Monoclonal Antibodies

Slides from IDSA

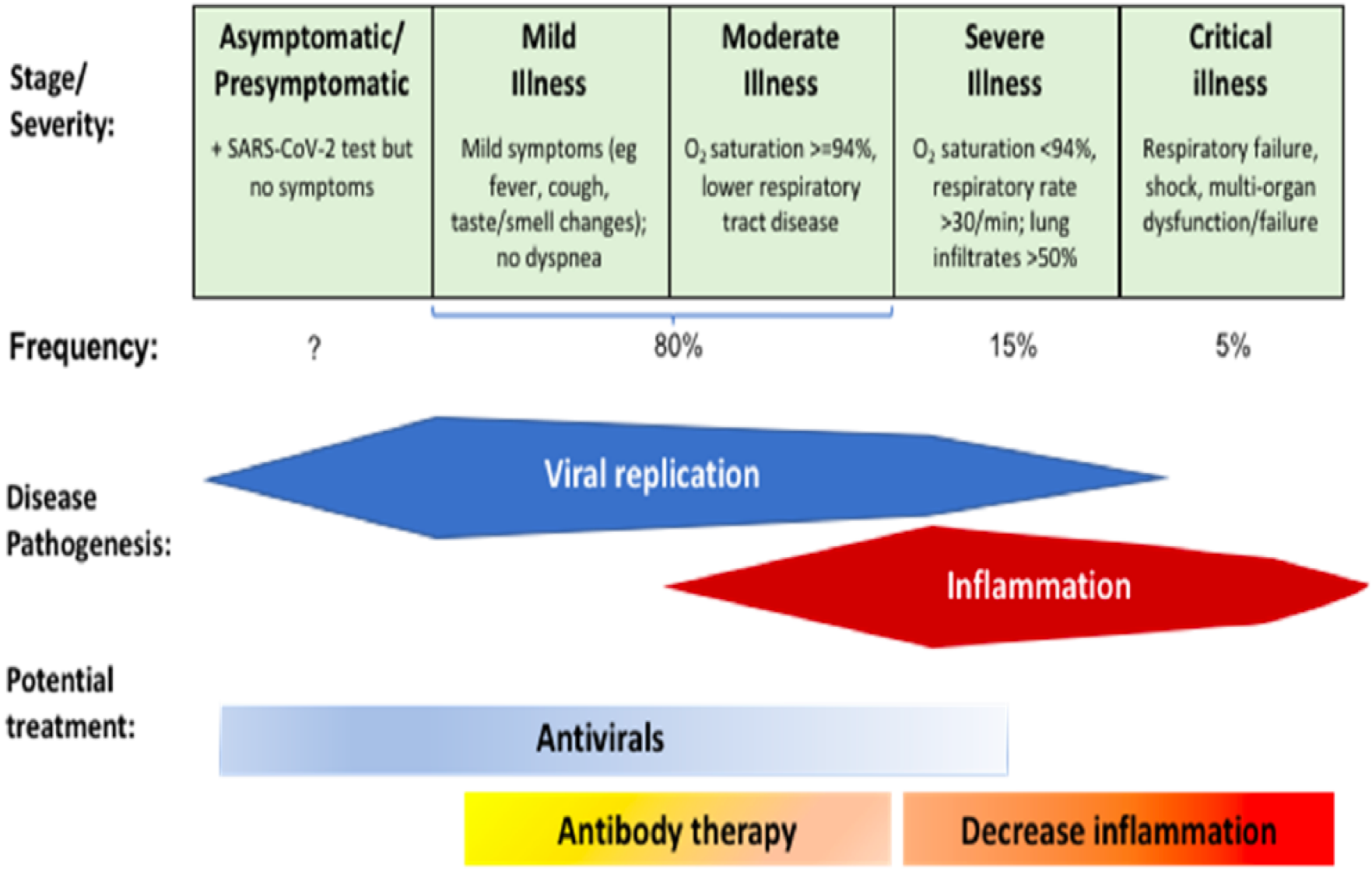
Boost immune responses

Monoclonal Antibodies

- Monoclonal antibodies against SARS-CoV-2 being studied for treatment and prevention
- Target spike protein of SARS-CoV-2
- Emergency Use Authorizations for treatment of ambulatory patients with mild to moderate COVID-19 at high risk of progression and within 10 days of symptom onset:
  - Bamlanivimab (700 mg)
  - Casirivimab + Imdevimab (2400 mg)

