Monoclonal Ab Treatment for COVID-19
(Casirivimab/imdevimab)

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Cody Takenaka, MD, MS, CMD
University Of Hawaii Dept of Geriatrics
Mechanism of Action

Monoclonal antibodies keep the virus from your cells

To make you sick, the coronavirus attaches to your cells with a "spike protein," which acts as a little hand.

Monoclonal antibodies form a barrier around the protein to prevent the virus from attaching to your cell.
FDA Emergency Use Authorization

Nov 2020

• Treatment of mild to moderate COVID-19 for patients who are at high risk for severe COVID-19, including hospitalization or death. (Age 65 and up)

July 2021

• Post-exposure prophylaxis of COVID-19 for individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
  - At high risk for exposure to COVID-19, including in the same Nursing Home
  - Not fully vaccinated or immunocompromised
Evidence

Double-blind, Phase 3 Randomized Controlled Trial: Treatment

Patients: PCR+ for COVID, onset of Sx ≤7d (n=3867)

Intervention: placebo, 600mg, or 1200mg of casirivimab/imdevimab IV

Outcomes: 2.2% absolute reduction and a 70% relative risk reduction in COVID-19-related hospitalizations or all-cause deaths in patients who received CAS 600 mg plus IMD 600 mg compared to those who received placebo (p=0.0024).
Workflow

- Review/update facility policy, prepare consent form, order templates & fact sheets

- STAT PCR testing
  - Contact/Droplet precautions

- Fill out order form

- Obtain written or document verbal consent from patient/family

- Inform Attending MD when order is needed

- Fax order & call to confirm receipt with Pharmacy
Administration: Casirivimab 600mg/Imdevimab 600mg co-formulated vial

- 5ml syringes (4), 21g needles to draw, 25/27g needle for SQ injection
- Allow vial to reach room temp (20 min from refrigerator)
- **DO NOT SHAKE VIAL**
- Draw 2.5ml into 4 syringes for a total 10ml dose & administer SQ ASAP (<4hrs at 77degF)
- If IV access is available w/0.2-micron polyethersulfone (PES) filter: Administer the 10ml dose in NS (50ml/20min or slower). Flush line with 25cc NS afterwards.
- Document lot# of vial, date/time & sites of administration
Avoid bruised or tender skin, waistline & 2 inches around navel & waistline.
Monitoring

Monitor for at least 1 hr after treatment

• 0.2% study participants had moderate to severe adverse events
• Hypersensitivity: fever, chills, nausea, headache, shortness of breath, low/high blood pressure, rapid/low heart rate, chest pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, hives, itching, muscle aches, feeling faint, dizziness and sweating.

Mandatory reporting within 7 days to www.fda.gov/medwatch/report.htm

• life-threatening adverse event
• inpatient hospitalization or prolongation of existing hospitalization
• persistent or significant incapacity or substantial disruption of ADLs
• congenital anomaly/birth defect
• medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.
References & Resources

Fact sheet for patients, parents & caregivers
https://www.fda.gov/media/143893/download

Fact sheet for Health Care Providers
https://www.fda.gov/media/145611/download

RegenCov website Instructions for Dosing & Administration
https://www.regencov.com/hcp/dosing/dosing-administration

HHS Combat COVID Monoclonal Ab video for patients: “Monoclonal Ab What is it and how does it work?”
https://youtu.be/a9ZdqAub0zA

Combat Covid Monoclonal Ab Call Center 1-877-332-6585