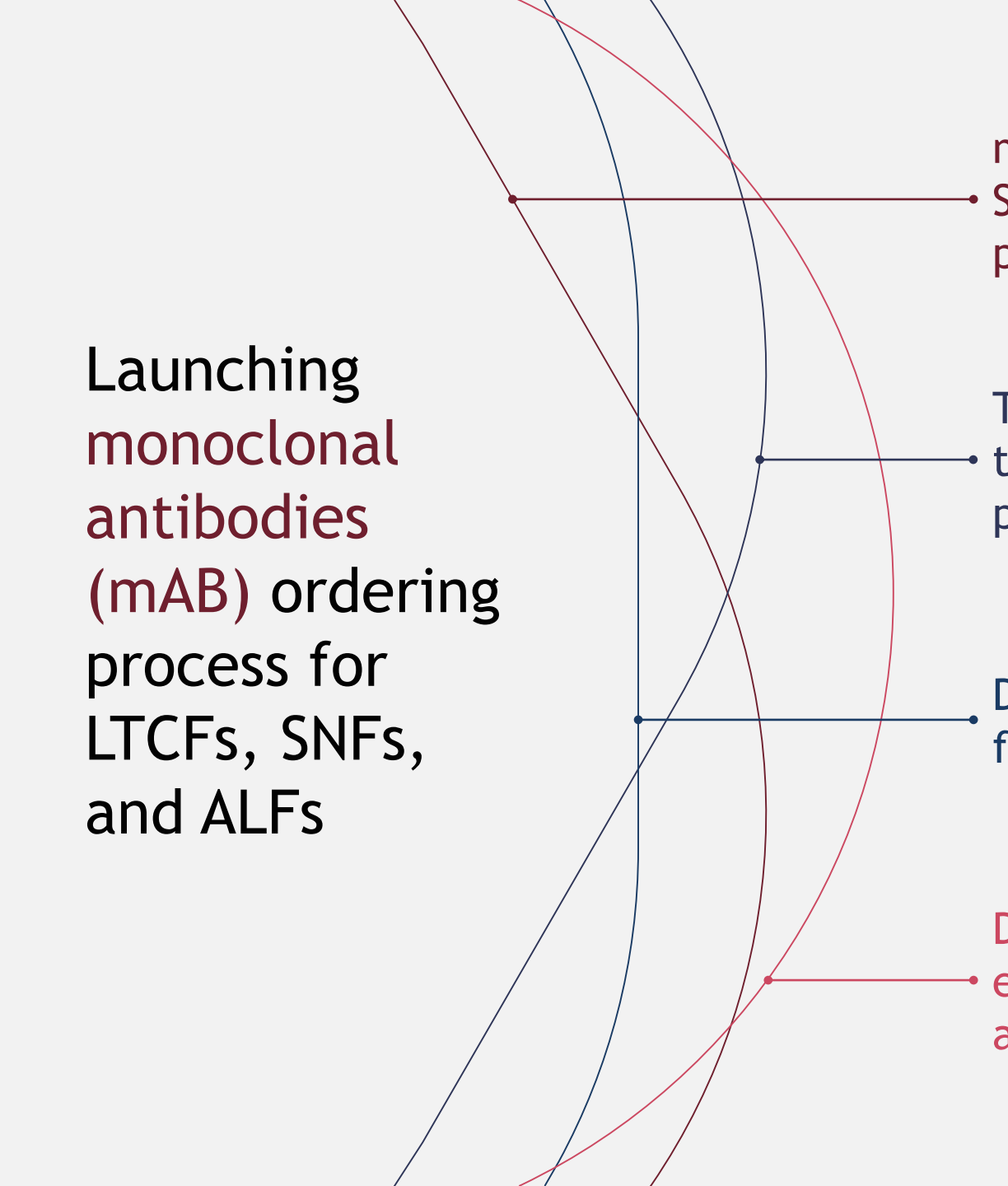
COVID-19 monoclonal antibody (mAB) infusions Phase 2 distribution

