COVID-19 Therapeutics in the Home Setting
Today’s Presenters

Ryan Garst, PharmD, MBA, BCSCP
Senior Director of Clinical Services

Bill Noyes, Senior Vice President of Reimbursement Policy
Today’s Agenda

• Current Therapeutic Options and Considerations for Home Infusion
  • Remdesivir
  • Bamlanivimab
  • Casirivimab/Imdevimab

• Becoming a mABs and vaccine provider

• Reimbursement Considerations
Current Situation¹ (11/30/20)

- Confirmed Cases
  - Global 62,953,556
  - United States 13,421,114

- Deaths
  - Global 1,463,349
  - United States 267,080

- CDC Hospitalizations
  - Highest peak week of 11/21 > 65 yrs old
  - 243.8 per 100,000
Therapeutic Options for COVID-19
# Remdesivir (Velkury®) Clinical Overview

**Gilead**

<table>
<thead>
<tr>
<th>Indications²</th>
<th>Dosing</th>
<th>Precautions/Warnings</th>
<th>Adverse Effects</th>
<th>Preparation &amp; Administration²</th>
</tr>
</thead>
</table>
| • Adults & Peds aged 12 and older weight at least 40kg with COVID-19 and hospitalized | • 200mg loading dose  
• 100mg days 2-5 or 2-10 depending on patient status | • Hypersensitivity  
• Elevated transaminase levels  
• Baseline & Q 3-5 days depending  
• Reduced effectiveness in combination with chloroquine & hydroxychloroquine³  
• Contraindicated in eGFR < 30ml/min | • Nausea  
• Elevated AST  
• Elevated ALT | • Two Dosage Forms  
• 100mg lyophilized powder  
• 100mg/20ml  
• 24-hour Room Temp; 48 hour Refrigerated**  
• 30-120 minute i |

https://www.acs.org/content/acs/en/molecule-of-the-week/archive/r/remdesivir.html
Remdesivir (Velkury®) Logistics

• Remdesivir: https://www.vekluryhcp.com/product-access/
  • Via ABC through end of 2020
  • Hospitals place direct orders with ABC and shipped directly to hospital

• Home Infusion via Hospital without Walls
  • New Guidance issued November 25, 2020
Monoclonal Antibody EUA’s for COVID-19

**Bamlanivimab (Eli Lilly)**
- FDA issued EUA on November 10, 2020
- BLAZE-1 Trial
  - Phase 2 Dosing Trial

**Casirivimab/Imdevimab (Regeneron)**
- FDA issues EUA on November 21, 2020
- R10933-10987-COV-2067 Trial
  - Phase 1/2/3 safety and efficacy trial

Neither indicated for:
- Adults/Peds hospitalized with COVID-19
- Adults/Peds requiring Oxygen
- Adults/Peds needing oxygen flow increases from baseline
<table>
<thead>
<tr>
<th>Indications</th>
<th>Dosing</th>
<th>Adverse Events</th>
<th>Preparation &amp; Storage</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults/Peds &gt; 12 yrs at least 40 kg</td>
<td>700mg/200ml administered within 2 days of positive test and within 10 days of symptom onset</td>
<td>Nausea</td>
<td>Vials to room temp</td>
<td>Bring to room temp prior to infusion</td>
</tr>
<tr>
<td>High-risk of progressing to severe disease or hospitalization</td>
<td></td>
<td>Dizziness</td>
<td>Final volume MUST be 200ml per FDA</td>
<td>Use 0.2/0.22-micron filter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Headache</td>
<td>Vial is 700mg/20ml</td>
<td>Via gravity or pump</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Remove 70ml from 250ml 0.9% NS</td>
<td>Over at least 60 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Add 20ml Bamlanivimab</td>
<td>Flush infusion line with NS post-infusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Storage: 7 hours room temp &amp; 24 hours refrigerated</td>
<td>• 50ml 0.9% NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Includes hang time</td>
<td>• Monitor for 1-hour post-infusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Protect from light, Do not shake/freeze</td>
<td></td>
</tr>
</tbody>
</table>
### COVID-19 mAB Clinical Information: Casirivimab/Imdevimab\(^6\)\(^,\)\(^7\)