FDA U.S. FOOD & DRUG ADMINISTRATION

Management Across the COVID-19 Spectrum



Gandhi RT, CID, 2020; Gandhi RT, Lynch J, del Rio C. NEJM 2020

Audience Response

- Are you offering monoclonal Antibody therapy at your site?
- Yes
- No
- No, but I would like to offer it

Antiviral Effect of Monoclonal Antibodies

- In outpatients with mild to moderate COVID-19, bamlanivimab and casirivimab + imdevimab appear to accelerate decline in SARS CoV-2 level compared to placebo

Bamlanivimab vs placebo

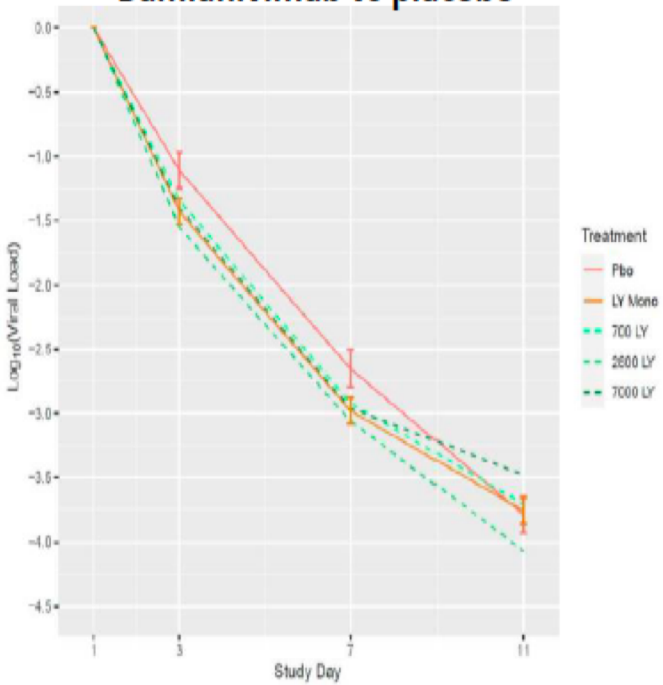
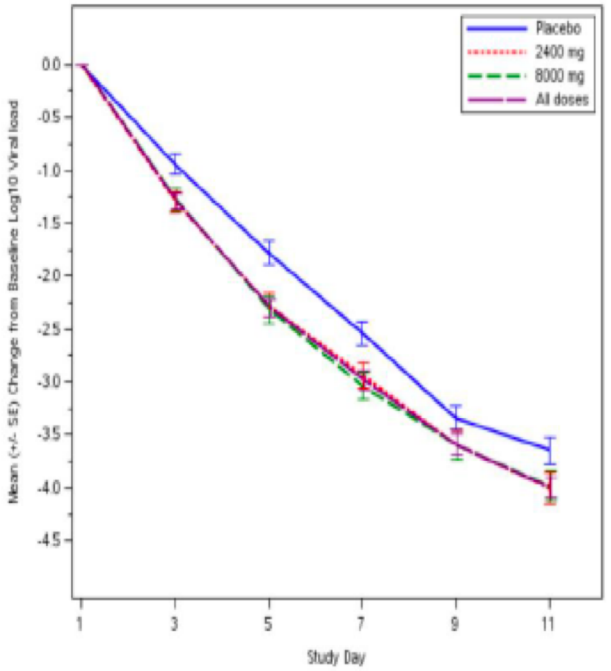


Figure 1: SARS-CoV-2 viral load change from baseline by visit.

Difference statistically significant for intermediate dose

Casirivimab/imdevimab vs placebo



Largest reduction in viral load in participants seronegative at baseline

Chen P et al, NEJM, 2020; http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf; https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fda-letter.pdf; Weinreich DM et al. N Engl J Med 2020 Dec 17

Bamlanivimab

- In outpatients with mild to moderate disease (n=452) enrolled within 3 days of positive SARS-CoV-2 test, lower rate of ED visits/hospitalization in those who received bamlanivimab vs. placebo, particularly among high-risk patients
- Time to symptom improvement: median 6 days with antibody, 8 days with placebo
- Safety of antibody and placebo appeared to be similar

Hospitalization/ED Visit: All Participants

Treatment	N	Events	Proportion
Placebo	156	9	6%
700 mg	101	1	1%
2800 mg	107	2	2%
7000 mg	101	2	2%
Pooled antibody	309	5	2%

Hospitalization/ED Visit: Participants at Higher Risk of Hospitalization

Treatment	N	Events	Proportion
Placebo	69	7	10%
700 mg	46	1	2%
2800 mg	46	1	2%
7000 mg	44	2	5%
Pooled antibody	136	4	3%

Chen P et al, NEJM, 2020; http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf

