Lilly Bamlanivimab Antibody Playbook

ELI LILLY CANADA INC. | APRIL 2021

For the Interim Authorization of bamlanivimab for the treatment of COVID-19

HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 DRUG BASED ON LIMITED CLINICAL TESTING IN HUMANS AND/OR QUALITY INFORMATION

Bamlanivimab is indicated for:

The treatment of adults and pediatric patients (12 years of age or older weighing 40 kg or more) with mild to moderate COVID-19 who are at high risk of progressing to severe COVID-19 illness and/or hospitalization.

The use of bamlanivimab is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 Interim order (IO)*, pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the sponsor to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

* https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8

Circulating SARS-CoV-2 viral variants may be associated with resistance to bamlanivimab. Health professionals should review pertinent information in section 7 WARNINGS AND PRECAUTIONS, General, and section 15 MICROBIOLOGY, Antiviral Resistance, for details regarding SARS-CoV-2 variants of concern in the product monograph.

Consult the product monograph for important information on contraindications, warnings, precautions, adverse reactions, interactions and dosing. The product monograph is also available through our medical department. Call us at 1-888-545-5972.

Revision Date	Revision Notes
December 17, 2020	Original Version
April 19, 2021	Interim authorization statement, indication, adverse events, preparation and administration

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EXECUTIVE SUMMARY

The world is currently in the midst of a global pandemic. As a global pharmaceutical company, we feel a responsibility to do our part to relieve the burden COVID-19 has placed on countries, communities and families around the world.

Clinical trials have shown that monoclonal antibodies may be effective in treating COVID-19. Lilly in partnership with AbCellara, A canadian company, has developed a monoclonal antibody called bamlanivimab. Bamlanivimab is a recombinant neutralizing human IgG1 monoclonal antibody directed against the spike protein of SARS-CoV-2. It is designed to block viral attachment and entry into human cells, thus neutralizing the virus.

This Antibody Playbook provides information for provincial, territorial and local public health programs to plan and operationalize a bamlanivimab antibody response to COVID-19. The sections of this document cover specific areas of COVID-19 antibody program planning and implementation, as well as links to resources to assist with those efforts. The sections described in this Playbook may also overlap with routine monoclonal antibody treatment and infusion program activities. This playbook represents guidance based on Lilly's Clinical Trial experience and National Infusion Center Association (NICA) experience in monoclonal antibody treatments and should not supersede local requirements for infusion sites of care. Please defer to local guidelines.

In addition, the Playbook includes information regarding planning and implementation based on varying infusion sites of care, such as:

- Existing hospital or community-based infusion sites of care
- Existing clinical space (e.g., primary care practices affiliated with hospital systems, urgent care locations, emergency departments, surgery centers, dialysis centers, plasma centers, respiratory clinics and other health care delivery entities approved to administer infusion therapies)

We expect most infusion treatments will be administered in one of these aforementioned infusion sites of care, but other infusion sites of care may also be considered. **This Playbook provides information that may or may not be applicable to certain spaces depending on existing capabilities.**

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SECTION 01

Population for Antibody Treatment AND Regulatory Notices

POPULATION FOR ANTIBODY TREATMENT

HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 DRUG BASED ON LIMITED CLINICAL TESTING IN HUMANS AND/OR QUALITY INFORMATION.

Bamlanivimab is indicated for:

The treatment of adults and pediatric patients (12 years of age or older weighing 40 kg or more) with mild to moderate COVID-19 who are at high risk of progressing to severe COVID-19 illness and/or hospitalization.

Limitations of Benefit in Patients with Severe COVID-19

Bamlanivimab should not be used in patients hospitalized with severe COVID-19 respiratory disease as benefit of treatment has not been observed in this setting.

Bamlanivimab, a monoclonal antibody, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Interim authorization is supported by a numerical reduction in hospitalization or emergency room visits in high risk patients treated with bamlanivimab compared to high risk patients treated with placebo

For more information, refer to the **bamlanivimab Product Monograph**.