<table>
<thead>
<tr>
<th>Indications</th>
<th>Dosing</th>
<th>Adverse Events</th>
<th>Preparation &amp; Storage</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adults/Peds &gt; 12 yrs at least 40 kg</td>
<td>• 1200mg/1200mg Casirivimab/Imdevimab administered as soon as possible after positive test and within 10 days of symptom onset</td>
<td>• Limited data in the 258 patients treated with 1200mg regimen</td>
<td>• Each product comes in 11.1ml vial or 2.5 ml vials</td>
<td>• Bring to room temp prior to infusion</td>
</tr>
<tr>
<td>• High-risk of progressing to severe disease or hospitalization</td>
<td></td>
<td>• Nausea</td>
<td>• See Fact Sheet for Healthcare Providers</td>
<td>• Use 0.2-micron filter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vomiting</td>
<td>• Final volume must be 250ml</td>
<td>• Via gravity or pump</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hyperglycemia</td>
<td>• Storage: 4 hours room temp &amp; 36 hours refrigerated**</td>
<td>• Over at least 60 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Limited data in the 258 patients treated with 1200mg regimen</td>
<td>• Includes hang time</td>
<td>• Flush infusion line with NS post-infusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Protect from light, Do not shake/freeze</td>
<td>• 50ml 0.9% NS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Monitor for 1-hour post-infusion</td>
</tr>
</tbody>
</table>
Defining Adverse Drug Reactions

• WHO Technical Report 498
  • Serious
• Reporting of ADR’s
  • MedWatch
    • https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
    • FDA Form 3500 (health professionals)
• Operation Warp Speed & Eli Lilly Monoclonal Antibody Playbook
Distribution Process for mAB COVID-19 Treatments

• Remdesivir: https://www.vekluryhcp.com/product-access/
  • Via ABC through end of 2020
  • Hospitals place direct orders with ABC and shipped directly to hospital

• Bamlanivimab and Casirivimab/Imdevimab
  • ABC is distributor
  • Bamlanivimab currently in Phase 2
  • Casrivimab/Imdevimab in Phase 1
  • Wednesdays are allocation days
  • HHS website
    • https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas_imd/Pages/default.aspx
Distribution Process for COVID-19 Treatments

Allocation and Distribution of Casirivimab/Imdevimab

![Step 1: HHS/ASPR determines allocation amounts for states and territories](image1.png)

- HHS determines amounts provided to States
- State Health Departments determine which entities receive product and how much
- ABC delivers product based on State directive
- Facilities identify patients for treatment

![Step 2: HHS/ASPR notifies health departments regarding allocation amounts](image2.png)

![Step 3: Health departments determine allocations for facilities in their jurisdictions](image3.png)

![Step 4: Distributor coordinates shipping details with receiving facilities](image4.png)

![Step 5: Receiving facilities administer drug to eligible patients based on Emergency Use Authorization](image5.png)
Reimbursement Considerations & Enrollment
Remdesivir Reimbursement Considerations

• Drug is only accessible via hospitals
• Can be used with hospital at home programs.
• Paid for via hospital payment system, DRG.
• If you partner with a hospital at home program, seek contractual arrangement for payment.
• Commercial payers, under hospital or under home infusion?
COVID Vaccines

- Vaccine at no charge for now
- 95% of AWP if buy and bill
- No copayment/coinsurance or deductible
- Bill Original Medicare even for those with Medicare Advantage
Reimbursement Considerations for Bamlanivimab

- Drug at no charge for now
- 95% of AWP if buy and bill
- No copayment/coinsurance or deductible
- Bill Original Medicare even for those with Medicare Advantage
- Health care providers should not include the monoclonal antibody codes on the claim when the product is provided for free.

Payment Allowances and Effective Dates for COVID-19 Monoclonal Antibodies and their Administration during the Public Health Emergency:

<table>
<thead>
<tr>
<th>Code</th>
<th>CPT Short Descriptor</th>
<th>Labeler Name</th>
<th>Vaccine/Procedure Name</th>
<th>Payment Allowance</th>
<th>Effective Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q0239</td>
<td>bamlanivimab-xxxx</td>
<td>Eli Lilly</td>
<td>Injection, bamlanivimab, 700 mg</td>
<td>$0.010*</td>
<td>11/10/2020 – TBD</td>
</tr>
<tr>
<td>M0239</td>
<td>bamlanivimab-xxxxx infusion</td>
<td>Eli Lilly</td>
<td>Intravenous infusion, bamlanivimab-xxxxx, includes infusion and post administration monitoring</td>
<td>$309.600***</td>
<td>11/10/2020 – TBD</td>
</tr>
</tbody>
</table>

* Since we anticipate that providers, initially, will not incur a cost for the product, CMS will update the payment allowance at a later date. Providers should not bill for the product if they received it for free.

