

Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelsystem.org.



Overview for Report: cder_iqp_wp025 (Report 2 of 4)

Request ID: cder_iqp_wp025

Request Description: In this report, we described COVID-19 therapeutic treatment and death among patients who were hospitalized with COVID-19 and among patients with severe COVID-19, stratified by racial and ethnic group. In addition to describing these groups overall, we also described the subset of each group with evidence of vaccination against COVID-19. This is report 2 of 4. Report 1 includes data from January 1, 2021 - April 30, 2021. Report 2 includes data from May 1, 2021 - August 31, 2021. Report 3 includes data from September 1, 2021 - December 31, 2021. Report 4 includes data from January 1, 2022 - April 30, 2022.

<u>Data Source:</u> We ran this query on June 13, 2022. This query contains data from 36 health care organizations (HCOs), provided through the TriNetX Live™ platform in the USA Network with No Shift from May 1, 2021 to August 31, 2021.

TriNetX aggregates electronic health record (EHR) systems data from its partner HCOs to create queryable datasets. TriNetX datasets primarily comprise clinical patient data such as demographics, diagnoses, procedures, labs, and medications. The USA Network with No Shift contains HCOs that do not date shift their data. For more information on the TriNetX Live™ platform and the TriNetX data visit their website here: https://trinetx.com/

Study Design: We identified individuals of different racial and ethnic groups with evidence of hospitalized COVID-19 and severe COVID-19, overall and among those with a history of vaccination against COVID-19. This was done using the Query Builder module in the TriNetX Live™ platform. We additionally characterized the demographic and geographic distribution of our cohorts using the Explore Cohort module. We further utilized the Compare Outcomes Analytics module to count the number of patients with a death record or evidence of various COVID-19 therapeutic treatments, including remdesivir, systemic glucocorticoids, baricitinib, COVID-19 convalescent plasma, IL-1 inhibitors, tocilizumab, bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, and sotrovimab.

<u>Cohort Definition:</u> Our cohorts of interest in this request were hospitalized COVID-19 and severe COVID-19. We defined hospitalized COVID-19 as evidence of a COVID-19 diagnosis or positive lab result with a record of an inpatient visit within three days before or after the COVID-19 record. We defined severe COVID-19 as evidence of a COVID-19 diagnosis or positive lab result with evidence of either an intensive care unit (ICU) encounter, extracorporeal membrane oxygenation (ECMO), or mechanical ventilation within seven days after the COVID-19 record. For cohorts with a history of COVID-19 vaccination, we required patients to have evidence of a COVID-19 vaccine any time prior to their COVID-19 record. For outcome evaluation, we defined our index date as the first day in which patients fulfilled all relevant cohort-defining events. Please see Appendix A for a list of codes used to define the cohorts in this request.

<u>Cohort Eligibility Criteria:</u> For each of our racial and ethnic demographic cohorts of interest, we defined the population by including an "ungrouped" demographic term for race or ethnicity in all Query Builder queries. We separately assessed the following racial and ethnic cohorts:

- 1) Overall
- 2) American Indian or Alaska Native OR Native Hawaiian or Other Pacific Islander
- 3) Asian
- 4) Black or African American
- 5) White
- 6) Unknown race and/or ethnicity (defined as patients who are missing EITHER a race OR an ethnicity term)
- 7) Hispanic/Latino
- 8) Non-Hispanic/Latino

cder_iqp_wp025 Page 1 of 66



Overview for Report: cder_iqp_wp025 (Report 2 of 4)

Outcomes of Interest: Our outcomes of interest in this request were death and the following grouped COVID-19 treatments: 1) remdesivir or systemic glucocorticoids, 2) baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors, 3) tocilizumab, and 4) bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab. We utilized the "Measures of Association" metric in the Compare Outcomes Analytics module to determine the number of patients with each outcome of interest. For the death outcome, we looked for evidence of a death record in the 0-30 days following the cohort-defining index criteria. For the COVID-19 treatment outcomes, we looked for evidence of the treatment of interest in the 0-14 days following index. We defined these COVID-19 treatments using RxNorm medication terms, Healthcare Common Procedure Coding System (HCPCS), and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) procedure codes. Please see Appendix B for a list of RxNorm terms and procedure codes used to define outcomes in this request.

Please see Appendices C-E for the specifications of parameters used in this request and design diagrams.

<u>Limitations:</u> Algorithms used to define cohorts and outcomes and mapping of source data to the data model are imperfect and susceptible to misclassification. Additionally, EHR data in the US lacks longitudinality. The information before or after patients' healthcare encounters could be missing, especially if patient care was administered across different HCOs that might not participate in the TriNetX USA network. We are unable to determine if absence of evidence of a condition implies a true absence of a condition or if the condition was not observed in the data. Therefore, data should be interpreted with these limitations in mind.

All counts provided through the TriNetX Live™ platform are rounded up to the nearest 10 to protect patient privacy. This rounding affects error, especially as sample sizes decrease. Error due to rounding can range from <0.09% when sample sizes are

>10,000 to nearly 20% as sample sizes drop. Thus, all estimates should be interpreted as ranges, and small sample sizes should be interpreted with caution.

Notes: We ran this query on June 13, 2022. A re-run of this query for the same query period in the future may not yield the same results owing to the dynamic nature of the TriNetX Live™ network.

Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's querying in the TriNetX platform, please refer to the Sentinel Website (https://www.sentinelinitiative.org/methods-data-tools/methods/trinetx-rapid-querying).

cder_iqp_wp025 Page 2 of 66



	Table of Contents						
Glossary Table 1	Terms for Analyses Using TriNetX Live™ Platform COVID-19 Therapeutics and Death Among Hospitalized Patients with COVID-19 and Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021, by Vaccination History						
Figure 1a	Demographics Among Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021						
Figure 1b	Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021						
Figure 1c	Demographics Among Asian Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021						
Figure 1d	Demographics Among Black or African American Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021						
Figure 1e	Demographics Among White Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021						
Figure 1f	Demographics Among Unknown Race or Unknown Ethnicity Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021						
Figure 1g	Demographics Among Hispanic/Latino Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021						
Figure 1h	Demographics Among Non-Hispanic/Latino Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021						
Figure 2a	Demographics Among Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 2b	Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 2c	Demographics Among Asian Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 2d	Demographics Among Black or African American Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 2e	Demographics Among White Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 2f	Demographics Among Unknown Race or Unknown Ethnicity Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 2g	Demographics Among Hispanic/Latino Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 2h	Demographics Among Non-Hispanic/Latino Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 3a	Demographics Among Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021						
Figure 3b	Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021						
Figure 3c	Demographics Among Asian Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021						
Figure 3d	Demographics Among Black or African American Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021						

cder_iqp_wp025 Page 3 of 66



	Table of Contents						
Figure 3e	Demographics Among White Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021						
Figure 3f	Demographics Among Unknown Race or Unknown Ethnicity Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021						
Figure 3g	Demographics Among Hispanic/Latino Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021						
Figure 3h	Demographics Among Non-Hispanic/Latino Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021						
Figure 4a	Figure 4a Demographics Among Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - 31, 2021						
Figure 4b	Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 4c Demographics Among Asian Patients with Severe COVID-19 and a History of Vaccination from May 1, August 31, 2021							
Figure 4d Demographics Among Black or African American Patients with Severe COVID-19 and a History of V from May 1, 2021 - August 31, 2021							
Figure 4e	Demographics Among White Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 4f	Demographics Among Unknown Race or Unknown Ethnicity Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 4g	Demographics Among Hispanic/Latino Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 4h	Demographics Among Non-Hispanic/Latino Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021						
Figure 5a	Geographic Distribution of Patients Hospitalized with COVID-19 from May 1, 2021 to August 31, 2021, by Race/Ethnicity						
Figure 5b	Geographic Distribution of Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 to August 31, 2021, by Race/Ethnicity						
Figure 5c	Geographic Distribution of Patients with Severe COVID-19 from May 1, 2021 to August 31, 2021, by Race/Ethnicity						
Figure 5d	Geographic Distribution of Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 to August 31, 2021, by Race/Ethnicity						
Appendix A	List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes, Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology (CPT), and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes, RxNorm Medication Codes, TriNetX Laboratory (TNX:LAB) Codes, and Visit Terms Used to Define Cohorts in this Request						

cder_iqp_wp025 Page 4 of 66



	Table of Contents								
Appendix B	List of Healthcare Common Procedure Coding System (HCPCS) and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes, and RxNorm Medication Codes Used to Define Outcomes in this Request								
Appendix C	Specifications Defining Query Builder Cohorts in this Request								
Appendix D	endix D Specifications Defining Analytics Modules in this Request								
Appendix E	Design Diagrams of Cohort Entry Requirements								

cder_iqp_wp025 Page 5 of 66



Glossary of Terms for Analyses Using TriNetX Live™ Platform*

Characteristic - A medical fact (e.g., diagnosis, procedure, lab result) that occurred on or before the cohort-defining index event.

Explore Cohort - A description module on the TriNetX platform that presents a clinical profile of patients in a given cohort. Patient counts are rounded up to the nearest 10 before percentages are calculated, so the sum each of the values in one category may not total to 100%.

Date Shifting - A data obfuscation technique that some HCOs use to preserve patient privacy. Date shifting entails assigning each patient a random number of days (eg, -365 to +365 days) and consistently adjusting each of their dates by that number of days, thus maintaining temporal relationships between records within a single patient.

Fact - (Medical Fact) A unit of utilization that represents a medical observation on a patient (e.g., diagnosis, procedure, clinical observation).

Filter - A method of limiting terms included in queries to a specific subset of data. Filters include age at time of event, data source (electronic health record or natural language processing); brand name, route, and strength for medication terms; occurrence (first or most recent) for lab terms; and priority for diagnosis and procedure terms.

Group - A series of codes and terms defined with Boolean logic that are used to create a query cohort. For each group, users have the ability to specified time periods of interest, and the number of instances that the group must occur for cohort entry.

Subgroup - Within a group, additional subgroups can be specified to define temporal relationships between the terms in the subgroup (e.g., terms in subgroup B must occur within 5 days after terms in subgroup A). Users can require that these temporal constraints be applied to the 1) first, 2) last, or 3) any instance of each subgroup.

Health Care Organization (HCO) - Organizations that contribute electronic healthcare record data to the TriNetX data networks. HCOs include academic institutions and community health provider systems and a single HCO may contain one or more individual sites or facilities.

Index - The first date when a patient meets all of the cohort-defining criteria. In Analytics modules, the index can be defined as the date when a patient meets all of the cohort criteria, or only one specific group's criteria.

Module - A subsection of the TriNetX platform that performs a distinct functionality. Cohorts are created using the Query Builder module. Descriptive modules include Healthcare Organizations, Explore Cohorts, Rate of Arrival, Summary Statistics, and Analyze Criteria. Advanced analytic modules include Analyze Outcomes, Compare Outcomes, Compare Cohorts, Treatment Pathways, and Incidence and Prevalence.

Network - An aggregation of HCOs contributing data to the platform. Multiple networks are available for querying on the platform; the different networks represent subsets of HCOs organized by date-shifting practices or availability of downloadable datasets.

Outcome - A medical fact (e.g., diagnosis, procedure, lab result) that occurred on or after the cohort-defining index event.

Query - In the TriNetX platform, a query is a distinct cohort with a unique set of terms and logic. Query cohorts are created using the Query Builder platform module.

Risk - In Advanced Analytics modules, risk refers to the percentage of patients in each cohort with the specified outcome of interest.

Priority - An indication whether the code was the condition that the provider spent the most time evaluating or treating during a visit. Possible values include primary, secondary, or unknown.

Term - The codes used to specify patient cohort criteria in a query. Code options include diagnoses, procedures, medications, labs, demographics, genomics, and visits. Terms can be linked together using and/or Boolean logic. TriNetX also creates terms that group together multiple medical codes into single clinical concepts.

cder_iqp_wp025 Page 6 of 66



Cannot Have Term - A category of terms within a query group that patients must not have evidence of to be included in the cohort.

Must Have Term - A category of terms within a query group that patients must have evidence of to be included in the cohort.

Time Constraint - used to define time periods of interest for each group within a query. Time constraints can be defined relative to the date the query was run (e.g., any time before today), or defined based on specific dates (e.g., January 1, 2015 to September 30, 2020).

