Today's Presenters

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

Bill Noyes, Senior Vice President
of Reimbursement Policy

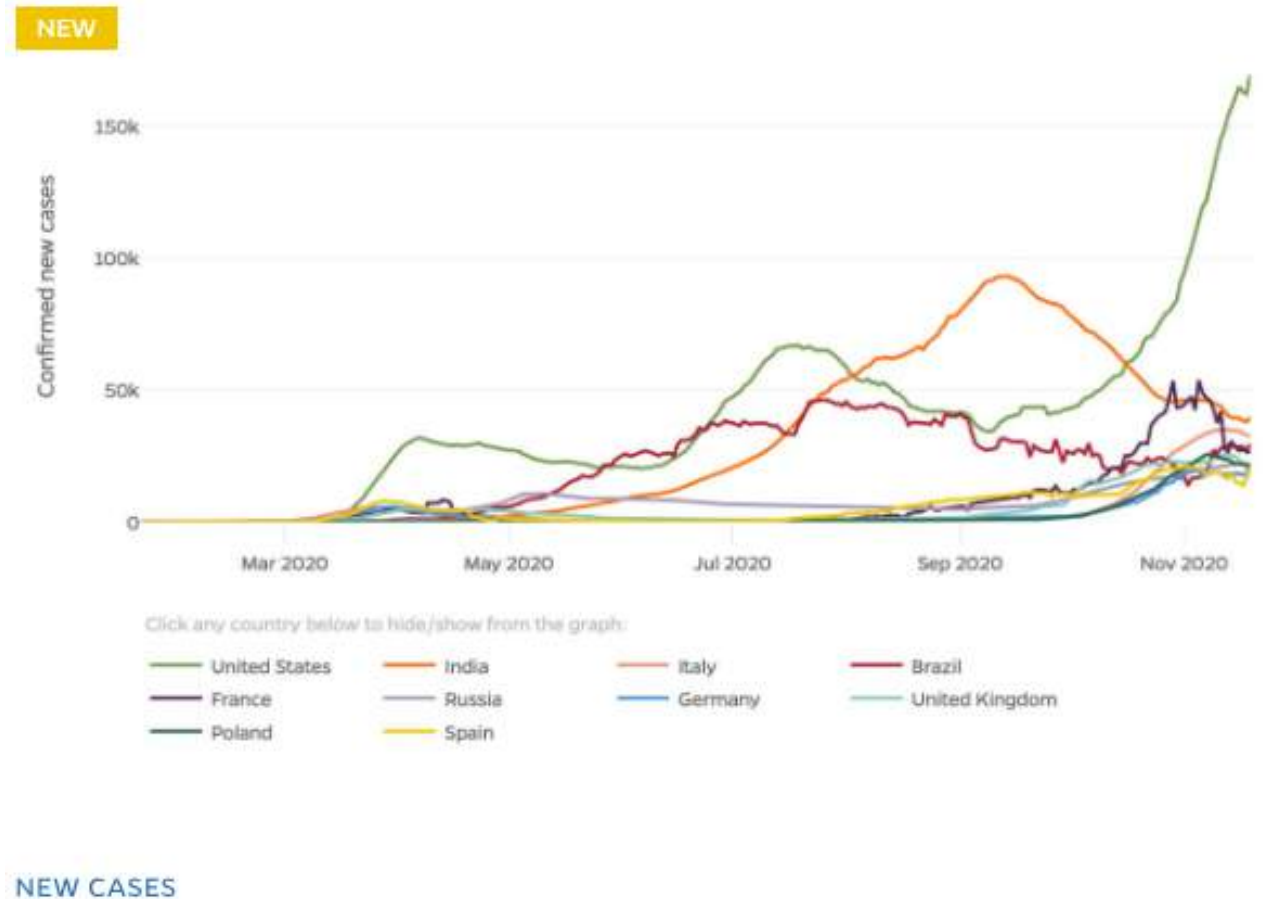**NHIA TALK INFUSION WEBINAR**

Today's Agenda

- Current Therapeutic Options and Considerations for Home Infusion
  - Remdesivir
  - Bamlanivimab
  - Casirivimab/Imdevimab
- Becoming a mABs and vaccine provider
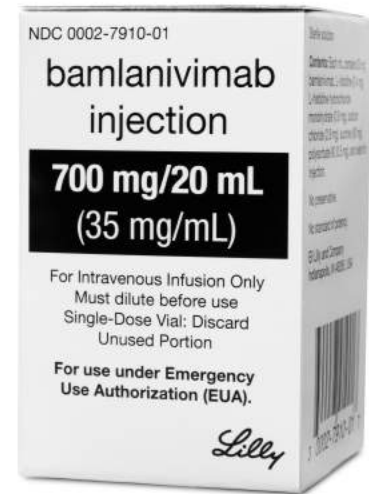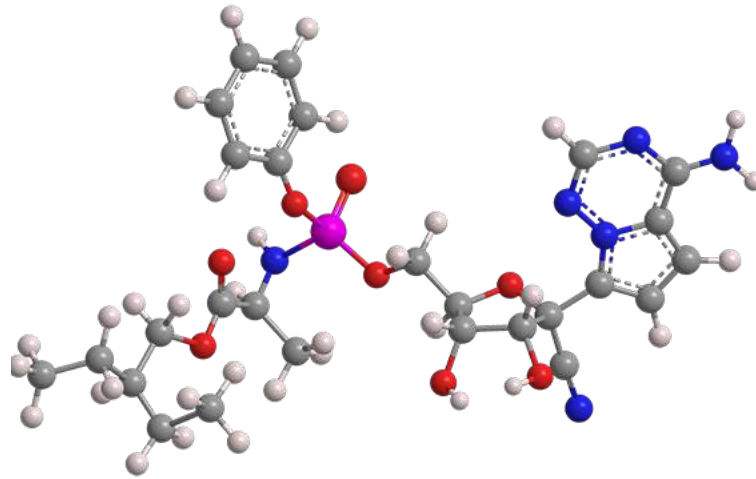- Reimbursement Considerations

Current Situation[1] (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

NEW

150k

100k

Confirmed new cases

50k

0

Mar 2020   May 2020   Jul 2020   Sep 2020   Nov 2020

Click any country below to hide/show from the graph:

— United States   — India   — Italy   — Brazil
— France   — Russia   — Germany   — United Kingdom
— Poland   — Spain

NEW CASES

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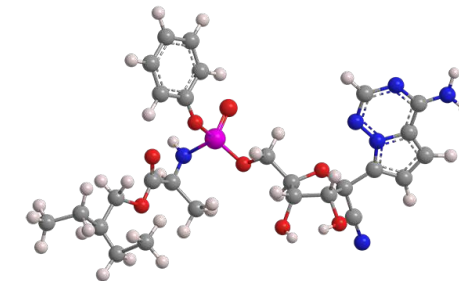# Therapeutic Options for COVID-19

Remdesivir (Velkury®) Clinical Overview[2]
Gilead

Indications[2]	Dosing	Precautions/Warnings	Adverse Effects	Preparation & Administration[2]

• 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 & hydroxychloroqiune[3]
		• 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

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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

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COVID-19 mAB Clinical Information: Bamlanivimab[4,5]

Indications	Dosing	Adverse Events	Preparation & Storage	Administration

