



COVID-19 Therapeutics Update: Monoclonal Antibodies

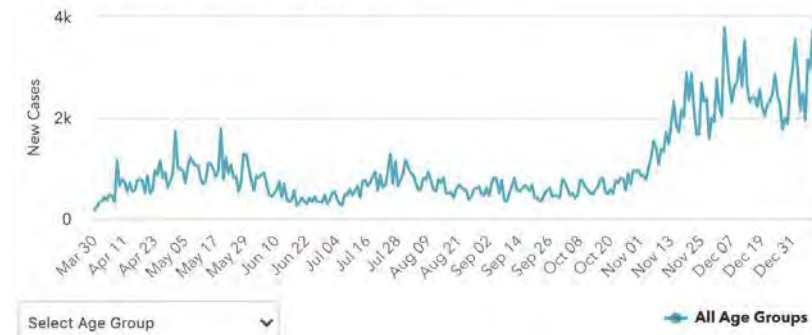
January 11, 2021

Agenda

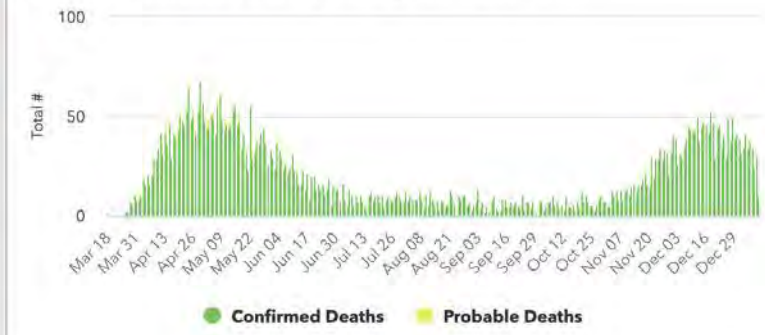
- Welcome
- Maryland COVID-19 Surveillance Summary
- Monoclonal Antibody (mAb) Treatment Overview
- Maryland mAb Program Overview (Nursing Homes)
- Nursing Home Partnership Expertise
 - *FutureCare (Fatima Sheikh, MD, CMD, MPH) & Jimmy Harrington (Vice President of Clinical Services)*
 - *Acts Retirement-Life Communities (Paul M. Reinbold, MD, CMD)*
 - *Chesapeake Vascular Access (Kris Gundrum, CPT President)*
- Open Discussion

Maryland COVID-19 Daily Report

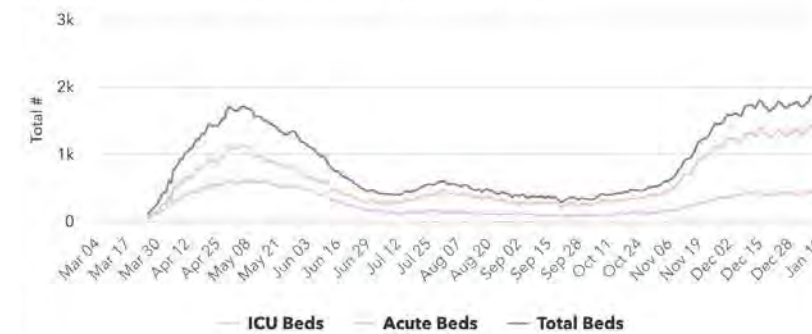
Daily New Number of Cases by Age - Full Screen View



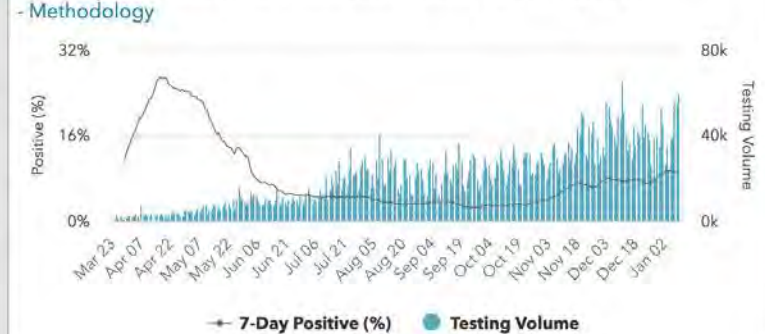
Confirmed and Probable Deaths, Totals by Date of Death



Daily Cases by Age Group
ICU and Acute Hospital Beds for COVID-19, Currently in Use



