

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 Request: cder_iqp_wp007

Request ID: cder_iqp_wp007_tnx_v02

<u>Request Description:</u> In this request, we assessed inpatient utilization of oral/injectable corticosteroids among hospitalized patients with and without a Coronavirus Disease (COVID-19) diagnosis in the TriNetX database.

<u>Data Source:</u> This request contains data from June 8, 2020 through July 19, 2020 from the TriNetX USA Network Database. Please see Appendix A for the counts of Health Care Organizations (HCOs) contributing data to the base hospitalized patient cohort within the database. This request was run on August 10, 2020.

<u>Study Design:</u> We identified a base population of hospitalized patients in the TriNetX Database. Within hospitalized patients we had two main cohorts of interest: patients with COVID-19 and patients without COVID-19. In the first cohort, we required evidence of a COVID-19 diagnosis or positive lab test within one week before or after evidence of a hospitalization. In the second cohort, we required no evidence of a COVID-19 diagnosis or positive lab test within one week before or after hospitalization. Please note that the cohorts of hospitalized patients identified with and without COVID-19 are not mutually exclusive. Please see Appendix B for a list of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and Logical Observation Identifiers Names and Codes (LOINC) lab codes used to define COVID-19 in this request.

Corticosteroid medication use was assessed in all hospitalized patients and among those with and without COVID-19 by weekly intervals. In the weekly intervals, we required evidence of corticosteroid use during the same calendar week as the hospitalization of interest. We also examined evidence of corticosteroid use that occurred within one week before or after the hospitalization with or without COVID-19 during the entire study period.

The corticosteroids of interest were as follows: any corticosteroid (including dexamethasone, methylprednisolone, betamethasone, cortisone, fludrocortisone, hydrocortisone, prednisolone, prednisone, and triamcinolone), dexamethasone (any form), oral dexamethasone, injectable dexamethasone, methylprednisolone (any form), oral methylprednisolone, injectable methylprednisolone, all other corticosteroids (any form), all other oral corticosteroids, and all other injectable corticosteroids. Please see Appendix C for a list of RxNorm and Healthcare Common Procedure Coding System (HCPCS) codes used to define corticosteroids in this request.

Please see Appendix D for a design diagram of cohort entry requirements.

<u>Limitations:</u> Algorithms used to define exposures and inclusion criteria are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

<u>Notes:</u> Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

cder_iqp_wp007 Page 1 of 36



	Table of Contents
Glossary	Glossary of Terms for Analyses Using TriNetX Live™ Platform
<u>Table 1</u>	Weekly Utilization of Oral/Injectable Corticosteroids among All Hospitalized Patients in the TriNetX Database, from June 8, 2020 to July 19, 2020
Table 2	Weekly Utilization of Oral/Injectable Corticosteroids among All Hospitalized Patients with COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020
Table 3	Weekly Utilization of Oral/Injectable Corticosteroids among All Hospitalized Patients without COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020
<u>Table 4</u>	Overall Utilization of Oral/Injectable Corticosteroids among All Hospitalized Patients with or without COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 1	Patient Characteristics for Hospitalized Patients with COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 2	Patient Characteristics for Hospitalized Patients with COVID-19 and Any Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 3	Patient Characteristics for Hospitalized Patients with COVID-19 and Any Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 4	Patient Characteristics for Hospitalized Patients with COVID-19 and Oral Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 5	Patient Characteristics for Hospitalized Patients with COVID-19 and Injectable Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 6	Patient Characteristics for Hospitalized Patients with COVID-19 and Any Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 7	Patient Characteristics for Hospitalized Patients with COVID-19 and Oral Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 8	Patient Characteristics for Hospitalized Patients with COVID-19 and Injectable Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 9	Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 10	Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Oral Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Figure 11	Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Injectable Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020
Appendix A	Number of TriNetX USA Network Database Health Care Organizations (HCOs) Contributing Data per Week in Base Hospitalization Cohort, from June 8, 2020 to July 19, 2020
Appendix B	List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes and Logical Observation Identifiers Names and Codes (LOINC) Lab Codes Used to Define COVID-19 in this Request
Appendix C	List of RxNorm Medication Codes and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Corticosteroids in this Request
Appendix D	Study Design Diagram for Cohort Entry Requirements

cder_iqp_wp007 Page 2 of 36



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.

cder_iqp_wp007 Page 3 of 36



Glossary of Terms for Analyses Using TriNetX Live™ Platform*

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_wp007 Page 4 of 36



Table 1. Weekly Utilization of Oral/Injectable Corticosteroids among All Hospitalized Patients in the TriNetX Database, from June 8, 2020 to July 19, 2020

	Week 1 (June 8, 2020 - June 14, 2020)	Week 2 (June 15, 2020 - June 21, 2020)	Week 3 (June 22, 2020 - June 28, 2020)	Week 4 (June 29, 2020 - July 5, 2020)	Week 5 (July 6, 2020 - July 12, 2020)	Week 6 (July 13, 2020 - July 19, 2020)
Number of Patients						
All hospitalized patients (any diagnosis)	67,350	64,890	67,640	58,440	48,440	38,770
Any corticosteroid use	15,790	15,290	15,600	13,690	12,760	10,740
Dexamethasone, any form	7,910	7,820	8,150	7,020	6,960	5,860
Oral dexamethasone	660	690	850	860	900	700
Injectable dexamethasone	4,410	4,130	4,380	3,720	3,450	2,780
Methylprednisolone, any form	4,540	4,400	4,160	3,980	3,710	3,280
Oral Methylprednisolone	250	260	310	270	180	120
Injectable Methylprednisolone	1,540	1,540	1,550	1,470	1,200	920
All other corticosteroids, any form	6,480	6,040	6,020	5,150	4,450	3,670
All other oral corticosteroids	2,450	2,410	2,450	2,210	1,780	1,300
All other injectable corticosteroids	1,080	980	1,060	910	770	710



Table 2. Weekly Utilization of Oral/Injectable Corticosteroids among All Hospitalized Patients with COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020

