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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).

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Overview for Report: cder_iqp_wp026 (Report 3 of 4)

Request ID: cder_iqp_wp026

Requester: Center for Drug Evaluation and Research (CDER)

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 3 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.

Data Source: We ran this query on June 30, 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 September 1, 2021 to December 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 or ethnicity (defined as patients who are missing EITHER a race OR an ethnicity term)

- 7) Hispanic/Latino
- 8) Non-Hispanic/Latino



Overview for Report: cder_iqp_wp026 (Report 3 of 4)

<u>Outcomes of Interest</u>: 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.

Limitations: 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.

<u>Notes:</u> We ran this query on June 30, 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).



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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.



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



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

	Hospitalized Patients with COVID-19 Patients with Severe			evere CO	VID-19			
	Ove	Overall Vaccinated		nated	Overall		Vacci	nated
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Patients of Any Race	56,920	100%	3,490	100%	11,190	100%	670	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	40,060	70.4%	2,310	66.2%	8,970	80.2%	540	80.6%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	5,410	9.5%	150	4.3%	2,500	22.3%	80	11.9%
Tocilizumab	1,370	2.4%	80	2.3%	750	6.7%	50	7.5%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	1,150	2.0%	110	3.2%	60	0.5%	10	1.5%
Death [0, 30 days]	5,040	8.9%	300	8.6%	3,920	35.0%	240	35.8%
Patients of American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Race*	270	100%	20	100%	70	100%	10	100%
Therapeutics [0, 14 days]								ſ
Remdesivir or systemic glucocorticoids	210	77.8%	20	100.0%	60	85.7%		
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	40	14.8%	10	50.0%	20	28.6%		
Tocilizumab	20	7.4%	0	0.0%	10	14.3%		
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	10	3.7%	0	0.0%	10	14.3%		
Death [0, 30 days]	30	11.1%	10	50.0%	20	28.6%		
Patients of Asian Race	930	100%	70	100%	140	100%	20	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	650	69.9%	40	57.1%	120	85.7%	10	50.0%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	60	6.5%	10	14.3%	30	21.4%	10	50.0%
Tocilizumab	40	4.3%	10	14.3%	20	14.3%	10	50.0%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	20	2.2%	10	14.3%	0	0.0%	0	0.0%
Death [0, 30 days]	50	5.4%	10	14.3%	40	28.6%	10	50.0%
Patients of Black or African American Race	11,000	100%	690	100%	1,940	100%	130	100%
Therapeutics [0, 14 days]								ſ
Remdesivir or systemic glucocorticoids	7,560	68.7%	450	65.2%	1,550	79.9%	100	76.9%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	760	6.9%	30	4.3%	360	18.6%	20	15.4%
Tocilizumab	230	2.1%	20	2.9%	140	7.2%	10	7.7%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	210	1.9%	20	2.9%	20	1.0%	10	7.7%
Death [0, 30 days]	760	6.9%	60	8.7%	600	30.9%	40	30.8%



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

	Hospital	Hospitalized Patients with COVID-19 Patients with Severe C			evere CO	VID-19		
	Ove	Overall		Vaccinated		Overall		nated
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Patients of White Race	39,030	100%	2,390	100%	7,890	100%	460	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	28,200	72.3%	1,600	66.9%	6,290	79.7%	380	82.6%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	4,160	10.7%	120	5.0%	1,860	23.6%	60	13.0%
Tocilizumab	930	2.4%	50	2.1%	490	6.2%	30	6.5%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	850	2.2%	90	3.8%	40	0.5%	10	2.2%
Death [0, 30 days]	3,790	9.7%	210	8.8%	2,870	36.4%	170	37.0%
Patients of Unknown Race or Unknown Ethnicity	10,010	100%	670	100%	2,870	100%	200	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	6,470	64.6%	430	64.2%	2,440	85.0%	160	80.0%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	890	8.9%	30	4.5%	740	25.8%	30	15.0%
Tocilizumab	360	3.6%	30	4.5%	280	9.8%	20	10.0%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	140	1.4%	20	3.0%	20	0.7%	10	5.0%
Death [0, 30 days]	900	9.0%	60	9.0%	1,010	35.2%	70	35.0%
Patients of Hispanic/Latino Ethnicity	8,370	100%	430	100%	1,140	100%	90	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	6,340	75.7%	280	65.1%	990	86.8%	70	77.8%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	700	8.4%	30	7.0%	260	22.8%	20	22.2%
Tocilizumab	280	3.3%	10	2.3%	110	9.6%	10	11.1%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	130	1.6%	20	4.7%	10	0.9%	10	11.1%
Death [0, 30 days]	370	4.4%	30	7.0%	320	28.1%	30	33.3%
Patients of Non-Hispanic/Latino Ethnicity	42,600	100%	2,640	100%	7,770	100%	440	100%
Therapeutics [0, 14 days]								
Remdesivir or systemic glucocorticoids	29,870	70.1%	1,750	66.3%	6,030	77.6%	350	79.5%
Baricitinib, COVID-19 convalescent plasma, or IL-1 inhibitors	4,080	9.6%	110	4.2%	1,630	21.0%	50	11.4%
Tocilizumab	820	1.9%	50	1.9%	410	5.3%	30	6.8%
Bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab	940	2.2%	90	3.4%	40	0.5%	10	2.3%
Death [0, 30 days]	3,970	9.3%	230	8.7%	2,760	35.5%	160	36.4%

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

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.



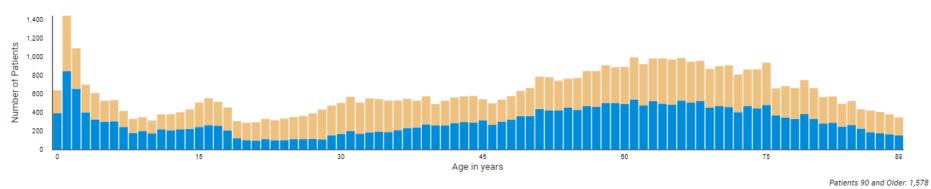
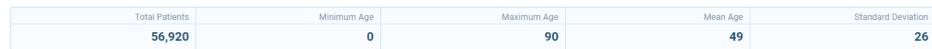


Figure 1a. Demographics Among Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021



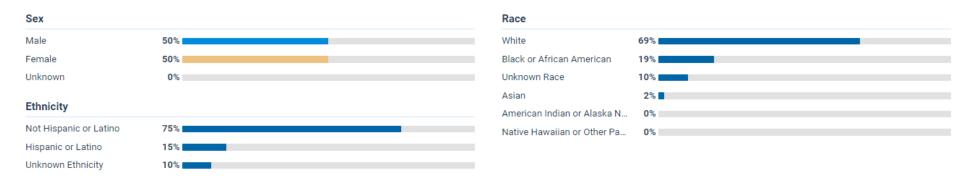
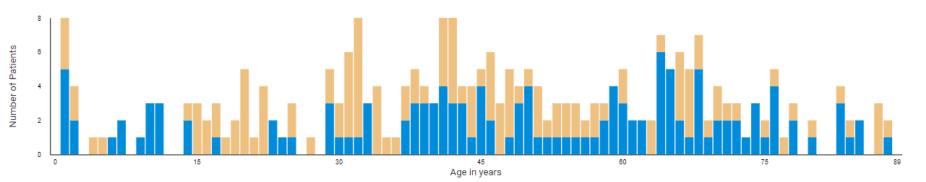


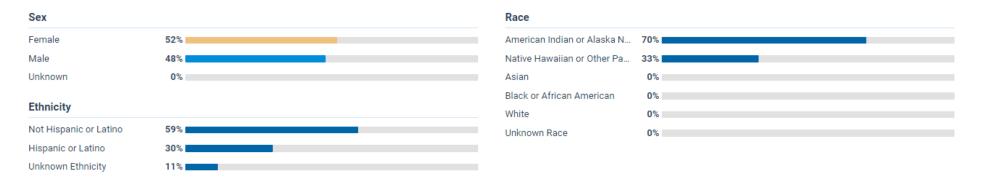


Figure 1b. Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021



Patients 90 and Older: 6

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
270	1	90	47	23





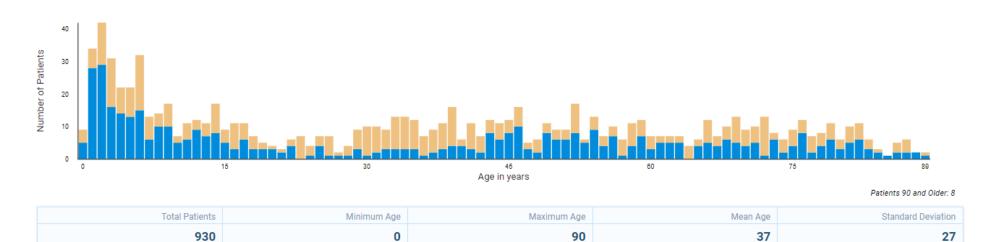
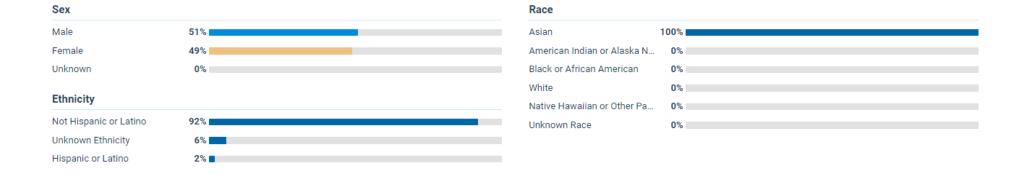