Delaware's Division of Public Health ordering process for LTCFs/SNFs/ALFs

JANUARY 2021

DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health

Launching monoclonal antibodies (mAB) ordering process for LTCFs, SNFs, and ALFs



mAB infusions can now be distributed to LTCFs, SNFs, and ALFs for administration to eligible patients

These facilities can provide mAB treatments themselves if capable, or can utilize infusion partners

DPH has developed a form and process for facilities to order mAB infusions

DPH will make further details available to eligible facilities and infusion partners via email and website updates

Monoclonal Antibodies (mAB): Overview, availability, and access information

What is a mAB infusion?

Monoclonal antibodies (mAB) can be administered to a patient via intravenous (IV) infusion in order to treat COVID-19

Monoclonal antibody treatment can only be provided under the order of a physician or licensed practitioner

This treatment is authorized for patients meeting the criteria specified in the FDA's EUAs[1] for these treatments, and, due to the extremely limited supply, patients must:

- Have tested positive for COVID-19 within the prior 7 days
- Be symptomatic
- Be at an increased risk of severe disease
- Not yet be sick enough to be hospitalized

Where is mAB available?

In Phase 1 of mAB distribution, this treatment became available through hospitals and health systems

In Phase 2, which is beginning now, mAB will be available for distribution through other non-hospital facilities such as long-term care centers; these facilities may provide mAB themselves if capable and willing, or can use an infusion partner

Given that supply is extremely limited, it is critical for providers to administer mAB in accordance with the criteria and protocol set forth by the FDA and CDC to ensure maximum effectiveness of available infusions

What are next steps to access?

For facilities wishing to provide mAB to eligible patients:

- Interested facilities can offer mAB internally if capable and willing, or can contact an infusion provider partner to coordinate a distribution plan
- Each facility can apply for an allocation of mAB for up to a 14-day period at a time, and will be asked to assert that they will administer mAB per proper protocol
- DPH will review all orders and allocate what is available on a pro-rata and demand-driven basis
- Once distributed, facilities may work internally or with their infusion partners to schedule and administer mAB infusions to patients

1. FDA EUA documents for mAB infusions: https://www.fda.gov/media/143602/download, https://www.fda.gov/media/143891/download

DPH mAB infusion ordering process for LTCFs, SNFs, and ALFs will consist of three key steps

1

Facilities submit mAB order and attestation forms

Facility requests mAB infusions for up to a 14-day period by submitting an order form to OEMS@delaware.gov

For first order, facility will also submit a clinically responsible attestation form, asserting understanding of mAB treatment protocols

2

DPH reviews orders and allocates mAB infusions

DPH reviews order and allocates limited supply in pro-rata fashion based upon COVID infection numbers per site if available, otherwise relative number of beds

If allocation is greater than request, remainder will be allocated on pro-rata basis

3

Facilities receive orders and plan for administration

After allocation process is completed, DPH will distribute orders to facilities

Orders will typically be distributed within three to five business days of order

Orders are due by Wednesday of a given week to be by processed by DPH by that Friday

Forms for mAB program: Infusion order and clinically responsible attestation

Order form to be completed by requesting facility for each mAB infusion order

SHOC Resource Form for mAB Events	**Requesting Agency Contact Information**	
Date:	Time:	Event:
Requestor's Name:		Title:
Requestor's Organization:		
Phone #:	Mobile #:	Fax #:
Email Address:		
mAB Distribution Information		
Will administer per mAB protocols? ☐ Yes ☐ No		Partnered w/Infusion Provider: ☐ Yes ☐ No
Asserted by:		Partner name:
Details of Infusion Event (include infusion dates and times, number of patients, requested infusions, and location where infusion will occur)		
mAB Infusion Information		
Number of infusions requested:		Infusions to occur: ☐ On-site at your facility ☐ Off-site (Specify):
Delivery Site Information		
Delivery Address *(include facility name, street, city, state and zip)*:		Drop Off Time:
Delivery Site POC (Point of Contact):		Email:
POC 24-hour Phone #:	POC Mobile #:	POC Fax #:
Additional Information or Comments:		
mAB Infusion Reporting Information		
Is this the first time your site is requesting mAB infusions? ☐ Yes ☐ No		
If answered *Yes* to first time requesting infusion question, please complete the **Clinically Responsible for mAB Infusion** form and submit with this document		
If answered *No* to first time requesting infusion question, please answer the following:		
Number of infusions requested in last order:		Number of infusions used from last order:
For infusions administered, please describe outcomes:		
No. of transfers:		No. of adverse reactions:
No. of hospitalizations:		No. of deaths:
Please submit this completed form to OEMS@delaware.gov. The remainder of this document is for internal processing.		