	Week 1 (June 8, 2020 - June 14, 2020)	Week 2 (June 15, 2020 - June 21, 2020)	Week 3 (June 22, 2020 - June 28, 2020)	Week 4 (June 29, 2020 - July 5, 2020)	Week 5 (July 6, 2020 - July 12, 2020)	Week 6 (July 13, 2020 - July 19, 2020)
Number of Patients						
All hospitalized patients with COVID-19	1,560	1,570	1,870	2,190	2,230	1,940
Any corticosteroid use	450	620	870	1,150	1,170	980
Dexamethasone, any form	110	280	560	810	820	680
Oral dexamethasone	10	80	190	250	330	260
Injectable dexamethasone	60	110	140	200	170	110
Methylprednisolone, any form	250	320	400	480	530	460
Oral Methylprednisolone	10	20	30	40	50	30
Injectable Methylprednisolone	100	140	150	180	120	110
All other corticosteroids, any form	170	210	220	250	230	210
All other oral corticosteroids	80	100	110	130	100	90
All other injectable corticosteroids	30	40	30	40	40	40



Table 3. Weekly Utilization of Oral/Injectable Corticosteroids among All Hospitalized Patients without COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020

	Week 1 (June 8, 2020 - June 14, 2020)	Week 2 (June 15, 2020 - June 21, 2020)	Week 3 (June 22, 2020 - June 28, 2020)	Week 4 (June 29, 2020 - July 5, 2020)	Week 5 (July 6, 2020 - July 12, 2020)	Week 6 (July 13, 2020 - July 19, 2020)
Number of Patients						
All hospitalized patients without COVID-19	65,760	63,300	65,730	56,220	46,170	36,820
Any corticosteroid use	15,330	14,660	14,720	12,530	11,570	9,760
Dexamethasone, any form	7,800	7,540	7,590	6,210	6,120	5,180
Oral dexamethasone	650	620	660	620	570	440
Injectable dexamethasone	4,350	4,020	4,240	3,520	3,280	2,680
Methylprednisolone, any form	4,290	4,090	3,760	3,510	3,180	2,830
Oral Methylprednisolone	250	240	280	240	140	100
Injectable Methylprednisolone	1,450	1,410	1,410	1,290	1,080	820
All other corticosteroids, any form	6,310	5,830	5,800	4,900	4,230	3,460
All other oral corticosteroids	2,370	2,310	2,350	2,090	1,680	1,210
All other injectable corticosteroids	1,060	950	1,040	870	730	670



Table 4. Overall Utilization of Oral/Injectable Corticosteroids among All Hospitalized Patients with or without COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020

	Patients with COVID-19	Patients without COVID-19
Number of Patients		
All hospitalized patients	7,930	251,550
Any corticosteroid use	4,270	72,590
Dexamethasone, any form	2,900	39,650
Oral dexamethasone	1,120	3,570
Injectable dexamethasone	810	21,940
Methylprednisolone, any form	2,080	20,010
Oral Methylprednisolone	190	1,620
Injectable Methylprednisolone	760	6,870
All other corticosteroids, any form	1,390	29,690
All other oral corticosteroids	670	11,430
All other injectable corticosteroids	240	5,170

cder_iqp_wp007 Page 8 of 36



Figure 1. Patient Characteristics for Hospitalized Patients with COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020

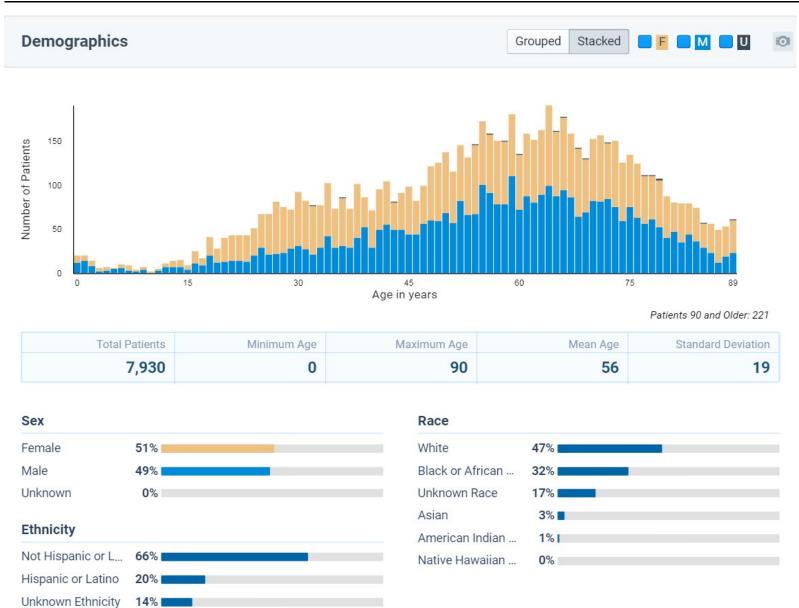
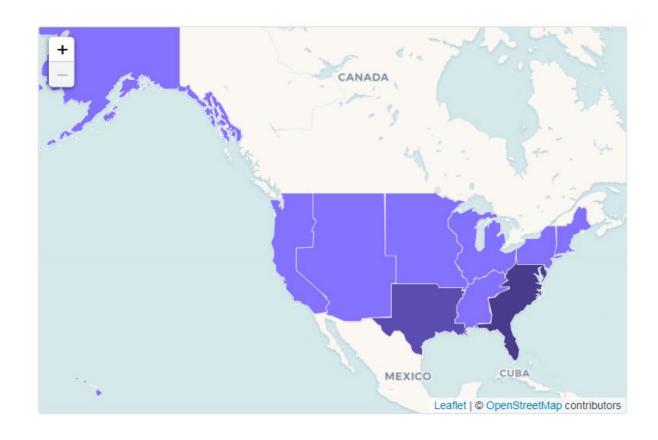




Figure 1. Patient Characteristics for Hospitalized Patients with COVID-19 in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	130	2%
Middle Atlantic	680	9%
East North Central	560	7%
West North Central	260	3%
South Atlantic	3,160	40%
East South Central	530	7%
West South Central	2,350	30%
Mountain	250	3%
Pacific	40	<1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 2. Patient Characteristics for Hospitalized Patients with COVID-19 and Any Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