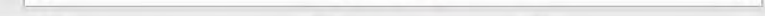
Deaths by Date of Death
Testing Volume, Tests per Day and Percent Positive Rate (7-Day Avg)



Hospitalizations, Current



Positivity Rate



3

Confirmed Cases
306,674
24hr Change: +3,310

Persons Tested Negative
2,636,065
24hr Change: +14,820

Testing Volume
6,145,245
24hr Change: +60,105

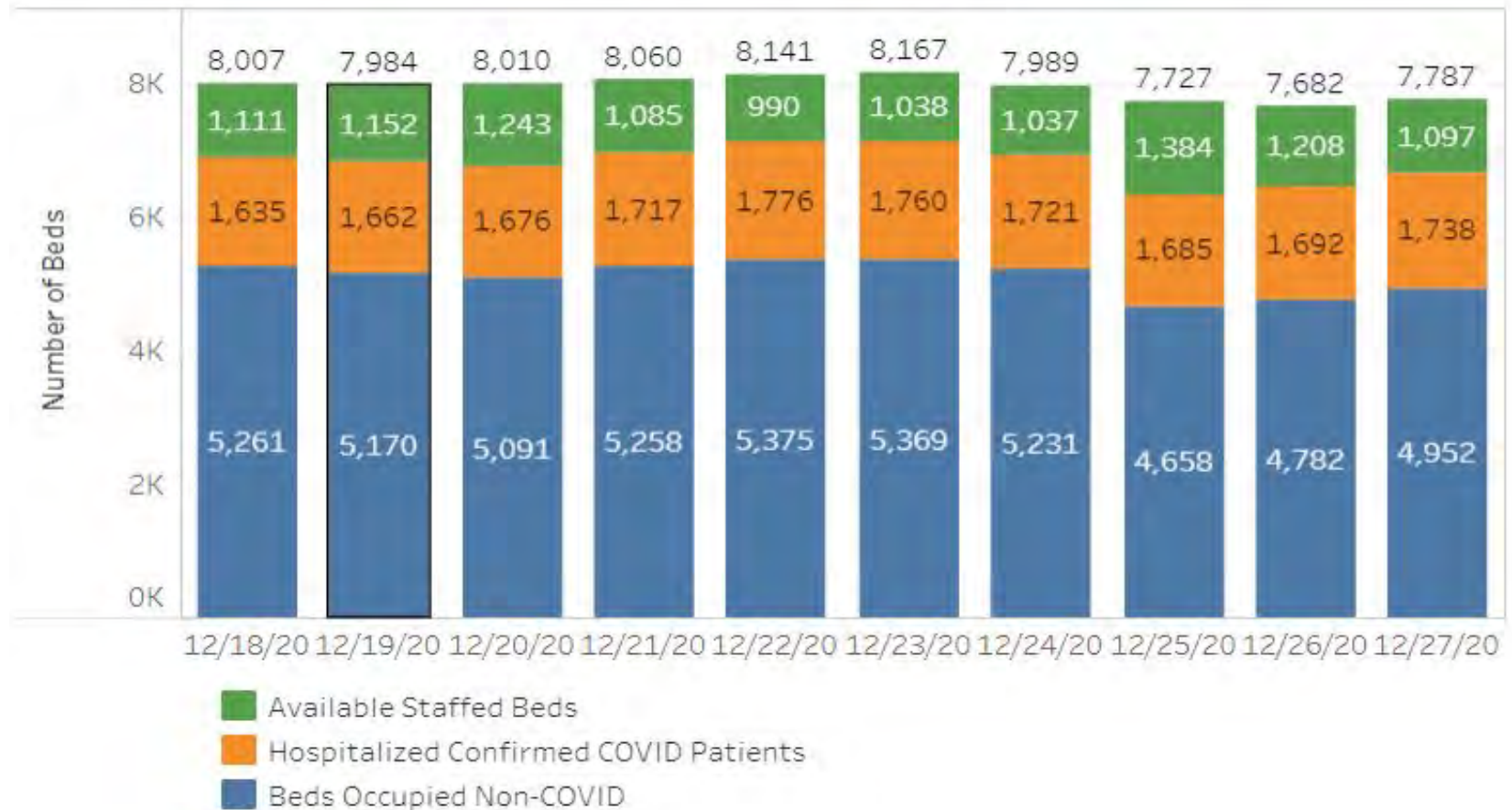
Testing % Positive
8.73%
24hr Change: -0.43