Figure 1c. Demographics Among Asian Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021





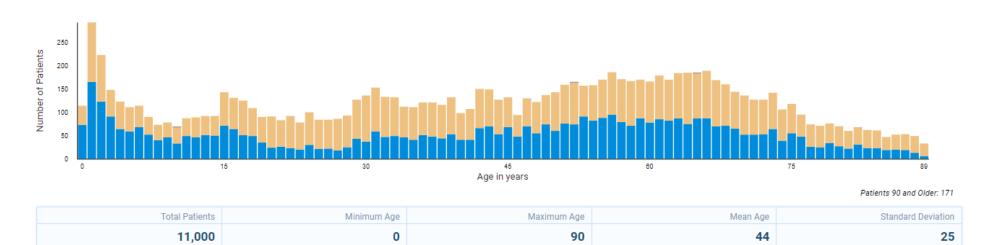
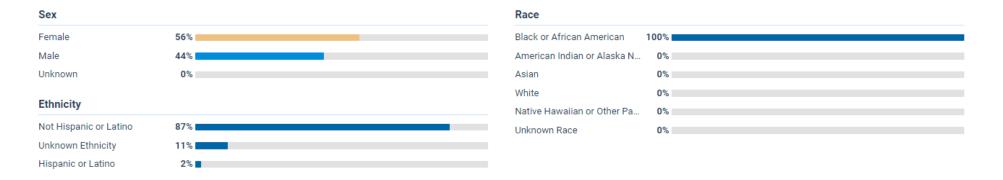


Figure 1d. Demographics Among Black or African American Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021





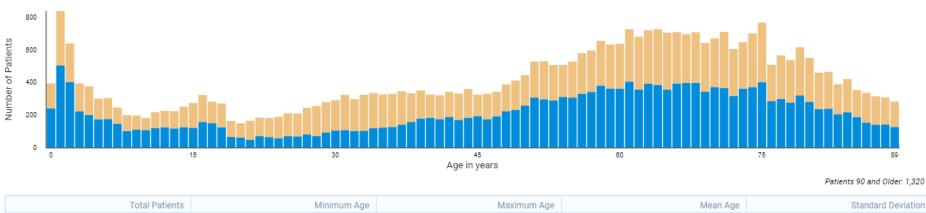
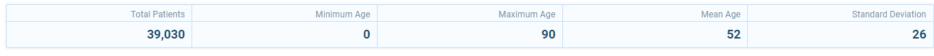
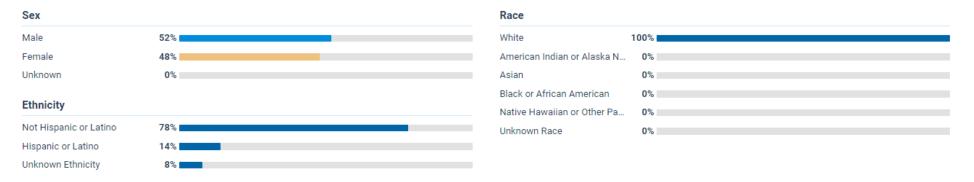


Figure 1e. Demographics Among White Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021







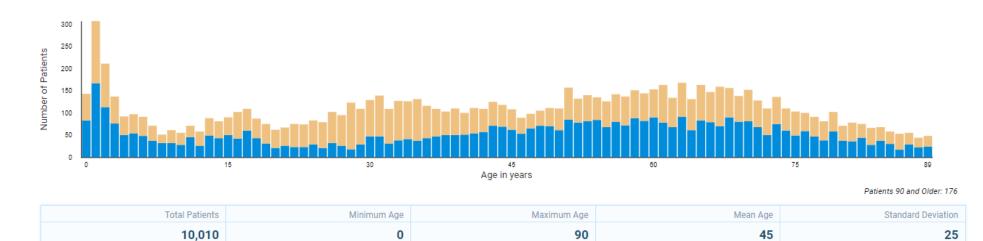
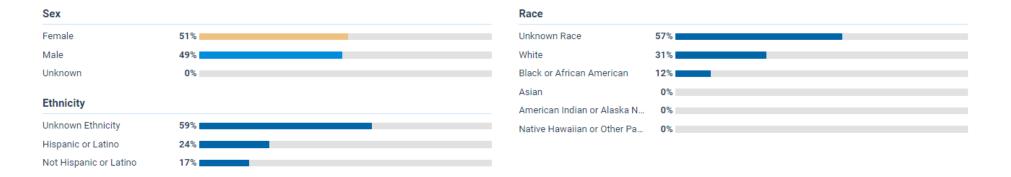


Figure 1f. Demographics Among Unknown Race or Unknown Ethnicity Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021





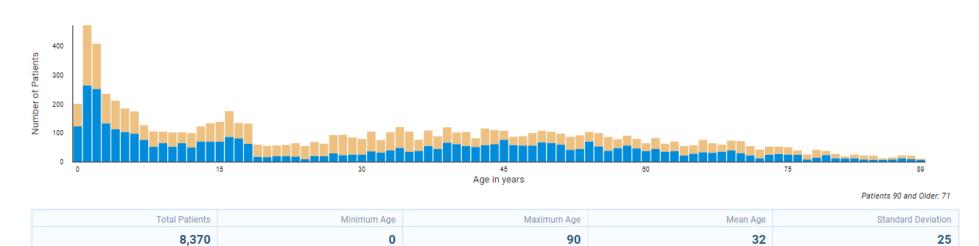
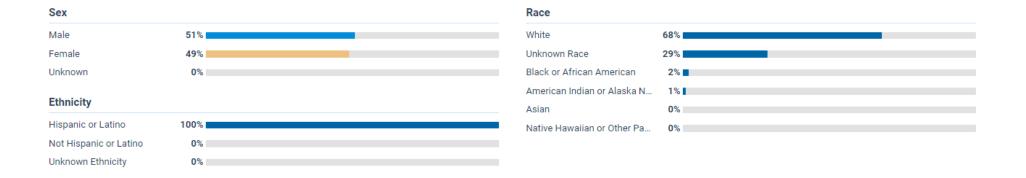


Figure 1g. Demographics Among Hispanic/Latino Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021





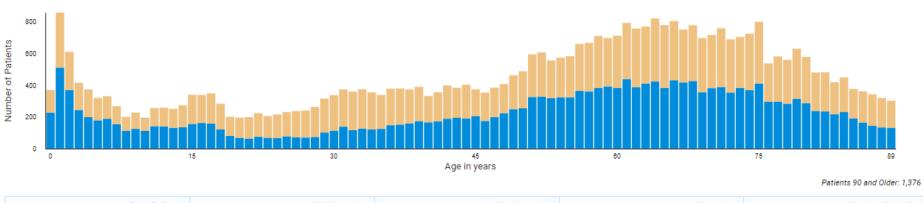
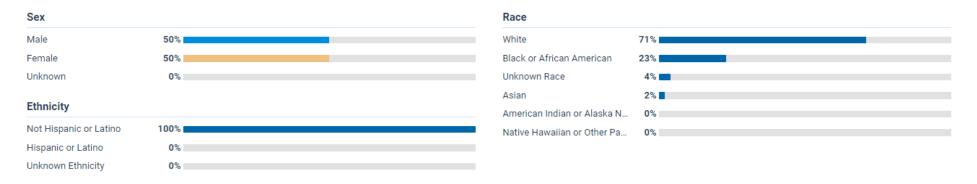


Figure 1h. Demographics Among Non-Hispanic/Latino Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021

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Standard Deviation	Mean Age	Maximum Age	Minimum Age	Total Patients
25	52	90	0	42,600





