Disclaimer

The following report(s) provides findings from a Food and Drug Administration (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

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

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_mpl1r_wp052_nsdp_v01

Request ID: cder_mpl1r_wp052_nsdp_v01

Query Description: The goal of this query was to estimate the cohort size and baseline characteristics of seven groups of patients with evidence of respiratory syncytial virus (RSV). The cohorts are individuals with a diagnosis of RSV (any setting, inpatient, and outpatient, separately), a diagnosis of bronchiolitis, a diagnosis of RSV or bronchiolitis, prior dispensings of palivizumab, or who obtained a diagnostic assay for RSV (PCR +/- Antigen), among children aged 1 month to 5 years of age, in the Sentinel Distributed Database (SDD).

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 4.0.0

Data Source: Data from January 1, 2008 to June 30, 2016 from 16 health plans contributing to the SDD were included in this report. This request was distributed on June 28, 2017. See Appendix A for a list of the dates of available data for each Data Partner.

Study Design: This request was designed to calculate the size of each cohort and the background rates of select covariates. In addition to age, sex, comorbidity score, other exposures of interest, and health service utilization, the following covariates were assessed during the baseline period: prematurity, congenital heart disease (CHD), chronic lung disease (CLD), and intensive care unit (ICU) stay. ICU stay was evaluated in the 15 days before and after the index date. All other covariates were evaluated in the patient's entire history prior to the index date, through two months (60 days) after the index date. Prematurity was evaluated only through the index date. The covariates were defined with National Drug Codes (NDCs), Current Procedural Terminology, Fourth Edition (CPT-4) procedure codes, Healthcare Common Procedure Coding System, Level II (HCPCS) procedure codes, the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes, International Classification of Disease, Tenth Edition, Clinical Modification (ICD-10-CM) diagnosis codes, and International Classification of Diseases, Tenth Edition, Procedure Coding System (ICD-10-PCS) procedure codes. See Appendices B-C for specific codes.

For each index exposure, the background rates for the other exposures of interest were also calculated. These rates were evaluated from 3 months prior to index (or any available history for those patients under the age of 6 months) through the 2 months post index.

Cohort Eligibility Criteria: Individuals ages 1-60 months were included in the query. Tables of results are reported separately for ages 1-6 months and 7-60 months. Those included in the cohort over the age of six months were required to be continuously enrolled in plans with medical and drug coverage for at least six months (183 days) prior to their vaccination date, during which gaps in coverage of up to 45 days were allowed. No enrollment was required of those patients less than six months of age.

In assessing qualifying incident exposures, members over the age of six months were excluded if they had the exposure of interest six months (183 days) prior to the index date. No incidence criteria was evaluated for those under six months of age.

Events of Interest: The exposures of interest were: diagnosis of RSV, diagnosis of bronchiolitis, diagnosis of RSV or bronchiolitis, palivizumab dispensing, and diagnostic assay for RSV (PCR +/- Antigen). RSV diagnosis was examined in any care setting, in the inpatient care setting, and in the outpatient care setting (emergency department and ambulatory care). The exposures were defined with NDCs, CPT-4 procedure codes, HCPCS procedure codes, and ICD-9-CM and ICD-10-CM diagnosis and procedure codes. Please see Appendices D-E for specific codes.

Limitations: Algorithms to define exposures and covariates are imperfect and, therefore, may be misclassified.

Please see Appendices F and G for the specifications of parameters used in the analyses for this request.

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

Sentinel

Table of Contents

Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) Tool*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the Sentinel Common Data Model.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

- **Ambulatory Visit (AV) -** includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters. Excludes emergency department encounters.
- **Emergency Department (ED) -** includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP) -** includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS) -** includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA) -** includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: (1): Cohort includes only the first valid treatment episode during the query period; (2): Cohort includes all valid treatment episodes during the query period; (3): Cohort includes all valid treatment episodes during the query period until an event

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled” sequence.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the MP algorithm: (0): counts all occurrences of an HOI during an exposure episode; (1): deduplicates occurrences of the same HOI code and code type on the same day; (2): deduplicates occurrences of the same HOI group on the same day (e.g., deduplicates at the group level).

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extension days are added after any episode gaps have been bridged

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Lookback Period (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug

Member-Years - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period all divided by

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Treatment Episode Truncation Indicator - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.

Users - number of members with exposure during the query period. Member must have no evidence of exposure(s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

Washout Period (drug/exposure) -** number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) -** number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

Table 1a. Baseline Characteristics of Patients Aged 1-6 Months, with an Incident Diagnosis of Respiratory Syncytial Virus (RSV) in Any Care Setting, from January 1, 2008 to June 30, 2016

	RSV Diagnosis – Any Care Setting	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	138,669	
Number of unique patients	138,669	
Demographics		
Mean Age	0.3	0.1
Age: 1M-6M	138,669	100.0%
Sex (Female)	59,323	42.8%
Sex (Male)	79,344	57.2%
Sex (Unknown)	2	0.0%
Index Care Setting: Cohort-defining events by care setting will not add up to 100%, due to existence of care settings other than those specificed		
RSV -- Inpatient (IP)	17,859	12.9%
RSV -- Outpatient (AV, ED)	112,977	81.5%
Recorded history of[3]:		
Prior Combined Comorbidity Raw Score	0.1	0.4
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	2,722	2.0%
Chronic Lung Disease (CLD)	301	0.2%
Congenital Heart Disease (CHD)	1,526	1.1%
Extremely preterm (< 29 weeks)	816	0.6%
Very preterm (29 to < 32 weeks)	2,094	1.5%
Moderate to late preterm (32 to < 37 weeks)	8,760	6.3%
Bronchiolitis	125,409	90.4%
Palivizumab	1,458	1.1%
Diagnostic Assay (PCR +/- Antigen)	72,695	52.4%
Health Service Utilization Intensity[4]:		
Mean number of ambulatory encounters (AV)	9.4	5.3
Mean number of emergency room encounters (ED)	0.7	1
Mean number of inpatient hospital encounters (IP)	0.9	0.8
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	1.1	2.6
Mean number of filled prescriptions	3.4	3.8
Mean number of generics	2.5	2.3
Mean number of unique drug classes	2.3	2

[1] All metrics are based on total number of episodes per group

[2] Value represents standard deviation when not specificed with %

[3] History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[4] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 1b. Baseline Characteristics of Patients Aged 7-60 Months, with an Incident Diagnosis of Respiratory Syncytial Virus (RSV) in Any Care Setting, from January 1, 2008 to June 30, 2016

	RSV Diagnosis – Any Care Setting	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	179,259	
Number of unique patients	179,259	
Demographics		
Mean Age	1.6	1
Age: 7M-12M	69,596	38.8%
Age: 13M-24M	64,671	36.1%
Age: 25M-60M	44,992	25.1%
Sex (Female)	80,410	44.9%
Sex (Male)	98,837	55.1%
Sex (Unknown)	12	0.0%
Index Care Setting: Cohort-defining events by care setting will not add up to 100%, due to existence of care settings other than those specificed		
RSV -- Inpatient (IP)	15,574	8.7%
RSV -- Outpatient (AV, ED)	150,073	83.7%
Recorded history of[3]:		
Prior Combined Comorbidity Raw Score	0.1	0.4
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	1,823	1.0%
Chronic Lung Disease (CLD)	979	0.5%
Congenital Heart Disease (CHD)	2,757	1.5%
Extremely preterm (< 29 weeks)	2,288	1.3%
Very preterm (29 to < 32 weeks)	3,244	1.8%
Moderate to late preterm (32 to < 37 weeks)	9,551	5.3%
Bronchiolitis	149,904	83.6%
Palivizumab	993	0.6%
Diagnostic Assay (PCR +/- Antigen)	88,033	49.1%
Health Service Utilization Intensity[4]:		
Mean number of ambulatory encounters (AV)	6.6	5.3
Mean number of emergency room encounters (ED)	0.6	0.9
Mean number of inpatient hospital encounters (IP)	0.2	0.4
Mean number of non-acute institutional encounters (IS)	0	0.1
Mean number of other ambulatory encounters (OA)	0.9	4.2
Mean number of filled prescriptions	4.8	4.4
Mean number of generics	3.6	2.6
Mean number of unique drug classes	3.1	2.2