Casirivimab/Imdevimab (C/I)

- In outpatients with mild to moderate disease (n=799) enrolled within 3 days of positive SARS-CoV-2 test, lower rate of hospitalization/ED visit in those who received casirivimab/imdevimab vs. placebo, particularly among high-risk patients
- Median time to symptom improvement: 5 days with C/I and 6 days with placebo
- Safety of antibodies and placebo similar
  - 1 anaphylactic reaction, 4 infusion reactions (8000 mg group)

Hospitalization/ED Visit: All Participants

Treatment	N	Events	Proportion
Placebo	231	10	4%
C/I 2400 mg	215	4	2%
C/I 8000 mg	219	4	2%
Pooled antibody	434	8	2%

Hospitalization/ED Visit: Participants at Higher Risk of Hospitalization

Treatment	N	Events	Proportion
Placebo	78	7	9%
C/I 2400 mg	70	2	3%
C/I 8000 mg	81	2	2%
Pooled antibody	151	4	3%

https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fda-letter.pdf; Weinreich DM et al. N Engl J Med 2020 Dec 17

Expanded Use Authorization Criteria: Ambulatory Patients with Mild to Moderate COVID-19 at High Risk for Progression - 1

- Body mass index (BMI) ≥35
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or receiving immunosuppressive treatment
- ≥65 years of age
- ≥55 years of age AND have
  - cardiovascular disease, OR
  - hypertension, OR
  - chronic obstructive pulmonary disease/other chronic respiratory disease

http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf
https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fda-letter.pdf

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mAb administration not limited to hospital setting

Potential administration sites

Hospital

- Hospital-based infusion centers
- Emergency departments
- Alternate care sites

Ambulatory center

- Infusion centers
- Urgent care clinics
- Dialysis centers
- FQHCs

Congregate living

- Skilled nursing facilities
- Long-term care facilities
- Others (Correctional facilities, etc.)

Mobile sites

- Trailer, etc.
- Other mobile sites

Home

- At patient's home with home infusion provider

Expansion to add'l sites

Ask:
Expand number of mAb administration sites within your jurisdiction

Expansion via:

- State-directed allocations
- Order product
  - Direct order *available soon* for infusion centers and urgent care clinics
  - Currently available through SPEED for SNFs/LTC, FQHC, correctional facilities, and dialysis centers

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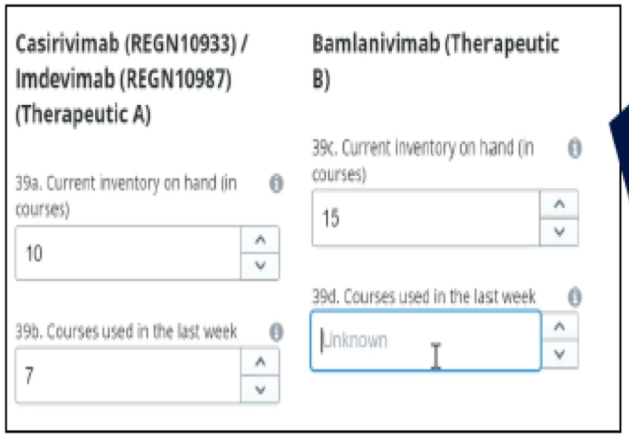
Reporting on COVID-19 therapeutics

Recap: Allocations to states and distribution to individual sites dependent on **mandatory therapeutics reporting** to ensure product is being allocated/distributed appropriately



Entering data into TeleTracking

- For each of the products in the Therapeutics section, enter in quantity of product **remaining on hand** and **used in the last week** quantity and press submit
- The number should be in **patient courses**

Update: To enable proper future allocations / distributions and to support utilization, **accurate reporting by sites / states is critical** to the overall process

- For upcoming reporting, sites should double check entries before submission to ensure mAb utilization is accurate

Helpful information

- **HHS/ASPR Website**
  https://www.phe.gov
  Current EUAs, allocation dashboards, background information, additional resources
- **HHS Website**
  CombatCOVID.hhs.gov
- **ASPR Regional Teams**
  consult the ASPR Regional Team in your area for questions regarding COVID-19 medical countermeasures or to request additional supply
- **Product locator tool**
  https://protect-public.hhs.gov/pages/therapeutics-distribution
- **Weekly Stakeholder Calls**
  Next calls on Wed, Feb 3
- **Weekly Zoom Office Hours**
  Thu, Jan 28; Tue, Feb 2

Find a location near you…

- https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations.

Contact your state DOH for more information:

Facilities in WA: should contact Jennifer Dixon at Jennifer.dixon@doh.wa.gov