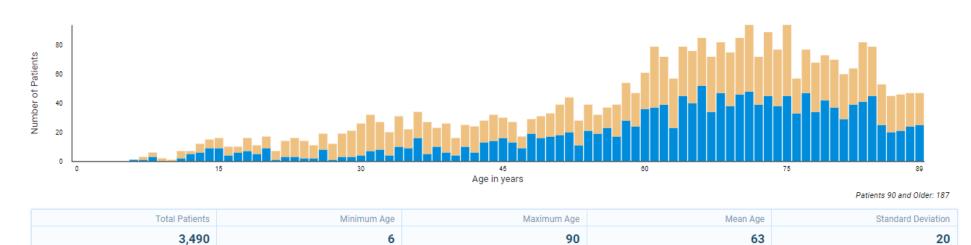


Figure 2a. Demographics Among Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021

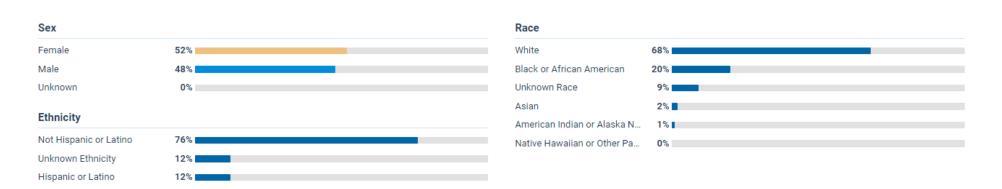
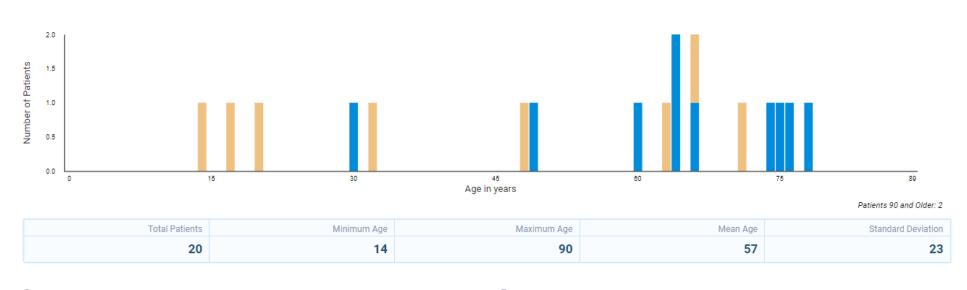
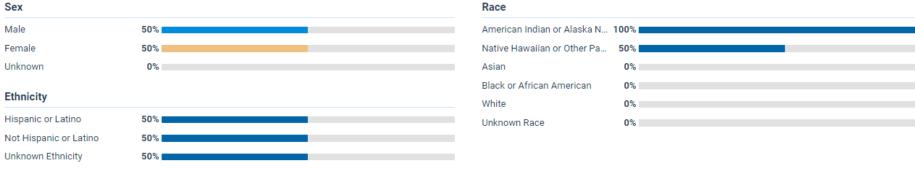




Figure 2b. Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021







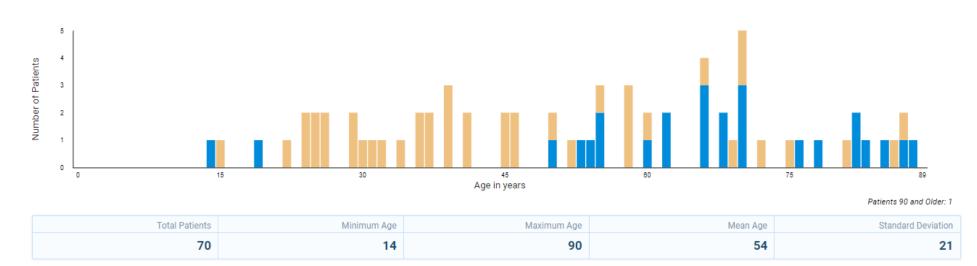


Figure 2c. Demographics Among Asian Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021

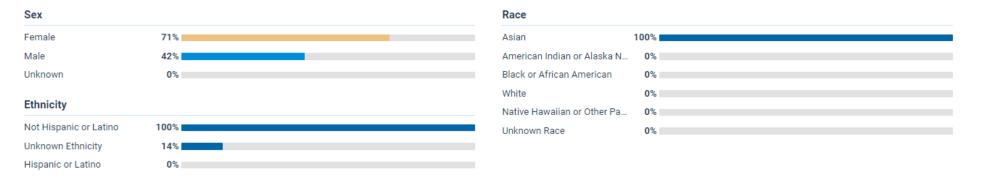
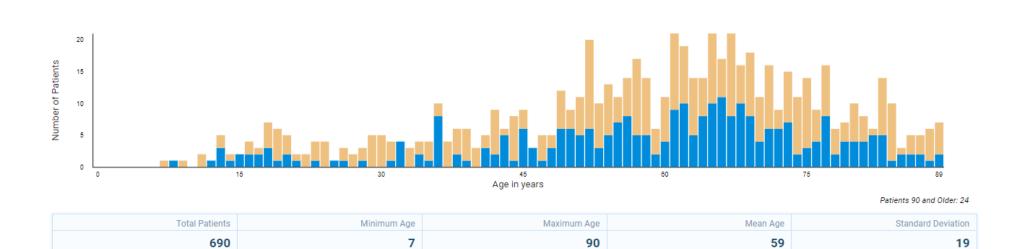
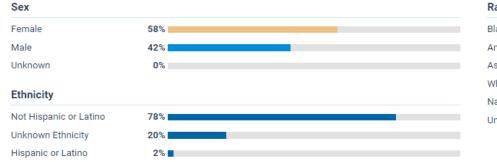




Figure 2d. Demographics Among Black or African American Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021





Race

Black or African American	100%
American Indian or Alaska N	. 0%
Asian	0%
White	0%
Native Hawaiian or Other Pa	0%
Unknown Race	0%



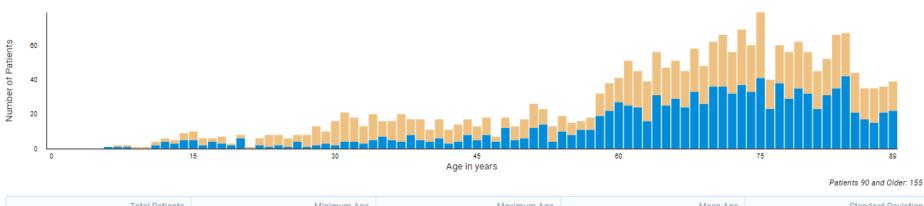


Figure 2e. Demographics Among White Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021



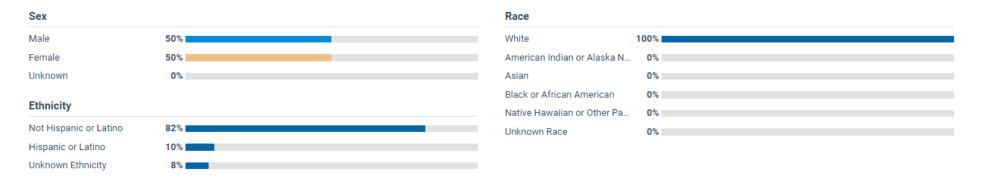
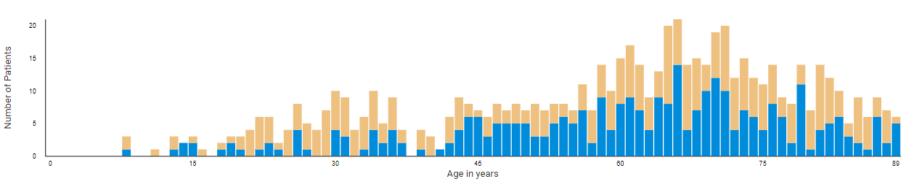


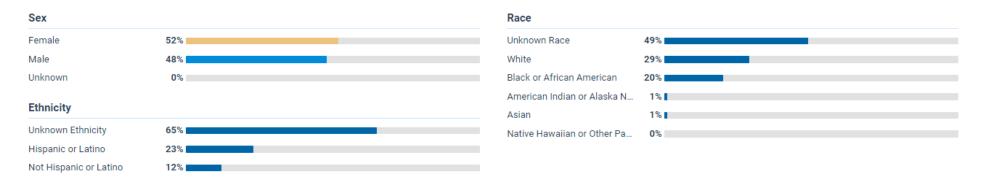


Figure 2f. Demographics Among Unknown Race or Unknown Ethnicity Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021