[1] All metrics are based on total number of episodes per group

[2] Value represents standard deviation when not specificed with %

[3] History defined as entire history prior to index date for prematurity and CHD and CLD, and 3 months prior to index for all other covariates. Evaluation window continues through index date for prematurity, and through 2 months post index date for all other covariates

[4] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 2a. Baseline Characteristics of Patients Aged 1-6 Months, with an Incident Diagnosis of Respiratory Syncytial Virus (RSV) in the Inpatient Care Setting, from January 1, 2008 to June 30, 2016

	RSV Diagnosis – Inpatient Care Setting[1]	
Characteristic[2]	**N/Mean**	**%/Std Dev[3]**
Number of episodes	24,192	
Number of unique patients	24,192	
Demographics		
Mean Age	0.3	0.1
Age: 1M-6M	24,192	100.0%
Sex (Female)	10,191	42.1%
Sex (Male)	14,000	57.9%
Sex (Unknown)	1	0.0%
Recorded history of[4]:		
Prior Combined Comorbidity Raw Score	0	0.6
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	2,472	10.2%
Chronic Lung Disease (CLD)	135	0.6%
Congenital Heart Disease (CHD)	613	2.5%
Extremely preterm (< 29 weeks)	261	1.1%
Very preterm (29 to < 32 weeks)	562	2.3%
Moderate to late preterm (32 to < 37 weeks)	2,326	9.6%
Bronchiolitis	23,726	98.1%
Palivizumab	388	1.6%
Diagnostic Assay (PCR +/- Antigen)	10,622	43.9%
Health Service Utilization Intensity[5]:		
Mean number of ambulatory encounters (AV)	9	6.2
Mean number of emergency room encounters (ED)	0.9	1.1
Mean number of inpatient hospital encounters (IP)	1.9	0.7
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	1.4	4.1
Mean number of filled prescriptions	3.6	4.4
Mean number of generics	2.5	2.6
Mean number of unique drug classes	2.3	2.2

[1] Care setting defined in the cohort definition, so covariates of index by care setting not included

[2] All metrics are based on total number of episodes per group

[3] Value represents standard deviation when not specificed with %

[4] History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[5] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 2b. Baseline Characteristics of Patients Aged 7-60 Months, with an Incident Diagnosis of Respiratory Syncytial Virus (RSV) in the Inpatient Care Setting, from January 1, 2008 to June 30, 2016

	RSV Diagnosis – Inpatient Care Setting[1]	
Characteristic[2]	**N/Mean**	**%/Std Dev[3]**
Number of episodes	20,002	
Number of unique patients	20,002	
Demographics		
Mean Age	1.7	1
Age: 7M-12M	7,137	35.7%
Age: 13M-24M	7,271	36.4%
Age: 25M-60M	5,594	28.0%
Sex (Female)	8,895	44.5%
Sex (Male)	11,106	55.50%
Sex (Unknown)	1	0.0%
Recorded history of[4]:		
Prior Combined Comorbidity Raw Score	0.4	0.7
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	1,808	9.0%
Chronic Lung Disease (CLD)	547	2.7%
Congenital Heart Disease (CHD)	1,082	5.4%
Extremely preterm (< 29 weeks)	882	4.4%
Very preterm (29 to < 32 weeks)	811	4.1%
Moderate to late preterm (32 to < 37 weeks)	1,644	8.2%
Bronchiolitis	18,112	90.6%
Palivizumab	303	1.5%
Diagnostic Assay (PCR +/- Antigen)	7,090	35.4%
Health Service Utilization Intensity[5]:		
Mean number of ambulatory encounters (AV)	8.4	7.9
Mean number of emergency room encounters (ED)	1	1.1
Mean number of inpatient hospital encounters (IP)	1.2	0.6
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	2.5	9.2
Mean number of filled prescriptions	7.1	6.8
Mean number of generics	4.6	3.2
Mean number of unique drug classes	4	2.7

[1] Care setting defined in the cohort definition, so covariates of index by care setting not included

[2] All metrics are based on total number of episodes per group

[3] Value represents standard deviation when not specificed with %

[4] History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[5] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 3a. Baseline Characteristics of Patients Aged 1-6 Months, with an Incident Diagnosis of Respiratory Syncytial Virus (RSV) in the Outpatient Care Setting, from January 1, 2008 to June 30, 2016

	RSV Diagnosis – Outpatient Care Setting[1]	
Characteristic[2]	**N/Mean**	**%/Std Dev[3]**
Number of episodes	119,363	
Number of unique patients	119,363	
Demographics		
Mean Age	0.3	0.1
Age: 1M-6M	119,363	100.0%
Sex (Female)	51,556	43.2%
Sex (Male)	67,805	56.8%
Sex (Unknown)	2	0.0%
Recorded history of[4]:		
Prior Combined Comorbidity Raw Score	0	0.4
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	1,573	1.3%
Chronic Lung Disease (CLD)	194	0.2%
Congenital Heart Disease (CHD)	1,101	0.9%
Extremely preterm (< 29 weeks)	605	0.5%
Very preterm (29 to < 32 weeks)	1,666	1.4%
Moderate to late preterm (32 to < 37 weeks)	7,324	6.1%
Bronchiolitis	106,960	89.6%
Palivizumab	1,167	1.0%
Diagnostic Assay (PCR +/- Antigen)	66,703	55.9%
Health Service Utilization Intensity[5]:		
Mean number of ambulatory encounters (AV)	10	5.3
Mean number of emergency room encounters (ED)	0.7	1
Mean number of inpatient hospital encounters (IP)	0.9	0.7
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	0.9	2.3
Mean number of filled prescriptions	3.4	3.8
Mean number of generics	2.5	2.3
Mean number of unique drug classes	2.3	2

[1] Care setting defined in the cohort definition, so covariates of index by care setting not included

[2] All metrics are based on total number of episodes per group

[3] Value represents standard deviation when not specificed with %

[4] History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[5] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 3b. Baseline Characteristics of Patients Aged 7-60 Months, with an Incident Diagnosis of Respiratory Syncytial Virus (RSV) in the Outpatient Care Setting, from January 1, 2008 to June 30, 2016

	RSV Diagnosis – Outpatient Care Setting[1]	
Characteristic[2]	**N/Mean**	**%/Std Dev[3]**
Number of episodes	156,019	
Number of unique patients	156,019	
Demographics		
Mean Age	1.6	1
Age: 7M-12M	61,177	39.2%
Age: 13M-24M	56,723	36.4%
Age: 25M-60M	38,119	24.4%
Sex (Female)	70,419	45.1%
Sex (Male)	85,589	54.90%
Sex (Unknown)	11	0.0%
Recorded history of[4]:		
Prior Combined Comorbidity Raw Score	0.1	0.4
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	863	0.6%
Chronic Lung Disease (CLD)	687	0.4%
Congenital Heart Disease (CHD)	2,110	1.4%
Extremely preterm (< 29 weeks)	1,797	1.2%
Very preterm (29 to < 32 weeks)	2,697	1.7%
Moderate to late preterm (32 to < 37 weeks)	8,127	5.2%
Bronchiolitis	128,845	82.6%
Palivizumab	792	0.5%
Diagnostic Assay (PCR +/- Antigen)	83,496	53.5%
Health Service Utilization Intensity[5]:		
Mean number of ambulatory encounters (AV)	6.6	5.1
Mean number of emergency room encounters (ED)	0.6	0.9
Mean number of inpatient hospital encounters (IP)	0.1	0.4
Mean number of non-acute institutional encounters (IS)	0	0.1
Mean number of other ambulatory encounters (OA)	0.8	3.8
Mean number of filled prescriptions	4.7	4.3
Mean number of generics	3.5	2.6
Mean number of unique drug classes	3.1	2.1

[1]Care setting defined in the cohort definition, so covariates of index by care setting not included

[2]All metrics are based on total number of episodes per group

[3]Value represents standard deviation when not specificed with %

[4]History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[5]Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 4a. Baseline Characteristics of Patients Aged 1-6 Months, with an Incident Diagnosis of Bronchiolitis, from January 1, 2008 to June 30, 2016