Confirmed Deaths
6,100
24hr Change: +25

Currently Hospitalized
1,950
24hr Change: 73

Hospital Capacity and Staffing

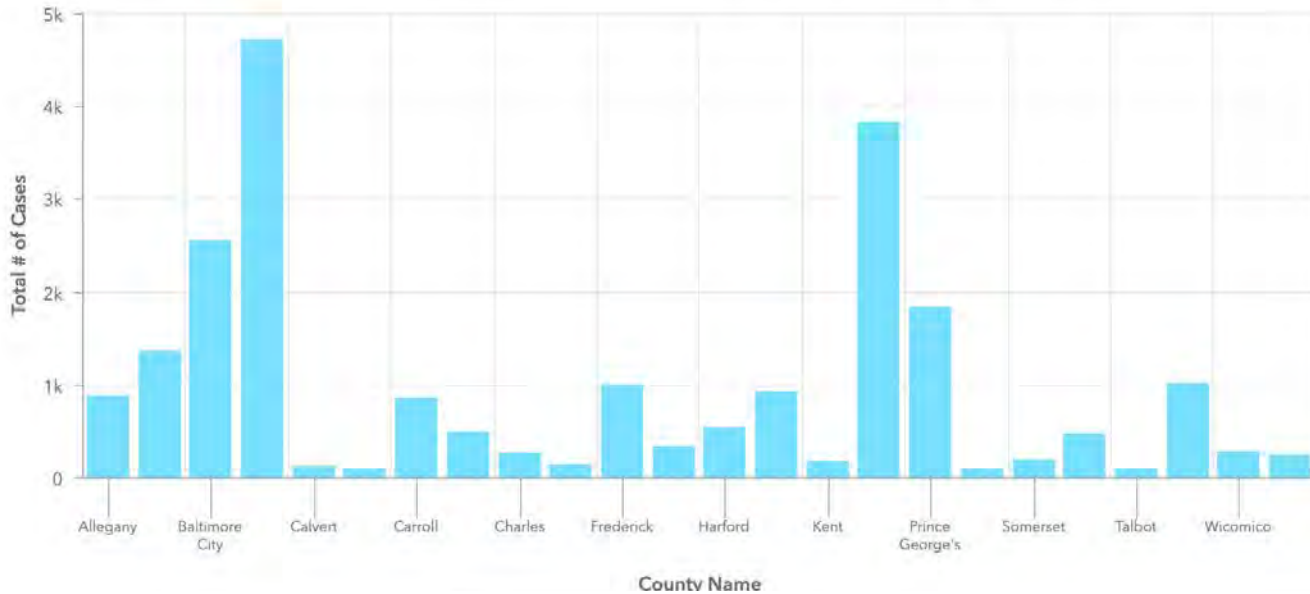
Figure 1. Statewide Occupied Staffed – Adult Care and ICU Beds (Over the last 10 days)