Patients 90 and Older: 21

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
670	8	90	60	20





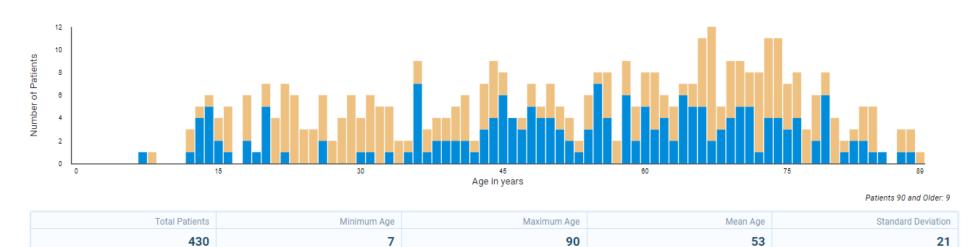


Figure 2g. Demographics Among Hispanic/Latino Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021

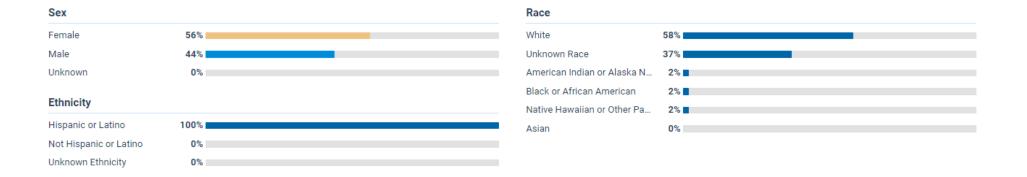
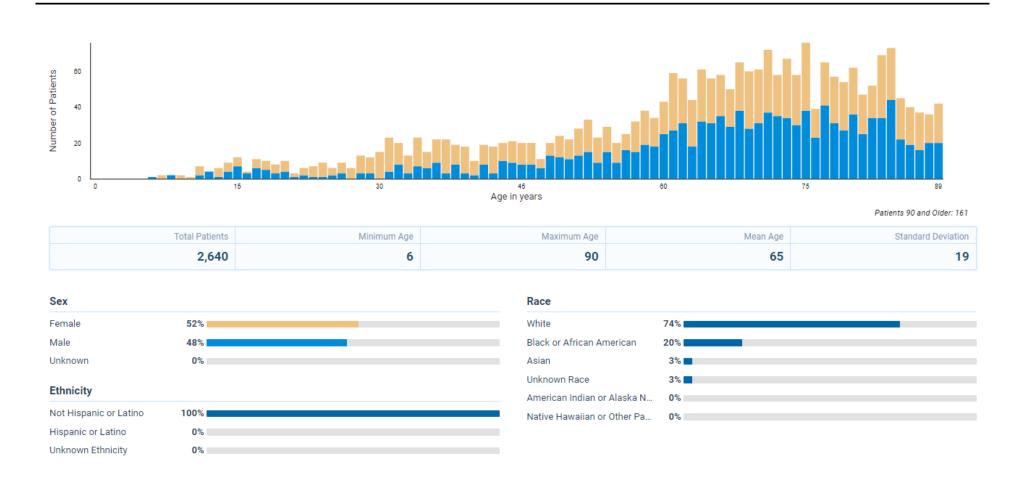




Figure 2h. Demographics Among Non-Hispanic/Latino Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021





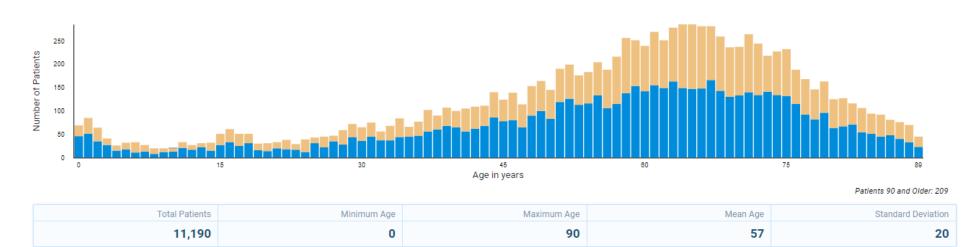


Figure 3a. Demographics Among Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021

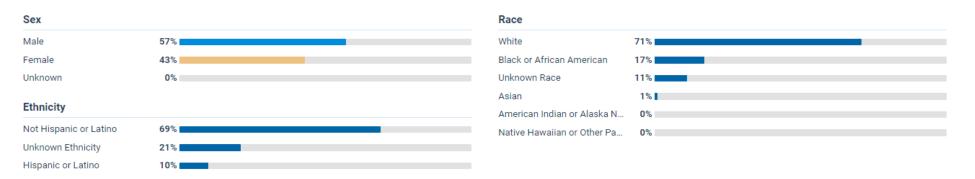




Figure 3b. Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021



Unknown Ethnicity

14%



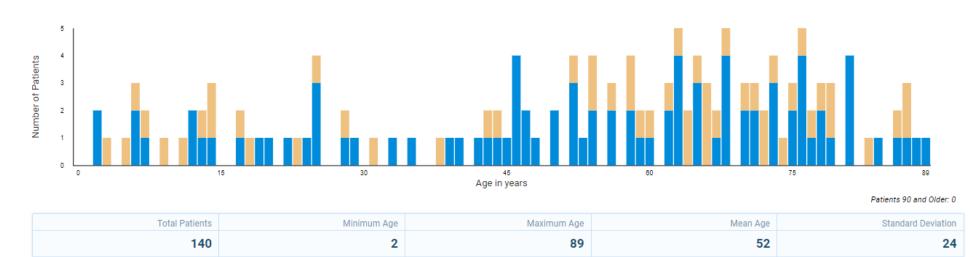
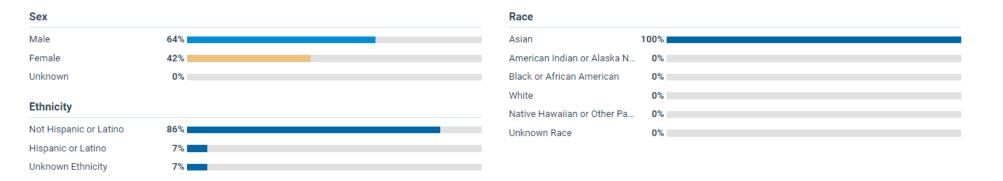


Figure 3c. Demographics Among Asian Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021





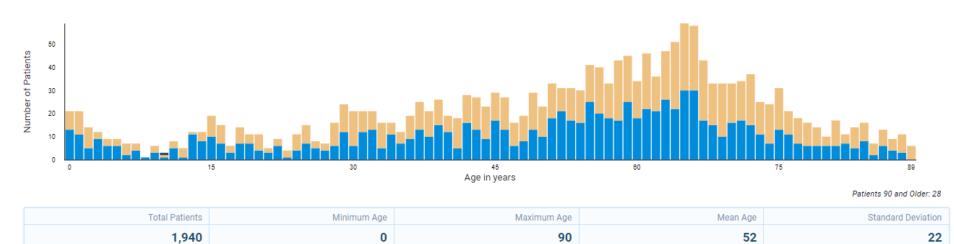
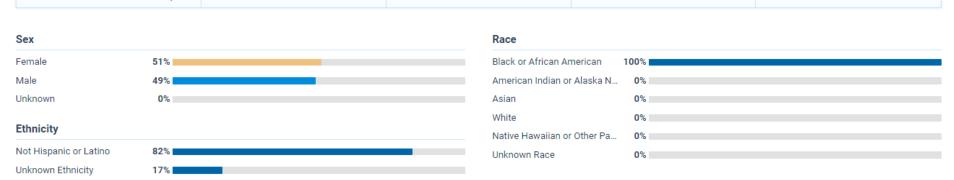


Figure 3d. Demographics Among Black or African American Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021



Hispanic or Latino

1%



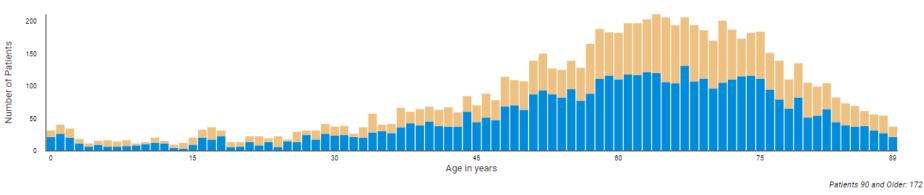
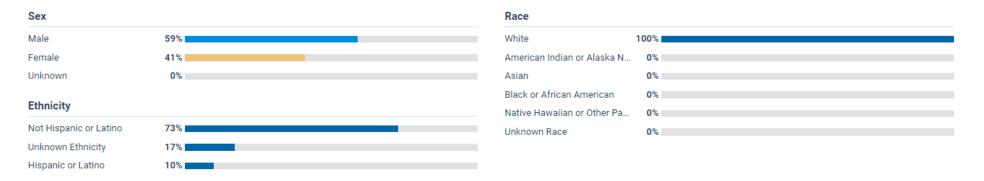