	Bronchiolitis Diagnosis	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	349,758	
Number of unique patients	349,758	
Demographics		
Mean Age	0.4	0.1
Age: 1M-6M	349,758	100.0%
Sex (Female)	142,362	40.7%
Sex (Male)	207,385	59.3%
Sex (Unknown)	11	0.0%
Index Care Setting: Cohort-defining events by care setting will not add up to 100%, due to existence of care settings other than those specificed		
Bronchiolitis -- Inpatient (IP)	21,261	6.1%
Bronchiolitis – Outpatient (AV, ED)	327,485	93.6%
Recorded history of[3]:		
Prior Combined Comorbidity Raw Score	0.1	0.4
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	3,459	1.0%
Chronic Lung Disease (CLD)	704	0.2%
Congenital Heart Disease (CHD)	3,260	0.9%
Extremely preterm (< 29 weeks)	1,790	0.5%
Very preterm (29 to < 32 weeks)	4,515	1.3%
Moderate to late preterm (32 to < 37 weeks)	20,357	5.8%
RSV	126,208	36.1%
Palivizumab	3,037	0.9%
Diagnostic Assay (PCR +/- Antigen)	118,461	33.9%
Health Service Utilization Intensity[4]:		
Mean number of ambulatory encounters (AV)	9.2	5.1
Mean number of emergency room encounters (ED)	0.6	0.9
Mean number of inpatient hospital encounters (IP)	0.8	0.7
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	1.2	2.7
Mean number of filled prescriptions	3.4	3.7
Mean number of generics	2.5	2.3
Mean number of unique drug classes	2.3	2

[1] All metrics are based on total number of episodes per group

[2] Value represents standard deviation when not specificed with %

[3] History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[4] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 4b. Baseline Characteristics of Patients Aged 7-60 Months, with an Incident Diagnosis of Bronchiolitis, from January 1, 2008 to June 30, 2016

	Bronchiolitis Diagnosis	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	514,532	
Number of unique patients	514,532	
Demographics		
Mean Age	1.7	1.1
Age: 7M-12M	190,391	37.0%
Age: 13M-24M	185,292	36.0%
Age: 25M-60M	138,849	27.0%
Sex (Female)	224,454	43.6%
Sex (Male)	290,056	56.4%
Sex (Unknown)	22	0.0%
Index Care Setting: Cohort-defining events by care setting will not add up to 100%, due to existence of care settings other than those specificed		
Bronchiolitis -- Inpatient (IP)	20,412	4.0%
Bronchiolitis – Outpatient (AV, ED)	481,721	93.6%
Recorded history of[3]:		
Prior Combined Comorbidity Raw Score	0.1	0.3
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	2,493	0.5%
Chronic Lung Disease (CLD)	1,945	0.4%
Congenital Heart Disease (CHD)	6,042	1.2%
Extremely preterm (< 29 weeks)	5,239	1.0%
Very preterm (29 to < 32 weeks)	8,170	1.6%
Moderate to late preterm (32 to < 37 weeks)	25,298	4.9%
RSV	137,564	26.7%
Palivizumab	2,254	0.4%
Diagnostic Assay (PCR +/- Antigen)	116,750	22.7%
Health Service Utilization Intensity[4]:		
Mean number of ambulatory encounters (AV)	5.9	4.6
Mean number of emergency room encounters (ED)	0.5	0.8
Mean number of inpatient hospital encounters (IP)	0.1	0.3
Mean number of non-acute institutional encounters (IS)	0	0.1
Mean number of other ambulatory encounters (OA)	0.8	3.4
Mean number of filled prescriptions	4.2	3.9
Mean number of generics	3.3	2.4
Mean number of unique drug classes	2.9	2

[1] All metrics are based on total number of episodes per group

[2] Value represents standard deviation when not specificed with %

[3] History defined as entire history prior to index date for prematurity and CHD and CLD, and 3 months prior to index for all other covariates. Evaluation window continues through index date for prematurity, and through 2 months post index date for all other covariates

[4] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 5a. Baseline Characteristics of Patients Aged 1-6 Months, with an Incident Diagnosis of Respiratory Syncytial Virus (RSV) or Bronchiolitis, from January 1, 2008 to June 30, 2016

	RSV or Bronchiolitis Diagnosis	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	363,402	
Number of unique patients	363,402	
Demographics		
Mean Age	0.4	0.1
Age: 1M-6M	363,402	100.0%
Sex (Female)	148,952	41.0%
Sex (Male)	214,439	59.0%
Sex (Unknown)	11	0.0%
Index Care Setting: Cohort-defining events by care setting will not add up to 100%, due to existence of care settings other than those specificed		
RSV or Bronchiolitis -- Inpatient (IP)	21,029	5.8%
RSV or Bronchiolitis -- Outpatient (AV, ED)	341,301	93.9%
Recorded history of[3]:		
Prior Combined Comorbidity Raw Score	0.1	0.4
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	3,553	1.0%
Chronic Lung Disease (CLD)	763	0.2%
Congenital Heart Disease (CHD)	3,503	1.0%
Extremely preterm (< 29 weeks)	2,023	0.6%
Very preterm (29 to < 32 weeks)	4,949	1.4%
Moderate to late preterm (32 to < 37 weeks)	21,199	5.8%
Palivizumab	3,389	0.9%
Diagnostic Assay (PCR +/- Antigen)	127,087	35.0%
Health Service Utilization Intensity[4]:		
Mean number of ambulatory encounters (AV)	9.2	5.1
Mean number of emergency room encounters (ED)	0.6	0.9
Mean number of inpatient hospital encounters (IP)	0.8	0.7
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	1.2	2.7
Mean number of filled prescriptions	3.3	3.7
Mean number of generics	2.5	2.3
Mean number of unique drug classes	2.3	1.9

[1] All metrics are based on total number of episodes per group

[2] Value represents standard deviation when not specificed with %

[3] History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[4] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 5b. Baseline Characteristics of Patients Aged 7-60 Months, with an Incident Diagnosis of Respiratory Syncytial Virus (RSV) or Bronchiolitis, from January 1, 2008 to June 30, 2016

	RSV or Bronchiolitis Diagnosis	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	539,865	
Number of unique patients	539,865	
Demographics		
Mean Age	1.7	1.1
Age: 7M-12M	198,218	36.7%
Age: 13M-24M	194,686	36.1%
Age: 25M-60M	146,961	27.2%
Sex (Female)	236,607	43.8%
Sex (Male)	303,236	56.2%
Sex (Unknown)	22	0.0%
Index Care Setting: Cohort-defining events by care setting will not add up to 100%, due to existence of care settings other than those specificed		
RSV or Bronchiolitis -- Inpatient (IP)	21,732	4.0%
RSV or Bronchiolitis -- Outpatient (AV, ED)	505,671	93.7%
Recorded history of[3]:		
Prior Combined Comorbidity Raw Score	0.1	0.3
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	2,610	0.5%
Chronic Lung Disease (CLD)	2,026	0.4%
Congenital Heart Disease (CHD)	6,368	1.2%
Extremely preterm (< 29 weeks)	5,474	1.0%
Very preterm (29 to < 32 weeks)	8,511	1.6%
Moderate to late preterm (32 to < 37 weeks)	26,367	4.9%
Palivizumab	2,406	0.4%
Diagnostic Assay (PCR +/- Antigen)	133,294	24.7%
Health Service Utilization Intensity[4]:		
Mean number of ambulatory encounters (AV)	5.9	4.6
Mean number of emergency room encounters (ED)	0.5	0.8
Mean number of inpatient hospital encounters (IP)	0.1	0.3
Mean number of non-acute institutional encounters (IS)	0	0.1
Mean number of other ambulatory encounters (OA)	0.8	3.5
Mean number of filled prescriptions	4.2	3.9
Mean number of generics	3.3	2.4
Mean number of unique drug classes	2.9	2

[1] All metrics are based on total number of episodes per group

[2] Value represents standard deviation when not specificed with %

[3] History defined as entire history prior to index date for prematurity and CHD and CLD, and 3 months prior to index for all other covariates. Evaluation window continues through index date for prematurity, and through 2 months post index date for all other covariates

[4] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 6a. Baseline Characteristics of Patients Aged 1-6 Months, with Palivizumab Treatment, from January 1, 2008 to June 30, 2016