• Adults/Peds > 12 yrs at least 40 kg
• High-risk of progressing to severe disease or hospitalization
	• 700mg/200ml administered within 2 days of positive test and within 10 days of symptom onset	• Nausea
		• Dizziness
		• Headache
			• Vials to room temp
			• Final volume MUST be 200ml per FDA
			• Vial is 700mg/20ml
			• Remove 70ml from 250ml 0.9% NS
			• Add 20ml Bamlanivimab
			• Storage: 7 hours room temp & 24 hours refrigerated
			  • Includes hang time
			• Protect from light, Do not shake/freeze
				• Bring to room temp prior to infusion
				• Use 0.2/0.22-micron filter
				• Via gravity or pump
				• Over at least 60 minutes
				• Flush infusion line with NS post-infusion
				  • 50ml 0.9% NS
				• Monitor for 1-hour post-infusion

COVID-19 mAB Clinical Information: Casirivimab/Imdevimab[6,7]

Indications	Dosing	Adverse Events	Preparation & Storage	Administration

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

Defining Adverse Drug Reactions

- WHO Technical Report 498[8]
  - 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)
      - https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=professional.

- 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

STEP 2 — HHS/ASPR notifies health departments regarding allocation amounts

STEP 3 — Health departments determine allocations for facilities in their jurisdictions

STEP 4 — Distributor coordinates shipping details with receiving facilities

STEP 5 — Receiving facilities administer drug to eligible patients based on Emergency Use Authorization