Treatment Pathway - In Advanced Analytics modules, the Treatment Pathways module returns the order in which patients received treatment and the prevalence of treatments, including combination of medications, following an index event.

TriNetX Codes - For commonly used laboratory terms, TriNetX aggregates Logical Observation Identifiers Names and Codes (LOINC) laboratory codes at a clinically significant level to new queryable TNX:LAB terms.

Visit - A type of term used to specify the type of medical encounter or facility where the encounter was recorded. Visit terms are derived by TriNetX from the source data. Visits are recorded separately from the codes or labs that occurred during the encounter; care settings are not attached to individual codes. Values for visit terms include: ambulatory, emergency, field, home health, inpatient encounter, inpatient acute, inpatient non-acute, laboratory, observation, pharmacy, pre-admission, short stay, virtual, and unknown.

*all terms may not be used in this report

cder_iqp_wp025 Page 7 of 66



Table 1. COVID-19 Therapeutics and Death Among Hospitalized Patients with COVID-19 and Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021, by Vaccination History^{1,2}

	Hospitalized Patients with COVID-19			Patients with Severe COVID-19				
	Ove	rall	Vaccinated		Overall		Vacci	nated
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Patients of Any Race	45,190	100%	1,980	100%	7,060	100%	300	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	31,700	70.1%	1,190	60.1%	5,980	84.7%	240	80.0%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	2,570	5.7%	70	3.5%	910	12.9%	30	10.0%
Tocilizumab	2,010	4.4%	60	3.0%	890	12.6%	40	13.3%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	220	0.5%	20	1.0%	20	0.3%	0	0.0%
Death [0, 30 days]	2,940	6.5%	120	6.1%	2,130	30.2%	90	30.0%
Patients of American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Race*	250	100%	20	100%	60	100%	10	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	200	80.0%	10	50.0%	60	100.0%		
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	30	12.0%	10	50.0%	20	33.3%		
Tocilizumab	20	8.0%	0	0.0%	10	16.7%		
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	0	0.0%	0	0.0%	0	0.0%		
Death [0, 30 days]	30	12.0%	10	50.0%	20	33.3%		
Patients of Asian Race*	1,150	100%	60	100%	150	100%	10	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	750	65.2%	40	66.7%	120	80.0%		
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	50	4.3%	10	16.7%	20	13.3%		
Tocilizumab	40	3.5%	10	16.7%	20	13.3%		
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	10	0.9%	10	16.7%	0	0.0%		
Death [0, 30 days]	40	3.5%	10	16.7%	30	20.0%		
Patients of Black or African American Race	9,260	100%	350	100%	1,370	100%	60	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	6,610	71.4%	220	62.9%	1,180	86.1%	50	83.3%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	480	5.2%	20	5.7%	150	10.9%	10	16.7%
Tocilizumab	470	5.1%	20	5.7%	170	12.4%	10	16.7%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	50	0.5%	10	2.9%	10	0.7%	0	0.0%
Death [0, 30 days]	580	6.3%	30	8.6%	390	28.5%	20	33.3%



Table 1. COVID-19 Therapeutics and Death Among Hospitalized Patients with COVID-19 and Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021, by Vaccination History^{1,2}

	Hospitalized Patients with COVID-19			Patients with Severe Co			VID-19	
	Ove	Overall V		Vaccinated		Overall		inated
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Patients of White Race	29,010	100%	1,400	100%	4,580	100%	220	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	20,610	71.0%	840	60.0%	3,870	84.5%	180	81.8%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	1,800	6.2%	50	3.6%	660	14.4%	20	9.1%
Tocilizumab	1,270	4.4%	40	2.9%	590	12.9%	30	13.6%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	160	0.6%	20	1.4%	10	0.2%	0	0.0%
Death [0, 30 days]	2,030	7.0%	90	6.4%	1,460	31.9%	70	31.8%
Patients of Unknown Race or Unknown Ethnicity	6,940	100%	220	100%	1,240	100%	40	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	4,500	64.8%	120	54.5%	1,030	83.1%	20	50.0%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	310	4.5%	10	4.5%	120	9.7%	10	25.0%
Tocilizumab	320	4.6%	10	4.5%	160	12.9%	10	25.0%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	30	0.4%	10	4.5%	10	0.8%	0	0.0%
Death [0, 30 days]	410	5.9%	10	4.5%	320	25.8%	10	25.0%
Patients of Hispanic/Latino Ethnicity	9,350	100%	240	100%	1,280	100%	40	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	7,220	77.2%	150	62.5%	1,150	89.8%	30	75.0%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	660	7.1%	10	4.2%	220	17.2%	10	25.0%
Tocilizumab	430	4.6%	10	4.2%	210	16.4%	10	25.0%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	30	0.3%	10	4.2%	0	0.0%	0	0.0%
Death [0, 30 days]	400	4.3%	20	8.3%	330	25.8%	10	25.0%
Patients of Non-Hispanic/Latino Ethnicity	33,710	100%	1,690	100%	5,300	100%	250	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	23,100	68.5%	1,010	59.8%	4,440	83.8%	200	80.0%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	1,800	5.3%	60	3.6%	650	12.3%	20	8.0%
Tocilizumab	1,450	4.3%	50	3.0%	620	11.7%	40	16.0%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	180	0.5%	20	1.2%	10	0.2%	0	0.0%
Death [0, 30 days]	2,360	7.0%	100	5.9%	1,670	31.5%	80	32.0%

¹COVID-19 vaccination history assessed from (Ever, -1) days prior to index.

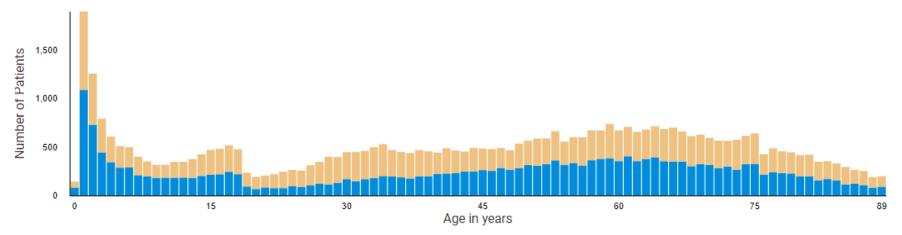
Page 9 of 66

²All counts are rounded up to the nearest 10 to protect patient privacy and should be interpreted as ranges.

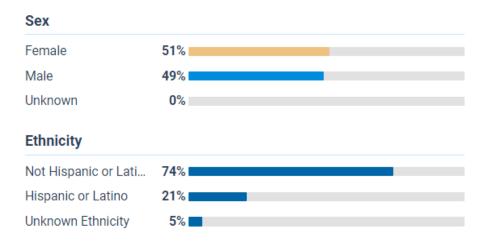
^{*}Detailed information cannot be displayed when cohort size is between 1-10.



Figure 1a. Demographics Among Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
45,190	0	90	45	26



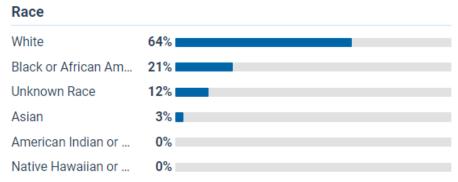
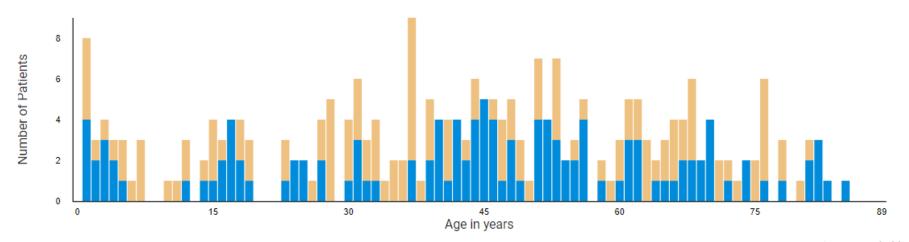
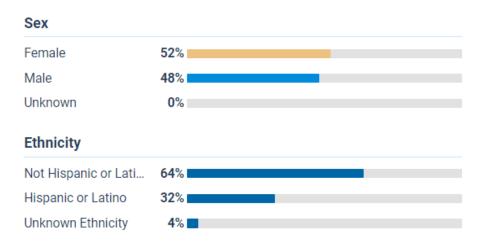




Figure 1b. Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
250	1	90	43	23



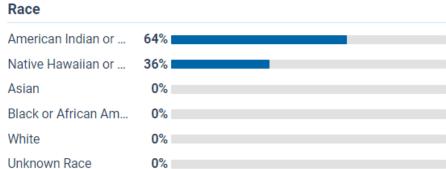
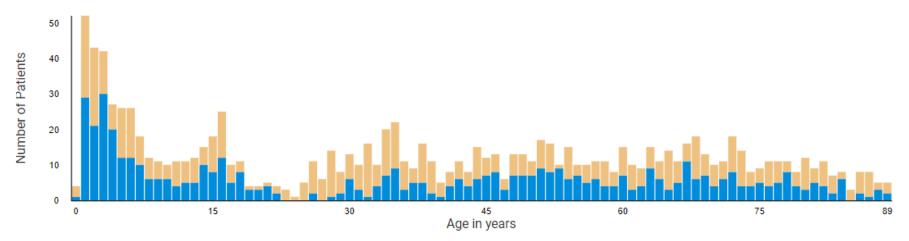




Figure 1c. Demographics Among Asian Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021



eviation	Standard De	Mean Age	Maximum Age	Minimum Age	Total Patients
28		39	90	0	1,150

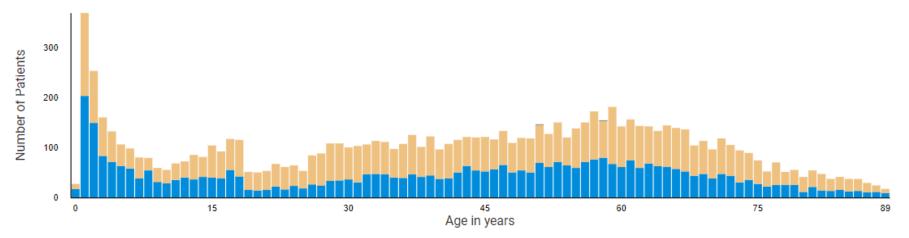
Race

Female 53% Male 47% Unknown 0% Ethnicity Not Hispanic or Lati... 97% Hispanic or Latino 2% Unknown Ethnicity 1%

Asian	100%
American Indian or	0%
Black or African Am	. 0%
White	0%
Native Hawaiian or	0%
Unknown Race	0%



Figure 1d. Demographics Among Black or African American Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021



9,260	0	90	42	25
Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation

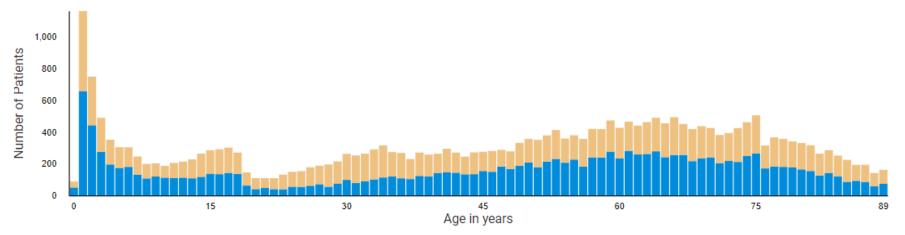
Race

Female 57% Male 43% Unknown 0% Ethnicity Not Hispanic or Lati... 94% Unknown Ethnicity 4% Hispanic or Latino 2%

Black or African Am.	. 100%
American Indian or	0%
Asian	0%
White	0%
Native Hawaiian or	0%
Unknown Race	0%



Figure 1e. Demographics Among White Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021