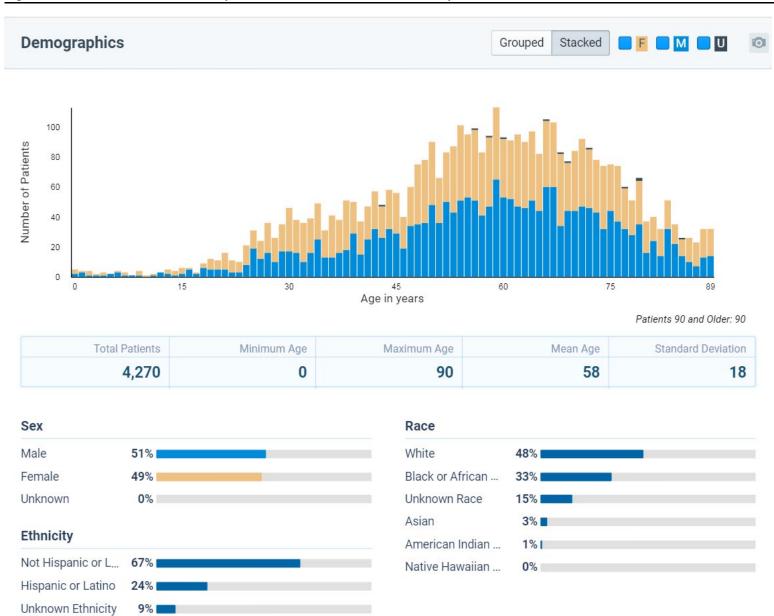
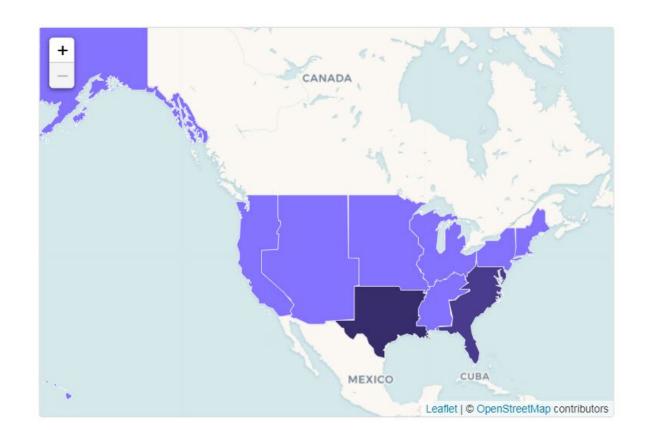




Figure 2. Patient Characteristics for Hospitalized Patients with COVID-19 and Any Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	40	<1%
Middle Atlantic	300	7%
East North Central	200	5%
West North Central	140	3%
South Atlantic	1,320	31%
East South Central	310	7%
West South Central	1,850	43%
Mountain	120	3%
Pacific	20	<1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 3. Patient Characteristics for Hospitalized Patients with COVID-19 and Any Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

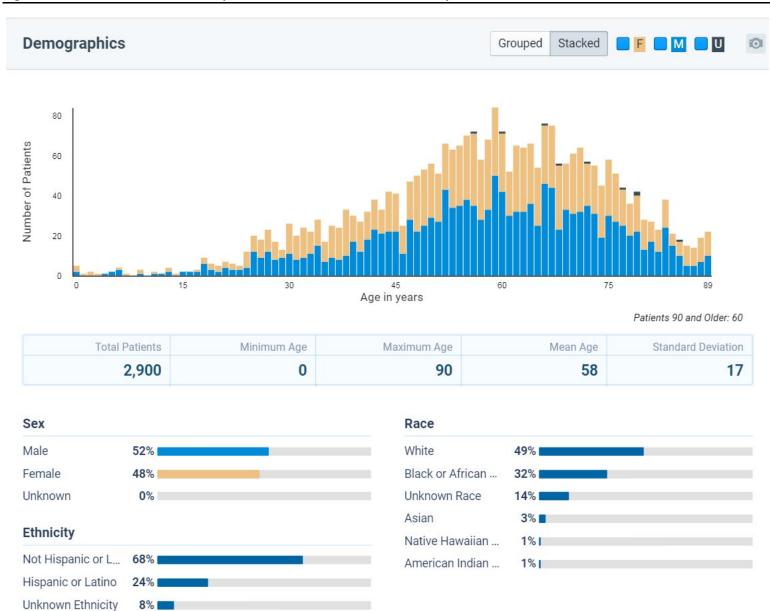
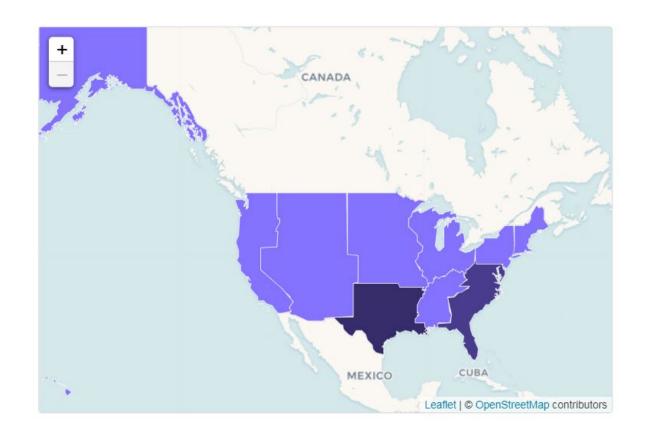




Figure 3. Patient Characteristics for Hospitalized Patients with COVID-19 and Any Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	20	<1%
Middle Atlantic	150	5%
East North Central	140	5%
West North Central	80	3%
South Atlantic	970	33%
East South Central	220	7%
West South Central	1,250	43%
Mountain	90	3%
Pacific	20	<1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 4. Patient Characteristics for Hospitalized Patients with COVID-19 and Oral Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