	Palivizumab[1]	
Characteristic[2]	**N/Mean**	**%/Std Dev[3]**
Number of episodes	18,208	
Number of unique patients	18,208	
Demographics		
Mean Age	0.3	0.1
Age: 1M-6M	18,208	100.0%
Sex (Female)	8,716	47.9%
Sex (Male)	9,492	52.1%
Sex (Unknown)	0	0.0%
Recorded history of[4]:		
Prior Combined Comorbidity Raw Score	0.5	1
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	239	1.3%
Chronic Lung Disease (CLD)	831	4.6%
Congenital Heart Disease (CHD)	2,385	13.1%
Extremely preterm (< 29 weeks)	3,529	19.4%
Very preterm (29 to < 32 weeks)	5,599	30.8%
Moderate to late preterm (32 to < 37 weeks)	4,787	26.3%
RSV	1,252	6.9%
Bronchiolitis	2,386	13.1%
Diagnostic Assay (PCR +/- Antigen)	2,627	14.4%
Health Service Utilization Intensity[5]:		
Mean number of ambulatory encounters (AV)	11.9	10
Mean number of emergency room encounters (ED)	0.4	0.9
Mean number of inpatient hospital encounters (IP)	1.1	0.9
Mean number of non-acute institutional encounters (IS)	0.1	0.4
Mean number of other ambulatory encounters (OA)	2.8	6.6
Mean number of filled prescriptions	5.7	5.9
Mean number of generics	2.9	2.6
Mean number of unique drug classes	2.7	2.3

[1]Palivixumab defined using both procedure and drug codes; care setting is not defined in the Sentinel Common Data Model for drug codes

[2]All metrics are based on total number of episodes per group

[3]Value represents standard deviation when not specificed with %

[4]History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[5]Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 6b. Baseline Characteristics of Patients Aged 7-60 Months, with Palivizumab Treatment, from January 1, 2008 to June 30, 2016

	Palivizumab[1]	
Characteristic[2]	**N/Mean**	**%/Std Dev[3]**
Number of episodes	4,979	
Number of unique patients	4,979	
Demographics		
Mean Age	1	0.4
Age: 7M-12M	3,405	68.4%
Age: 13M-24M	1,490	29.9%
Age: 25M-60M	84	1.7%
Sex (Female)	2,260	45.4%
Sex (Male)	2,719	54.6%
Sex (Unknown)	0	0.0%
Recorded history of[4]:		
Prior Combined Comorbidity Raw Score	0.5	1
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	63	1.3%
Chronic Lung Disease (CLD)	788	15.8%
Congenital Heart Disease (CHD)	1,511	30.3%
Extremely preterm (< 29 weeks)	2,138	42.9%
Very preterm (29 to < 32 weeks)	796	16.0%
Moderate to late preterm (32 to < 37 weeks)	537	10.8%
RSV	420	8.4%
Bronchiolitis	930	18.7%
Diagnostic Assay (PCR +/- Antigen)	842	16.9%
Health Service Utilization Intensity[5]:		
Mean number of ambulatory encounters (AV)	14.5	12.7
Mean number of emergency room encounters (ED)	0.6	1.1
Mean number of inpatient hospital encounters (IP)	0.4	0.8
Mean number of non-acute institutional encounters (IS)	0	0.3
Mean number of other ambulatory encounters (OA)	6.3	16.1
Mean number of filled prescriptions	12.2	11.3
Mean number of generics	5.3	4.1
Mean number of unique drug classes	4.8	3.5

[1] Palivixumab defined using both procedure and drug codes; care setting is not defined in the Sentinel Common Data Model for drug codes

[2] All metrics are based on total number of episodes per group

[3] Value represents standard deviation when not specificed with %

[4] History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[5] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 7a. Baseline Characteristics of Patients Aged 1-6 Months, with a Diagnostic Assay for RSV (PCR +/- Antigen), from January 1, 2008 to June 30, 2016

	Diagnostic Assay for RSV (PCR +/- Antigen)	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	226,507	
Number of unique patients	226,507	
Demographics		
Mean Age	0.3	0.1
Age: 1M-6M	226,507	100.0%
Sex (Female)	99,927	44.1%
Sex (Male)	126,574	55.9%
Sex (Unknown)	6	0.0%
Index Care Setting: Cohort-defining events by care setting will not add up to 100%, due to existence of care settings other than those specificed		
Assay -- Inpatient (IP)	6,738	3.0%
Assay -- Outpatient (AV, ED)	210,877	93.1%
Recorded history of[3]:		
Prior Combined Comorbidity Raw Score	0.1	0.4
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	1,758	0.8%
Chronic Lung Disease (CLD)	537	0.2%
Congenital Heart Disease (CHD)	2,627	1.2%
Extremely preterm (< 29 weeks)	1,452	0.6%
Very preterm (29 to < 32 weeks)	3,372	1.5%
Moderate to late preterm (32 to < 37 weeks)	13,806	6.1%
RSV	70,432	31.1%
Bronchiolitis	113,659	50.2%
Palivizumab	3,002	1.3%
Health Service Utilization Intensity[4]:		
Mean number of ambulatory encounters (AV)	8.9	5.2
Mean number of emergency room encounters (ED)	0.8	1.1
Mean number of inpatient hospital encounters (IP)	0.8	0.7
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	0.9	2.9
Mean number of filled prescriptions	3.2	3.7
Mean number of generics	2.3	2.3
Mean number of unique drug classes	2.1	2

[1]All metrics are based on total number of episodes per group

[2]Value represents standard deviation when not specificed with %

[3]History defined as entire history prior to index date through index date for prematurity, and through 2 months post index date for all other covariates

[4]Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Table 7b. Baseline Characteristics of Patients Aged 7-60 Months, with a Diagnostic Assay for RSV (PCR +/- Antigen), from January 1, 2008 to June 30, 2016

	Diagnostic Assay for RSV (PCR +/- Antigen)	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	319,032	
Number of unique patients	319,032	
Demographics		
Mean Age	1.7	1
Age: 7M-12M	115,804	36.3%
Age: 13M-24M	120,472	37.8%
Age: 25M-60M	82,756	25.9%
Sex (Female)	145,259	45.5%
Sex (Male)	173,760	54.5%
Sex (Unknown)	13	0.0%
Index Care Setting: Cohort-defining events by care setting will not add up to 100%, due to existence of care settings other than those specificed		
Assay -- Inpatient (IP)	7,713	2.4%
Assay -- Outpatient (AV, ED)	297,093	93.1%
Recorded history of[3]:		
Prior Combined Comorbidity Raw Score	0.1	0.4
Intensive Care Unit (ICU) Stay 15 Days Prior to or After Index	1,667	0.5%
Chronic Lung Disease (CLD)	1,334	0.4%
Congenital Heart Disease (CHD)	4,532	1.4%
Extremely preterm (< 29 weeks)	3,467	1.1%
Very preterm (29 to < 32 weeks)	4,919	1.5%
Moderate to late preterm (32 to < 37 weeks)	15,896	5.0%
RSV	77,920	24.4%
Bronchiolitis	116,468	36.5%
Palivizumab	2,150	0.7%
Health Service Utilization Intensity[4]:		
Mean number of ambulatory encounters (AV)	6.1	5.2
Mean number of emergency room encounters (ED)	0.7	1
Mean number of inpatient hospital encounters (IP)	0.1	0.4
Mean number of non-acute institutional encounters (IS)	0	0.1
Mean number of other ambulatory encounters (OA)	0.8	4.1
Mean number of filled prescriptions	4.5	4.6
Mean number of generics	3.4	2.7
Mean number of unique drug classes	3	2.2

[1] All metrics are based on total number of episodes per group

[2] Value represents standard deviation when not specificed with %

[3] History defined as entire history prior to index date for prematurity and CHD and CLD, and 3 months prior to index for all other covariates. Evaluation window continues through index date for prematurity, and through 2 months post index date for all other covariates

[4] Comorbidity and medical / drug utilization evaluated for entire history prior to index date through 2 months post index

Appendix A: Dates of Available Data for Each Data Partner up to Request End Date (6/30/2016)