- 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

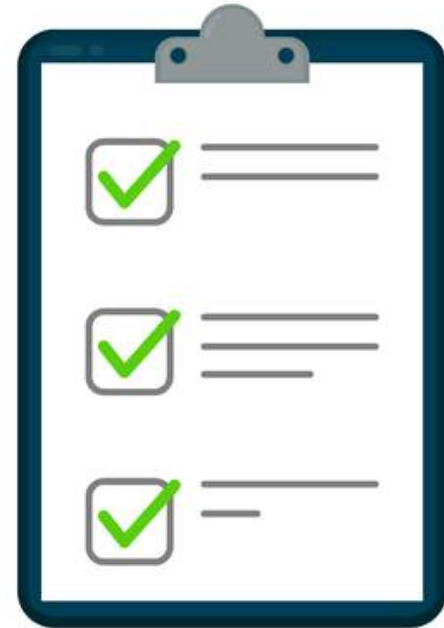# Reimbursement Considerations & Enrollment

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.
- Commerical 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

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

Code	CPT Short Descriptor	Labeler Name	Vaccine/Procedure Name	Payment Allowance	Effective Dates
91300	SARSCOV2 VAC 30MCG/0.3ML IM	Pfizer	Pfizer-Biontech Covid-19 Vaccine	$0.010*	xx/xx/xxxx – TBD
0001A	ADM SARSCOV2 30MCG/0.3ML 1ST	Pfizer	Pfizer-Biontech Covid-19 Vaccine Administration – First Dose	$16.940**	xx/xx/xxxx – TBD
0002A	ADM SARSCOV2 30MCG/0.3ML 2ND	Pfizer	Pfizer-Biontech Covid-19 Vaccine Administration – Second Dose	$28.390**	xx/xx/xxxx – TBD
91301	SARSCOV2 VAC 100MCG/0.5ML IM	Moderna	Moderna Covid-19 Vaccine	$0.010*	xx/xx/xxxx – TBD
0011A	ADM SARSCOV2 100MCG/0.5ML1ST	Moderna	Moderna Covid-19 Vaccine Administration – First Dose	$16.940**	xx/xx/xxxx – TBD
0012A	ADM SARSCOV2 100MCG/0.5ML2ND	Moderna	Moderna Covid-19 Vaccine Administration – Second Dose	$28.390**	xx/xx/xxxx – TBD

* 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.

** These rates will also be geographically adjusted for many providers. Certain settings utilize other payment methodologies, such as payment based on reasonable costs.

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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:

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

* 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.

https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

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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.

https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

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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 <mark>high risk</mark> 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
  o cardiovascular disease, OR
  o hypertension, OR
  o chronic obstructive pulmonary disease/other chronic respiratory disease

- Are 12 – 17 years of age AND have o BMI ≥85th percentile for their age and gender based on CDC growth charts, OR
  o sickle cell disease, OR
  o congenital or acquired heart disease, OR
  o neurodevelopmental disorders, for example, cerebral palsy, OR
  o a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  o 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

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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.

Institutional	Non-Institutional
- Hospital - Hospital Outpatient Department - Skilled Nursing Facility (includes Parts A and B)* - Critical Access Hospital - End-Stage Renal Disease Facility - Home Health Agency - Hospice - Comprehensive Outpatient Rehabilitation Facility - Federally Qualified Health Center** - Rural Health Clinic*** - Indian Health Services Facility	- Physician - Non-Physician - Clinic/Group Practice - Pharmacy (enrolled as Part B) - Mass Immunizer (roster bill only)