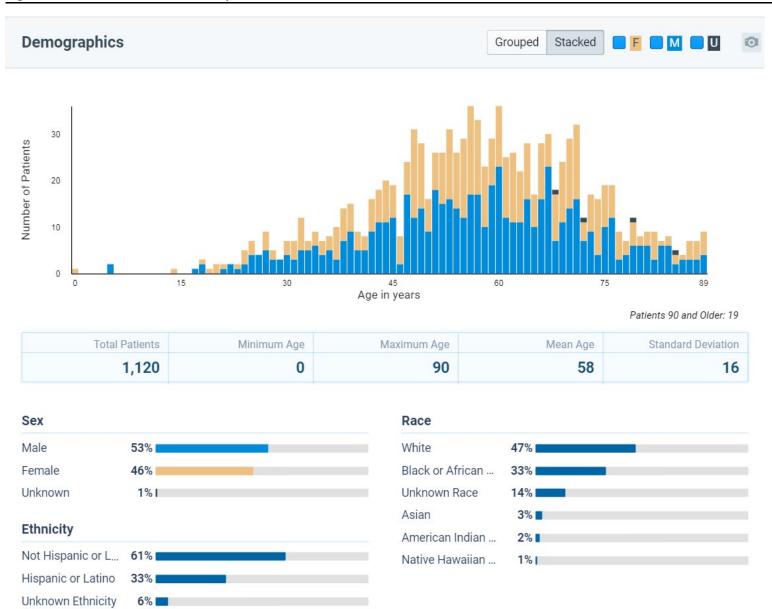
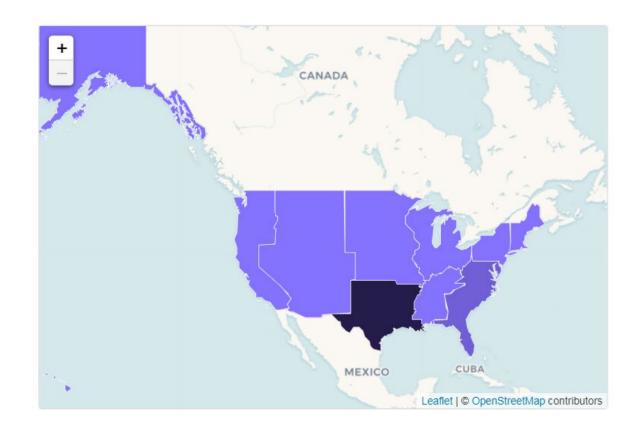




Figure 4. Patient Characteristics for Hospitalized Patients with COVID-19 and Oral Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	10	<1%
Middle Atlantic	60	5%
East North Central	70	6%
West North Central	20	2%
South Atlantic	180	16%
East South Central	90	8%
West South Central	680	59%
Mountain	40	3%
Pacific	10	<1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 5. Patient Characteristics for Hospitalized Patients with COVID-19 and Injectable Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

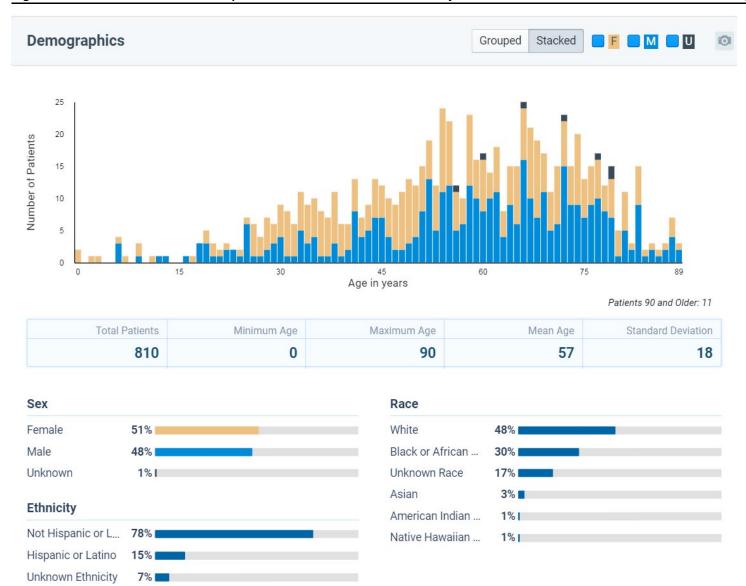
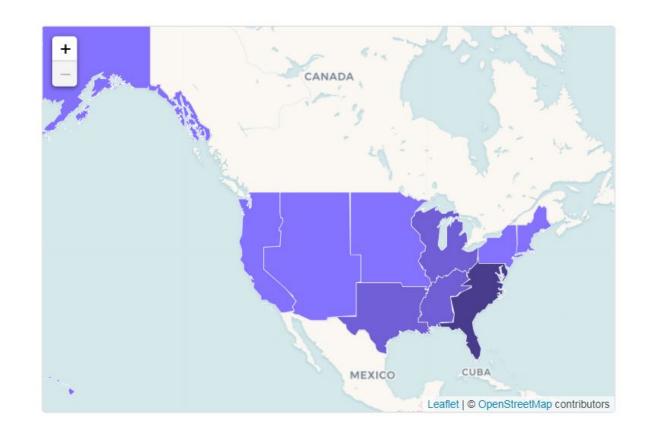




Figure 5. Patient Characteristics for Hospitalized Patients with COVID-19 and Injectable Dexamethasone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	10	1%
Middle Atlantic	40	5%
East North Central	100	12%
West North Central	70	8%
South Atlantic	320	38%
East South Central	140	17%
West South Central	90	11%
Mountain	60	7%
Pacific	10	1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 6. Patient Characteristics for Hospitalized Patients with COVID-19 and Any Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

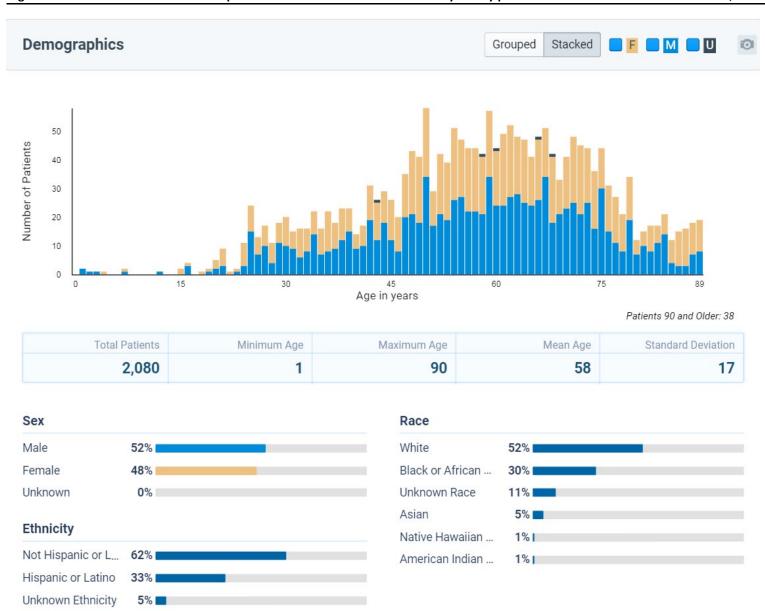
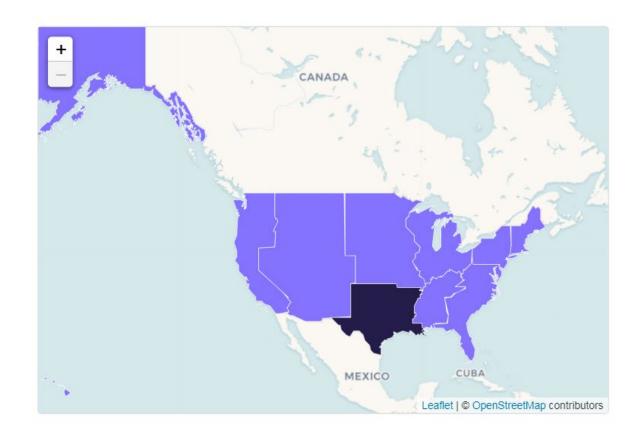