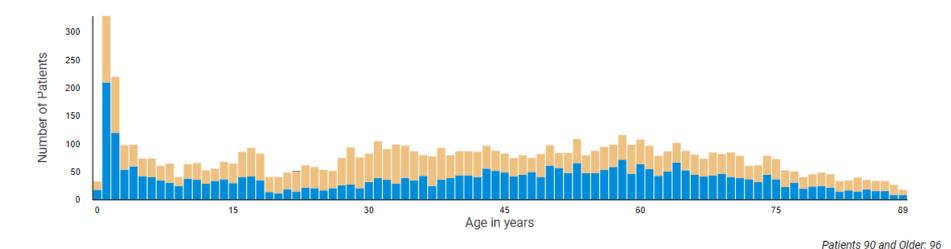
Total Patie	ts Minimum Age	Maximum Age	Mean Age	Standard Deviation
29,0	0 0	90	47	27

Male 51% Female 49% Unknown 0% Ethnicity Not Hispanic or Lati... 75% Hispanic or Latino 22% Unknown Ethnicity 3%

Race	
White	100%
American Indian or	0%
Asian	0%
Black or African Am	. 0%
Native Hawaiian or	0%
Unknown Race	0%



Figure 1f. Demographics Among Unknown Race or Unknown Ethnicity Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
6,940	0	90	41	25

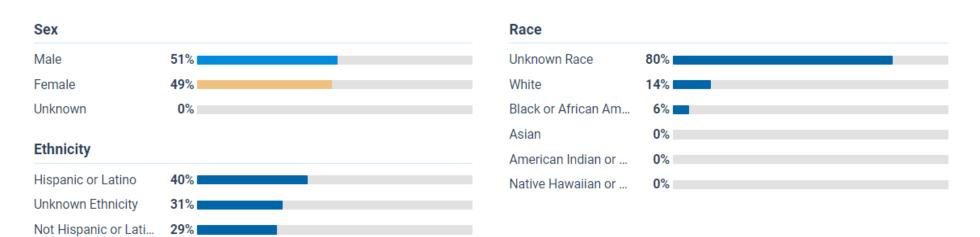
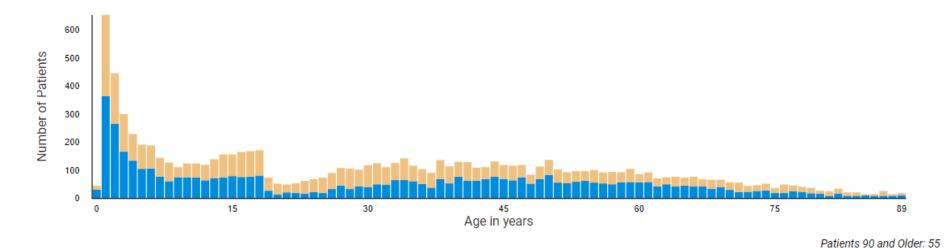




Figure 1g. Demographics Among Hispanic/Latino Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
9,350	0	90	32	24

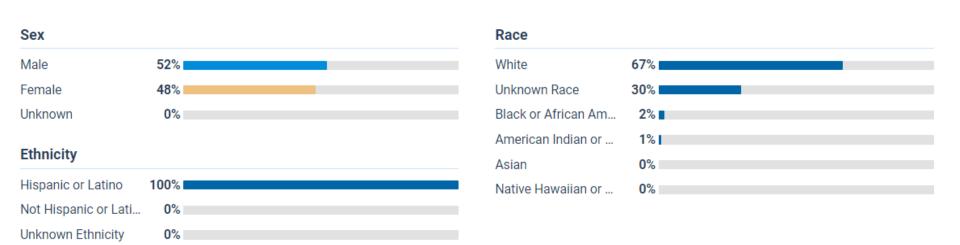
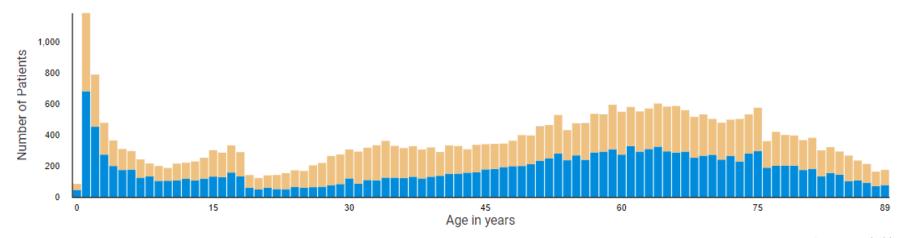
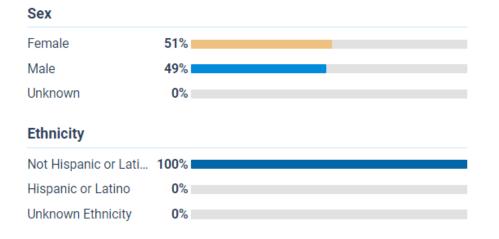




Figure 1h. Demographics Among Non-Hispanic/Latino Patients Hospitalized with COVID-19 from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
33,710	0	90	49	26



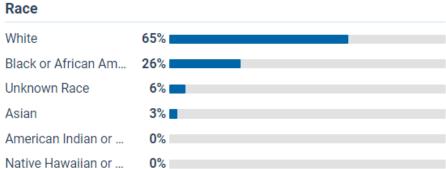
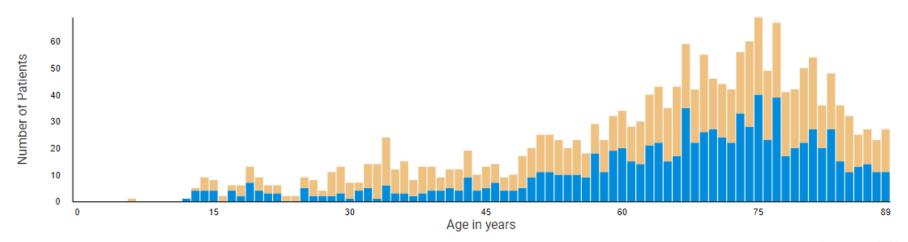




Figure 2a. Demographics Among Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,980	6	90	65	18

Female 53% Male 47% Unknown 0% Ethnicity Not Hispanic or Lati... 85% Hispanic or Latino 12% Unknown Ethnicity 3%

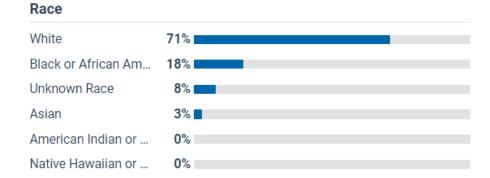
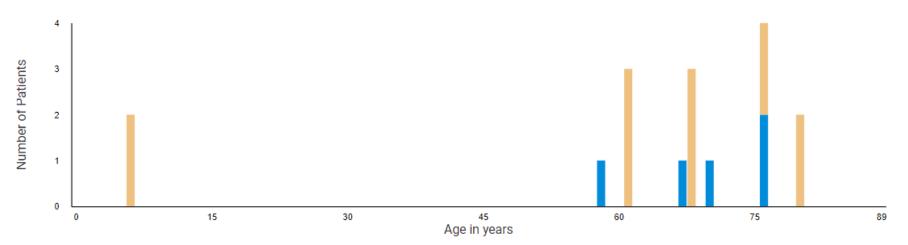




Figure 2b. Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
20	6	90	66	23

Male 50% Female 50% Unknown 0% Ethnicity Hispanic or Latino 50% Not Hispanic or Lati... 50% Unknown Ethnicity 0%

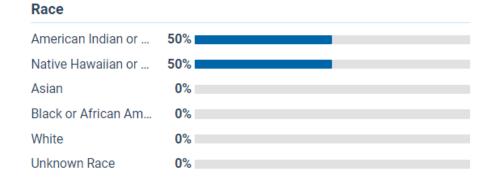
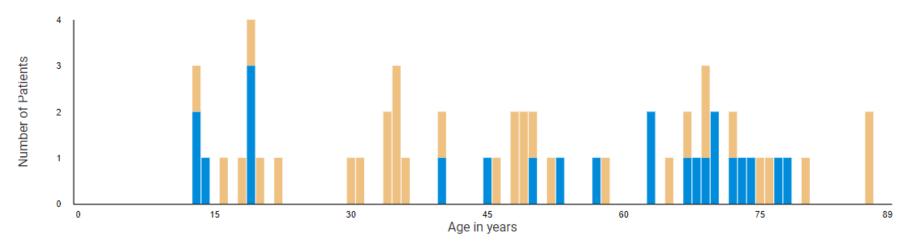




Figure 2c. Demographics Among Asian Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
60	13	90	52	24

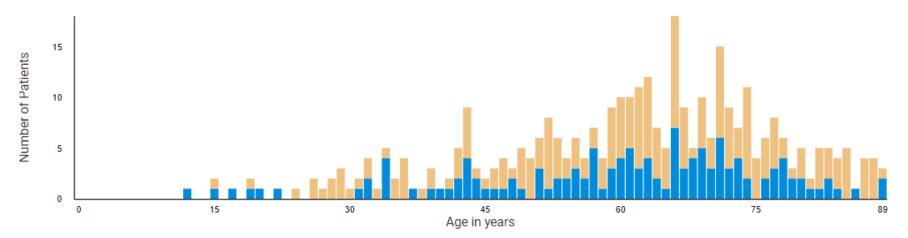
Female 66% Male 50% Unknown 0% Ethnicity Not Hispanic or Lati... 100% Unknown Ethnicity 16% Hispanic or Latino 0%

Race

Asian	100%
American Indian or	0%
Black or African Am	0%
White	0%
Native Hawaiian or	0%
Unknown Race	0%



Figure 2d. Demographics Among Black or African American Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
350	12	90	61	16

Female 63% Male 37% Unknown 0% Ethnicity Not Hispanic or Lati... 94% Hispanic or Latino 3% Unknown Ethnicity 3%

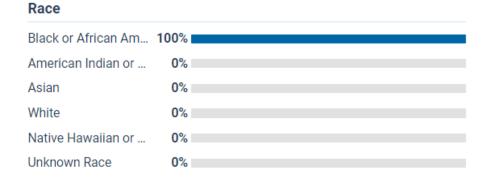
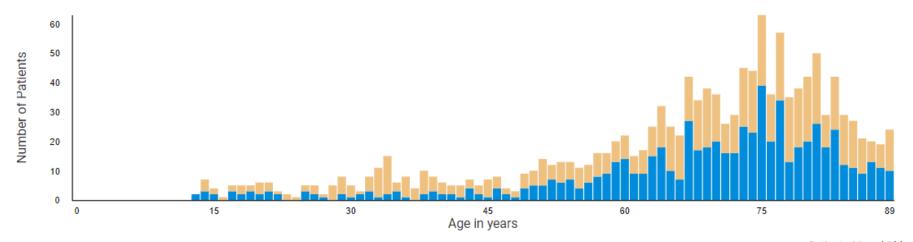


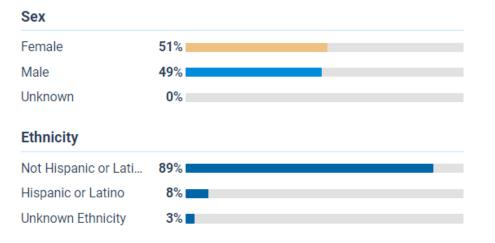


Figure 2e. Demographics Among White Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,400	13	90	67	18

Race



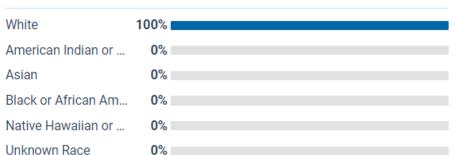
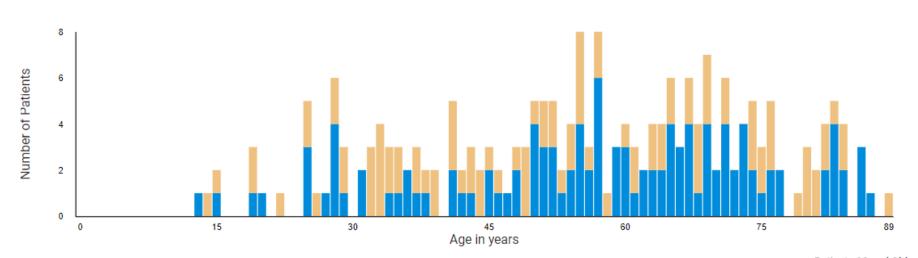
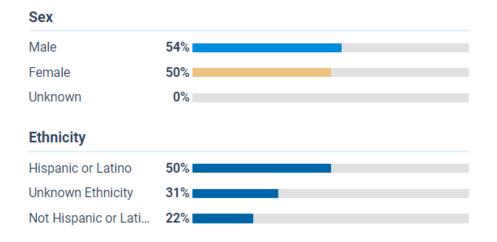