High risk is defined as patients who meet at least one of the following criteria:

- Are ≥65 years of age
- Have a body mass index (BMI) ≥35 for patients ≥ 18 years of age
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥55 years of age AND have
  - cardiovascular disease, OR
  - hypertension, OR
  - chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have
  - BMI ≥85th percentile for their age and gender based on CDC growth charts, **https://www.cdc.gov/growthcharts/clinical_charts.htm**, OR
  - sickle cell disease, OR
  - congenital or acquired heart disease, OR
  - neurodevelopmental disorders, for example, cerebral palsy, OR
  - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

†Patients with **mild** COVID-19 illness may exhibit a variety of signs and symptoms (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell). They do not have shortness of breath, dyspnea on exertion, or abnormal imaging.

Moderate COVID-19 illness is defined as evidence of lower respiratory disease during clinical assessment or imaging, with SpO2 ≥94% on room air at sea level.

Source: National Institutes of Health

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Bamlanivimab must be administered by intravenous (IV) infusion.

Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

Health care providers can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html)
- Calling toll-free at 1-866-234-2345

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

- The recommended dose of bamlanivimab is a single intravenous (IV) infusion of 700 mg administered as soon as possible after positive test for COVID-19 using a direct SARS-CoV-2 validated testing method within 10 days following the onset of clinical signs and symptoms of infection.

- Bamlanivimab is available as concentrated solution and must be diluted prior to administration.
- Administer bamlanivimab 700 mg via IV infusion over at least 60 minutes via pump or gravity.
- Clinically monitor patients during infusion and observe patients after infusion is complete according to standard practice.
- Patients treated with bamlanivimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and frequent handwashing) according to public health guidelines.

The authorized dosage may be updated as additional data from clinical trials becomes available.

For information on clinical trials that are testing the use of bamlanivimab in COVID-19, please see **www.clinicaltrials.gov**.

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†Patients with **mild** COVID-19 illness may exhibit a variety of signs and symptoms (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell). They do not have shortness of breath, dyspnea on exertion, or abnormal imaging.

Moderate COVID-19 illness is defined as evidence of lower respiratory disease during clinical assessment or imaging, with SpO2 ≥94% on room air at sea level.

Source: National Institutes of Health

IMPORTANT SAFETY INFORMATION

There are limited clinical data available for bamlanivimab. Serious and unexpected adverse events may occur that have not been previously reported with bamlanivimab use.

Potential Risk of Treatment Failure due to Antiviral Resistance

There is a potential risk of treatment failure due to the development of viral SARS-CoV-2 variants that are resistant to bamlanivimab. Health professionals should review the Antiviral Resistance information in section 15 of the Product Monograph for details regarding SARS CoV-2 variants of concern. Use of bamlanivimab alone should only be considered if other monoclonal antibodies that retain neutralization activity against prevalent variants are not available.

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

There is a potential for serious hypersensitivity reaction, including anaphylaxis with administration of bamlanivimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy.

Infusion-related reactions have been observed with administration of bamlanivimab. Signs and symptoms of infusion related reactions may include:

- Urticaria, pruritis, rash, swelling of the face, and chest discomfort.

If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.

Limitations of Benefit and Potential Risk in Patients with Severe COVID-19

Bamlanivimab should not be used in patients hospitalized with severe COVID-19 respiratory disease as benefit of treatment has not been observed in this setting. Bamlanivimab, a monoclonal antibody, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Adverse Events

Treatment-emergent Adverse events reported in ≥ 1% of All Bamlanivimab-Treated Participants vs Placebo were: urinary tract infection (1.4% vs 1.8%), dizziness (1.3% vs 1.3%) and hypertension (1.2% vs 1.4%). Additionally, anaphylaxis occurred in 0.2% and infusion related reactions occurred in 1.3% of all bamlanivimab-treated participants.

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IMPORTANT SAFETY INFORMATION

Use in Specific Populations

Pregnancy

There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcome. Bamlanivimab should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Breastfeeding

There are no available data on the presence of bamlanivimab in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for bamlanivimab and any potential adverse effects on the breastfed child from bamlanivimab or from the underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

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SECTION 02

Infusion Site of Care Requirements

INFUSION SITE OF CARE REQUIREMENTS

Preparation, Storage and Handling

Prepare sterile infusions in a manner consistent with local laws, regulations, guidelines and policies. This playbook represents Canadian guidance based on Lilly's Clinical Trial experience and National Infusion Center Association* (NICA) experience in monoclonal antibody treatments and should not supersede local requirements for infusion sites of care. **Please defer to local guidelines**.