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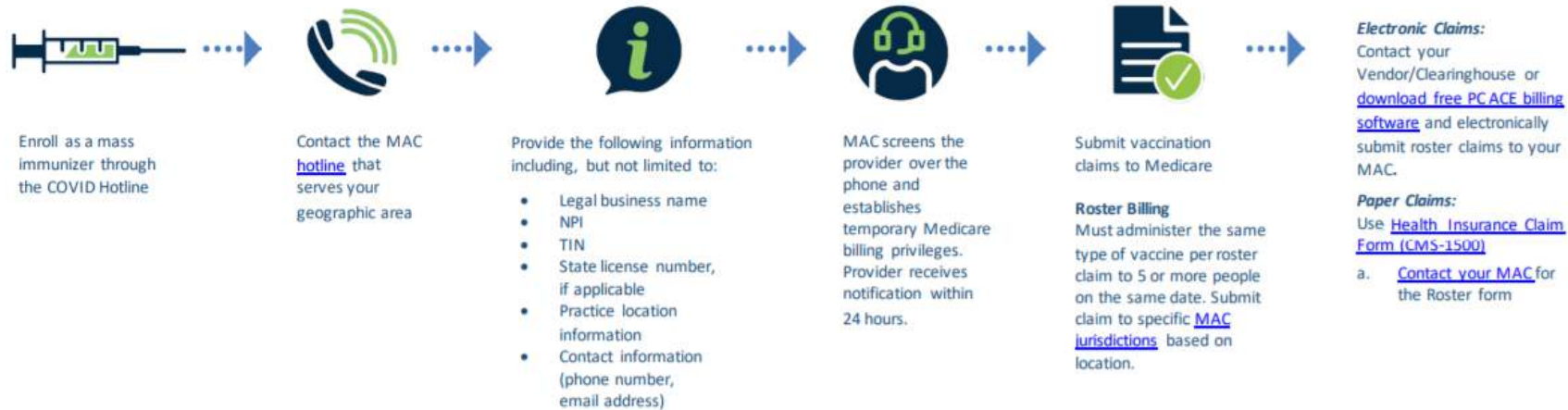
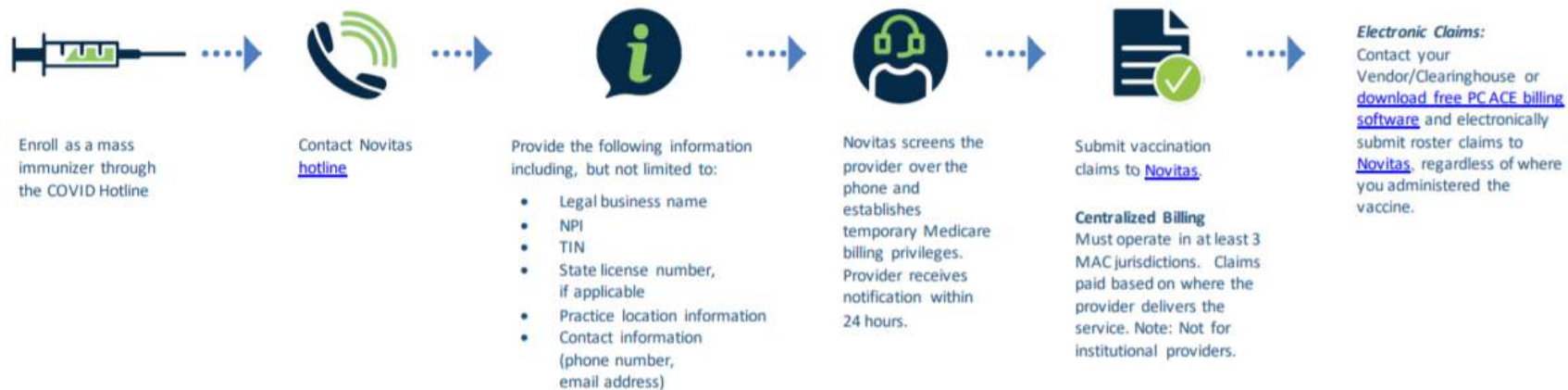| Institutional	Non-Institutional	Durable Medical Equipment (DME)
• Outpatient Physical Therapy • Occupational Therapy • Speech Pathology Services • Histocompatibility Laboratory • Religious Non-Medical Health Care Institution	• Independent Clinical Laboratory • Ambulance Service Supplier • Independent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

https://www.cms.gov/files/document/covid-19-mac-webpages-and-hotlines.pdf

3a Enroll in Medicare as Mass Immunizer to Roster Bill *(e.g. Senior Center)*

Enroll as a mass immunizer through the COVID Hotline

Contact the MAC hotline that serves your geographic area

Provide the following information including, but not limited to:
- Legal business name
- NPI
- TIN
- State license number, if applicable
- Practice location information
- Contact information (phone number, email address)

MAC screens the provider over the phone and establishes temporary Medicare billing privileges. Provider receives notification within 24 hours.

Submit vaccination claims to Medicare

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.

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

3b Enroll in Medicare as a Mass Immunizer to Centralize Bill *(e.g. Pharmacy)*

Enroll as a mass immunizer through the COVID Hotline

Contact Novitas hotline

Provide the following information including, but not limited to:
- Legal business name
- NPI
- TIN
- State license number, if applicable
- Practice location information
- Contact information (phone number, email address)

Novitas screens the provider over the phone and establishes temporary Medicare billing privileges. Provider receives notification within 24 hours.

Submit vaccination claims to Novitas.

Centralized Billing
Must operate in at least 3 MAC jurisdictions. Claims paid based on where the provider delivers the service. Note: Not for institutional providers.

Electronic Claims:
Contact your Vendor/Clearinghouse or download free PC ACE billing software and electronically submit roster claims to Novitas, regardless of where you administered the vaccine.

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).

