Monoclonal Antibody Therapy for COVID+ Patients at Mass General Brigham

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Key Background

• Two emergency use authorizations issued for monoclonal antibody therapy for outpatients with mild to moderate Covid-19 at high risk of progressing to severe disease

• Multiple challenges
  o Outpatient infusions for infectious patients
  o Scarce drug and infusion capabilities
  o Need to infuse patients early in course of disease
  o Serious concerns about equitable distribution
  o Shared decision making in setting of weak evidence base
Emergency Use Authorizations (EUAs)

- Emergency use authorizations (EUAs) for two monoclonal antibody (mAb) therapies (bamlanivimab and casirivimab/imdevimab) to treat outpatients with mild to moderate COVID-19 who are at high risk of progressing to severe disease.
- Outpatients with mild or moderate symptoms
- No more than 10 days of symptoms
- Age ≥ 65
- Adults with BMI ≥ 35
- CKD, diabetes, immunosuppressed
- Age ≥ 55 with cardiovascular disease, hypertension, COPD or other chronic respiratory conditions
- Age 12-17 with variety of conditions (e.g., sickle cell, obesity)
- Excluded if newly hypoxic or requiring more than baseline supplemental O2
Core allocation principles

- **Facilitate research**: Important to ensure we get more definitive answers.
- **Promote equity**: Ensure access to hard hit communities and vulnerable patients.
- **Ensure safety**: Small chance of serious adverse events and may be harmful later in disease.
- **Act quickly**: Deliver within short time window after test performance.
- **Maximize benefit**: Give to those most likely to be helped.
- **Optimize shared decision making**: Challenging with paucity of data.

mAbs for COVID-19
Key Challenges

• How are patients identified for entry into a lottery to minimize referral bias in favor of those with access and privilege?
  • Equity favors entering patients automatically if eligible
  • But may get low yield and have unused capacity

• How is shared decision making done and by whom?
  • Challenging messaging given unclear benefits

• How is research preserved?
  • Prior EUA’s have interfered with ability to enroll in trials

• What does it mean to equitably distribute a therapy that might not work?
Mass General Brigham (MGB) Approach

• **Eligibility:** Patients age >=65 or with BMI >=35 are considered eligible for this treatment currently.

• **Automated Internal Referral Pathway (phase 1):** to ensure timely process

• **Option to Opt Out:** If a provider does not wish for their patient to be considered for this treatment, they may opt out when submitting the COVID test order

• **Lottery to Ensure Equity:** All patients tested within the MGB system meeting this eligibility criteria are automatically referred to a lottery and may be contacted by our COVID hotline to offer the option of receiving this treatment

• **Shared Decision Making:** Assent process prior to scheduling with provider

• **At Home** treatment pathway option (CVS/Coram or NELC)

• **External Referral Pathway (phase 2):** Clinician directed referral pathway for patients tested inside and outside the MGB system
**Intentional Referral:** As of 1/5/21, MGB clinicians are able to refer outpatients with a positive SARS-CoV-2 test performed anywhere who are either age ≥ 65 and/or have BMI ≥ 35 for mAb therapy in Epic.

- In order to place a referral, clinicians will need to verify:
  - The referral the date the positive test was performed
  - The date symptoms started
  - **Shared Decision Making:** They will also have to verify that they have discussed the therapy with the patient and that the patient is both eligible and interested in receiving the monoclonal antibodies. It will be important to let patients know that it may not be possible to provide the therapy to all patients who are referred.

- If demand for mAb therapy exceeds the ability to provide it on any given day, patients will be selected by lottery (built into the Epic™ system).
CVS has an additional supply of bamlanivimab that it is providing via home infusion through its partner Coram.

Available to patients who live within 75 miles of Norwood, MA.

The referral to CVS is done through a separate pathway:

- To access medication orders must be completed and faxed to the number on the fax order sheet.
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Starting a conversation about mAb therapy

• Giving a drug by emergency use authorization requires patient assent
  ○ Goal is an informed shared decision-making conversation

• Where to start: Establish eligibility for therapy (at MGB)
  1. Age ≥ 65 years old, BMI ≥ 35
     • For BMI ≥ 35 confirm no significant weight loss
  2. First positive test ≤ 3 days ago
  3. Symptoms started ≤ 9 days ago
  4. Symptomatic COVID of mild/moderate intensity
Key Points to review with eligible patients

• What is a monoclonal antibody?
• Practical information about how it’s given
  o Infusion location, mode of delivery, duration of treatment/observation
• What Emergency Use Authorization means
• Summary of what is known about how these therapies may benefit high risk individuals
  o May prevent hospitalization/ED visits in high-risk patients
• Summary of what is known about potential adverse reactions
• Discuss how this will impact vaccination timing
  o Patient should NOT get vaccinated within 90 days of therapy
Special considerations

• Pregnancy & Breastfeeding
  o For all eligible women of childbearing potential please ask about pregnancy and breastfeeding
  o Neither pregnancy nor breastfeeding are necessarily exclusions, but both require careful consideration of risks and benefits to mother and child
  o MGH maternal fetal medicine in available to discuss these cases

• Previously vaccinated
  o We do not know if COVID mAb is safe to give to patients who have already had COVID vaccination
Lottery and Scheduling

- Because of capacity limitations, it is possible all interested and eligible patients will not be able to receive the therapy on a given day. Patients will then be placed in a lottery.
- If the patient is able to receive the therapy, the patient will be contacted by a scheduler and will receive an appointment for infusion for the next day.
- **Treatment will require ~3-4 hours at the infusion center** – this includes checking in, 1 hour for the infusion, and 1 hour for monitoring after the infusion.
- If the patient is within 30 miles of the hospital and needs transportation, the schedulers may be able to assist in arranging transportation.
- Patients who meet clinical requirements under EUA but do not receive dose allocation can consider ongoing clinical trials of the same or similar therapies. Active MGB clinical trials can be found here: https://rally.partners.org/.

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