Congregate Settings Summary

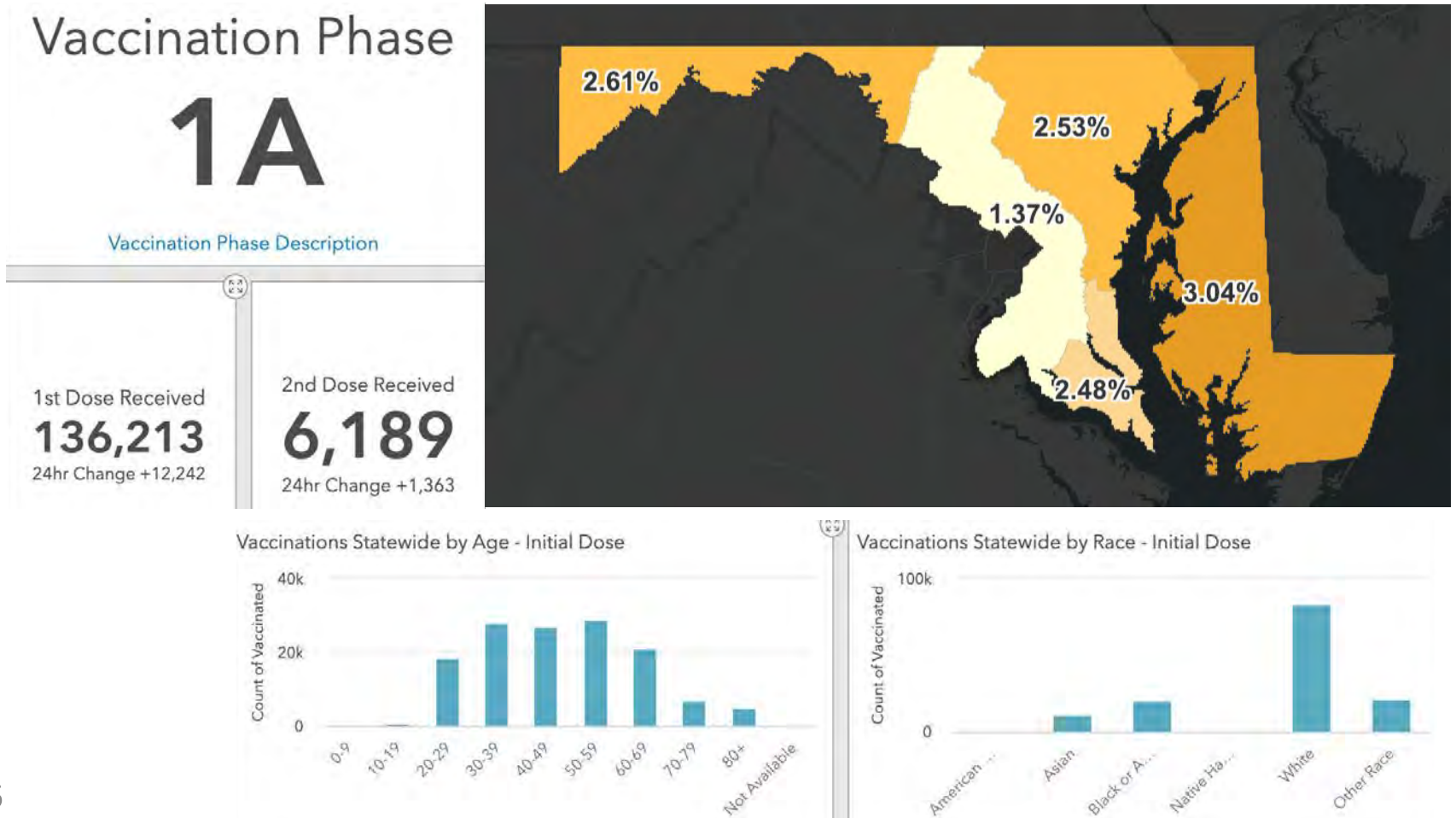
Figure 2. Summary of Maryland COVID-19 Cases and Deaths in Congregate Settings, Nursing, Assisted Living, and Group Homes

Confirmed Staff Cases	Confirmed Staff Deaths	Confirmed Resident Cases	Confirmed Resident Deaths
9,826	32	12,672	2,482



COVID-19 Vaccination Summary

Figure 3. Summary of Maryland COVID-19 Vaccinations Statewide



Overview of monoclonal antibody treatment

**This information is current as of January 11, 2021.
Information may be updated further upon FDA
EUA conditions of use.**



Context: United State Government

- Two monoclonal antibody (mAb) therapies granted EUA:
 - Bamlanivimab (LY-CoV555)
 - Regeneron Products (casirivimab/imdevimab)
- The USG has purchased a limited number of doses and is coordinating the weekly allocation of the mAb therapeutics to state health departments

Principles for USG allocation & distribution

1. Maximize existing infrastructure within USG as well as manufacturer and distribution channels
2. Allocations must ensure both temporal and geographic equity
3. USG to allocate to state and territorial health departments based on
 - Confirmed Hospitalizations (7- Day Incident)
 - Confirmed Cases (7- Day Incident)
4. States/Territories responsible for allocation to final points of care
5. Manufacturer tracks pharmacovigilance and follows mandatory reporting guidance



About monoclonal antibodies

- Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus and are intended to prevent the progression of disease
- mAbs likely to be most beneficial if given to patients early in symptom progression
- Product delivered via single IV infusion administration
- Early evidence suggest promise of mAb products in **OUTPATIENT** settings to **REDUCE HOSPITALIZATION**

About monoclonal antibodies (cont)

About monoclonal antibodies:

EUA authorizes use of mAbs for treatment of high-risk* COVID-19 outpatients (ages ≥ 12 y/o, weight ≥ 40 kg) with mild-to-moderate symptoms at risk for progressing to severe disease/hospitalization

1. Direct SARS-CoV-2 test (e.g., PCR, rapid antigen test) must be positive
2. Administered as soon as possible after positive test result and within 10 days of symptom onset
3. Provider to review EUA fact sheet
4. Patient/caregiver to be provided with EUA fact sheet
5. Administered in a setting where healthcare providers have direct access to medications to manage severe reactions