Data Partner ID	Min Date	Max Date
DP0001	1/1/2008	6/30/2016
DP0002	1/1/2008	6/30/2016
DP0003	1/1/2008	6/30/2016
DP0004	1/1/2008	6/30/2016
DP0005	1/1/2008	10/31/2015
DP0006	1/2/2008	5/31/2015
DP0007	1/1/2008	10/31/2014
DP0008	1/1/2008	6/30/2016
DP0009	1/1/2008	6/30/2016
DP0010	1/1/2008	6/30/2016
DP0011	1/1/2008	6/30/2016
DP0012	1/1/2008	6/30/2016
DP0013	1/1/2008	6/30/2016
DP0014	1/1/2008	6/30/2016
DP0015	1/1/2008	12/31/2015
DP0016	1/1/2012	3/31/2016

Min Date and Max Date are first calculated by individual table (enrollment, dispensing, etc). Max Date is defined as the greatest year-month with a record count that is within 80% of the previous year-month. After Min Date and Max Dates are calculated by individual tables, the overall DP Max Date is the minimum of all the table Max Dates

Appendix B: List of Diagnosis and Procedure Codes Used to Define Covariates in this Request

With Code Types: International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes, International Classification of Disease, Tenth Edition, Clinical Modification (ICD-10-CM) diagnosis codes, International Classification of Disease, Tenth Edition, Procedure Coding System (ICD-10-PCS) procedure codes, Healthcare Common Procedure Coding System (HCPCS) procedure codes, and Current Procedural Terminology, 4th Edition (CPT-4) procedure codes.

Chronic Lung Disease (CLD): ICD-9: 770.7 claim and either A) CLD medication B) Oxygen Dependence Diagnosis Code or C) Oxygen Procedure Code

Congenital Heart Disease (CHD): Cyanotic, or Acyanotic and A) CLD medication or B) Oxygen Procedure Code

Condition	Code	Code Category	Code Type	Description
CLD - Diagnosis	770.7	Diagnosis	ICD-9-CM	Chronic respiratory disease arising in the perinatal period
CLD - Diagnosis	P270	Diagnosis	ICD-10-CM	Wilson-Mikity syndrome
CLD - Diagnosis	P278	Diagnosis	ICD-10-CM	Other chronic respiratory diseases originating in the perinatal period
CLD - Diagnosis	P279	Diagnosis	ICD-10-CM	Unspecified chronic respiratory disease originating in the perinatal period
CLD - Diagnosis	P271	Diagnosis	ICD-10-CM	Bronchopulmonary dysplasia originating in the perinatal period
CHD - Cyanotic	745.0	Diagnosis	ICD-9-CM	Bulbus cordis anomalies and anomalies of cardiac septal closure, common truncus
CHD - Cyanotic	745.10	Diagnosis	ICD-9-CM	Complete transposition of great vessels
CHD - Cyanotic	745.1	Diagnosis	ICD-9-CM	Transposition of great vessels
CHD - Cyanotic	745.11	Diagnosis	ICD-9-CM	Transposition of great vessels, double outlet right ventricle
CHD - Cyanotic	745.12	Diagnosis	ICD-9-CM	Corrected transposition of great vessels
CHD - Cyanotic	745.19	Diagnosis	ICD-9-CM	Other transposition of great vessels
CHD - Cyanotic	745.2	Diagnosis	ICD-9-CM	Tetralogy of Fallot
CHD - Cyanotic	745.3	Diagnosis	ICD-9-CM	Bulbus cordis anomalies and anomalies of cardiac septal closure, common ventricle
CHD - Cyanotic	746.1	Diagnosis	ICD-9-CM	Congenital tricuspid atresia and stenosis
CHD - Cyanotic	746.2	Diagnosis	ICD-9-CM	Ebstein's anomaly
CHD - Cyanotic	746.7	Diagnosis	ICD-9-CM	Hypoplastic left heart syndrome
CHD - Cyanotic	747.3	Diagnosis	ICD-9-CM	Anomalies of pulmonary artery
CHD - Cyanotic	747.4	Diagnosis	ICD-9-CM	Congenital anomalies of great veins
CHD - Cyanotic	747.40	Diagnosis	ICD-9-CM	Congenital anomaly of great veins unspecified
CHD - Cyanotic	747.41	Diagnosis	ICD-9-CM	Total congenital anomalous pulmonary venous connection
CHD - Cyanotic	747.42	Diagnosis	ICD-9-CM	Partial congenital anomalous pulmonary venous connection
CHD - Cyanotic	747.49	Diagnosis	ICD-9-CM	Other congenital anomalies of great veins
CHD - Cyanotic	Q203	Diagnosis	ICD-10-CM	Discordant ventriculoarterial connection
CHD - Cyanotic	Q262	Diagnosis	ICD-10-CM	Total anomalous pulmonary venous connection
CHD - Cyanotic	Q200	Diagnosis	ICD-10-CM	Common arterial trunk
CHD - Cyanotic	Q201	Diagnosis	ICD-10-CM	Double outlet right ventricle
CHD - Cyanotic	Q213	Diagnosis	ICD-10-CM	Tetralogy of Fallot
CHD - Cyanotic	Q263	Diagnosis	ICD-10-CM	Partial anomalous pulmonary venous connection
CHD - Cyanotic	Q264	Diagnosis	ICD-10-CM	Anomalous pulmonary venous connection, unspecified
CHD - Cyanotic	Q204	Diagnosis	ICD-10-CM	Double inlet ventricle
CHD - Cyanotic	Q224	Diagnosis	ICD-10-CM	Congenital tricuspid stenosis
CHD - Cyanotic	Q229	Diagnosis	ICD-10-CM	Congenital malformation of tricuspid valve, unspecified
CHD - Cyanotic	Q228	Diagnosis	ICD-10-CM	Other congenital malformations of tricuspid valve
CHD - Cyanotic	Q226	Diagnosis	ICD-10-CM	Hypoplastic right heart syndrome
CHD - Cyanotic	Q234	Diagnosis	ICD-10-CM	Hypoplastic left heart syndrome
CHD - Cyanotic	Q205	Diagnosis	ICD-10-CM	Discordant atrioventricular connection
CHD - Cyanotic	Q202	Diagnosis	ICD-10-CM	Double outlet left ventricle
CHD - Cyanotic	Q225	Diagnosis	ICD-10-CM	Ebstein's anomaly
CHD - Cyanotic	Q269	Diagnosis	ICD-10-CM	Congenital malformation of great vein, unspecified
CHD - Cyanotic	Q260	Diagnosis	ICD-10-CM	Congenital stenosis of vena cava
CHD - Cyanotic	Q268	Diagnosis	ICD-10-CM	Other congenital malformations of great veins