Figure 6. Patient Characteristics for Hospitalized Patients with COVID-19 and Any Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	20	<1%
Middle Atlantic	160	8%
East North Central	50	2%
West North Central	20	<1%
South Atlantic	180	9%
East South Central	120	6%
West South Central	1,540	73%
Mountain	10	<1%
Pacific	10	<1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 7. Patient Characteristics for Hospitalized Patients with COVID-19 and Oral Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

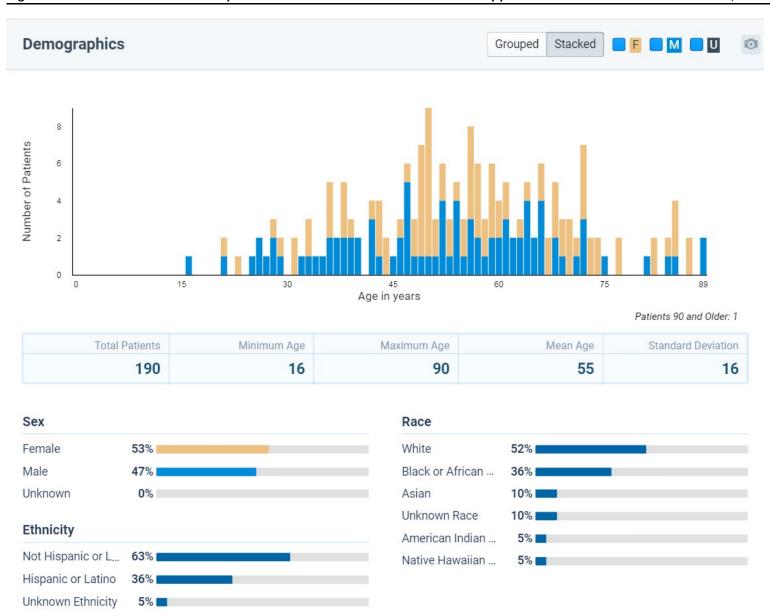
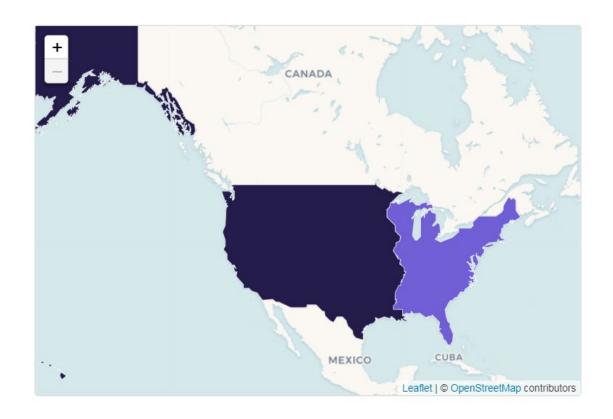




Figure 7. Patient Characteristics for Hospitalized Patients with COVID-19 and Oral Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
East	30	16%
West	160	84%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 8. Patient Characteristics for Hospitalized Patients with COVID-19 and Injectable Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19,

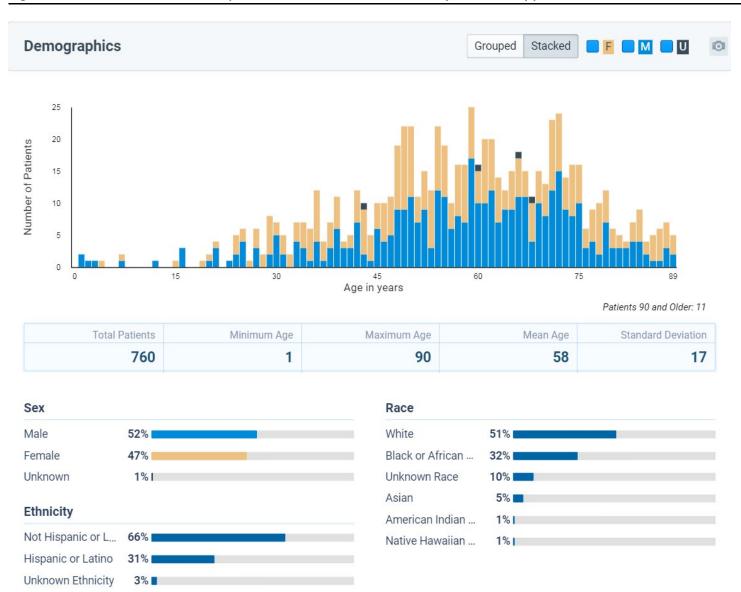
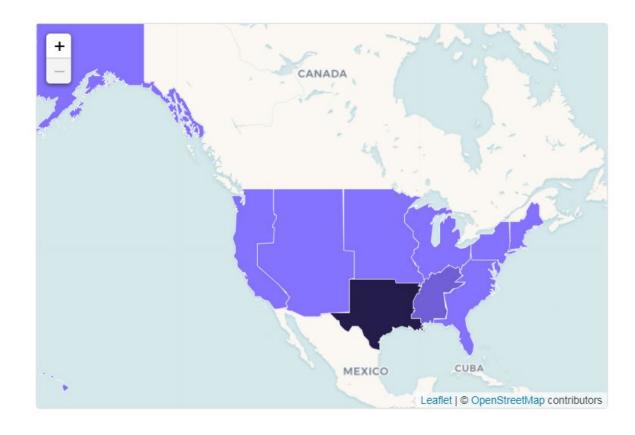