Figure 3e. Demographics Among White Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021







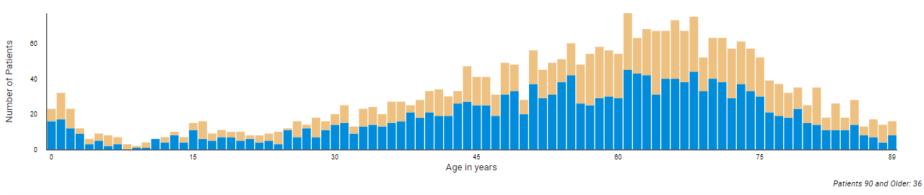
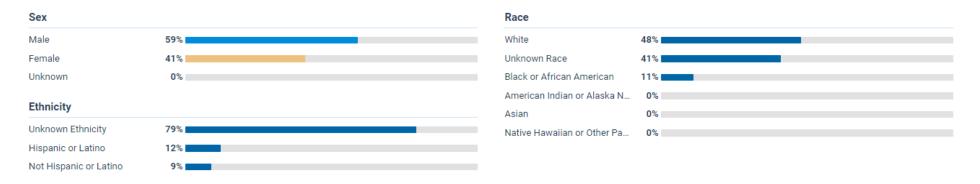


Figure 3f. Demographics Among Unknown Race or Unknown Ethnicity Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021







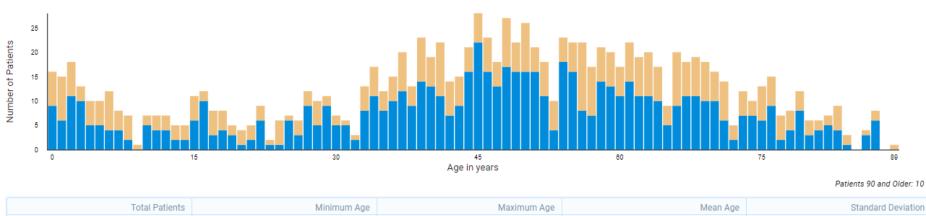
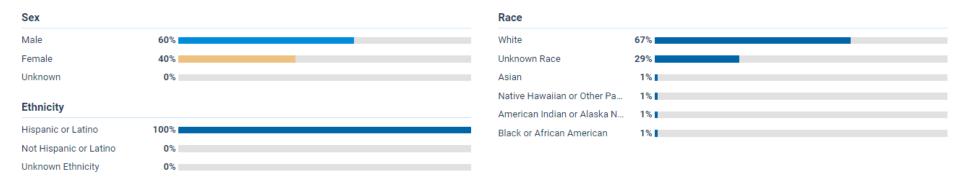


Figure 3g. Demographics Among Hispanic/Latino Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021

Total Patients	Minimum Age	Maximum Age	Mean Age	Standard Deviation
1,140	0	90	46	22





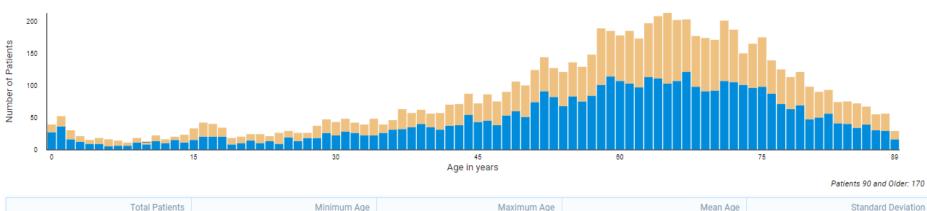
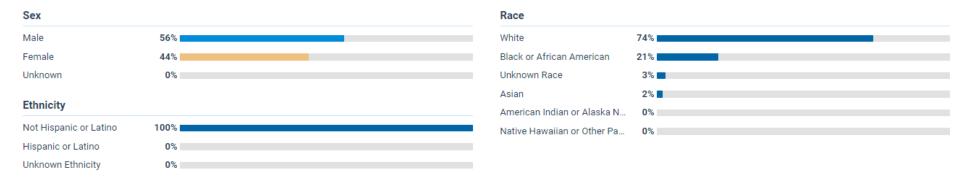


Figure 3h. Demographics Among Non-Hispanic/Latino Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021







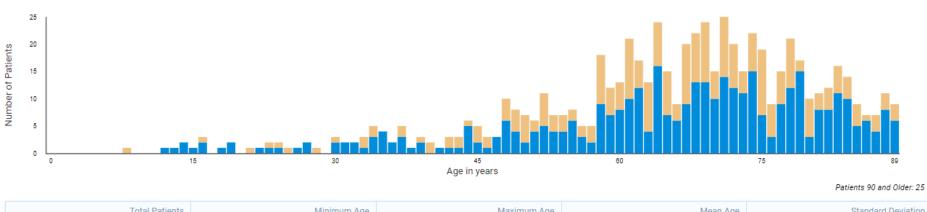


Figure 4a. Demographics Among Patients with Severe COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021



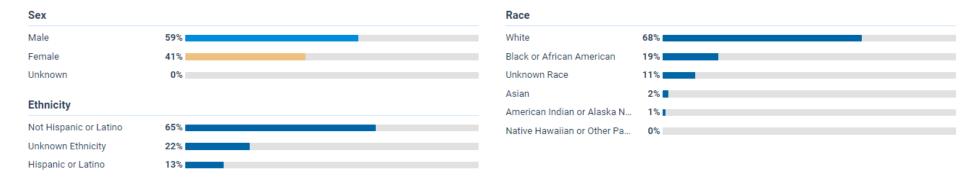




Figure 4b. Demographics Among American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander Patients with Severe COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021

*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 September 1, 2021 - December 31, 2021

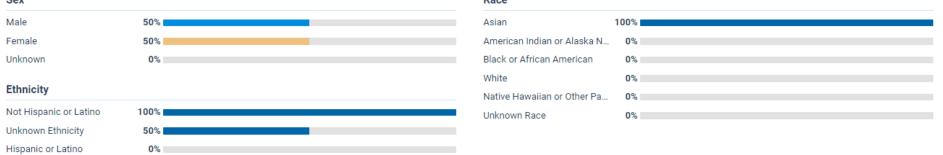
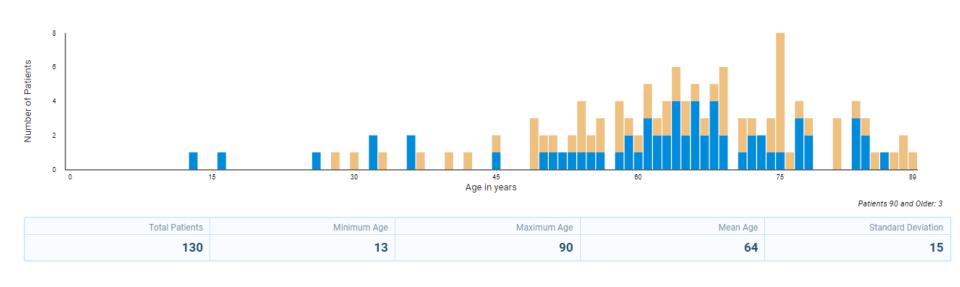
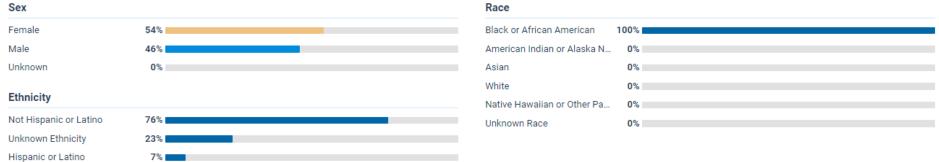




Figure 4d. Demographics Among Black or African American Patients with Severe COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021







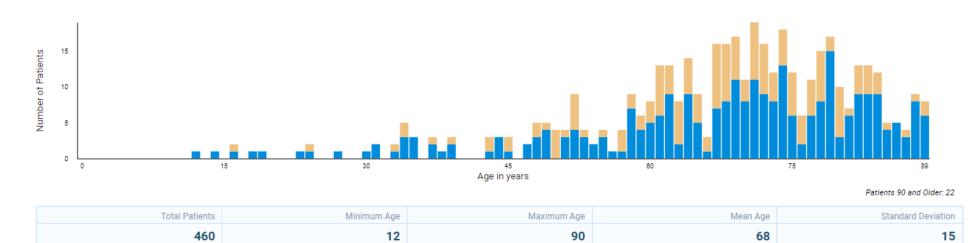


Figure 4e. Demographics Among White Patients with Severe COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021