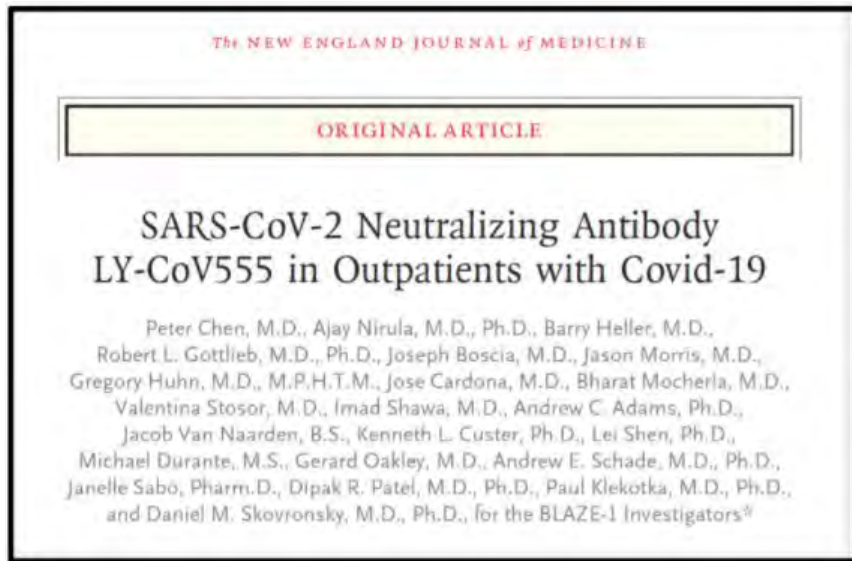
*high risk criteria listed on slide 8

<https://www.fda.gov/media/13766/download>

<https://www.fda.gov/media/135757/download>

Phase 2 Clinical Trial Results:

Bamlanivimab in Outpatients with COVID-19



All study-patients: Hospitalization or ED visit within 29 days of administration

- Treatment group (n=309), 1.6%
- Placebo group (n=143), 6.3%
- **Number needed to treat (NNT) to avoid hospitalization/ED = 21.3**

Study-patients with BMI ≥ 35 of Age ≥ 65 , Hospitalization/ED within 29 days

- Treatment group (n=95), 4.2%
- Placebo group (n=48), 14.6%
- **NNT = 9.6**

High-risk Criteria

All patients (who meet at least 1 of the following criteria):

- BMI ≥ 35
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease
- Receiving immunosuppressive treatment
- Age ≥ 65 years
- Age ≥ 55 years AND have any of the following
 - Cardiovascular disease
 - Hypertension
 - COPD/other chronic respiratory disease

Adolescents (Age 12-17 years) who meet at least 1 of the following criteria:

- BMI ≥ 85 th percentile for age/gender
- Sickle cell disease
- Congenital or acquired heart disease
- Neurodevelopmental disorders (e.g. cerebral palsy)
- Medical-related technological dependence [e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)]
- Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

Limitations of Authorized Use

Monoclonal antibodies are not authorized for use in patients:

- Who are hospitalized due to COVID-19

OR

- Who require oxygen therapy due to COVID-19

OR

- Who require an increase in baseline oxygen flow rate due to underlying non-COVID-19 related comorbidity

COVID-19 Therapeutics Overview

Maryland mAb Program Overview

Three-pronged Approach



Existing hospital or
clinical spaces



Congregate care settings



Community-access
points

Pharmacy Services & Partnerships

Pharmacy

- Remedi SeniorCare
- Omnicare
- Craig's Pharmacy
- Pharmerica
- Pharmscript
- Polaris
- Advanced Pharmacy / Partners Pharmacy