Figure 8. Patient Characteristics for Hospitalized Patients with COVID-19 and Injectable Methylprednisolone Use in the TriNetX Database, from June 8, 2020 to July 19,

US Regions	Patients	Percent
New England	10	1%
Middle Atlantic	30	4%
East North Central	40	5%
West North Central	20	3%
South Atlantic	70	9%
East South Central	100	13%
West South Central	500	63%
Mountain	10	1%
Pacific	10	1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 9. Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

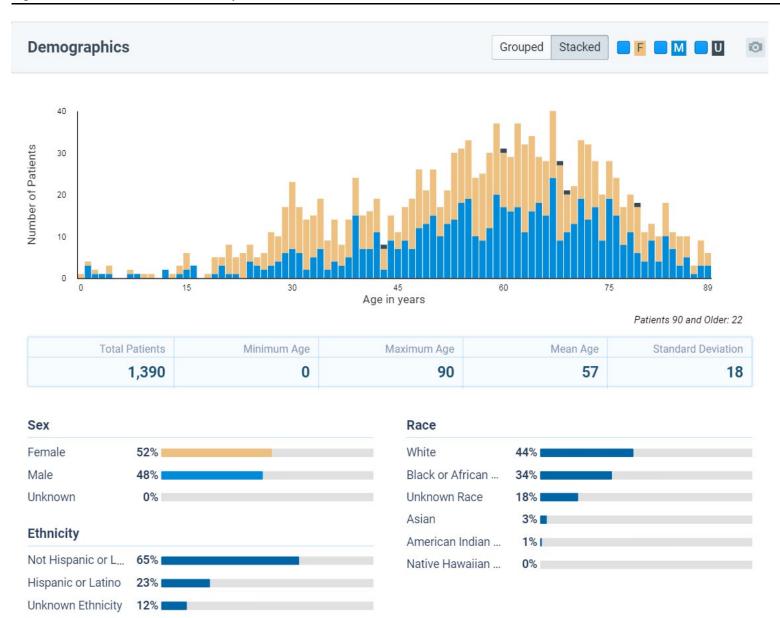
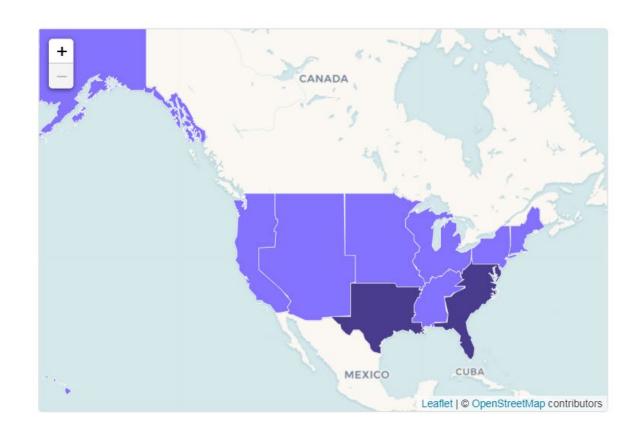




Figure 9. Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	30	2%
Middle Atlantic	140	10%
East North Central	90	6%
West North Central	80	6%
South Atlantic	480	34%
East South Central	90	6%
West South Central	460	32%
Mountain	50	3%
Pacific	10	<1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 10. Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Oral Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

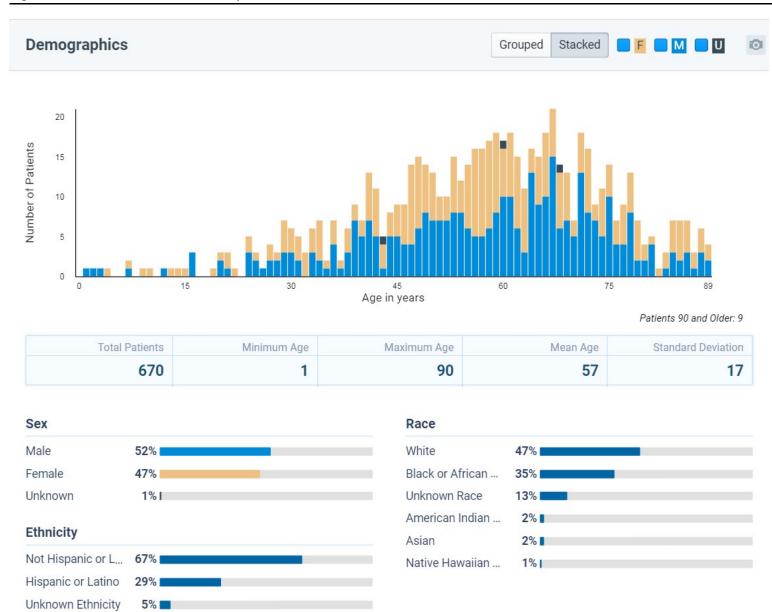
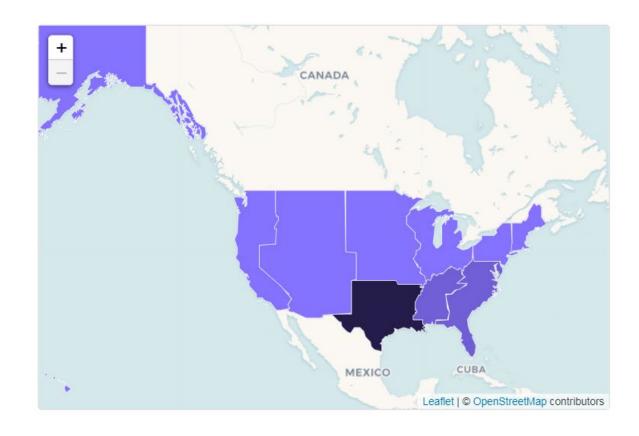




Figure 10. Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Oral Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	10	1%
Middle Atlantic	30	4%
East North Central	50	7%
West North Central	40	6%
South Atlantic	120	17%
East South Central	70	10%
West South Central	350	50%
Mountain	20	3%
Pacific	10	1%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Figure 11. Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Injectable Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