Figure 2f. Demographics Among Unknown Race or Unknown Ethnicity Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
220	13	90	57	19



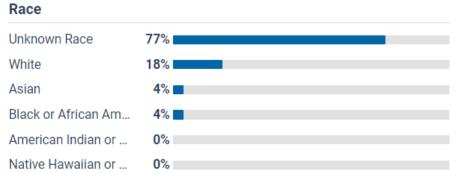
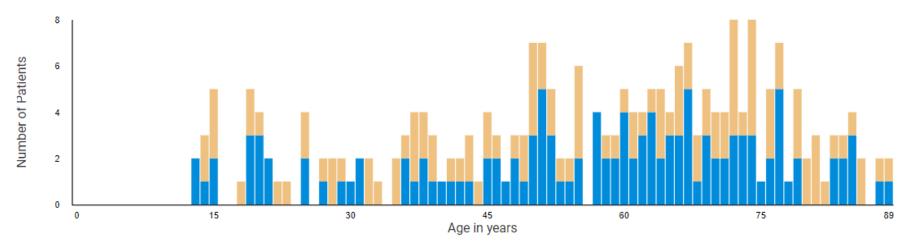
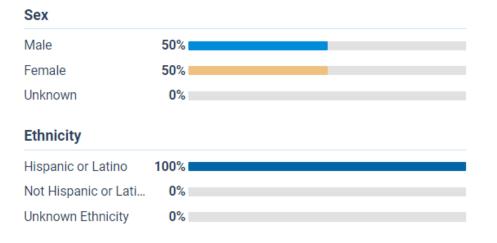




Figure 2g. Demographics Among Hispanic/Latino Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Standard Deviation	5.0	Maximum Age	Minimum Age	Total Patients
20	56	90	13	240



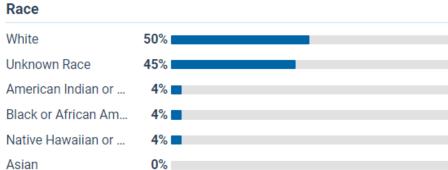
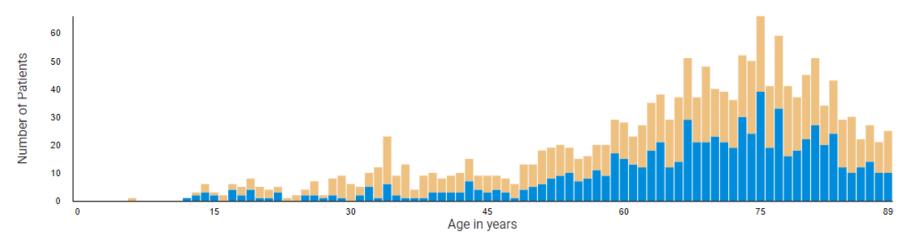
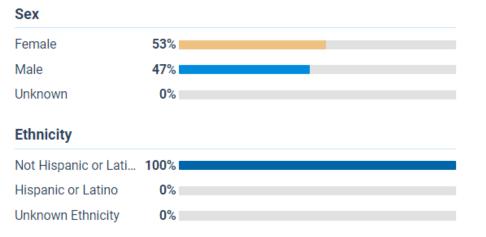




Figure 2h. Demographics Among Non-Hispanic/Latino Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,690	6	90	66	18



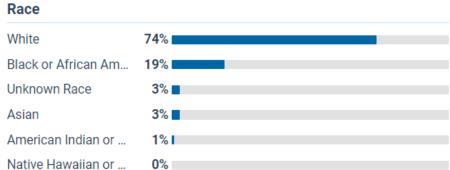
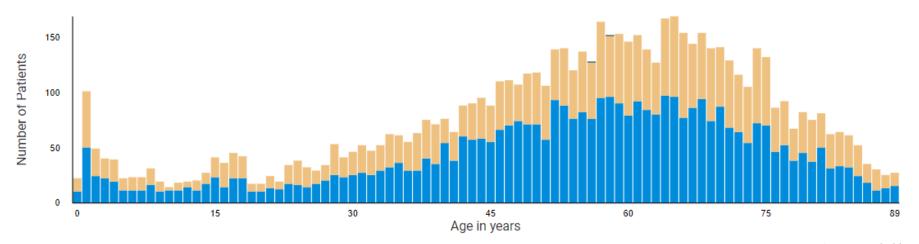




Figure 3a. Demographics Among Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
7,060	0	90	54	21

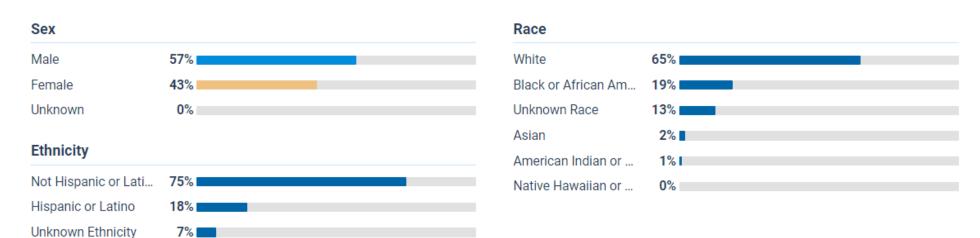
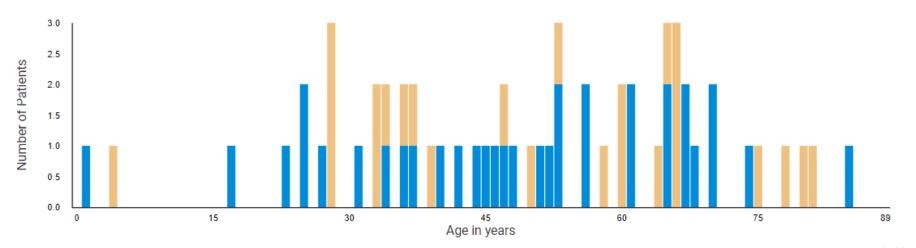


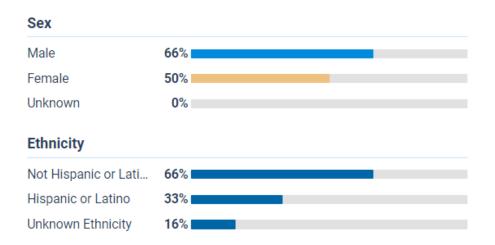


Figure 3b. Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
60	1	90	50	20

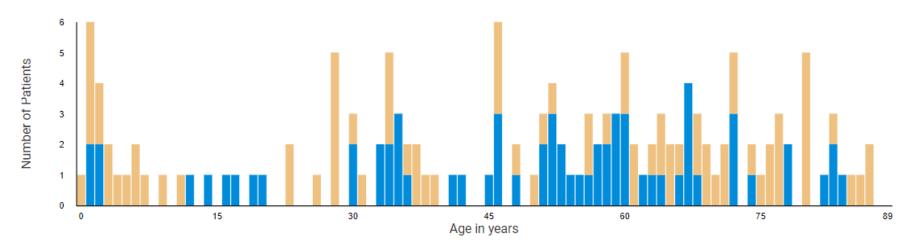
Race



American Indian or	66%
Native Hawaiian or	50% ■
Asian	0%
Black or African Am	0%
White	0%
Unknown Race	0%



Figure 3c. Demographics Among Asian Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021



Standard Deviation	Mean Age	Maximum Age	Minimum Age	Total Patients
26	49	90	0	150

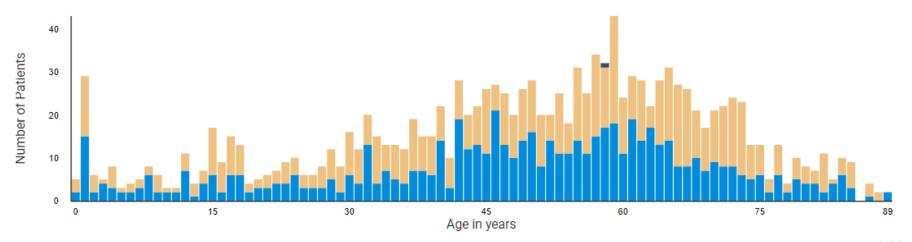
Race

Female 53% Male 47% Unknown 0% Ethnicity Not Hispanic or Lati... 93% Hispanic or Latino 6% Unknown Ethnicity 6%

Asian	100%
American Indian or	0%
Black or African Am	0%
White	0%
Native Hawaiian or	0%
Unknown Race	0%

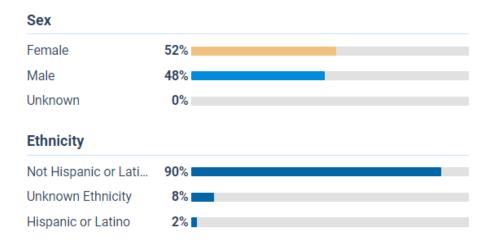


Figure 3d. Demographics Among Black or African American Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,370	0	90	49	21

Race



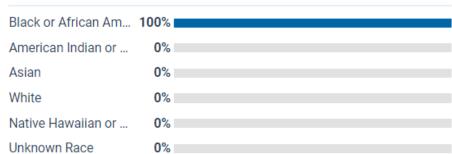
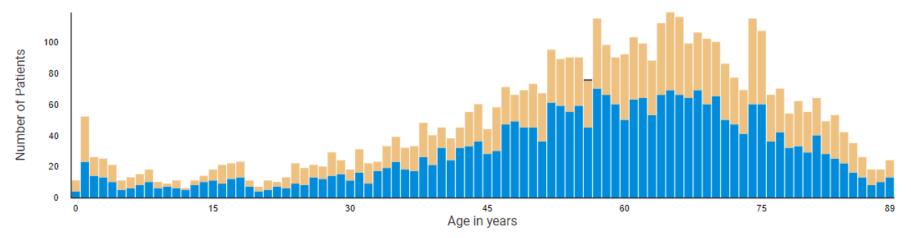




Figure 3e. Demographics Among White Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021



4,580	0	90	56	20
Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation

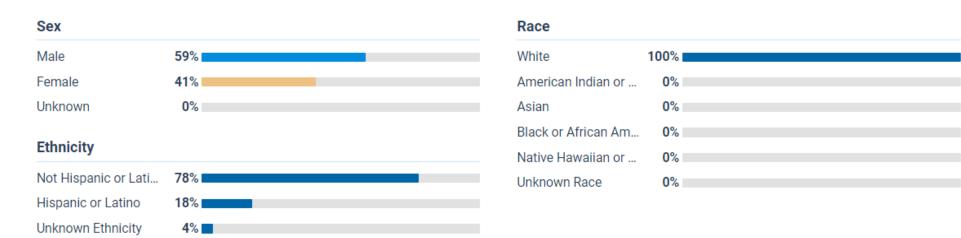
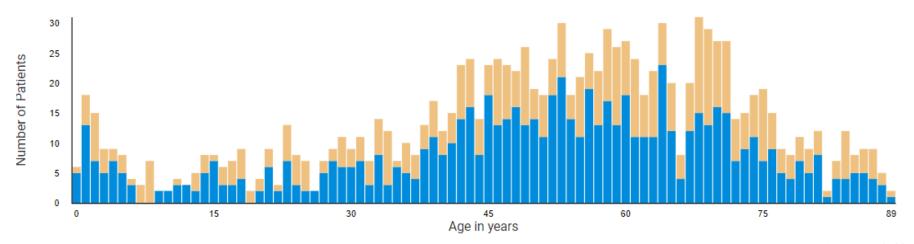
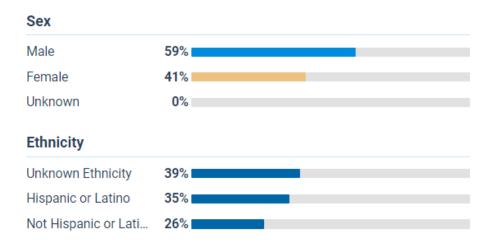