- Use aseptic technique and applicable good clinical practice for intravenous solution preparations of bamlanivimab in accordance with NICA standards.
- Only use materials which are listed as compatible with bamlanivimab for preparation and administration of the infusion solutions (see **Compatible Materials** section below).
- Gather the recommended materials for infusion:
    - Polyvinylchloride (PVC) infusion set containing a 0.20/0.22 micron filter.
    - Use new, sterile syringes and needles to prepare each dosing solution of bamlanivimab.
- Refrigerate bamlanivimab drug product when not in use at 2°C to 8°C (36°F to 46°F).
- Bamlanivimab should be free of any visible particulate matter. Obtain new vial(s) and/or IV bags if the drug product contains any visible particulate matter.
- All medication must be stored, inventoried and destroyed according to applicable regulations.
- Bamlanivimab is administered by intravenous (IV) infusion either using an infusion pump or gravity infusion. Consider use of a rate control or infusion rate monitoring device if using gravity infusion. Tubing with an integrated rate flow regulator can also be considered if an infusion pump is not available.
- The IV solutions are intended for immediate patient administration. If immediate administration is not possible, store the diluted bamlanivimab infusion solution for up to 48 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) and up to 14 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration. The hold time includes preparation, solution hold, infusion and flush. Any solution which exceeds these time period requirements MUST BE DISCARDED and a fresh solution MUST BE PREPARED.

Find more information on National Infusion Center Association (NICA) standards for outpatient infusion.

Compatible Materials

Individual infusion sites of care should follow best medical practices when determining materials to use. Procurement of materials from a specific vendor or vendors is not required. If alternate materials are used, the compatibility of these materials should be confirmed with that vendor. Bamlanivimab has no known incompatibilities with conventional medical supplies and equipment. During clinical trials, Lilly has used the following materials:

- Polypropylene syringes
- Stainless steel needles
- Polyvinylchloride (PVC) IV bags with or without DEHP
- Polyvinylchloride (PVC) infusion sets with or without DEHP containing an in-line polyethersulfone (PES)* filter (Please see footnote.)

Storage

Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze, shake or expose to direct light.

Preparation

Bamlanivimab for injection must be diluted with 0.9% Sodium Chloride. The solution for infusion should be prepared by a qualified healthcare professional using aseptic technique:

- Gather the materials for preparation:
    - Polyvinyl chloride (PVC) or polyethylene (PE)-lined PVC, sterile infusion bag.
        - Prefilled 250 mL infusion bag containing 0.9% Sodium Chloride Injection. Only 0.9% Sodium Chloride should be used for dilution.
    - One 20 mL vial of bamlanivimab (700 mg/20 mL)
- Remove the bamlanivimab vial from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not expose to direct heat. Do not shake.
- Inspect bamlanivimab visually for particulate matter and discoloration.
    - Bamlanivimab is a clear to opalescent and colorless to slightly yellow to slightly brown solution.
    - If particulate matter or discolorations are identified, discard the vial.
- Withdraw 20 mL bamlanivimab from 1 vial and inject into a prefilled infusion bag containing 250 mL of 0.9% Sodium Chloride Injection. Gently invert IV bag by hand approximately 10 times to mix.
- Discard any product remaining in the vial.
- This product is preservative-free and therefore, the infusion solution should be administered immediately.
    - If immediate administration is not possible, store the bamlanivimab infusion solution for up to 48 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) and up to 14 hours at room temperature (20°C to 25°C [68°F to 77°F]) including transportation and infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration.

*If alternate materials are used, the compatibility of these materials should be confirmed with that vendor. Bamlanivimab has no known incompatibilities with conventional medical supplies and equipment.

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Administration

Bamlanivimab for injection should be administered by a qualified healthcare professional.