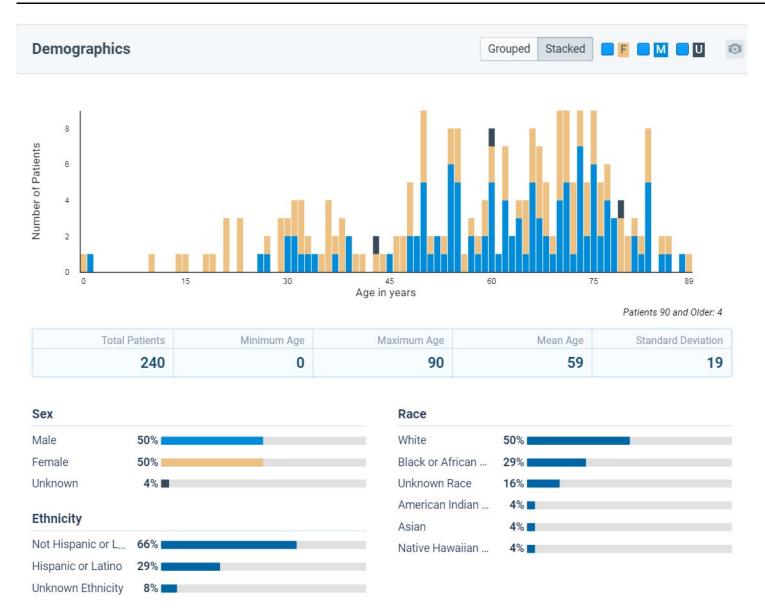
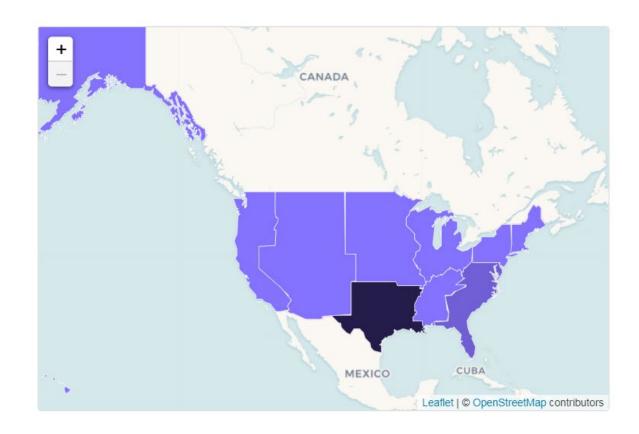




Figure 11. Patient Characteristics for Hospitalized Patients with COVID-19 and All Other Injectable Corticosteroid Use in the TriNetX Database, from June 8, 2020 to July 19, 2020

US Regions	Patients	Percent
New England	10	4%
Middle Atlantic	20	7%
East North Central	20	7%
West North Central	20	7%
South Atlantic	40	14%
East South Central	10	4%
West South Central	140	50%
Mountain	10	4%
Pacific	10	4%

Patient location is determined by location of HCO headquarters



Generated by TriNetX



Appendix A. Number of TriNetX USA Network Database Health Care Organizations (HCOs) Contributing Data per Week in Base Hospitalization Cohort, from June 8, 2020 to July 19, 2020

Week	Number of HCOs ¹
Week 1 (June 8, 2020 - June 14, 2020)	46
Week 2 (June 15, 2020 - June 21, 2020)	45
Week 3 (June 22, 2020 - June 28, 2020)	43
Week 4 (June 29, 2020 - July 5, 2020)	40
Week 5 (July 6, 2020 - July 12, 2020)	40
Week 6 (July 13, 2020 - July 19, 2020)	34

¹The TriNetX USA Network Database has a total of 63 HCOs eligible to contribute data.

cder_iqp_wp007 Page 31 of 36



Appendix B. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes and Logical Observation Identifiers Names and Codes (LOINC) Lab Codes Used to Define COVID-19 in this Request

Code	Description	Code Category	Code Type
	COVID-19		
B97.2	Coronavirus as the cause of diseases classified elsewhere	Diagnosis	ICD-10-CM
U07.1	COVID-19, virus identified	Diagnosis	ICD-10-CM
U07.2	COVID-19, virus not identified (WHO)		
B34.2	Coronavirus infection, unspecified site	Diagnosis	ICD-10-CM
J12.81	Pneumonia due to SARS-associated coronavirus	Diagnosis	ICD-10-CM
B97.21	SARS-associated coronavirus causing diseases classd elswhr	Diagnosis	ICD-10-CM
94307-6	SARS coronavirus 2 N gene [Presence] in Unspecified specimen by Nucleic acid amplification using primer-probe set N1	Lab	LOINC
94308-4	SARS coronavirus 2 N gene [Presence] in Unspecified specimen by Nucleic acid amplification using primer-probe set N2	Lab	LOINC
94309-2	SARS coronavirus 2 RNA [Presence] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94310-0	SARS-like coronavirus N gene [Presence] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94311-8	SARS coronavirus 2 N gene [Cycle Threshold #] in Unspecified specimen by Nucleic acid amplification using primer-probe set N1	Lab	LOINC
94312-6	SARS coronavirus 2 N gene [Cycle Threshold #] in Unspecified specimen by Nucleic acid amplification using primer-probe set N2	Lab	LOINC
94313-4	SARS-like coronavirus N gene [Cycle Threshold #] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94314-2	SARS coronavirus 2 RdRp gene [Presence] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94315-9	SARS coronavirus 2 E gene [Presence] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94316-7	SARS coronavirus 2 N gene [Presence] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94500-6	SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94502-2	SARS-related coronavirus RNA [Presence] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94509-7	SARS coronavirus 2 E gene [Cycle Threshold #] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94510-5	SARS coronavirus 2 N gene [Cycle Threshold #] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94511-3	SARS coronavirus 2 ORF1ab region [Cycle Threshold #] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94533-7	SARS coronavirus 2 N gene [Presence] in Respiratory specimen by NAA with probe detection	Lab	LOINC

cder_iqp_wp007 Page 32 of 36



Appendix B. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes and Logical Observation Identifiers Names and Codes (LOINC) Lab Codes Used to Define COVID-19 in this Request