CHD - Cyanotic	Q261	Diagnosis	ICD-10-CM	Persistent left superior vena cava
CHD - Cyanotic	Q208	Diagnosis	ICD-10-CM	Other congenital malformations of cardiac chambers and connections
CHD - Acyanotic	745.4	Diagnosis	ICD-9-CM	Ventricular septal defect
CHD - Acyanotic	745.60	Diagnosis	ICD-9-CM	Unspecified type congenital endocardial cushion defect
CHD - Acyanotic	745.6	Diagnosis	ICD-9-CM	Endocardial cushion defects
CHD - Acyanotic	745.61	Diagnosis	ICD-9-CM	Ostium primum defect
CHD - Acyanotic	745.69	Diagnosis	ICD-9-CM	Other congenital endocardial cushion defect
CHD - Acyanotic	745.7	Diagnosis	ICD-9-CM	Cor biloculare
CHD - Acyanotic	745.8	Diagnosis	ICD-9-CM	Other bulbus cordis anomalies and anomalies of cardiac septal closure
CHD - Acyanotic	745.9	Diagnosis	ICD-9-CM	Unspecified congenital defect of septal closure
CHD - Acyanotic	746.0	Diagnosis	ICD-9-CM	Congenital anomalies of pulmonary valve
CHD - Acyanotic	746.00	Diagnosis	ICD-9-CM	Unspecified congenital pulmonary valve anomaly
CHD - Acyanotic	746.01	Diagnosis	ICD-9-CM	Congenital atresia of pulmonary valve
CHD - Acyanotic	746.02	Diagnosis	ICD-9-CM	Congenital stenosis of pulmonary valve
CHD - Acyanotic	746.09	Diagnosis	ICD-9-CM	Other congenital anomalies of pulmonary valve
CHD - Acyanotic	746.3	Diagnosis	ICD-9-CM	Congenital stenosis of aortic valve
CHD - Acyanotic	746.4	Diagnosis	ICD-9-CM	Congenital insufficiency of aortic valve
CHD - Acyanotic	746.5	Diagnosis	ICD-9-CM	Congenital mitral stenosis
CHD - Acyanotic	746.6	Diagnosis	ICD-9-CM	Congenital mitral insufficiency
CHD - Acyanotic	746.8	Diagnosis	ICD-9-CM	Other specified congenital anomaly of heart
CHD - Acyanotic	746.81	Diagnosis	ICD-9-CM	Congenital subaortic stenosis
CHD - Acyanotic	746.82	Diagnosis	ICD-9-CM	Cor triatriatum
CHD - Acyanotic	746.83	Diagnosis	ICD-9-CM	Congenital infundibular pulmonic stenosis
CHD - Acyanotic	746.84	Diagnosis	ICD-9-CM	Congenital obstructive anomalies of heart, not elsewhere classified
CHD - Acyanotic	746.85	Diagnosis	ICD-9-CM	Congenital coronary artery anomaly
CHD - Acyanotic	746.89	Diagnosis	ICD-9-CM	Other specified congenital anomaly of heart
CHD - Acyanotic	746.9	Diagnosis	ICD-9-CM	Unspecified congenital anomaly of heart
CHD - Acyanotic	747	Diagnosis	ICD-9-CM	Other congenital anomalies of circulatory system
CHD - Acyanotic	747.0	Diagnosis	ICD-9-CM	Patent ductus arteriosus
CHD - Acyanotic	747.10	Diagnosis	ICD-9-CM	Coarctation of aorta (preductal) (postductal)
CHD - Acyanotic	747.1	Diagnosis	ICD-9-CM	Coarctation of aorta
CHD - Acyanotic	747.11	Diagnosis	ICD-9-CM	Congenital interruption of aortic arch
CHD - Acyanotic	747.20	Diagnosis	ICD-9-CM	Unspecified congenital anomaly of aorta
CHD - Acyanotic	747.2	Diagnosis	ICD-9-CM	Other congenital anomaly of aorta
CHD - Acyanotic	747.21	Diagnosis	ICD-9-CM	Congenital anomaly of aortic arch
CHD - Acyanotic	747.22	Diagnosis	ICD-9-CM	Congenital atresia and stenosis of aorta
CHD - Acyanotic	747.29	Diagnosis	ICD-9-CM	Other congenital anomaly of aorta
CHD - Acyanotic	747.60	Diagnosis	ICD-9-CM	Congenital anomaly of the peripheral vascular system, unspecified site
CHD - Acyanotic	747.61	Diagnosis	ICD-9-CM	Congenital gastrointestinal vessel anomaly
CHD - Acyanotic	747.62	Diagnosis	ICD-9-CM	Congenital renal vessel anomaly
CHD - Acyanotic	747.63	Diagnosis	ICD-9-CM	Congenital upper limb vessel anomaly
CHD - Acyanotic	747.64	Diagnosis	ICD-9-CM	Congenital lower limb vessel anomaly
CHD - Acyanotic	747.69	Diagnosis	ICD-9-CM	Congenital anomaly of other specified site of peripheral vascular system
CHD - Acyanotic	747.81	Diagnosis	ICD-9-CM	Congenital anomaly of cerebrovascular system
CHD - Acyanotic	747.82	Diagnosis	ICD-9-CM	Congenital spinal vessel anomaly
CHD - Acyanotic	747.83	Diagnosis	ICD-9-CM	Persistent fetal circulation
CHD - Acyanotic	747.89	Diagnosis	ICD-9-CM	Other specified congenital anomaly of circulatory system
CHD - Acyanotic	Q210	Diagnosis	ICD-10-CM	Ventricular septal defect
CHD - Acyanotic	Q208	Diagnosis	ICD-10-CM	Other congenital malformations of cardiac chambers and connections
CHD - Acyanotic	Q206	Diagnosis	ICD-10-CM	Isomerism of atrial appendages
CHD - Acyanotic	Q218	Diagnosis	ICD-10-CM	Other congenital malformations of cardiac septa
CHD - Acyanotic	Q214	Diagnosis	ICD-10-CM	Aortopulmonary septal defect
CHD - Acyanotic	Q219	Diagnosis	ICD-10-CM	Congenital malformation of cardiac septum, unspecified
CHD - Acyanotic	Q230	Diagnosis	ICD-10-CM	Congenital stenosis of aortic valve
CHD - Acyanotic	Q231	Diagnosis	ICD-10-CM	Congenital insufficiency of aortic valve
CHD - Acyanotic	Q232	Diagnosis	ICD-10-CM	Congenital mitral stenosis
CHD - Acyanotic	Q233	Diagnosis	ICD-10-CM	Congenital mitral insufficiency
CHD - Acyanotic	Q209	Diagnosis	ICD-10-CM	Congenital malformation of cardiac chambers and connections, unspecified
CHD - Acyanotic	Q249	Diagnosis	ICD-10-CM	Congenital malformation of heart, unspecified
CHD - Acyanotic	Q250	Diagnosis	ICD-10-CM	Patent ductus arteriosus
CHD - Acyanotic	Q212	Diagnosis	ICD-10-CM	Atrioventricular septal defect
CHD - Acyanotic	Q223	Diagnosis	ICD-10-CM	Other congenital malformations of pulmonary valve