- Gather the recommended materials for infusion:
    - Polyvinylchloride (PVC) or polyethylene (PE)-lined PVC infusion set
    - Use of an in-line or add-on 0.20/0.22 micron polyethersulfone (PES) filter is strongly recommended.
- Attach the infusion set to the IV bag.
- Prime the infusion set.
- Administer the entire infusion solution in the bag via pump or gravity over at least 1 hour at a minimum infusion rate of 270 mL/h. Due to potential overfill of prefilled bags, the entire infusion solution in the bag should be administered to avoid underdosage. Do not co-infuse with electrolytes of other medications.
- Once infusion is complete, flush the tubing to ensure delivery of the required dose.
- Clinically monitor patients during administration and observe patients after infusion is complete according to standard practice.
- If the infusion must be discontinued due to an infusion reaction, discard any unused product.

*If alternate materials are used, the compatibility of these materials should be confirmed with that vendor. Bamlanivimab has no known incompatibilities with conventional medical supplies and equipment.

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Infusion sites of care can use the following chart to calculate a 60 minute drip rate when administering via gravity infusion.

60 Minute Drip Rate for Gravity Infusion				
VTBI (mL)	**Duration (min)**	**Drip factor (drops per milliliter)**	**Drops per minute**	**Drops per 15 seconds**
200	**60**	**10 gtt/mL**	**33 gtt/min**	**8 drops per 15 seconds**
200	**60**	**12 gtt/mL**	**40 gtt/min**	**10 drops per 15 seconds**
200	**60**	**15 gtt/mL**	**50 gtt/min**	**13 drops per 15 seconds**
200	**60**	**20 gtt/mL**	**67 gtt/min**	**17 drops per 15 seconds**
200	**60**	**60 gtt/mL**	**200 gtt/min**	**50 drops per 15 seconds**

- At the discretion of the infusion site of care medical staff, the proposed infusion rate may be reduced and the corresponding infusion time increased for infusion reactions or patient circumstances.
- This product is preservative-free and therefore, the diluted infusion solution should be administered immediately. If immediate administration is not possible, store the diluted bamlanivimab infusion solution for up to 48 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) and up to 14 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time. If refrigerated, allow the infusion solution to equilibrate to room temperature for approximately 20 minutes prior to administration. The hold time includes preparation, solution hold, infusion and flush. Any solution which exceeds these time period requirements MUST BE DISCARDED and a fresh solution MUST BE PREPARED.
- After the entire infusion **has been administered**, flush the infusion line as per infusion site of care requirements or with sufficient volume to flush residual volume from tubing to ensure patient receives entire dose. Discard unused product.
- For additional information, please see **Bamlanivimab Product Monograph.**

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SECTION 03

Recommended Infusion Site of Care Resources and Equipment Considerations

STAFFING RECOMMENDATIONS

Staffing requirements may vary by jurisdiction. Follow your local requirements when determining the staff needed for your infusion site of care. Based on Lilly's clinical trial experience, the following roles should be considered to ensure the safest care environment for patients receiving bamlanivimab antibody infusion.

Infusion sites of care should have appropriately trained medical staff to administer infusion treatments and identify and manage potential adverse reactions. It is recommended that participants who experience a systemic hypersensitivity reaction be treated per the local standard of care.

Role	Recommendations
Patient intake	Person with basic administrative skills
Drug infusion preparation	Health care professional trained in IV admixture preparation (such as a nurse, pharmacist, pharmacy tech)
Infusion: start IV	Health care professional trained to start an IV
Infusion: administer infusion	Health care professional trained in IV admixture preparation (such as a nurse, pharmacist, pharmacy tech)
Infusion monitoring	Healthcare professional trained in: • assessing infusion-related reactions • treating infusion-related reactions • vital sign monitoring
Post-infusion observation	Healthcare professional trained in: • assessing infusion-related reactions • treating infusion-related reactions • vital sign monitoring • providing discharge education for the patient
Patient release	Person with basic administrative skills
Waste removal and cleaning	Person trained in COVID-19 cleaning and disinfection

Notes:

- At least one health care professional should have appropriate training and demonstrated competencies.
- The same health care professional may perform more than one role.
- Provincial or country requirements may dictate specific qualifications for some roles.