Figure 3f. Demographics Among Unknown Race or Unknown Ethnicity Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021



Standard Deviation	Mean Age	Maximum Age	Minimum Age	Total Patients
22	51	90	0	1,240



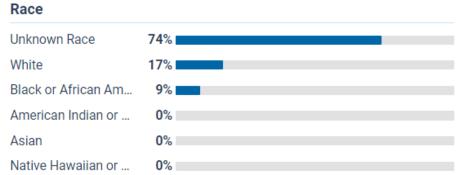
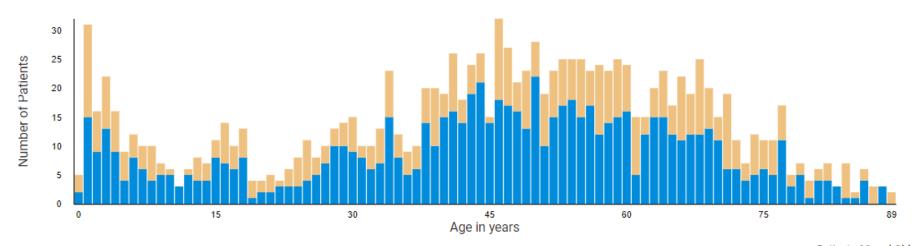


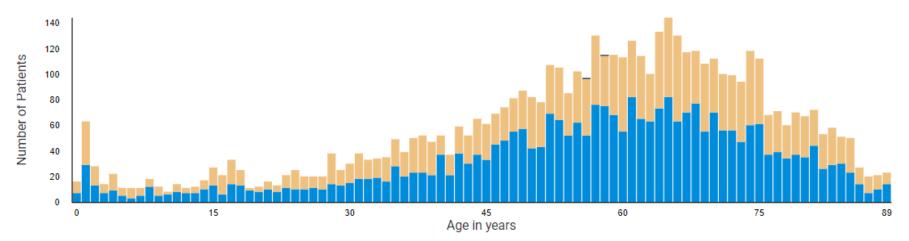
Figure 3g. Demographics Among Hispanic/Latino Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021



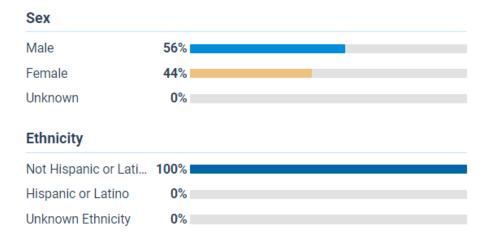
Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,280	0	90	45	22



Figure 3h. Demographics Among Non-Hispanic/Latino Patients with Severe COVID-19 from May 1, 2021 - August 31, 2021



Standard Deviation	Mean Age	Maximum Age	Minimum Age	Total Patients
20	56	90	0	5,300



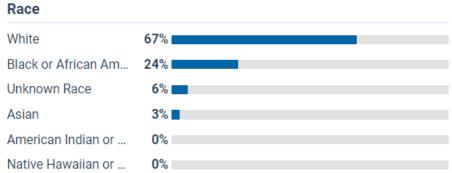
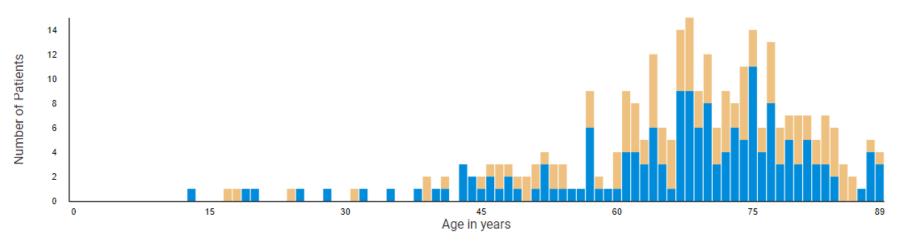




Figure 4a. Demographics Among Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
300	13	90	67	15

Male 57% Female 43% Unknown 0% Ethnicity Not Hispanic or Lati... 83% Hispanic or Latino 13% Unknown Ethnicity 6%

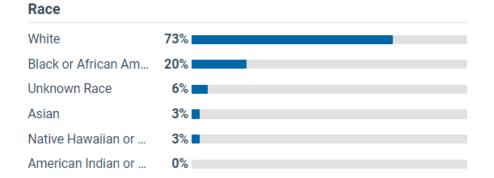




Figure 4b. Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021

*Cohort was too small so detailed information cannot be displayed.

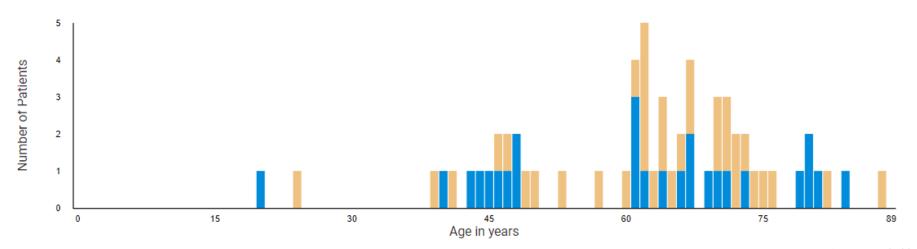


Figure 4c. Demographics Among Asian Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021

*Cohort was too small so detailed information cannot be displayed.



Figure 4d. Demographics Among Black or African American Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
60	20	88	62	14

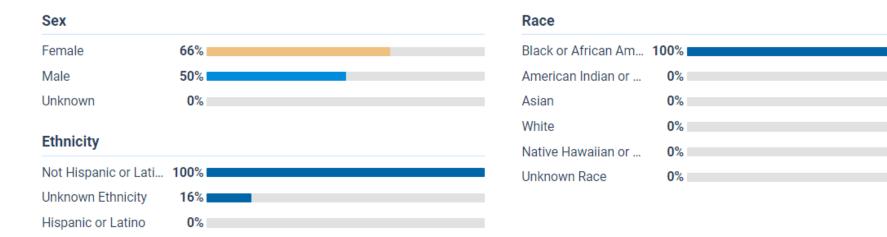
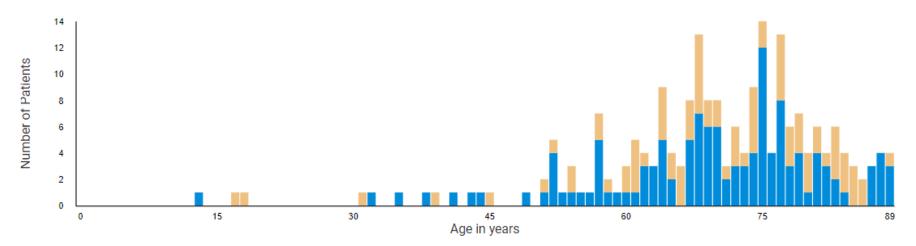




Figure 4e. Demographics Among White Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
220	13	90	70	13

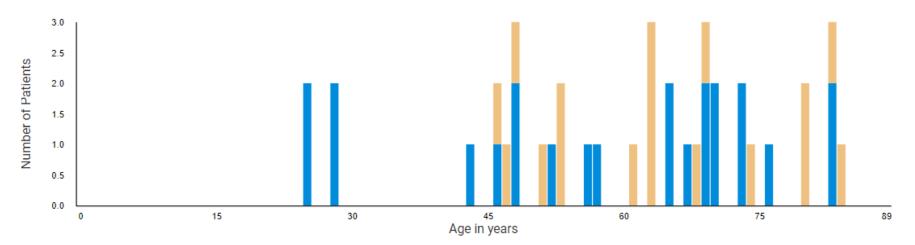
Race

Male 59% Female 41% Unknown 0% Ethnicity Not Hispanic or Lati... 81% Hispanic or Latino 13% Unknown Ethnicity 9%

White	100%
American Indian or	0%
Asian	0%
Black or African Am	0%
Native Hawaiian or	0%
Unknown Race	0%



Figure 4f. Demographics Among Unknown Race or Unknown Ethnicity Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
40	25	84	60	16

Male 50% Female 50% Unknown 0% Ethnicity Unknown Ethnicity 50% Hispanic or Latino 25% Not Hispanic or Lati... 25%

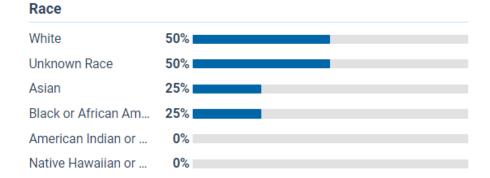
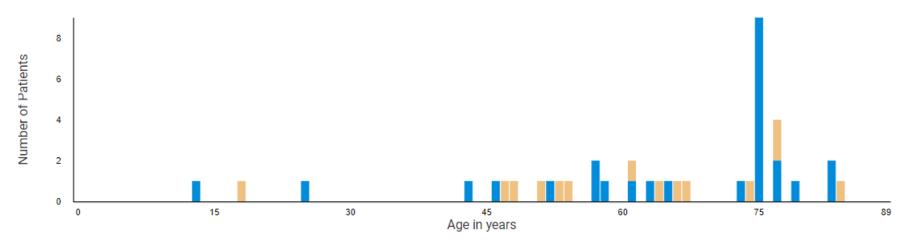




Figure 4g. Demographics Among Hispanic/Latino Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
40	13	84	63	17

Male 50% Female 50% Unknown 0% Ethnicity Hispanic or Latino 100% Not Hispanic or Lati... 0% Unknown Ethnicity 0%

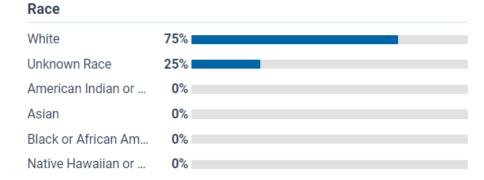
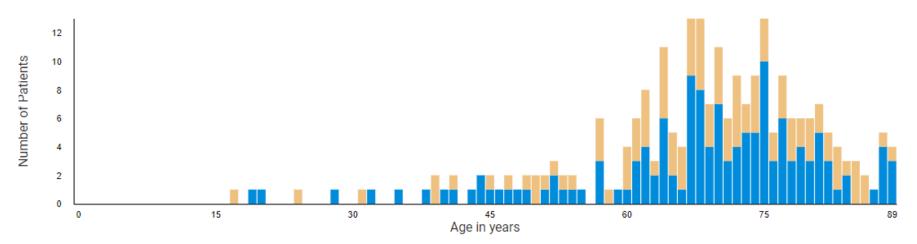




Figure 4h. Demographics Among Non-Hispanic/Latino Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 - August 31, 2021



Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
250	17	90	68	14





Figure 5a. Geographic Distribution of Patients Hospitalized with COVID-19 from May 1, 2021 to August 31, 2021, by Race/Ethnicity

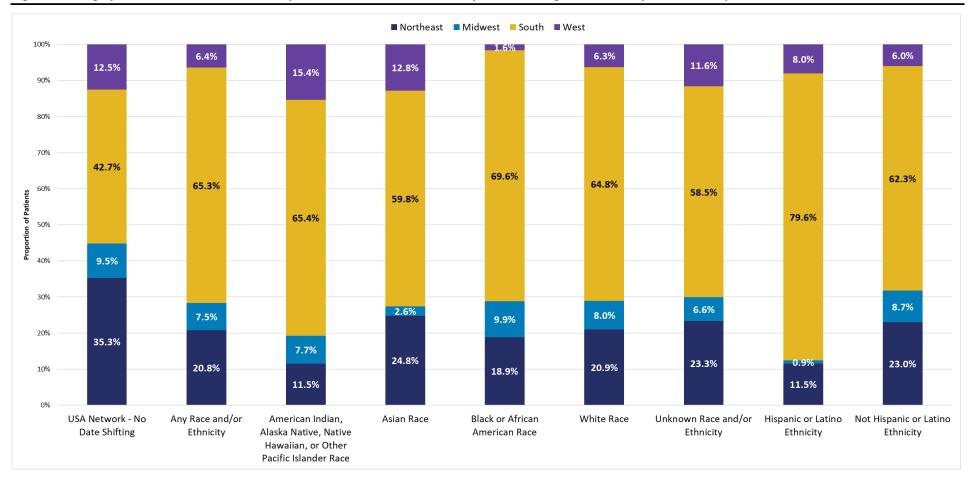




Figure 5b. Geographic Distribution of Patients Hospitalized with COVID-19 and a History of Vaccination from May 1, 2021 to August 31, 2021, by Race/Ethnicity