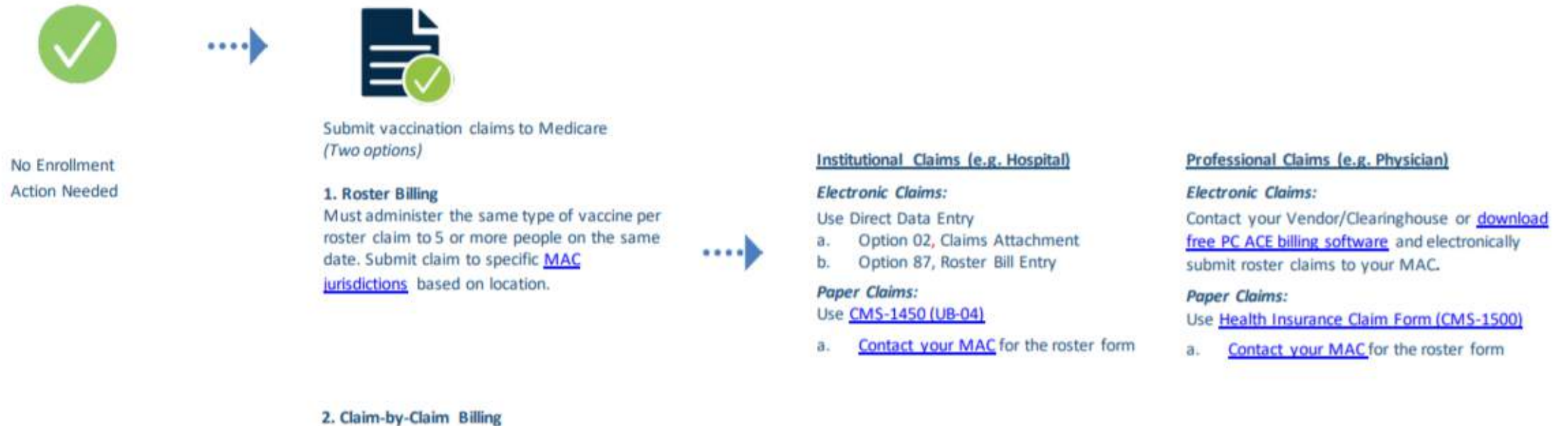# Hotline Enrollment is Temporary

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)*

No Enrollment
Action Needed

Submit vaccination claims to Medicare
(Two options)

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.

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

2. Claim-by-Claim Billing

https://www.cms.gov/files/document/covid-19-vaccine-enrollment-scenario-1.pdf

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Billing for COVID Treatments

Currently Enrolled Mass Immunizer *(e.g. Pharmacy)*

No Enrollment
Action Needed

Submit vaccination claims to Medicare
(Two options)

1. Centralized Billing
Must operate in at least 3 MAC jurisdictions.
Claims paid based on where the provider delivers
the service. Submit claim to Novitas.

2. 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.

Electronic Claims:
Contact your Vendor/Clearinghouse or download free PC ACE billing
software and electronically submit roster claims to your MAC.

Paper Claims: Not Applicable for Centralized Billing Claims
Use Health Insurance Claim Form (CMS-1500)

b.   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.

https://www.cms.gov/files/document/covid-19-vaccine-enrollment-scenario-1.pdf

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

1. Johns Hopkins Coronavirus Resource Center. https://coronavirus.jhu.edu/. Accessed 11/30/20.

2. Remdesivir Prescribing Information. https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf. Accessed 11/28/20.

3. Remdesivir by Gilead Sciences: FDA Warns of Newly Discovered Potential Drug Interaction That May Reduce Effectiveness of Treatment. https://www.fda.gov/safety/medical-product-safety-information/remdesivir-gilead-sciences-fda-warns-newly-discovered-potential-drug-interaction-may-reduce. Accessed 11/28/2020.

4. Bamlanivimab EUA Letter of Authorization. https://www.fda.gov/media/143602/download. Accessed 11.28.2020.

5. Bamlanivimab Fact Sheet for Healthcare Providers. http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf. Accessed 11/28/2020.

6. Casirivimab/Imdevimab EUA Letter of Authorization. https://www.fda.gov/media/143891/download. Accessed 11/28/2020.

7. Casrivimab/imdevimab Fact Sheet for Healthcare Providers. https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf. Accessed 11/28/2020.

8. International Drug Monitoring: The Role of National Centres. WHO Technical Report 498-1972. https://www.who-umc.org/media/2680/who-technical-report-498.pdf

9. Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction. https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

10. Enrollment for Administering COVID-19 Vaccine Shots. https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots

11. Want to Enroll in Medicare to Bill for Administering the COVID-19 Vaccine? Here's how… https://www.cms.gov/files/document/covid-19-vaccine-enrollment-scenario-2.pdf

12. COVID-19 MAC Webpages and Hotlines. https://www.cms.gov/files/document/covid-19-mac-webpages-and-hotlines.pdf

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