INFUSION SITE OF CARE MATERIALS

Equipment requirements may vary by jurisdiction. Follow your local requirements when determining the equipment needed for your infusion site of care. Based on Lilly's clinical trial experience, the following equipment should be considered to ensure the safest infusion site of care environment for patients receiving bamlanivimab antibody infusion. Additional recommended equipment and emergency medical supplies can be found in Appendix B.

Below are recommended non-consumable materials which are needed in an infusion site of care:

- Infusion pumps (if available)
- Infusion pump bracket for IV pole (if available)
- Chairs for infusion
- Mobile IV poles
- Emergency medical management equipment and backboard, including a reaction management kit (see Appendix B)
- Privacy screens
- Chairside table
- Locking refrigerator with temperature monitoring capability
- Transilluminator (vein finder)
- Vital sign monitoring equipment (see Appendix B)

Below are recommended consumable items which are needed in an infusion site of care:

Consumable Items Recommended supplies are based on Lilly's clinical trial experience.

PPE	Infusion supplies*	General supplies
Gloves	IV and catheters**	Biohazard disposal bag
Gowns	0.20/0.22µm filter	Disposable disinfecting wipes
Eye and face protection (e.g., goggles, safety glasses, face shields)	250mL PVC IV bags (infusion prep), if required	Thermometer probe covers (if required)
NIOSH-certified, disposable N95 filter facepiece respirators or better	250mL 0.9% sodium chloride (infusion prep)	70% alcohol wipes
	Pre-filled saline syringes	Paper towels
	Appropriately sized syringes	Trash bins and liners
	Alcohol wipes	Infusion Reaction Kit (see Appendix B)
	2x2 gauze pads	
	Adhesive bandages	
	Tegaderm bio-occlusive dressing	
	Absorbent underpads (blue pads)	
	Extension set tubing	
	Sterile needles - stainless steel 18ga	
	IV administration sets (tubing)	
	Sharps containers	
	Transpore tape	

* Listed supplies are reflective of quantities/volumes used in Lilly clinical trials. Infusion sites of care may substitute alternate quantities and volumes as needed based on best medical practices and local requirements.

**24g catheter is sufficient

SECTION 04

Education and Awareness

EDUCATION AND AWARENESS

Attacking the coronavirus will require a diverse set of approaches, including both vaccines and treatments, such as antibodies.

Q. What's the difference between vaccines and monoclonal antibody drugs?

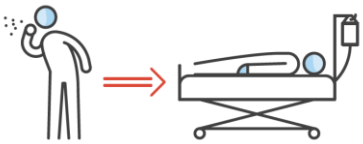
A. While there are some similarities, here's how they are different:

- Monoclonal antibody drugs, like bamlanivimab, provide passive immunity by giving the body antibodies to protect itself. Vaccines provide active immunity by helping the body make its own antibodies to protect itself.
- Monoclonal antibody drugs are designed to start working faster than vaccines, while protection provided by vaccines will generally last longer.
- Generally, scientists are able to develop antibody treatments faster than they are able to develop vaccines.

Developing any approach against COVID-19 involves assessing key factors:

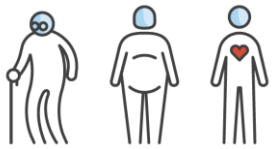
Viral exposure

A vaccine will not help an already-infected patient



Stage of disease

When to apply the medicine to prevent the infection or treat the disease



At-risk populations

Factors linked to worse outcomes (e.g., age, concurrent diseases)

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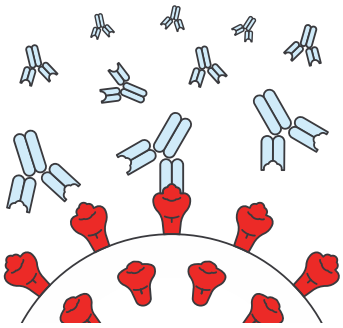
NEUTRALIZING ANTIBODIES AS POTENTIAL TREATMENTS

Identified and characterized using various methods, including from the blood of COVID-19 survivors, neutralizing antibodies target the viral spike protein that SARS-CoV-2 uses to gain entry into host cells. Neutralizing antibodies, therefore, are specifically designed to treat COVID-19.