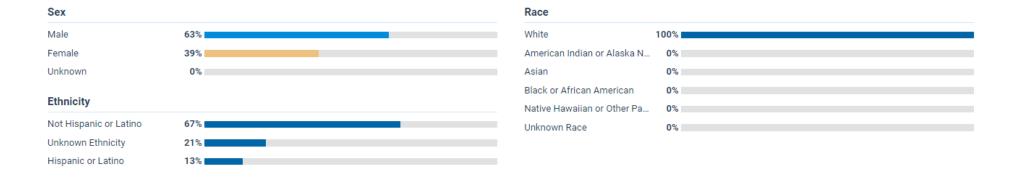
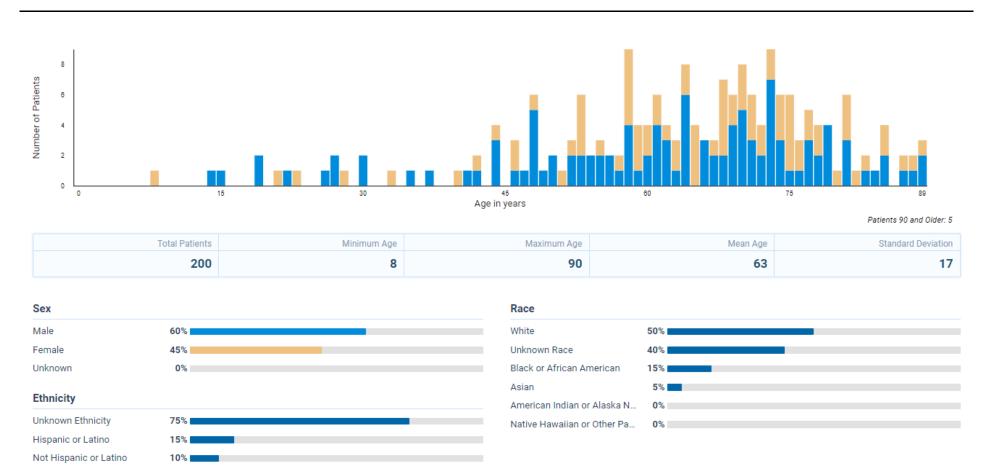




Figure 4f. Demographics Among Unknown Race or Unknown Ethnicity Patients with Severe COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021





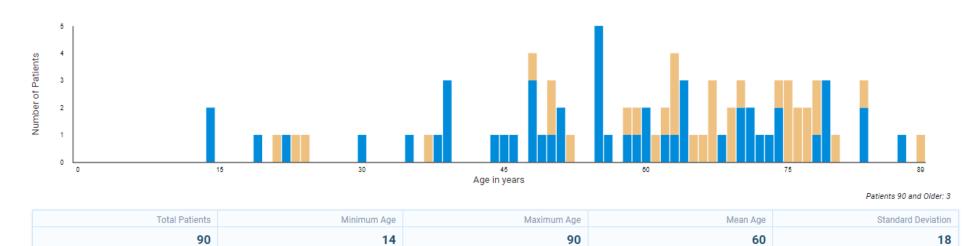


Figure 4g. Demographics Among Hispanic/Latino Patients with Severe COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021



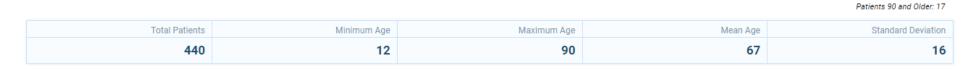


Number of Parishing States and St

30

15

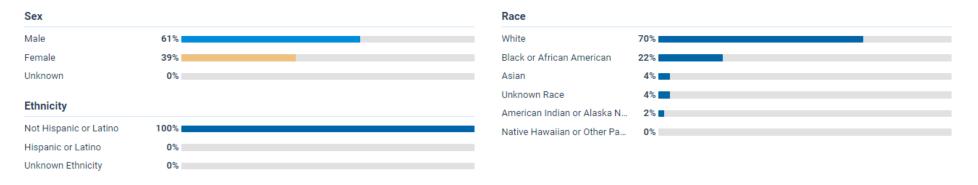
Figure 4h. Demographics Among Non-Hispanic/Latino Patients with Severe COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021



45 Age in years

60

75



0



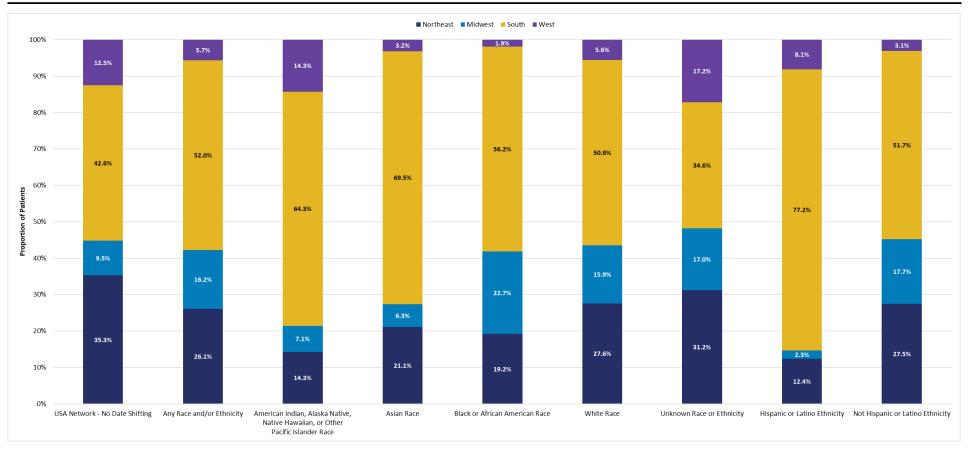


Figure 5a. Geographic Distribution of Patients Hospitalized with COVID-19 from September 1, 2021 - December 31, 2021, by Race/Ethnicity



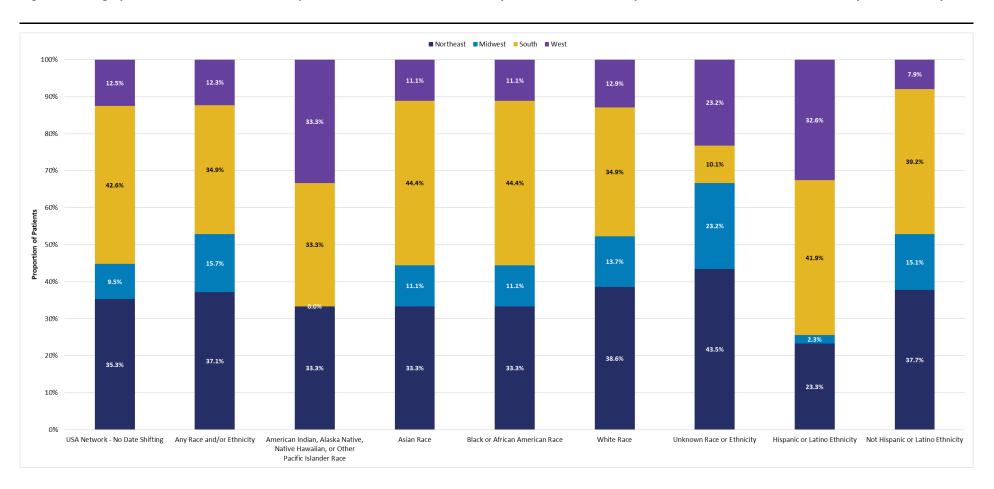


Figure 5b. Geographic Distribution of Patients Hospitalized with COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021, by Race/Ethnicity



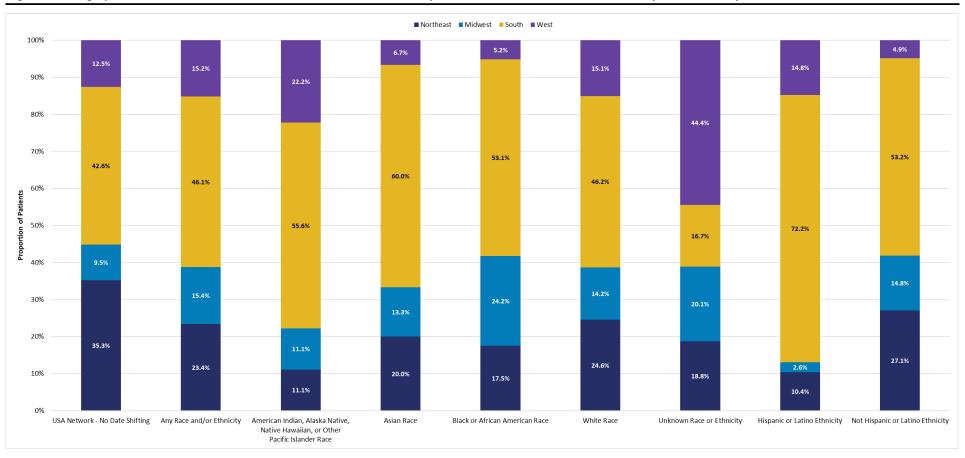


Figure 5c. Geographic Distribution of Patients with Severe COVID-19 from September 1, 2021 - December 31, 2021, by Race/Ethnicity