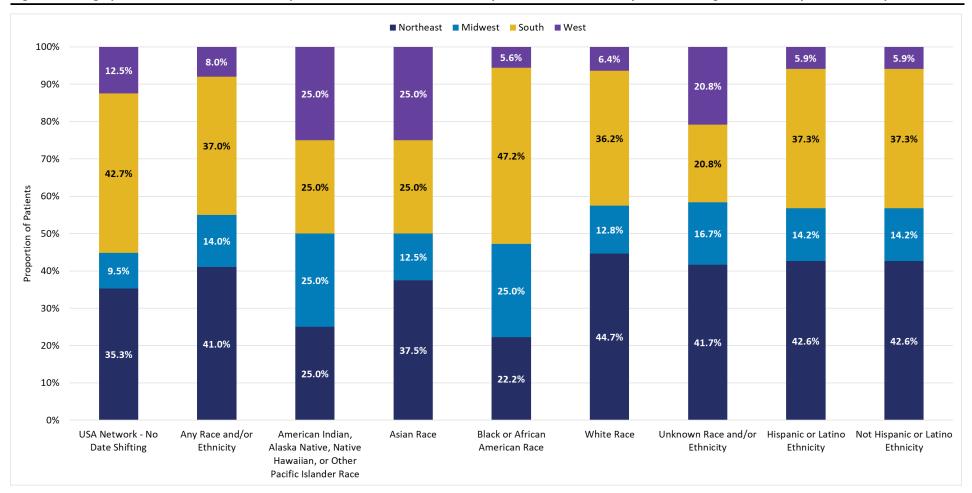




Figure 5c. Geographic Distribution of Patients with Severe COVID-19 from May 1, 2021 to August 31, 2021, by Race/Ethnicity

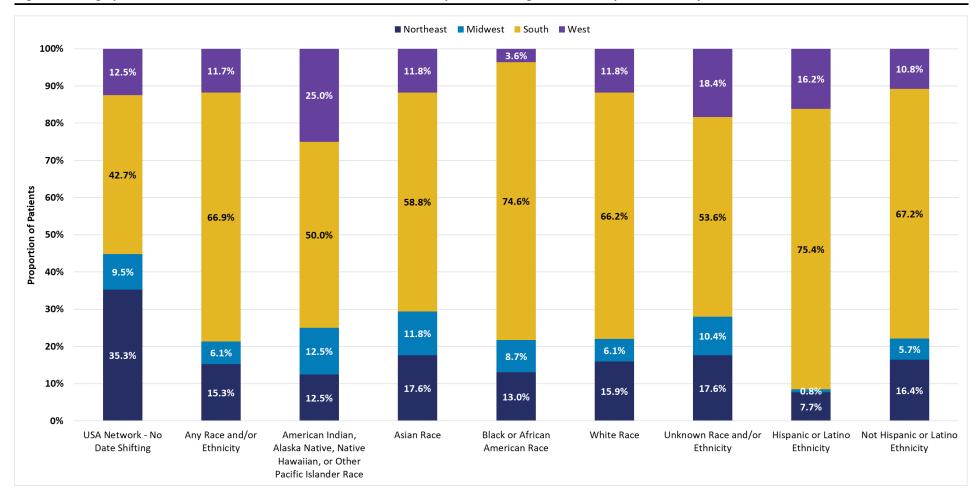
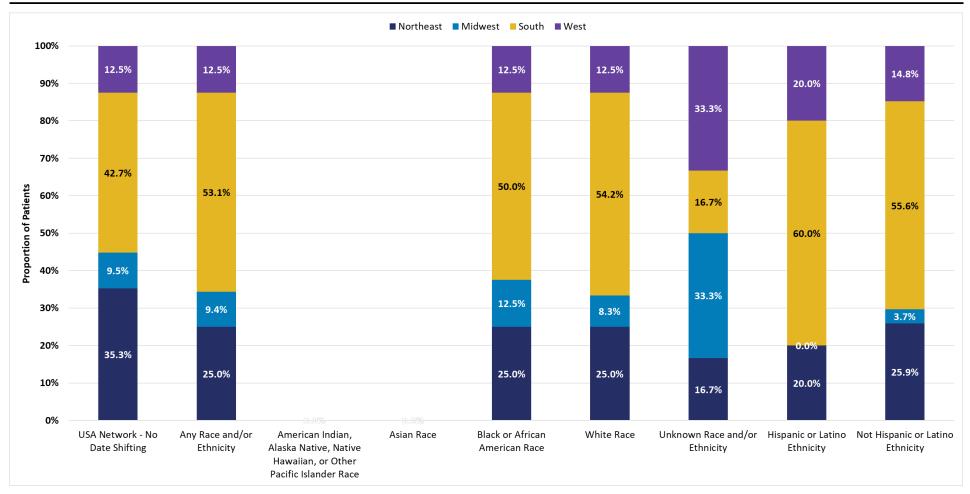




Figure 5d. Geographic Distribution of Patients with Severe COVID-19 and a History of Vaccination from May 1, 2021 to August 31, 2021, by Race/Ethnicity





		Code		
Code	Description	Category	Code Type	Filter
	COVID-19			
U07.1	COVID-19	Diagnosis	ICD-10-CM	n/a
9088	SARS coronavirus 2 and related RNA [presence]		TNX:LAB	Positive
	Hospitalization			
1013659	Hospital Inpatient Services	Procedure	CPT	n/a
1013699	Initial Inpatient Consultation Services	Procedure	CPT	n/a
1013729	Critical Care Services	Procedure	CPT	n/a
	Inpatient Encounter	Visit	Visit	n/a
	Inpatient Acute	Visit	Visit	n/a
	Inpatient Non-acute	Visit	Visit	n/a
	Short Stay	Visit	Visit	n/a
	COVID-19 Vaccination			
213	SARS-CoV-2 (COVID-19) Vaccine	Medication	RxNorm	n/a
91300	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus	Procedure	CPT	n/a
	disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30			
	mcg/0.3mL dosage, diluent reconstituted, for intramuscular use			
91301	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus		CPT	n/a
	disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100			
	mcg/0.5mL dosage, for intramuscular use			
91302	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus	Procedure	CPT	n/a
	disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus			
	Oxford 1 (ChAdOx1) vector, preservative free, 5x10^10 viral particles/0.5mL			
	dosage, for intramuscular use			
91303	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus	Procedure	CPT	n/a
	disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26)			
	vector, preservative free, 5x10^10 viral particles/0.5mL dosage, for			
	intramuscular use			
91305	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus	Procedure	CPT	n/a
	disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30			
	mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use			
				,
91306	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus	Procedure	CPT	n/a
	disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50			
	mcg/0.25 mL dosage, for intramuscular use			
91307	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus	Procedure	CPT	n/a
	disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10			
	mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use			
			105 15	,
XW013S6	Introduction of COVID-19 Vaccine Dose 1 into Subcutaneous Tissue,	Procedure	ICD-10-PCS	n/a
	Percutaneous Approach, New Technology Group 6			

cder_iqp_wp022 Page 46 of 66



		Code		
Code	Description	Category	Code Type	Filter
XW013T6	Introduction of COVID-19 Vaccine Dose 2 into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 6	Procedure	ICD-10-PCS	n/a
XW013U6	Introduction of COVID-19 Vaccine into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 6	Procedure	ICD-10-PCS	n/a
XW023S6	Introduction of COVID-19 Vaccine Dose 1 into Muscle, Percutaneous Approach, New Technology Group 6	Procedure	ICD-10-PCS	n/a
XW023T6	Introduction of COVID-19 Vaccine Dose 2 into Muscle, Percutaneous Approach, New Technology Group 6	Procedure	ICD-10-PCS	n/a
XW023U6	Introduction of COVID-19 Vaccine into Muscle, Percutaneous Approach, New Technology Group 6	Procedure	ICD-10-PCS	n/a
840534001	Administration of SARS-CoV-2 antigen vaccine	Procedure	CPT	n/a
	Severe COVID-19			
	Intensive Care Unit (ICU)			
G0390	Trauma response team associated with hospital critical care service	Procedure	HCPCS	n/a
G0509	Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth	Procedure	HCPCS	n/a
G0508	Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth	Procedure	HCPCS	n/a
99485	Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; first 30 minutes	Procedure	СРТ	n/a
99486	Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)	Procedure	СРТ	n/a
99478	Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams)	Procedure	CPT	n/a
99479	Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams)	Procedure	CPT	n/a
99480	Subsequent intensive care, per day, for the evaluation and management of the recovering infant (present body weight of 2501-5000 grams)	Procedure	СРТ	n/a

cder_iqp_wp022 Page 47 of 66



		Code		
ode	Description	Category	Code Type	Filter
9472	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age	Procedure	СРТ	n/a
9476	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age	Procedure	СРТ	n/a
9469	Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger	Procedure	СРТ	n/a
)188T	Remote real-time interactive video-conferenced critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes	Procedure	СРТ	n/a
)189T	Remote real-time interactive video-conferenced critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)	Procedure	СРТ	n/a
99471	Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age	Procedure	СРТ	n/a
99475	Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age	Procedure	СРТ	n/a
9468	Initial inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger	Procedure	СРТ	n/a
99477	Initial hospital care, per day, for the evaluation and management of the neonate, 28 days of age or younger, who requires intensive observation, frequent interventions, and other intensive care services	Procedure	CPT	n/a
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes	Procedure	CPT	n/a
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)	Procedure	CPT	n/a
99466	Critical care face-to-face services, during an interfacility transport of critically ill or critically injured pediatric patient, 24 months of age or younger; first 30-74 minutes of hands-on care during transport		CPT	n/a
99467	Critical care face-to-face services, during an interfacility transport of critically ill or critically injured pediatric patient, 24 months of age or younger; each additional 30 minutes (List separately in addition to code for primary service)		СРТ	n/a

Extracorporeal Membrane Oxygenation (ECMO)

cder_iqp_wp022 Page 48 of 66



		Code		
Code	Description	Category	Code Type	Filter
33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	Procedure	СРТ	n/a
33988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	Procedure	CPT	n/a
33957	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)	Procedure	СРТ	n/a
33958	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)	Procedure	СРТ	n/a
33959	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age (includes fluoroscopic guidance, when performed)	Procedure	СРТ	n/a
33962	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)	Procedure	СРТ	n/a
33963	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age (includes fluoroscopic guidance, when performed)	Procedure	СРТ	n/a
33964	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition central cannula(e) by sternotomy or thoracotomy, 6 years and older (includes fluoroscopic guidance, when performed)	Procedure	СРТ	n/a
33965	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age	Procedure	СРТ	n/a
33966	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older	Procedure	СРТ	n/a
33969	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age	Procedure	СРТ	n/a
33984	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older	Procedure	СРТ	n/a

cder_iqp_wp022 Page 49 of 66



		Code		
Code	Description	Category	Code Type	Filter
33985	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age	Procedure	СРТ	n/a
33986	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older	Procedure	CPT	n/a
33951	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)	Procedure	СРТ	n/a
33952	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)	Procedure	СРТ	n/a
33953	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age	Procedure	CPT	n/a
33954	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older	Procedure	CPT	n/a
33955	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age	Procedure	CPT	n/a
33956	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older	Procedure	CPT	n/a
33946	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous	Procedure	CPT	n/a
33947	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-arterial	Procedure	CPT	n/a
33948	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-venous	Procedure	СРТ	n/a
33949	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-arterial	Procedure	CPT	n/a
33987	Arterial exposure with creation of graft conduit (eg, chimney graft) to facilitate arterial perfusion for ECMO/ECLS (List separately in addition to code for primary procedure)	Procedure	СРТ	n/a
5A15223	Extracorporeal Membrane Oxygenation, Continuous	Procedure	ICD-10-PCS	n/a
5A1522F	Extracorporeal Oxygenation, Membrane, Central	Procedure	ICD-10-PCS	n/a