Appendix B: List of Diagnosis and Procedure Codes Used to Define Covariates in this Request

With Code Types: International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes, International Classification of Disease, Tenth Edition, Clinical Modification (ICD-10-CM) diagnosis codes, International Classification of Disease, Tenth Edition, Procedure Coding System (ICD-10-PCS) procedure codes, Healthcare Common Procedure Coding System (HCPCS) procedure codes, and Current Procedural Terminology, 4th Edition (CPT-4) procedure codes.

Chronic Lung Disease (CLD): ICD-9: 770.7 claim and either A) CLD medication B) Oxygen Dependence Diagnosis Code or C) Oxygen Procedure Code

Congenital Heart Disease (CHD): Cyanotic, or Acyanotic and A) CLD medication or B) Oxygen Procedure Code

Condition	Code	Code Category	Code Type	Description
CHD - Acyanotic	Q220	Diagnosis	ICD-10-CM	Pulmonary valve atresia
CHD - Acyanotic	Q221	Diagnosis	ICD-10-CM	Congenital pulmonary valve stenosis
CHD - Acyanotic	Q222	Diagnosis	ICD-10-CM	Congenital pulmonary valve insufficiency
CHD - Acyanotic	Q244	Diagnosis	ICD-10-CM	Congenital subaortic stenosis
CHD - Acyanotic	Q242	Diagnosis	ICD-10-CM	Cor triatriatum
CHD - Acyanotic	Q243	Diagnosis	ICD-10-CM	Pulmonary infundibular stenosis
CHD - Acyanotic	Q248	Diagnosis	ICD-10-CM	Other specified congenital malformations of heart
CHD - Acyanotic	Q245	Diagnosis	ICD-10-CM	Malformation of coronary vessels
CHD - Acyanotic	Q238	Diagnosis	ICD-10-CM	Other congenital malformations of aortic and mitral valves
CHD - Acyanotic	Q239	Diagnosis	ICD-10-CM	Congenital malformation of aortic and mitral valves, unspecified
CHD - Acyanotic	Q251	Diagnosis	ICD-10-CM	Coarctation of aorta
CHD - Acyanotic	Q2521	Diagnosis	ICD-10-CM	Interruption of aortic arch
CHD - Acyanotic	Q2540	Diagnosis	ICD-10-CM	Congenital malformation of aorta unspecified
CHD - Acyanotic	Q2529	Diagnosis	ICD-10-CM	Other atresia of aorta
CHD - Acyanotic	Q253	Diagnosis	ICD-10-CM	Supravalvular aortic stenosis
CHD - Acyanotic	Q2541	Diagnosis	ICD-10-CM	Absence and aplasia of aorta
CHD - Acyanotic	Q259	Diagnosis	ICD-10-CM	Congenital malformation of great arteries, unspecified
CHD - Acyanotic	Q258	Diagnosis	ICD-10-CM	Other congenital malformations of other great arteries
CHD - Acyanotic	Q2549	Diagnosis	ICD-10-CM	Other congenital malformations of aorta
CHD - Acyanotic	Q2544	Diagnosis	ICD-10-CM	Congenital dilation of aorta
CHD - Acyanotic	Q2543	Diagnosis	ICD-10-CM	Congenital aneurysm of aorta
CHD - Acyanotic	Q2542	Diagnosis	ICD-10-CM	Hypoplasia of aorta
CHD - Acyanotic	Q279	Diagnosis	ICD-10-CM	Congenital malformation of peripheral vascular system, unspecified
CHD - Acyanotic	Q265	Diagnosis	ICD-10-CM	Anomalous portal venous connection
CHD - Acyanotic	Q2733	Diagnosis	ICD-10-CM	Arteriovenous malformation of digestive system vessel
CHD - Acyanotic	Q266	Diagnosis	ICD-10-CM	Portal vein-hepatic artery fistula
CHD - Acyanotic	Q271	Diagnosis	ICD-10-CM	Congenital renal artery stenosis
CHD - Acyanotic	Q2734	Diagnosis	ICD-10-CM	Arteriovenous malformation of renal vessel
CHD - Acyanotic	Q272	Diagnosis	ICD-10-CM	Other congenital malformations of renal artery
CHD - Acyanotic	Q2731	Diagnosis	ICD-10-CM	Arteriovenous malformation of vessel of upper limb
CHD - Acyanotic	Q2732	Diagnosis	ICD-10-CM	Arteriovenous malformation of vessel of lower limb
CHD - Acyanotic	Q2739	Diagnosis	ICD-10-CM	Arteriovenous malformation, other site
CHD - Acyanotic	Q278	Diagnosis	ICD-10-CM	Other specified congenital malformations of peripheral vascular system
CHD - Acyanotic	Q282	Diagnosis	ICD-10-CM	Arteriovenous malformation of cerebral vessels
CHD - Acyanotic	Q283	Diagnosis	ICD-10-CM	Other malformations of cerebral vessels
CHD - Acyanotic	P293	Diagnosis	ICD-10-CM	Persistent fetal circulation
CHD - Acyanotic	Q2730	Diagnosis	ICD-10-CM	Arteriovenous malformation, site unspecified
CHD - Acyanotic	Q288	Diagnosis	ICD-10-CM	Other specified congenital malformations of circulatory system
CHD - Acyanotic	Q281	Diagnosis	ICD-10-CM	Other malformations of precerebral vessels
CHD - Acyanotic	Q280	Diagnosis	ICD-10-CM	Arteriovenous malformation of precerebral vessels
CHD - Acyanotic	Q274	Diagnosis	ICD-10-CM	Congenital phlebectasia
Oxygen Diagnosis	V46.2	Diagnosis	ICD-9-CM	Dependence on machine for supplemental oxygen
Oxygen Diagnosis	Z9981	Diagnosis	ICD-10-CM	Dependence on supplemental oxygen
Oxygen Procedure	93.96	Procedure	ICD-9-CM	Other oxygen enrichment
Oxygen Procedure	3E0F7GC	Procedure	ICD-10-PCS	Introduction of Other Therapeutic Substance into Respiratory Tract, Via Natural or Artificial Opening
Oxygen Procedure	E0424	Procedure	HCPCS	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
Oxygen Procedure	E0431	Procedure	HCPCS	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
Oxygen Procedure	E0434	Procedure	HCPCS	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
Oxygen Procedure	E0439	Procedure	HCPCS	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing
Oxygen Procedure	E0441	Procedure	HCPCS	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit
Oxygen Procedure	E0442	Procedure	HCPCS	Stationary oxygen contents, liquid, 1 month's supply = 1 unit
Oxygen Procedure	E0443	Procedure	HCPCS	Portable oxygen contents, gaseous, 1 month's supply = 1 unit
Oxygen Procedure	E0444	Procedure	HCPCS	Portable oxygen contents, liquid, 1 month's supply = 1 unit
Oxygen Procedure	E0450	Procedure	HCPCS	Volume control ventilator, without pressure support mode, may include pressure control mode, used with invasive interface (e.g., tracheostomy tube)
Oxygen Procedure	E1390	Procedure	HCPCS	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate
Oxygen Procedure	E1392	Procedure	HCPCS	Portable oxygen concentrator, rental
Oxygen Procedure	E1400	Procedure	HCPCS	Oxygen concentrator, manufacturer specified maximum flow rate does not exceed two liters per minute, at 85 percent or greater concentration
Oxygen Procedure	E1401	Procedure	HCPCS	Oxygen concentrator, manufacturer specified maximum flow rate greater than two liters per minute, does not exceed three liters per minute, at 85 percent or greater concentration
Oxygen Procedure	E1402	Procedure	HCPCS	Oxygen concentrator, manufacturer specified maximum flow rate greater than three liters per minute, does not exceed four liters per minute, at 85 percent or greater concentration
Oxygen Procedure	E1403	Procedure	HCPCS	Oxygen concentrator, manufacturer specified maximum flow rate greater than four liters per minute, does not exceed five liters per minute, at 85 percent or greater concentration
Oxygen Procedure	E1404	Procedure	HCPCS	Oxygen concentrator, manufacturer specified maximum flow rate greater than five liters per minute, at 85 percent or greater concentration
Oxygen Procedure	E1405	Procedure	HCPCS	Oxygen and water vapor enriching system with heated delivery
Oxygen Procedure	E1406	Procedure	HCPCS	Oxygen and water vapor enriching system without heated delivery
Extremely preterm (< 29 weeks)	765.21	Diagnosis	ICD-9-CM	Less than 24 completed weeks of gestation
Extremely preterm (< 29 weeks)	765.22	Diagnosis	ICD-9-CM	24 completed weeks of gestation
Extremely preterm (< 29 weeks)	765.23	Diagnosis	ICD-9-CM	25-26 completed weeks of gestation
Extremely preterm (< 29 weeks)	765.24	Diagnosis	ICD-9-CM	27-28 completed weeks of gestation
Very preterm (29 < 32 weeks)	765.25	Diagnosis	ICD-9-CM	29-30 completed weeks of gestation
Very preterm (29 < 32 weeks)	765.26	Diagnosis	ICD-9-CM	31-32 completed weeks of gestation
Moderate to late preterm (32 to < 37 weeks)	765.27	Diagnosis	ICD-9-CM	33-34 completed weeks of gestation
Moderate to late preterm (32 to < 37 weeks)	765.28	Diagnosis	ICD-9-CM	35-36 completed weeks of gestation
Extremely preterm (< 29 weeks)	P0721	Diagnosis	ICD-10-CM	Extreme immaturity of newborn, gestational age less than 23 completed weeks
Extremely preterm (< 29 weeks)	P0722	Diagnosis	ICD-10-CM	Extreme immaturity of newborn, gestational age 23 completed weeks
Extremely preterm (< 29 weeks)	P0723	Diagnosis	ICD-10-CM	Extreme immaturity of newborn, gestational age 24 completed weeks
Extremely preterm (< 29 weeks)	P0724	Diagnosis	ICD-10-CM	Extreme immaturity of newborn, gestational age 25 completed weeks
Extremely preterm (< 29 weeks)	P0725	Diagnosis	ICD-10-CM	Extreme immaturity of newborn, gestational age 26 completed weeks
Extremely preterm (< 29 weeks)	P0726	Diagnosis	ICD-10-CM	Extreme immaturity of newborn, gestational age 27 completed weeks
Extremely preterm (< 29 weeks)	P0731	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 28 completed weeks
Very preterm (29 < 32 weeks)	P0732	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 29 completed weeks
Very preterm (29 < 32 weeks)	P0733	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 30 completed weeks
Very preterm (29 < 32 weeks)	P0734	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 31 completed weeks
Very preterm (29 < 32 weeks)	P0735	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 32 completed weeks
Moderate to late preterm (32 to < 37 weeks)	P0736	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 33 completed weeks
Moderate to late preterm (32 to < 37 weeks)	P0737	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 34 completed weeks
Moderate to late preterm (32 to < 37 weeks)	P0738	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 35 completed weeks
Moderate to late preterm (32 to < 37 weeks)	P0739	Diagnosis	ICD-10-CM	Preterm newborn, gestational age 36 completed weeks
Intensive Care Unit (ICU) Stay	31500	Procedure	CPT-4	Intubation, endotracheal, emergency procedure
Intensive Care Unit (ICU) Stay	94002	Procedure	CPT-4	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing;
Intensive Care Unit (ICU) Stay	94003	Procedure	CPT-4	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing;
Intensive Care Unit (ICU) Stay	94004	Procedure	CPT-4	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day
Intensive Care Unit (ICU) Stay	94660	Procedure	CPT-4	Continuous positive airway pressure ventilation (CPAP), initiation and management
Intensive Care Unit (ICU) Stay	99468	Procedure	CPT-4	Initial inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age
Intensive Care Unit (ICU) Stay	99471	Procedure	CPT-4	Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29
Intensive Care Unit (ICU) Stay	99475	Procedure	CPT-4	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