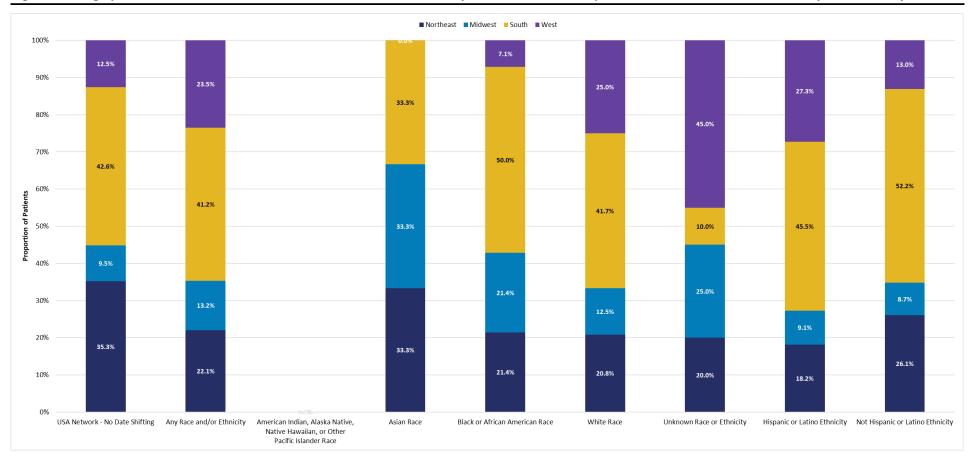


Figure 5d. Geographic Distribution of Patients with Severe COVID-19 and a History of Vaccination from September 1, 2021 - December 31, 2021, by Race/Ethnicity*

*Detailed information cannot be displayed when cohort size is between 1-10



		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	СРТ	n/a
1013699	Initial Inpatient Consultation Services	Procedure	СРТ	n/a
1013729	Critical Care Services	Procedure	СРТ	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	СРТ	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	Procedure	СРТ	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	СРТ	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	СРТ	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	СРТ	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	СРТ	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	СРТ	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			
XW013S6	Introduction of COVID-19 Vaccine Dose 1 into Subcutaneous Tissue,	Procedure	ICD-10-PCS	n/a
	Percutaneous Approach, New Technology Group 6			



		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	СРТ	n/a
	Severe COVID-19		-	1 -
	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	СРТ	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	СРТ	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



		Code		
Code	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
9471	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
9475	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
9477	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	СРТ	n/a
9291	Critical care, evaluation and management of the critically ill or critically in injured patient; first 30-74 minutes	Procedure	СРТ	n/a
9292	Critical care, evaluation and management of the critically ill or critically in injured patient; each additional 30 minutes (List separately in addition to code for primary service)	Procedure	СРТ	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		СРТ	n/a
9467	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)



		Code		
Code	Description	Category	Code Type	Filter
3989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	Procedure	СРТ	n/a
3988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	Procedure	СРТ	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



		Code		
Code	Description	Category	Code Type	Filter
3985	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
3986	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	СРТ	n/a
3951	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
3953	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	СРТ	n/a
3954	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	СРТ	n/a
3955	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	СРТ	n/a
3956	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	СРТ	n/a
3946	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous	Procedure	СРТ	n/a
33947	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-arterial	Procedure	СРТ	n/a
33948	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-venous	Procedure	СРТ	n/a
3949	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-arterial	Procedure	СРТ	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
A15223	Extracorporeal Membrane Oxygenation, Continuous	Procedure	ICD-10-PCS	n/a
	Extracorporeal Oxygenation, Membrane, Central	Procedure	ICD-10-PCS	n/a



		Code		
Code	Description	Category	Code Type	Filter
A1522G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial	Procedure	ICD-10-PCS	n/a
A1522H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous	Procedure	ICD-10-PCS	n/a
A15A2F	Extracorporeal Oxygenation, Membrane, Central, Intraoperative	Procedure	ICD-10-PCS	n/a
A15A2G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial, Intraoperative		ICD-10-PCS	n/a
A15A2H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous, Intraoperative	Procedure	ICD-10-PCS	n/a
	Mechanical Ventilation			
1500	Intubation, endotracheal, emergency procedure	Procedure	СРТ	n/a
0396	ALS specialized service disposable supplies; esophageal intubation	Procedure	HCPCS	n/a
4004	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day	Procedure	СРТ	n/a
4002	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
4003	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day	Procedure	СРТ	n/a
4483	Moisture exchanger, disposable, for use with invasive mechanical ventilation	Procedure	HCPCS	n/a
0481	Intrapulmonary percussive ventilation system and related accessories	Procedure	HCPCS	n/a
4662	Continuous negative pressure ventilation (CNP), initiation and management	Procedure	СРТ	n/a
9HN7BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
9HN8BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS	n/a
BH13EZ	Insertion of Endotracheal Airway into Trachea, Percutaneous Approach	Procedure	ICD-10-PCS	n/a
BH17EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
BH18EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS	n/a
CHY7BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
CHY8BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS	n/a
DH57BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening	Procedure	ICD-10-PCS	n/a
DH58BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS	n/a



		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



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
	Remdesivir			
2284718	Remdesivir	Medication	RxNorm	n/a
XW033E5	Introduction of Remdesivir Anti-infective into Peripheral Vein,	Procedure	ICD-10-PCS	n/a
	Percutaneous Approach, New Technology Group 5			
XW043E5	Introduction of Remdesivir Anti-infective into Central Vein,	Procedure	ICD-10-PCS	n/a
	Percutaneous Approach, New Technology Group 5			
	Systemic Glucocorticoids			,
8640	Prednisone	Medication		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



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	0239 Injection, bamlanivimab-xxxx, 700 mg		HCPCS	n/a
XW033F6	Introduction of bamlanivimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	Procedure	ICD-10-PCS	n/a
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 and post administration monitoring	Procedure	HCPCS	n/a
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			

	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			



	Overall	American Indian or Alaska Nati	ve, or Native Hawaiian or Other Pacific Islander		Asian	
Cohort 1a: Hospitalized with CO	OVID - Overall	Cohort 1b: Hospitalized with Co Native Hawaiian/Other Pacific	DVID - American Indian/Alaska Native, or Islander	Cohort 1c: Hospitalized with COVID - 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	9/1/2021 - 12/31/2021	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	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	
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	DVID and Vaccine - American Indian/Alaska her Pacific Islander	Cohort 2c: Hospitalized with C	COVID and Vaccine - Asian	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	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	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	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	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	
Must Have :		AND Subgroup 2B:		AND Subgroup 2B:		



	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	9/1/2021 - 12/31/2021	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	Cohort 3c: Severe COVID - Asi	
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	9/1/2021 - 12/31/2021	Must Have :		Must Have :	
AND Subgroup 1B:		Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021
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:			accine - American Indian/Alaska Native, or	Cohort 4c: Severe COVID and	Vaccine - Asian
		Native Hawaiian/Other Pacific	Islander		
Must Have :		Ungrouped Terms:		Ungrouped Terms:	
Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	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 U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021
		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)
		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	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021