cder_iqp_wp022 Page 50 of 66



		Code		
Code	Description	Category	Code Type	Filter
5A1522G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial	Procedure	ICD-10-PCS	n/a
5A1522H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous	Procedure	ICD-10-PCS	n/a
5A15A2F	Extracorporeal Oxygenation, Membrane, Central, Intraoperative	Procedure	ICD-10-PCS	n/a
5A15A2G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial, Intraoperative	Procedure	ICD-10-PCS	n/a
5A15A2H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous, Intraoperative	Procedure	ICD-10-PCS	n/a
	Mechanical Ventilation			
31500	Intubation, endotracheal, emergency procedure	Procedure	CPT	n/a
A0396	ALS specialized service disposable supplies; esophageal intubation	Procedure	HCPCS	n/a
94004	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day	Procedure	СРТ	n/a
94002	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day	Procedure	СРТ	n/a
94003	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day	Procedure	CPT	n/a
A4483	Moisture exchanger, disposable, for use with invasive mechanical ventilation	Procedure	HCPCS	n/a
E0481	Intrapulmonary percussive ventilation system and related accessories	Procedure	HCPCS	n/a
94662	Continuous negative pressure ventilation (CNP), initiation and management	Procedure	CPT	n/a
09HN7BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
09HN8BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS	n/a
OBH13EZ	Insertion of Endotracheal Airway into Trachea, Percutaneous Approach	Procedure	ICD-10-PCS	n/a
OBH17EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
OBH18EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS	n/a
OCHY7BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
OCHY8BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS	n/a
ODH57BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
ODH58BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS	n/a

cder_iqp_wp022 Page 51 of 66



		Code		_
Code	Description	Category	Code Type	Filter
0WHQ73Z	Insertion of Infusion Device into Respiratory Tract, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
0WHQ7YZ	Insertion of Other Device into Respiratory Tract, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
5A09357	Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, Continuous Positive Airway Pressure	Procedure	ICD-10-PCS	n/a
5A09457	Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, Continuous Positive Airway Pressure	Procedure	ICD-10-PCS	n/a
5A09557	Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, Continuous Positive Airway Pressure	Procedure	ICD-10-PCS	n/a
5A1935Z	Respiratory Ventilation, Less than 24 Consecutive Hours	Procedure	ICD-10-PCS	n/a
5A1945Z	Respiratory Ventilation, 24-96 Consecutive Hours	Procedure	ICD-10-PCS	n/a
5A1955Z	Respiratory Ventilation, Greater than 96 Consecutive Hours	Procedure	ICD-10-PCS	n/a

cder_iqp_wp022 Page 52 of 66



Appendix B. List of Healthcare Common Procedure Coding System (HCPCS) and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes, and RxNorm Medication Codes Used to Define Outcomes in this Request

		Code		
Code	Description	Category	Code Type	Filter
2204710	Remdesivir	Madiantina	Dullarina	- /-
2284718	Remdesivir	Medication	RxNorm	n/a
XW033E5	Introduction of Remdesivir Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5	Procedure	ICD-10-PCS	n/a
XW043E5	Introduction of Remdesivir Anti-infective into Central Vein,	Procedure	ICD-10-PCS	n/a
XWU43E3	Percutaneous Approach, New Technology Group 5	riocedule	ICD-10-FC3	ii/a
	Systemic Glucocorticoids			
8640	Prednisone	Medication	RxNorm	n/a
3264	Dexamethasone	Medication	RxNorm	Unknown, oral, & injectable
6902	Methylprednisolone	Medication	RxNorm	Unknown, oral, & injectable
8638	Prednisolone	Medication	RxNorm	Unknown, oral, & injectable
1514	Betamethasone	Medication	RxNorm	Oral & injectable
2878	Cortisone	Medication	RxNorm	
41126	Fluticasone	Medication	RxNorm	
25255	Formoterol	Medication	RxNorm	
5492	Hydrocortisone	Medication	RxNorm	Oral & injectable
108118	Mometasone	Medication	RxNorm	
10759	Triamcinolone	Medication	RxNorm	Oral & injectable
	Baricitinib			
2047232	Baricitinib	Medication	RxNorm	n/a
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6	Procedure	ICD-10-PCS	n/a
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6	Procedure	ICD-10-PCS	n/a
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6	Procedure	ICD-10-PCS	n/a
	COVID-19 Convalescent Plasma			
XW13325	Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5	Procedure	ICD-10-PCS	n/a
XW14325	Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5	Procedure	ICD-10-PCS	n/a
	IL-1 Inhibitors			
72435	Anakinra	Medication	RxNorm	n/a
853491	Canakinumab	Medication	RxNorm	n/a
	Tocilizumab			
612864	Tocilizumab	Medication	RxNorm	n/a

cder_iqp_wp022 Page 53 of 66



Appendix B. List of Healthcare Common Procedure Coding System (HCPCS) and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes, and RxNorm Medication Codes Used to Define Outcomes in this Request

		Code		
Code	Description	Category	Code Type	Filter
	Bamlanivimab			
2463114	Bamlanivimab	Medication	RxNorm	n/a
M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring	Procedure	HCPCS	n/a
Q0239	Injection, bamlanivimab-xxxx, 700 mg	Procedure	HCPCS	n/a
XW033F6	Introduction of bamlanivimab monoclonal antibody into peripheral	Procedure	ICD-10-PCS	n/a
	vein, percutaneous approach, new technology group 6			
XW043F6	Introduction of bamlanivimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	Procedure	ICD-10-PCS	n/a
	Bamlanivimab/Etesevimab			
M0245	Intravenous infusion, bamlanivimab and etesevimab, includes infusion	Procedure	HCPCS	n/a
	and post administration monitoring			
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg	Procedure	HCPCS	n/a
	Casirivimab/Imdevimab			
2465242	Casirivimab	Medication	RxNorm	n/a
2465249	Imdevimab	Medication	RxNorm	n/a
M0243	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring	Procedure	HCPCS	n/a
Q0243	Injection, casirivimab and imdevimab, 2400 mg	Procedure	HCPCS	n/a
M0244	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring the home or residence; this includes a beneficiary's home that has been made provider based to the hospital during the covid 19 public health emergency	Procedure	HCPCS	n/a
	Sotrovimab			
2550731	Sotrovimab	Medication	RxNorm	n/a
M0247	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring	Procedure	HCPCS	n/a
Q0247	Injection, sotrovimab, 500 mg		HCPCS	n/a

cder_iqp_wp022 Page 54 of 66



	Overall	American Indian or Alaska Nati	ve, or Native Hawaiian or Other Pacific Islander		Asian
Cohort 1a: Hospitalized with CC	OVID - Overall	Cohort 1b: Hospitalized with CO Native Hawaiian/Other Pacific	OVID - American Indian/Alaska Native, or Islander	Cohort 1c: Hospitalized with C	OVID - Asian
Group 1:	Time Restrictions	Ungrouped Terms:		Ungrouped Terms:	
Subgroup 1A:		Must Have:		Must Have:	
Must Have :		American Indian/Alaska Native	OR Native Hawaiian/Other Pacific Islander	Asian	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Group 1:	Time Restrictions	Group 1:	Time Restrictions
AND Subgroup 1B:		Subgroup 1A:		Subgroup 1A:	
Must Have :		Must Have :		Must Have :	
Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021
Cohort 2a: Hospitalized with CO	OVID and Vaccine - Overall	AND Subgroup 1B:		AND Subgroup 1B:	
Group 1:	Time Restrictions	Must Have :		Must Have :	
Subgroup 1A:		Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Hospitalization	[-3, 3] from Any Instance of COVID (1A)
Must Have :		Cohort 2b: Hospitalized with Co Native, or Native Hawaiian/Otl	OVID and Vaccine - American Indian/Alaska ner Pacific Islander	Cohort 2c: Hospitalized with C	OVID and Vaccine - Asian
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Ungrouped Terms:		Ungrouped Terms:	
AND Subgroup 1B:		Must Have:		Must Have:	
Must Have :		American Indian/Alaska Native	OR Native Hawaiian/Other Pacific Islander	Asian	
Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Group 1:	Time Restrictions	Group 1:	Time Restrictions
Group 2:	Time Restrictions	Subgroup 1A:		Subgroup 1A:	
Subgroup 2A:		Must Have :		Must Have :	
Must Have :		Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	AND Subgroup 1B:		AND Subgroup 1B:	
AND Subgroup 2B:		Must Have :		Must Have :	
Must Have :		Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Hospitalization	[-3, 3] from Any Instance of COVID (1A)
COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	Group 2:	Time Restrictions	Group 2:	Time Restrictions
Cohort 3a: Severe COVID - Over		Subgroup 2A:		Subgroup 2A:	
Group 1:	Time Restrictions	Must Have :		Must Have :	
Subgroup 1A:		Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021
Must Have :		AND Subgroup 2B:		AND Subgroup 2B:	

cder_iqp_wp022 Page 55 of 66



	Overall	American Indian or Alaska Nati	ve, or Native Hawaiian or Other Pacific Islander		Asian
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Must Have :		Must Have :	
AND Subgroup 1B:		COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)
Must Have :		Cohort 3b: Severe COVID - Ame Hawaiian/Other Pacific Islande	rican Indian/Alaska Native, or Native r	Cohort 3c: Severe COVID - Asia	an
ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)	Ungrouped Terms:		Ungrouped Terms:	
Cohort 4a: Severe COVID and V	accine- Overall	Must Have:		Must Have:	
Group 1:	Time Restrictions	American Indian/Alaska Native	OR Native Hawaiian/Other Pacific Islander	Asian	
Subgroup 1A:		Group 1:	Time Restrictions	Group 1:	Time Restrictions
Must Have :		Subgroup 1A:		Subgroup 1A:	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Must Have :		Must Have :	
AND Subgroup 1B:		Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021
Must Have :		AND Subgroup 1B:		AND Subgroup 1B:	
ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)	Must Have :		Must Have :	
Group 2:	Time Restrictions	ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)	ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)
Subgroup 2A:		Cohort 4b: Severe COVID and V Native Hawaiian/Other Pacific	accine - American Indian/Alaska Native, or	Cohort 4c: Severe COVID and	Vaccine - Asian
Must Have :		Ungrouped Terms:		Ungrouped Terms:	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Must Have:		Must Have:	
AND Subgroup 2B:		American Indian/Alaska Native	OR Native Hawaiian/Other Pacific Islander	Asian	
Must Have :		Group 1:	Time Restrictions	Group 1:	Time Restrictions
COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	Subgroup 1A:		Subgroup 1A:	
		Must Have :		Must Have :	
		Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021
		U07.1 COVID diagnosis		U07.1 COVID diagnosis	
		AND Subgroup 1B:		AND Subgroup 1B:	
		Must Have :		Must Have :	
		ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)	ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)
		Group 2:	Time Restrictions	Group 2:	Time Restrictions
		Subgroup 2A:		Subgroup 2A:	
		Must Have :		Must Have :	
		Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021

cder_iqp_wp022 Page 56 of 66



Overall

American Indian or Alaska Native, or Native Hawaiian or Other Pacific Islander

AND Subgroup 2B:	
Must Have :	
COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)