*** Medicare will pay a rate of $309.60 for many providers. These rates will also be geographically adjusted for many providers. Certain settings utilize other payment methodologies, such as payment based on reasonable costs.

Billing and Documentation for Monoclonal Antibody COVID-19 Infusion Administration

• Health care providers can bill for the administration of the monoclonal antibody infusion on a single claim for COVID-19 monoclonal antibody administration or submit claims on a roster bill, in accordance with the FDA EUA.

• CMS expects that health care providers will maintain appropriate medical documentation that supports the medical necessity of the service.
  • This includes documentation that supports that the terms of the EUA are met, including that it is being used for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) for a patient that is at high risk for progressing to severe COVID-19 and/or hospitalization.
  • The documentation should also include the name of the practitioner who ordered or made the decision to administer the infusion, even in cases where claims for these services are submitted on roster bills.

This EUA is for the use of the unapproved product bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization [see Limitations of Authorized Use]. High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- 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 a BMI ≥85th percentile for their age and gender based on CDC growth charts, 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.
Who Can Bill for COVID Treatments

Health care providers administering this monoclonal antibody infusion will follow the same enrollment process as those administering the other COVID-19 vaccines. Review provider enrollment information: https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots
If you’re enrolled in Medicare under these institutional or non-institutional provider types, you don’t need to take any action to administer and bill the COVID-19 shot, either through individual claims or roster bill, without enrolling as a mass immunizer.

<table>
<thead>
<tr>
<th>Institutional</th>
<th>Non-Institutional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>Physician</td>
</tr>
<tr>
<td>Hospital Outpatient Department</td>
<td>Non-Physician</td>
</tr>
<tr>
<td>Skilled Nursing Facility (includes Parts A and B)*</td>
<td>Clinic/Group Practice</td>
</tr>
<tr>
<td>Critical Access Hospital</td>
<td>Pharmacy (enrolled as Part B)</td>
</tr>
<tr>
<td>End-Stage Renal Disease Facility</td>
<td>Mass Immunizer (roster bill only)</td>
</tr>
<tr>
<td>Home Health Agency</td>
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<tr>
<td>Hospice</td>
<td></td>
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<tr>
<td>Comprehensive Outpatient Rehabilitation Facility</td>
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<tr>
<td>Federally Qualified Health Center**</td>
<td></td>
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<tr>
<td>Rural Health Clinic***</td>
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<tr>
<td>Indian Health Services Facility</td>
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</tbody>
</table>
If you’re enrolled in Medicare under these provider types and you want to bill for administering COVID-19 shots, you must also separately enroll as a mass immunizer. Enrolling over the phone as a mass immunizer is easy and quick — call your MAC-specific enrollment hotline (PDF) and give your valid Legal Business Name (LBN), National Provider Identifier (NPI), Tax Identification Number (TIN), practice location and state license, if applicable.

<table>
<thead>
<tr>
<th>Institutional</th>
<th>Non-Institutional</th>
<th>Durable Medical Equipment (DME)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Outpatient Physical Therapy</td>
<td>• Independent Clinical Laboratory</td>
<td>• Durable Medical Equipment Supplier</td>
</tr>
<tr>
<td>• Occupational Therapy</td>
<td>• Ambulance Service Supplier</td>
<td>• Pharmacy (enrolled as DME supplier)</td>
</tr>
<tr>
<td>• Speech Pathology Services</td>
<td>• Independent Diagnostic Testing Facility</td>
<td></td>
</tr>
<tr>
<td>• Histocompatibility Laboratory</td>
<td>• Intensive Cardiac Rehabilitation Supplier</td>
<td></td>
</tr>
<tr>
<td>• Religious Non-Medical Health Care Institution</td>
<td>• Mammography Center</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Medicare Diabetes Prevention Program Suppliers</td>
<td></td>
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<tr>
<td></td>
<td>• Portable X-ray Supplier</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Radiation Therapy Center</td>
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<tr>
<td></td>
<td>• Opioid Treatment Program</td>
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<tr>
<td></td>
<td>• Organ Procurement Organization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Home Infusion Therapy Supplier</td>
<td></td>
</tr>
</tbody>
</table>

Hotline tips:
The provider would call the A/B MAC that services their geographic area. Or if the provider will be centralized billing they would call the Novitas hotline.