Code	Description	Code Category	Code Type
94534-5	SARS coronavirus 2 RdRp gene [Presence] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94559-2	SARS coronavirus 2 ORF1ab region [Presence] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94565-9	SARS coronavirus 2 RNA [Presence] in Nasopharynx by NAA with non-probe detection	Lab	LOINC
94639-2	SARS coronavirus 2 ORF1ab region [Presence] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94640-0	SARS coronavirus 2 S gene [Presence] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94641-8	SARS coronavirus 2 S gene [Presence] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94642-6	SARS coronavirus 2 S gene [Cycle Threshold #] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94643-4	SARS coronavirus 2 S gene [Cycle Threshold #] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94644-2	SARS coronavirus 2 ORF1ab region [Cycle Threshold #] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94645-9	SARS coronavirus 2 RdRp gene [Cycle Threshold #] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94646-7	SARS coronavirus 2 RdRp gene [Cycle Threshold #] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94647-5	SARS-related coronavirus RNA [Presence] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94660-8	SARS coronavirus 2 RNA [Presence] in Serum or Plasma by NAA with probe detection	Lab	LOINC
94532-9	SARS-related coronavirus+MERS coronavirus RNA [Presence] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94756-4	SARS coronavirus 2 N gene [Presence] in Respiratory specimen by Nucleic acid amplification using CDC primer-probe set N1	Lab	LOINC
94757-2	SARS coronavirus 2 N gene [Presence] in Respiratory speciment by Nucleic acid amplification using CDC primer-probe set N2	Lab	LOINC
94758-0	SARS coronavirus 2 E gene [Presence] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94759-8	SARS coronavirus 2 RNA [Presence] in Nasopharynx by NAA with probe detection	Lab	LOINC
94765-5	SARS coronavirus 2 E gene [Presence] in Serum or Plasma by NAA with probe detection	Lab	LOINC
94766-3	SARS coronavirus 2 N gene [Presence] in Serum or Plasma by NAA with probe detection	Lab	LOINC

cder_iqp_wp007 Page 33 of 36



Appendix B. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes and Logical Observation Identifiers Names and Codes (LOINC) Lab Codes Used to Define COVID-19 in this Request

Code	Description	Code Category	Code Type
94767-1	SARS coronavirus 2 S gene [Presence] in Serum or Plasma by NAA with probe detection	Lab	LOINC
94745-7	SARS coronavirus 2 RNA [Cycle Threshold #] in Respiratory specimen by NAA with probe detection	Lab	LOINC
94746-5	SARS coronavirus 2 RNA [Cycle Threshold #] in Unspecified specimen by NAA with probe detection	Lab	LOINC
94763-0	SARS coronavirus 2 [Presence] in Unspecified specimen by Organism specific culture	Lab	LOINC
94558-4	SARA coronavirus 2 Ag [Presence] in Respiratory specimen by Rapid immunoassay	Lab	LOINC
94819-0	SARS coronavirus 2 RNA [Log #/volume] (viral load) in Unspecified specimen by NAA with probe detection	Lab	LOINC

Codes included were those available as of request run date (August 10, 2020).

cder_iqp_wp007 Page 34 of 36



Appendix C. List of RxNorm Medication Codes and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Corticosteroids in this Request

Code	Description	Code Category	Code Type
	Corticosteroids		
3264	dexamethasone	Medication	RxNorm
J8540	Dexamethasone, oral, 0.25 mg	Procedure	HCPCS
J7638	Dexamethasone, inhalation solution, compounded product, administered through	Procedure	HCPCS
	dme, unit dose form, per milligram		
J7637	Dexamethasone, inhalation solution, compounded product, administered through	Procedure	HCPCS
	dme, concentrated form, per milligram		
J1100	Injection, dexamethasone sodium phosphate, 1 mg	Procedure	HCPCS
J1094	Injection, dexamethasone acetate, 1 mg	Procedure	HCPCS
J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg	Procedure	HCPCS
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	Procedure	HCPCS
6902	methylprednisolone	Medication	RxNorm
J7509	Methylprednisolone oral, per 4 mg	Procedure	HCPCS
J1030	Injection, methylprednisolone acetate, 40 mg	Procedure	HCPCS
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	Procedure	HCPCS
J1040	Injection, methylprednisolone acetate, 80 mg	Procedure	HCPCS
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	Procedure	HCPCS
J1020	Injection, methylprednisolone acetate, 20 mg	Procedure	HCPCS
1514	betamethasone	Medication	RxNorm
J7624	Betamethasone, inhalation solution, compounded product, administered through	Procedure	HCPCS
	dme, unit dose form, per milligram		
J0702	Injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg	Procedure	HCPCS
2878	cortisone	Medication	RxNorm
4452	fludrocortisone	Medication	RxNorm
5492	hydrocortisone	Medication	RxNorm
J1720	Injection, hydrocortisone sodium succinate, up to 100 mg	Procedure	HCPCS
J1700	Injection, hydrocortisone acetate, up to 25 mg	Procedure	HCPCS
J1710	Injection, hydrocortisone sodium phosphate, up to 50 mg	Procedure	HCPCS
8638	prednisolone	Medication	RxNorm
J7510	Prednisolone oral, per 5 mg	Procedure	HCPCS
J2650	Injection, prednisolone acetate, up to 1 ml	Procedure	HCPCS
8640	prednisone	Medication	RxNorm
J7512	Prednisone, immediate release or delayed release, oral 1 mg	Procedure	HCPCS
10759	triamcinolone	Medication	RxNorm
J7683	Triamcinolone, inhalation solution, compounded product, administered through dme, concentrated form, per milligram	Procedure	HCPCS
17604		Dunnalium	Hebes
J7684	Triamcinolone, inhalation solution, compounded product, administered through dme, unit dose form, per milligram	Procedure	HCPCS
12201		Drocodura	HCDCC
J3301 J3300	Injection, triamcinolone acetonide, not otherwise specified, 10 mg	Procedure Procedure	HCPCS HCPCS
J3300	Injection, triamcinolone acetoneide, preservative free, 1 mg Injection, triamcinolone hexacetonide, per 5 mg	Procedure	HCPCS HCPCS
J3308 J3302	Injection, triamcinolone nexacetonide, per 5 mg	Procedure	HCPCS HCPCS
J3302 J3304	Injection, triamcinolone diacetate, per 5 mg Injection, triamcinolone acetoneide, preservative free, extended-release, microsphere		HCPCS
13304	formulation, 1 mg	Trocedure	TICECS
	iormalation, I mg		

cder_iqp_wp007 Page 35 of 36