Q. What are antibodies?

A. Antibodies are naturally made in our bodies to fight infection.

- Whenever the immune system meets a new foreign substance in the body, it makes new antibodies that attack the foreign substance. The next time that substance shows up, the immune system can produce the same antibodies to help the body fight it off before it can make a person sick. These types of naturally occurring antibodies provide active immunity.
- Vaccines work in a similar way, helping the body make antibodies to attack specific foreign substances and providing active immunity in the body.
- Antibody drugs are different. They are man-made antibodies that are given directly through an infusion or injection rather than prompting the body to make the antibodies for itself. This type of immunity is called passive immunity.

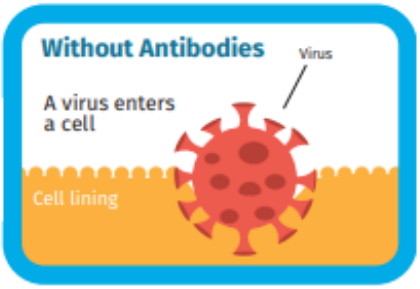
Find more information about monoclonal antibody drugs and vaccines from the following resources:

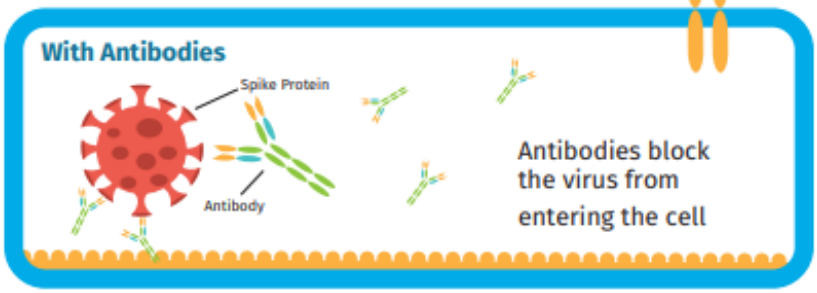
- **www.coronavirusprevention network.org**

Monoclonal Antibodies

What are antibodies?

Antibodies are naturally made in our bodies to fight infection.





What are **MONOCLONAL ANTIBODIES?**

Monoclonal antibodies **(mAbs)** are antibodies developed in a laboratory to help our bodies fight infection.

Nearly **100** mAbs are FDA* approved to treat health conditions including cancers and autoimmune diseases.

mAbs are also being studied for the treatment and prevention of COVID-19.

How are mAbs administered?

mAbs are given through intravenous infusion (i.e., through a vein) or injection.

OR

How often infusions or injections of mAbs are needed depends on the specific mAbs.

What are common side effects of mAbs?

Allergic reactions | Flu-like Symtoms | Nausea & Vomiting | Diarrhea | Low blood pressure

ama-assn.org cancer.org mayoclinic.org medicinenet.com nature.com synabs.be uptodate.com

COVID-19 Prevention Network
PreventCOVID.org

* Health Canada has also approved several mAbs

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APPENDIX A

Lilly Monoclonal Antibody Clinical Trial Modeling Information

LILLY MONOCLONAL ANTIBODY CLINICAL TRIAL MODELING INFORMATION

Assuming the infusion site of care setup details provided below, this information can be used to model the estimated number of infusions (patients) an infusion site of care can serve, depending on its capacity.

Each infusion site of care will vary in terms of the amount of chairs for infusion, staffing considerations, work day length and more. The information provided here is meant as a general guide based upon Lilly's clinical trial experience. In some cases, ideal criteria are included, such as for observation time. In other instances, such as the consent and intake time, there are estimated ranges shown, with "+" or "-" conditions in parentheses.