Clinically responsible attestation form to be completed upon submission of first mAB order

Clinically Responsible for mAB Infusion Form To be completed by the clinically responsible person at each site administering mAB infusions on or before the submission of that site's first mAB order		
Monoclonal antibodies (mAB) can be administered to a patient via intravenous (IV) infusion in order to treat COVID-19. Monoclonal antibody treatment can only be provided under the order of a physician or licensed practitioner. Given that supply is extremely limited, it is critical for providers to administer mAB in accordance with the criteria and protocol set forth by the FDA and CDC to ensure maximum effectiveness of available infusions. To acknowledge your understanding of these criteria and the proper administration of mAB infusions, please initial by each of the criteria below and sign the bottom of the form in the designated fields.		
I understand that to receive a mAB infusion, a patient must have tested positive for COVID-19 within the prior 7 days	Initial:	Date:
I understand that to receive a mAB infusion, a patient must be symptomatic	Initial:	Date:
I understand that to receive a mAB infusion, a patient must be at an increased risk of severe disease	Initial:	Date:
I understand that to receive a mAB infusion, a patient must not yet be sick enough to be hospitalized	Initial:	Date:
I assert that I will administer mAB infusions according to the above criteria as well as any guidelines set forth by the FDA and CDC in order to use these infusions appropriately given their limited supply	Initial:	Date:
Clinically Responsible Signature and Contact Information		
Clinically Responsible Person's Signature:	Date:	
Clinically Responsible Person's Name:	Title:	
Clinically Responsible Person's Organization:		
Phone #:	Mobile #:	Fax #:
Email Address:		
mAB Distribution Information		
Desired date of infusion event:		
Will you partner w/Infusion Provider: ☐ Yes ☐ No		
Partner name (if applicable):		
Please submit this completed form to OEMS@delaware.gov. The remainder of this document is for internal processing.		

DPH provides options for storage and distribution to accommodate varying needs of LTCFs, SNFs, and ALFs

mAB infusion storage information

Basic storage information (for additional information, please refer to EUA documents):

- Eli Lilly's bamlanivimab[1]:
  - Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in original carton to protect from light
  - Do not freeze, shake, or expose to direct light
- Regeneron's casirivimab and imdevimab[2]:
  - Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in the individual original carton to protect from light
  - Do not freeze, shake, or expose to direct light

Infusions should be stored in dedicated medication/pharmaceutical refrigerators with continuous temperature monitoring

DPH mAB infusion distribution options

DPH will deliver mAB infusions refrigerated and undiluted

DPH can deliver infusions to facility's location of choice, e.g., directly to the facility or to a hospital or infusion partner location

- Email confirmation will be required from both the facility and delivery location if different

Facilities can specify distribution and delivery preferences on the mAB infusion order form

- For specific needs or questions beyond the scope of the order form, please email OEMS@delaware.gov

1. Bamlanivimab EUA fact sheet (https://www.fda.gov/media/143603/download) and EUA (https://www.fda.gov/media/143602/download); 2. Casirivimab and imdevimab EUA fact sheet (https://www.fda.gov/media/143892/download) and EUA (https://www.fda.gov/media/143891/download)

Looking for more information?

DPH will share more details on its COVID-19 mAB webpage and with facilities and partners

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