	Asian
AND Subgroup 2B:	
Must Have :	
COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)

cder_iqp_wp022 Page 57 of 66



Black	k or African American		White	Unkr	nown Race/Ethnicity
Cohort 1d: Hospitalized with	COVID - Black or African American	Cohort 1e: Hospitalized with	COVID - White	Cohort 1f: Hospitalized with COVID -	Unknown
Ungrouped Terms:		Ungrouped Terms:		Ungrouped Terms:	
Must Have:		Must Have:		Cannot Have:	
Black or African American		White		Hawaiian AND hispanic) OR (Native H	American Indian AND non-hispanic) OR (Native awaiian AND non-hispanic) OR (asian AND hispanic) ck AND hispanic) OR (black AND non-hispanic) OR non-hispanic)
Group 1:	Time Restrictions	Group 1:	Time Restrictions	Group 1:	Time Restrictions
Subgroup 1A:		Subgroup 1A:		Subgroup 1A:	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021
AND Subgroup 1B:		AND Subgroup 1B:		AND Subgroup 1B:	
Must Have :		Must Have :		Must Have :	
Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Hospitalization	[-3, 3] from Any Instance of COVID (1A)
Cohort 2d: Hospitalized with American	COVID and Vaccine - Black or African	Cohort 2e: Hospitalized with	COVID and Vaccine - White	Cohort 2f: Hospitalized with COVID a	nd Vaccine - Unknown
Ungrouped Terms:		Ungrouped Terms:		Ungrouped Terms:	
Must Have:		Must Have:		Cannot Have:	
Black or African American		White		American Indian/Alaska Native OR As Hawaiian/Other Pacific Islander OR W	ian OR Black/African American OR Native /hite OR Hispanic OR Non-Hispanic
Group 1:	Time Restrictions	Group 1:	Time Restrictions	Group 1:	Time Restrictions
Subgroup 1A:		Subgroup 1A:		Subgroup 1A:	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021
AND Subgroup 1B:		AND Subgroup 1B:		AND Subgroup 1B:	
Must Have :		Must Have :		Must Have :	
Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Hospitalization	[-3, 3] from Any Instance of COVID (1A)
Group 2:	Time Restrictions	Group 2:	Time Restrictions	Group 2:	Time Restrictions
Subgroup 2A:		Subgroup 2A:		Subgroup 2A:	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021
AND Subgroup 2B:		AND Subgroup 2B:		AND Subgroup 2B:	
] [

cder_iqp_wp022 Page 58 of 66



Black	k or African American		White	Unkn	nown Race/Ethnicity
Must Have :		Must Have :		Must Have :	
COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)
Cohort 3d: Severe COVID - B	lack or African American	Cohort 3e: Severe COVID - W	hite	Cohort 3f: Severe COVID - Unknown	
Ungrouped Terms:		Ungrouped Terms:		Ungrouped Terms:	
Must Have:		Must Have:		Cannot Have:	
Black or African American		White		American Indian/Alaska Native OR Asi Hawaiian/Other Pacific Islander OR W	ian OR Black/African American OR Native /hite OR Hispanic OR Non-Hispanic
Group 1:	Time Restrictions	Group 1:	Time Restrictions	Group 1:	Time Restrictions
Subgroup 1A:		Subgroup 1A:		Subgroup 1A:	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1	5/1/2021 - 8/31/2021
U07.1 COVID diagnosis	5, 2, 2022 5, 4022	U07.1 COVID diagnosis	0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0	COVID diagnosis	-, -,,
AND Subgroup 1B:		AND Subgroup 1B:		AND Subgroup 1B:	
Must Have :		Must Have :		Must Have :	
	[0, 7] days after Any Instance of COVID (1A)	ICU or ECMO or Mechanical		ICU or ECMO or Mechanical	[0, 7] days after Any Instance of COVID (1A)
Ventilation	AMaria Blad a Africa Amaria	Ventilation	(1A)	Ventilation	
Conort 4d: Severe COVID and	d Vaccine - Black or African American	Cohort 4e: Severe COVID and	i vaccine - white	Cohort 4f: Severe COVID and Vaccine	- Unknown
Ungrouped Terms:		Ungrouped Terms:		Ungrouped Terms:	
Must Have:		Must Have:		Cannot Have:	
Black or African American		White		American Indian/Alaska Native OR Asi Hawaiian/Other Pacific Islander OR W	ian OR Black/African American OR Native /hite OR Hispanic OR Non-Hispanic
Group 1:	Time Restrictions	Group 1:	Time Restrictions	Group 1:	Time Restrictions
Subgroup 1A:		Subgroup 1A:		Subgroup 1A:	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1	5/1/2021 - 8/31/2021
U07.1 COVID diagnosis		U07.1 COVID diagnosis		COVID diagnosis	
AND Subgroup 1B: Must Have :		AND Subgroup 1B: Must Have :		AND Subgroup 1B: Must Have :	
	[0, 7] days after Any Instance of COVID (1A)	ICU or ECMO or Mechanical	[0, 7] days after Any Instance of COVID	ICU or ECMO or Mechanical	[0, 7] days after Any Instance of COVID (1A)
Ventilation	[U, 7] days after Any instance of COVID (1A)	Ventilation	(1A)	Ventilation	[0, 7] days after Any instance of COVID (1A)
Group 2:	Time Restrictions	Group 2:	Time Restrictions	Group 2:	Time Restrictions
Subgroup 2A:		Subgroup 2A:		Subgroup 2A:	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021

cder_iqp_wp022 Page 59 of 66



В	ack or African American		White		Unknown Race/Ethnicity
AND Subgroup 2B:		AND Subgroup 2B:		AND Subgroup 2B:	
Must Have :		Must Have :		Must Have :	
COVID-19 vaccination	[Ever, -1] days before Any Instance of	COVID-19 vaccination	[Ever, -1] days before Any Instance of	COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)

cder_iqp_wp022 Page 60 of 66



	Hispanic		Non-Hispanic	
Cohort 1g: Hospitalized with Co	OVID - Hispanic	Cohort 1h: Hospitalized with COVID - Non-Hispanic		
Ungrouped Terms:		Ungrouped Terms:		
Must Have:		Must Have:		
Hispanic		Non-Hispanic		
Group 1:	Time Restrictions	Group 1:	Time Restrictions	
Subgroup 1A:		Subgroup 1A:		
Must Have :		Must Have :		
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	
AND Subgroup 1B:		AND Subgroup 1B:		
Must Have :		Must Have :		
Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Hospitalization	[-3, 3] from Any Instance of COVID (1A)	
Cohort 2g: Hospitalized with Co	OVID and Vaccine - Hispanic	Cohort 2h: Hospitalized with Co	OVID and Vaccine - Non-Hispanic	
Ungrouped Terms:		Ungrouped Terms:		
Must Have:		Must Have:		
Hispanic		Non-Hispanic		
Group 1:	Time Restrictions	Group 1:	Time Restrictions	
Subgroup 1A:		Subgroup 1A:		
Must Have :		Must Have :		
Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	
U07.1 COVID diagnosis AND Subgroup 1B:		U07.1 COVID diagnosis AND Subgroup 1B:		
Must Have :		Must Have :		
Hospitalization	[-3, 3] from Any Instance of COVID (1A)	Hospitalization	[-3, 3] from Any Instance of COVID (1A)	
Group 2:	Time Restrictions	Group 2:	Time Restrictions	
Subgroup 2A:		Subgroup 2A:		
Must Have :		Must Have :		
Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	
U07.1 COVID diagnosis		U07.1 COVID diagnosis		
AND Subgroup 2B:		AND Subgroup 2B:		

cder_iqp_wp022 Page 61 of 66



	Hispanic		Non-Hispanic	
Must Have :		Must Have :		
COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	
Cohort 3g: Severe COVID - His	panic	Cohort 3h: Severe COVID - Nor	ı-Hispanic	
Ungrouped Terms:		Ungrouped Terms:		
Must Have:		Must Have:		
Hispanic		Non-Hispanic		
Group 1:	Time Restrictions	Group 1:	Time Restrictions	
Subgroup 1A:		Subgroup 1A:		
Must Have :		Must Have :		
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	
AND Subgroup 1B:		AND Subgroup 1B:		
Must Have :		Must Have :		
ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)	ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)	
Cohort 4g: Severe COVID and	Vaccine - Hispanic	Cohort 4h: Severe COVID and Vaccine - Non-Hispanic		
Ungrouped Terms:		Ungrouped Terms:		
Must Have:		Must Have:		
Hispanic		Non-Hispanic		
Group 1:	Time Restrictions	Group 1:	Time Restrictions	
Subgroup 1A:		Subgroup 1A:		
Must Have :		Must Have :		
Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR	5/1/2021 - 8/31/2021	
U07.1 COVID diagnosis		U07.1 COVID diagnosis		
AND Subgroup 1B:		AND Subgroup 1B:		
Must Have :		Must Have :		
ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)	ICU or ECMO or Mechanical Ventilation	[0, 7] days after Any Instance of COVID (1A)	
Group 2:	Time Restrictions	Group 2:	Time Restrictions	
Subgroup 2A:		Subgroup 2A:		
Must Have :		Must Have :		
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	5/1/2021 - 8/31/2021	

cder_iqp_wp022 Page 62 of 66



	Hispanic	Non-Hispanic		
AND Subgroup 2B:		AND Subgroup 2B:		
Must Have :		Must Have :		
COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	

cder_iqp_wp022 Page 63 of 66



Appendix D. Specifications Defining Analytics Modules in this Request

#	Module	Analysis Type	Cohorts	Evaluation Window	Index on First Day Patient Has Met:	Outcomes
1	Compare Outcomes	Measures of Association	All cohorts	0-30 days	All cohort criteria	Death
2	Compare Outcomes	Measures of Association	All cohorts	0-14 days	All cohort criteria	 Remdesivir or systemic glucocorticoids Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors Tocilizumab Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab

cder_iqp_wp025 Page 64 of 66



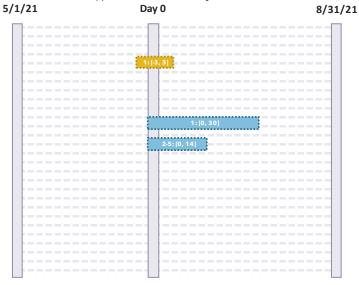
"Hospitalized COVID-19"

This cohort will be replicated for each race and each ethnicity group



First (+) SARS-CoV-2 Test or COVID -19 Diagnosis





NOTE: Data obtained from the TriNetX Live® platform, aggregated from 36 health care organizations (HCOs) in the USA No Date Shift
Events occurring outside of a given HCO may not be captured due to the fragmented nature of electronic health care data.

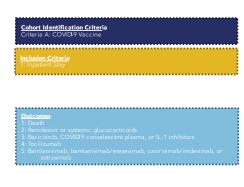
"Hospitalized COVID-19 with Vaccination"

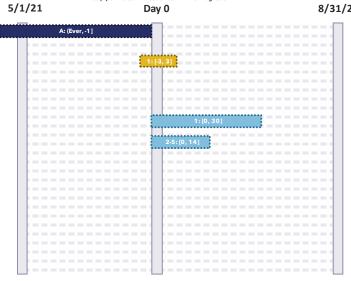
This cohort will be replicated for each race and each ethnicity group

Index date

First (+) SARS-CoV-2 Test or COVID -19 Diagnosis

8/31/21 Day 0





NOTE: Data obtained from the TriNetX Live® platform, aggregated from 36 health care organizations (HCOs) in the USA No Date Shift
Events occurring outside of a given HCO may not be captured due to the fragmented nature of electronic health care data.

Page 65 of 66 cder_iqp_wp025

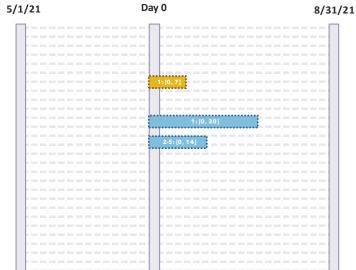
Appendix E. Design Diagrams of Cohort Entry Requirements

"Severe COVID-19"

This cohort will be replicated for each race and each ethnicity group

Index date

First (+) SARS-CoV-2 Test or COVID -19 Diagnosis



NOTE: Data obtained from the TriNetX Live* platform, aggregated from 36 health care organizations (HCOs) in the USA No Date Shift
Events occurring outside of a given HCO may not be captured due to the fragmented nature of electronic health care data.

"Severe COVID-19 with Vaccination"

This cohort will be replicated for each race and each ethnicity group

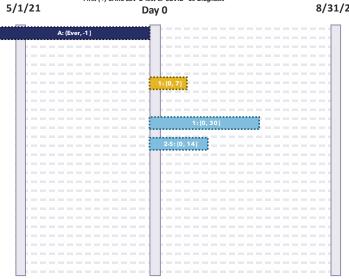
Index date

First (+) SARS-CoV-2 Test or COVID -19 Diagnosis

8/31/21







<u>NOTE</u>: Data obtained from the TriNetX Live* platform, aggregated from 36 health care organizations (HCOs) in the USA No Date Shift Events occurring outside of a given HCO may not be captured due to the fragmented nature of electronic health care data.

Page 66 of 66 cder_iqp_wp025