Infusion Timing

Criteria	Details	Additional Notes
Consent and intake time	30 min (+/- 15 min)	Consent and intake may occur outside of the infusion chair, such as at the prescriber's location, and consent and intake time may vary per patient.
IV prep time	30 min	This step usually does not take place until the patient is in the chair for infusion and vascular access has been obtained.
Infusion time	60 min (+30 min)	Infusion time should be a minimum of 60 minutes, although more time may be necessary.
Observation time*	60 min (approx.)	It is clinically recommended to monitor patients during infusion and observe patients according to standard practice after infusion is complete. Sites of care should follow local requirements when determining appropriate observation periods.
TOTAL TIME	**165–225 min (approx.)**	**This represents the estimated total time from consent through observation of the patient.**

*It is recommended that infusion sites of care have a protocol in place for patients who refuse to stay for post-infusion observation. For example, this may include an AMA form, release of responsibility waiver, etc.

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APPENDIX B

Basic Equipment Recommendations

BASIC EQUIPMENT RECOMMENDATIONS

Equipment requirements may vary by jurisdiction. Follow your local requirements when determining the equipment needed for your infusion center. Based on Lilly's clinical trial experience, the following equipment should be considered to ensure the safest care environment for patients receiving bamlanivimab antibody infusion.

Basic Equipment Recommendations	
Drug preparation	Locked refrigerator with min/max temp monitoring Prep table or area 18ga needles Appropriate sized syringes 250mL PVC IV bags (infusion prep), if required 250mL 0.9% sodium chloride Sterile alcohol prep pads PPE gloves all sizes PPE face shields or goggles PPE N95 masks Sharps containers Drug transport bags (if using mobile pharmacy) Alcohol sanitizing wipes Step-by-step instruction sheet (with images)
Patient intake and release	Signage with patient instructions Phone for intake worker Schedule or list of appointments Office supplies (e.g. pens, stapler, scissors, paper clips, etc.) Clipboard with patient intake and monitoring sheet Patient intake and monitoring form Check-in table Chair(s) for check-in staff Bleach sanitizing wipes Hand sanitizer PPE gloves all sizes PPE face shields or goggles PPE N95 masks PPE gowns

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Basic Equipment Recommendations

Infusion area supplies	Chairs for infusion Chairside table IV poles IV pump (or gravity feed) Vital signs monitoring equipment (BP, HR, resp rate, temp, 02 sat) Supply cart or other storage cabinet Hand sanitizer Hand soap Biohazard trash can Bleach wipes (cleaning non-electronic equipment) Alcohol wipes (cleaning electronic equipment) Medical emergency supplies Sterile alcohol prep pads IV catheters IV extension tubing Tourniquet PVC infusion sets 0.20/0.22µm filter Gauze pads Adhesive bandages 0.9% sodium chloride flush syringes Bio-occlusive dressing Tape 50mL 0.9% sodium chloride bags PPE-gloves all sizes PPE-face shields or goggles PPE-N95 masks PPE-gowns
Observation area	Vital signs monitoring equipment (BP, HR, resp rate, temp, 02 sat) Table for staff Chairs for patients and staff Bleach sanitizing wipes Hand sanitizer PPE-gloves all sizes PPE-face shields or goggles PPE-N95 masks PPE-gowns

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MEDICAL EMERGENCY SUPPLIES AND MEDICATIONS

Emergency medical management equipment should contain the following items:

Some medications listed below should only be administered by HCP with appropriate qualifications

	Essential	Recommended
Medications	Salbutamol inhaler Diphenhydramine injection Epinephrine 0.1 mg/mL (1 mg/10mL) OR epinephrine auto-injector 0.3 mg Methylprednisone injection	Adenosine injection Atropine sulfate Chewable ASA Dextrose 50% injection Insta glucose Nitroglycerine Ondansetron injection Sodium bicarb injection
IV supplies	0.9% Sodium chloride flush (10mL) 0.9% Sodium chloride bag (500mL)	IV admin set IV start kit IV catheter Non-DEHP cath/extension set 5% dextrose bag
Airway	Barrier mask for CPR Ambu Bag	Nasopharyngeal/oral airway suction
Emergency medical management	Infusion sites of care should have a standard operating procedure in place instructing infusion site of care staff how emergency events should be managed, including appropriate contacts (911, physician, etc.), ACLS protocol and any follow-up activities.	

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