Home Infusion

- CAIS Inc.
- Option Care Health

Dialysis

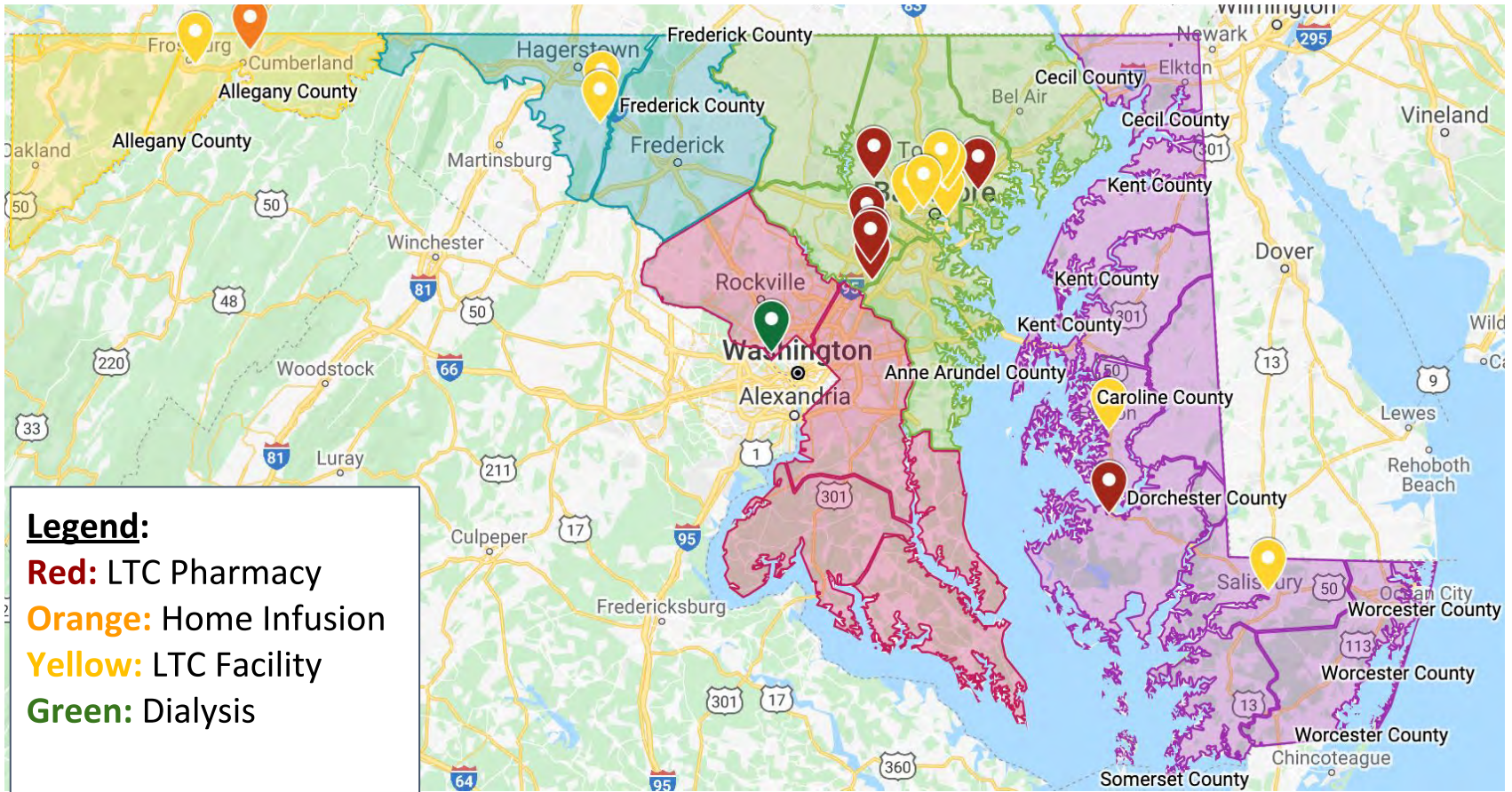
- US Renal Care