Do not call the National Supplier Clearinghouse (NSC).
Hotline Enrollment is Temporary

Medicare billing privileges established via the Medicare Provider Enrollment Hotline are being granted on a provisional basis as a result of the public health emergency declaration and are temporary. Upon the lifting of the COVID-19 PHE declaration, providers and suppliers, will be asked to submit a complete CMS-855 enrollment application in order to establish full Medicare billing privileges. Failure to respond to the MAC’s request within 30 days of the notification, will result in the deactivation of your temporary billing privileges. No payments can be made for services provided while your temporary billing privileges are deactivated.
Billing for COVID Treatments

Currently Enrolled as Other Eligible Provider (e.g. Physician/Non-Physician, Hospital, Clinic/Group Practice)

1. Roster Billing
   - Must administer the same type of vaccine per roster claim to 5 or more people on the same date.
   - Submit claim to specific MAC jurisdictions based on location.

2. Claim-by-Claim Billing

Institutional Claims (e.g. Hospital)
- Electronic Claims:
  - Use Direct Data Entry
    a. Option 02, Claims Attachment
    b. Option 87, Roster Bill Entry
- Paper Claims:
  - Use CMS-1450 (UB-04)
    a. Contact your MAC for the roster form

Professional Claims (e.g. Physician)
- Electronic Claims:
  - Contact your Vendor/Clearinghouse or download free PC ACE billing software and electronically submit roster claims to your MAC.
- Paper Claims:
  - Use Health Insurance Claim Form (CMS-1500)
    a. Contact your MAC for the roster form

Health care providers can bill for the administration of the monoclonal antibody infusion on a single claim for COVID-19 monoclonal antibody administration or submit claims on a roster bill, in accordance with the FDA EUA.

COVID-19 Treatments in SNFs

A SNF may either administer the vaccine directly to a resident who’s in a covered Part A stay or under arrangement pursuant to which the SNF pays an outside immunizer to administer the vaccine. In both these situations the SNF must bill Medicare. However, during the public health emergency, we’ll allow Medicare enrolled immunizers *who are not under arrangement with the SNF* to vaccinate Medicare SNF residents and bill directly to get reimbursed from Medicare.
Resources

Show your support for the National Home Infusion Foundation this Giving Tuesday

NHIF’s research and benchmarking programs are collecting groundbreaking data, and your contribution at any level makes a difference in supporting NHIF’s work.

Donate now at nhia.org/nhif_donate
Register Now for NHIA’s 2021 Conference

KEEPING YOU CONNECTED - THE PREMIER HOME & SPECIALTY INFUSION CONFERENCE IN A VIRTUAL FORMAT

JOIN THOUSANDS OF HOME AND SPECIALTY INFUSION THERAPY PROFESSIONALS FOR THREE EXCITING DAYS OF INSPIRING SPEAKERS, CUTTING EDGE INDUSTRY INFORMATION, AND OVER 50 SESSIONS ACCREDITED FOR CONTINUING EDUCATION CREDITS

REGISTER NOW AND SECURE EARLY BIRD PRICING - EARLY BIRD DISCOUNT ENDS DECEMBER 31, 2020
REGISTER NOW AT BIT.LY/NHIA-2021-CONFERENCE
Tell Congress: Support the Preserving Patient Access to Home Infusion Act (H.R. 6218 & S. 3457)

Members of Congress need to hear from you now about why it is important to fix the Part B home infusion therapy services benefit, so that patients can continue to receive these crucial therapies in the comfort of their homes.

NHIA has worked with our congressional champions to introduce legislation that will ensure providers are paid each day of infusion, and to remove the face-to-face requirement for billing.

Support NHIA’s efforts to pass this legislation and send your Representatives and Senators a letter now.

Access and send a customizable letter now at bit.ly/action-alert-patient-access