Overall

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

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



Black or African American	White	Unknown 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	(American Indian AND hispanic) OR (American Indian AND non-hispanic) OR (Native Hawaiian AND hispanic) OR (Native Hawaiian AND non-hispanic) OR (asian AND hispanic) OR (asian AND non-hispanic) OR (black AND hispanic) OR (black AND non-hispanic) OR (white AND hispanic) OR (white AND 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 9/1/2021 - 12/31/2021 U07.1 COVID diagnosis	Positive SARS-COV-2 test OR 9/1/2021 - 12/31/2021 U07.1 COVID diagnosis	Positive SARS-COV-2 test OR U07.1 9/1/2021 - 12/31/2021 COVID diagnosis
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 (1/	A) Hospitalization [-3, 3] from Any Instance of COVID (1A)
Cohort 2d: Hospitalized with COVID and Vaccine - Black or African American	Cohort 2e: Hospitalized with COVID and Vaccine - White	Cohort 2f: Hospitalized with 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 Asian OR Black/African American OR Native Hawaiian/Other Pacific Islander OR White 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 9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR 9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 9/1/2021 - 12/31/2021
U07.1 COVID diagnosis AND Subgroup 1B:	U07.1 COVID diagnosis AND Subgroup 1B:	COVID diagnosis 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 (1)	
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 9/1/2021 - 12/31/2021 U07.1 COVID diagnosis	Positive SARS-COV-2 test OR 9/1/2021 - 12/31/2021 U07.1 COVID diagnosis	Positive SARS-COV-2 test OR U07.1 9/1/2021 - 12/31/2021 COVID diagnosis
AND Subgroup 2B:	AND Subgroup 2B:	AND Subgroup 2B:



Black	or African American		White	Unkr	10wn 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 - Bla	ack or African American	Cohort 3e: Severe COVID - W	/hite	Cohort 3f: Severe COVID - Unknown	
Ungrouped Terms:		Ungrouped Terms:		Ungrouped Terms:	
ongrouped remain		ongrouped remain		ongrouped remoi	
Must Have:		Must Have:		Cannot Have:	
Black or African American		White		· · ·	ian OR Black/African American OR Native
Group 1:	Time Restrictions	Group 1:	Time Restrictions	Hawaiian/Other Pacific Islander OR W Group 1:	/hite OR Hispanic OR Non-Hispanic Time Restrictions
Subgroup 1A:		Subgroup 1A:		Subgroup 1A:	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1	9/1/2021 - 12/31/2021
U07.1 COVID diagnosis		U07.1 COVID diagnosis AND Subgroup 1B:		COVID diagnosis	
AND Subgroup 1B:		AND Subgroup 18:		AND Subgroup 1B:	
Must Have :		Must Have :		Must Have :	
ICU or ECMO or Mechanical	[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		Ventilation	(1A)	Ventilation	
Cohort 4d: Severe COVID and	Vaccine - Black or African American	Cohort 4e: Severe COVID and	d Vaccine - White	Cohort 4f: Severe COVID and Vaccine	e - Unknown
Ungrouped Terms:		Ungrouped Terms:		Ungrouped Terms:	
Must Have:		Must Have:		Cannot Have:	
Black or African American		White		· · ·	ian OR Black/African American OR Native
Group 1:	Time Restrictions	Group 1:	Time Restrictions	Hawaiian/Other Pacific Islander OR W Group 1:	Time Restrictions
Subgroup 1A:		Subgroup 1A:		Subgroup 1A:	
Subgroup 1A.		Subgroup IA.		Subgroup IA.	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1	9/1/2021 - 12/31/2021
U07.1 COVID diagnosis		U07.1 COVID diagnosis		COVID diagnosis	
AND Subgroup 1B:		AND Subgroup 1B:		AND Subgroup 1B:	
Must Have :		Must Have :		Must Have :	
ICU or ECMO or Mechanical	[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 Group 2:	Time Restrictions	Ventilation Group 2:	(1A) Time Restrictions	Ventilation Group 2:	Time Restrictions
Subgroup 2A:		Subgroup 2A:	This Restrictions	Subgroup 2A:	
Must Have :		Must Have :		Must Have :	
Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1	9/1/2021 - 12/31/2021
U07.1 COVID diagnosis		U07.1 COVID diagnosis		COVID diagnosis	



Black 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 (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)



	Hispanic		Non-Hispanic	
Cohort 1g: Hospitalized with COVID - 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	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	
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 C	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 U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021	
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)	
Group 2:	Time Restrictions	Group 2:	Time Restrictions	
Subgroup 2A:		Subgroup 2A:		
Must Have :		Must Have :		
Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021	
U07.1 COVID diagnosis AND Subgroup 2B:		U07.1 COVID diagnosis AND Subgroup 2B:		
HND SUDGIOUP ZB:		AND SUDGLOUD SE:		



	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 COVIE (2A)
Cohort 3g: Severe COVID - Hisp	panic	Cohort 3h: Severe 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	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021
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 \	/accine - Hispanic	Cohort 4h: Severe COVID and V	/accine - 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	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR	9/1/2021 - 12/31/2021
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	9/1/2021 - 12/31/2021	Positive SARS-COV-2 test OR U07.1 COVID diagnosis	9/1/2021 - 12/31/2021



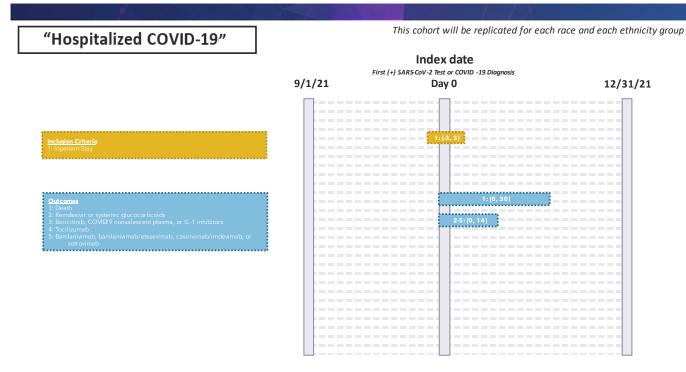
	Hispanic	Non-Hispanic		
AND Subgroup 2B:		AND Subgroup 2B:		
Must Have :		Must Have :		
COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	COVID-19 vaccination	[Ever, -1] days before Any Instance of COVID (2A)	



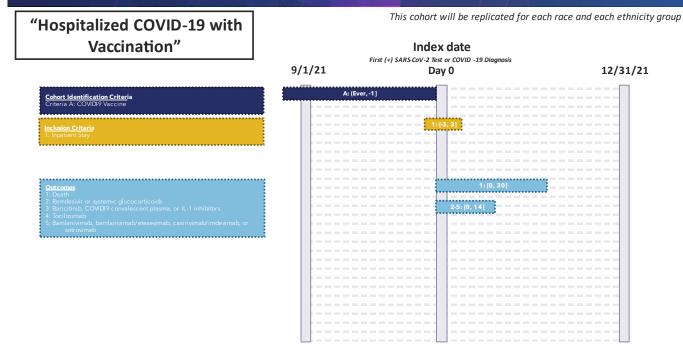
Appendix D. Specifications Defining Analytics Modules in this Request

			_	Evaluation	Index on First Day	
#	Module	Analysis Type	Cohorts	Window	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



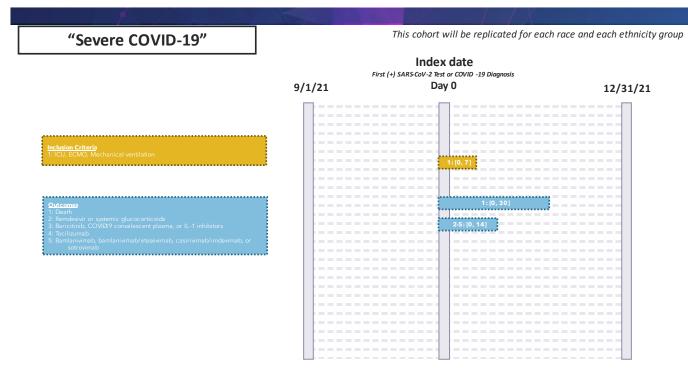


<u>NOTE</u>: Data obtained from the TriNetX Live® platform, aggregated from 36 health care organizations (HCOs) in the USA No Date Shift Network Events occurring outside of a given HCO may not be captured due to the fragmented nature of electronic health care data.

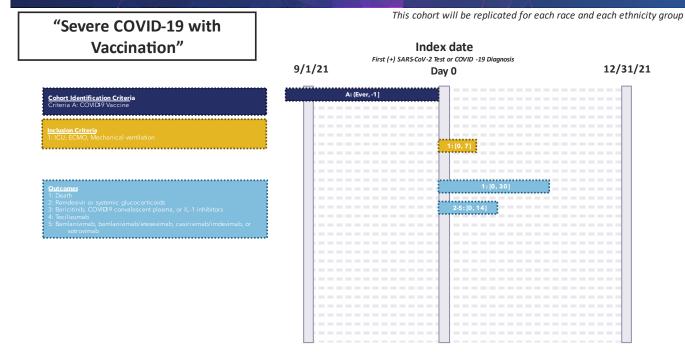


<u>NOTE</u>: Data obtained from the TriNetX Live® platform, aggregated from 36 health care organizations (HCOs) in the USA No Date Shift Network. Events occurring outside of a given HCO may not be captured due to the fragmented nature of electronic health care data.





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