Vascular Access

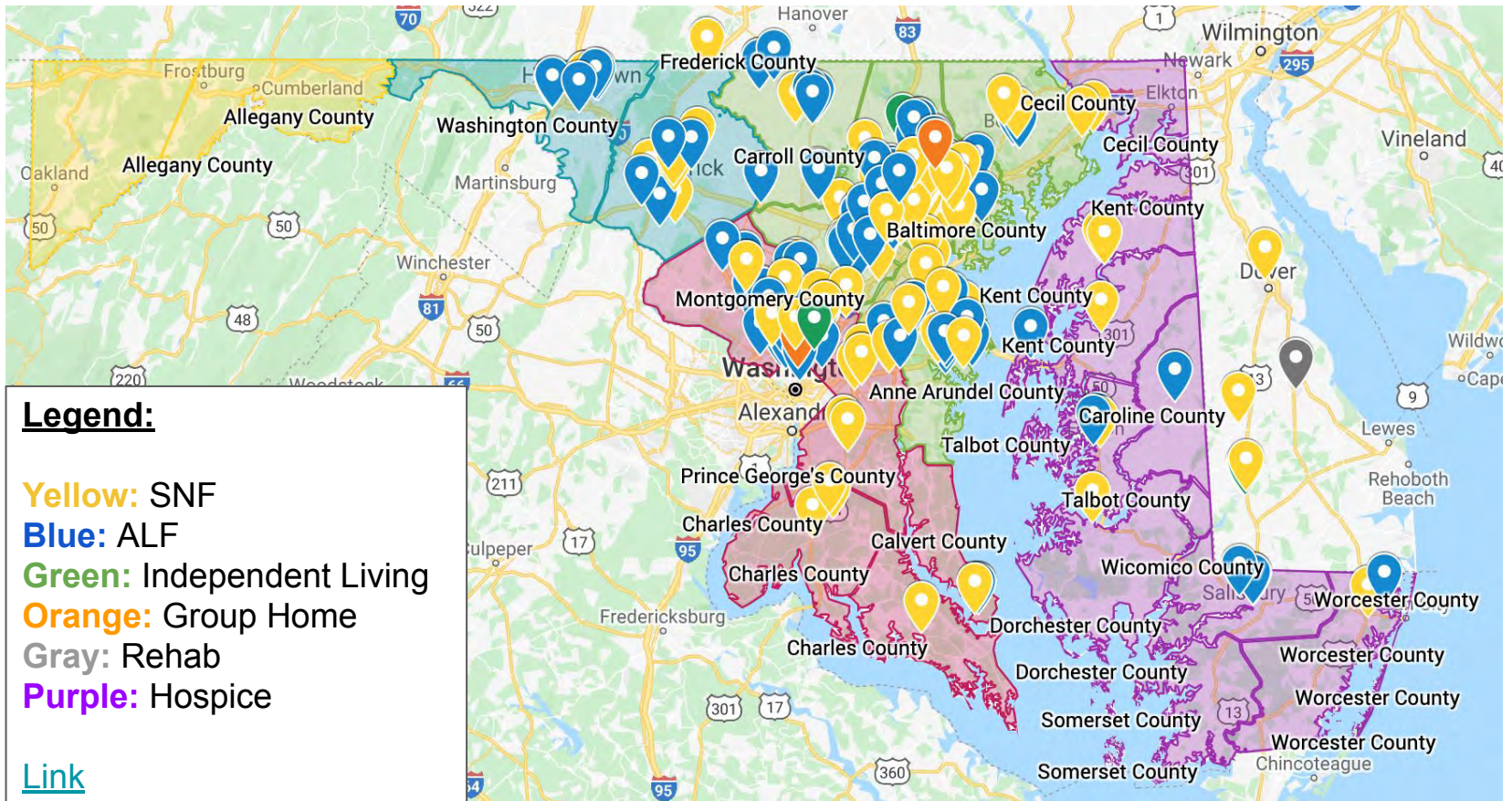
- Chesapeake Vascular Access
- Advanced PICC Specialist



Pharmacy & Partner Locations

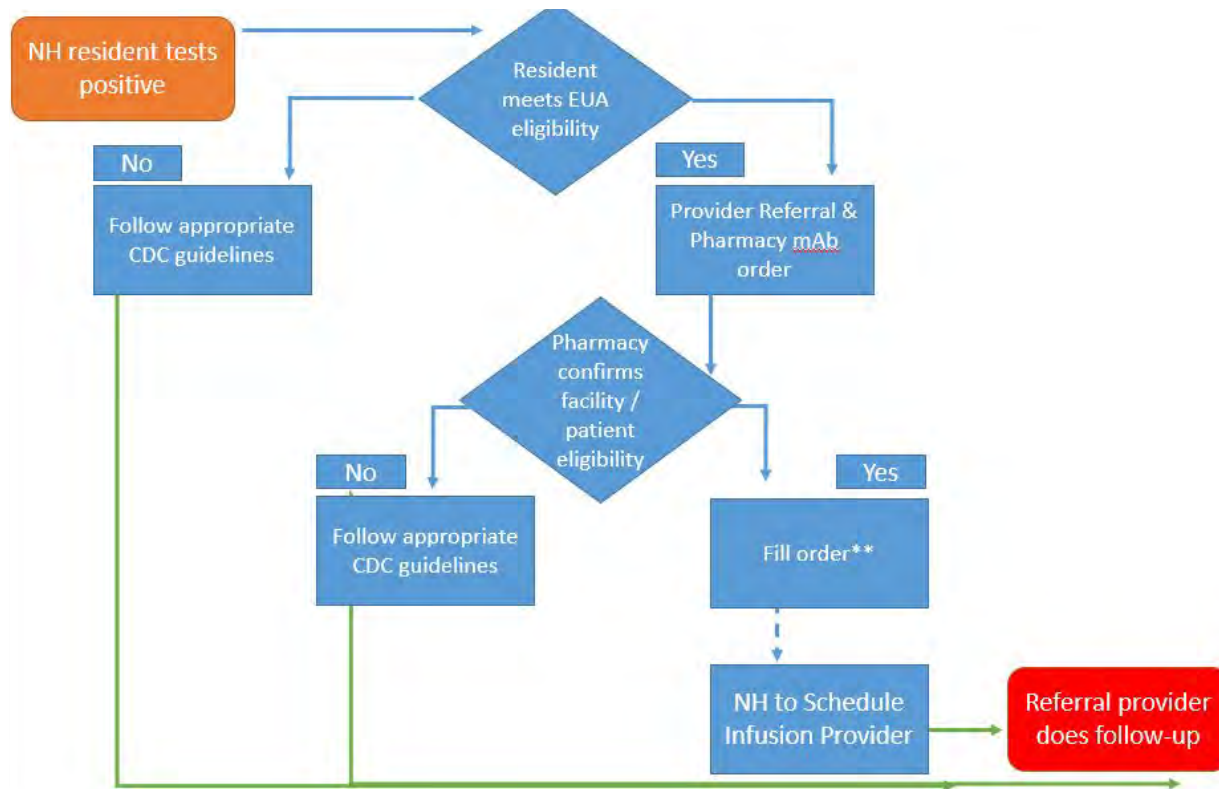


LTC Facilities Served by Partner Pharmacies



Nursing Home Referral Pathway

Figure 5. Referral Pathway for nursing home partners to order and receive treatment



Process for Prescribing/Ordering

1. Screen resident with positive COVID-19 test for eligibility criteria in EUA (PCR or antigen)
2. Contact prescriber to order using your LTC pharmacy intake/ordering form
3. Review mAb information with patient and provide appropriate “Fact Sheet for Patients”
4. Pharmacy reviews referral/order and confirms patient eligibility
5. Pharmacy and/or NH coordinate mAb delivery, supplies, and staff capable of administering infusion *Note: NH may use separate infusion provider*
6. mAbs are delivered to NH, administered to patient, and patient is observed for at least 1 hour
7. NH schedules follow-up with PCP
8. Report any adverse events

Site Administration Checklist

- Identify dedicated space and plan to manage patient flow
- Ensure dedicated source of supplies
- Assign sufficient personnel to meet expected demand
 - Identify staff (internal/external) with appropriate competencies for mAb administration
- Prepare for drug administration process
 - Pre-visit: Clear treatment and monitoring plan
 - Treatment
 - Post-treatment
- Ensure process for reimbursement in place
- Prepare for reporting needs

Staffing Needs

Role	Needed skills/ profile
Patient Intake	Scheduling and administrative skills
Drug preparation	Pharmacist or pharmacy technician trained in IV preparation
Infusion: Start IV	Nurse or other HCP trained to begin an IV
Infusion: Administer infusion	Nurse or other HCP trained in administering an IV
Infusion monitoring	Nurse or other HCP trained in vital sign monitoring
Post infusion observation	Nurse or other HCP trained in vital sign monitoring
Patient release	Administrative skills
Cleaning	Person trained in COVID cleaning / disinfection

Communication Needs

Education Essential to Inform and Reduce Hesitancy

- For Medical Directors and Attending Providers
- For Facility Administrators
- For Nursing Leads and Directors
- For Staff
- For Resident and their POAs

Nursing Home Partnership Expertise

- FutureCare (Fatima Sheikh, MD, CMD, MPH) & Jimmy Harrington (Vice President of Clinical Services)
- Acts Retirement-Life Communities (Paul M. Reinbold, MD, CMD)
- Chesapeake Vascular Access (Kris Gundrum, CPT President)

Next Steps

- Build out regional subsidiary sites
- Expand allocation and distribution to nursing homes partners
- Leverage long-term care pharmacy chain partnerships for distribution of mAbs to additional nursing home populations

Open Forum for Questions?

- How does a nursing home order and receive mAbs?
- How does a nursing home partner decide which patients should receive mAb treatment?
- What does a nursing home do if a patient has an adverse reaction to the mAb treatment?
- How can a nursing home partner bill for providing mAb to patients?

COVID-19 Therapeutics

Thank you!