Appendix C: List of Generic Names Used to Define Covariates in this Request

Chronic Lung Disease (CLD): ICD-9: 770.7 claim and either A) CLD medication B) Oxygen Dependence Diagnosis Code or C) Oxygen Procedure Code
Congenital Heart Disease (CHD): Cyanotic, or Acyanotic and A) CLD medication or B) Oxygen Procedure Code

Condition	Generic Name
CLD - Medication	LEVALBUTEROL HCL
CLD - Medication	ALBUTEROL
CLD - Medication	IPRATROPIUM BROMIDE/ALBUTEROL SULFATE
CLD - Medication	ALBUTEROL SULFATE
CLD - Medication	FORMOTEROL FUMARATE DIHYDRATE, MICRONIZED
CLD - Medication	TERBUTALINE SULFATE
CLD - Medication	FLUTICASONE PROPIONATE/SALMETEROL XINAFOATE
CLD - Medication	FORMOTEROL FUMARATE
CLD - Medication	METAPROTERENOL SULFATE
CLD - Medication	BUDESONIDE/FORMOTEROL FUMARATE
CLD - Medication	FLUTICASONE FUROATE/VILANTEROL TRIFENATATE
CLD - Medication	LEVALBUTEROL TARTRATE
CLD - Medication	ARFORMOTEROL TARTRATE
CLD - Medication	SALMETEROL XINAFOATE
CLD - Medication	PIRBUTEROL ACETATE
CLD - Medication	INDACATEROL MALEATE/GLYCOPYRROLATE
CLD - Medication	GLYCOPYRROLATE/FORMOTEROL FUMARATE
CLD - Medication	MOMETASONE FUROATE/FORMOTEROL FUMARATE
CLD - Medication	ISOPROTERENOL HCL
CLD - Medication	OLODATEROL HCL
CLD - Medication	TIOTROPIUM BROMIDE/OLODATEROL HCL
CLD - Medication	INDACATEROL MALEATE
CLD - Medication	UMECLIDINIUM BROMIDE/VILANTEROL TRIFENATATE
CLD - Medication	FLUNISOLIDE
CLD - Medication	FLUTICASONE PROPIONATE, MICRONIZED
CLD - Medication	FLUTICASONE PROPIONATE
CLD - Medication	CICLESONIDE
CLD - Medication	TRIAMCINOLONE ACETONIDE
CLD - Medication	BECLOMETHASONE DIPROPIONATE
CLD - Medication	BUDESONIDE
CLD - Medication	FLUTICASONE FUROATE
CLD - Medication	FLUNISOLIDE/MENTHOL
CLD - Medication	MOMETASONE FUROATE
CLD - Medication	THEOPHYLLINE ANHYDROUS
CLD - Medication	GUAIFENESIN/THEOPHYLLINE
CLD - Medication	THEOPHYLLINE/DEXTROSE 5 % IN WATER
CLD - Medication	GUAIFENESIN/DYPHYLLINE
CLD - Medication	THEOPHYLLINE/DIETARY SUPPLEMENT,MISC.COMB.NO.9
CLD - Medication	AMINOPHYLLINE
CLD - Medication	THEOPHYLLINE/CAFFEINE/AA COMB13/CINNAMON/HERBAL 135
CLD - Medication	DYPHYLLINE
CLD - Medication	GUAIFENESIN/THEOPHYLLINE ANHYDROUS/PSEUDOEPHEDRINE
CLD - Medication	MONTELUKAST SODIUM
CLD - Medication	ZILEUTON
CLD - Medication	ZAFIRLUKAST
CLD - Medication	MOEXIPRIL HCL/HYDROCHLOROTHIAZIDE
CLD - Medication	QUINAPRIL HCL/HYDROCHLOROTHIAZIDE
CLD - Medication	TRIAMTERENE/HYDROCHLOROTHIAZIDE
CLD - Medication	LISINOPRIL/HYDROCHLOROTHIAZIDE
CLD - Medication	CHLOROTHIAZIDE
CLD - Medication	VALSARTAN/HYDROCHLOROTHIAZIDE
CLD - Medication	CANDESARTAN CILEXETIL/HYDROCHLOROTHIAZIDE
CLD - Medication	TELMISARTAN/HYDROCHLOROTHIAZIDE
CLD - Medication	AMLODIPINE BESYLATE/VALSARTAN/HYDROCHLOROTHIAZIDE
CLD - Medication	HYDROCHLOROTHIAZIDE
CLD - Medication	BISOPROLOL FUMARATE/HYDROCHLOROTHIAZIDE
CLD - Medication	IRBESARTAN/HYDROCHLOROTHIAZIDE
CLD - Medication	EPROSARTAN MESYLATE/HYDROCHLOROTHIAZIDE
CLD - Medication	ENALAPRIL MALEATE/HYDROCHLOROTHIAZIDE
CLD - Medication	METOPROLOL TARTRATE/HYDROCHLOROTHIAZIDE
CLD - Medication	LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE
CLD - Medication	FOSINOPRIL SODIUM/HYDROCHLOROTHIAZIDE
CLD - Medication	TRICHLORMETHIAZIDE
CLD - Medication	BENAZEPRIL HCL/HYDROCHLOROTHIAZIDE
CLD - Medication	ALISKIREN HEMIFUMARATE/HYDROCHLOROTHIAZIDE
CLD - Medication	CAPTOPRIL/HYDROCHLOROTHIAZIDE
CLD - Medication	ALISKIREN HEMIFUMARATE/AMLODIPINE/HYDROCHLOROTHIAZIDE
CLD - Medication	OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE
CLD - Medication	OLMESARTAN MEDOXOMIL/AMLODIPINE BESYLATE/HYDROCHLOROTHIAZIDE
CLD - Medication	SPIRONOLACTONE/HYDROCHLOROTHIAZIDE
CLD - Medication	METOPROLOL SUCCINATE/HYDROCHLOROTHIAZIDE
CLD - Medication	AMILORIDE HCL/HYDROCHLOROTHIAZIDE
CLD - Medication	CHLOROTHIAZIDE SODIUM
CLD - Medication	HYDRALAZINE HCL/HYDROCHLOROTHIAZIDE
CLD - Medication	PROPRANOLOL HCL/HYDROCHLOROTHIAZIDE
CLD - Medication	NADOLOL/BENDROFLUMETHIAZIDE
CLD - Medication	METHYLDOPA/HYDROCHLOROTHIAZIDE
CLD - Medication	METHYCLOTHIAZIDE
CLD - Medication	INDAPAMIDE
CLD - Medication	METOLAZONE
CLD - Medication	ATENOLOL/CHLORTHALIDONE

Appendix C: List of Generic Names Used to Define Covariates in this Request

Chronic Lung Disease (CLD): ICD-9: 770.7 claim and either A) CLD medication B) Oxygen Dependence Diagnosis Code or C) Oxygen Procedure Code

Congenital Heart Disease (CHD): Cyanotic, or Acyanotic and A) CLD medication or B) Oxygen Procedure Code

Condition	Generic Name
CLD - Medication	CHLORTHALIDONE
CLD - Medication	AZILSARTAN MEDOXOMIL/CHLORTHALIDONE
CLD - Medication	CLONIDINE HCL/CHLORTHALIDONE
CLD - Medication	FUROSEMIDE
CLD - Medication	TORSEMIDE
CLD - Medication	BUMETANIDE
CLD - Medication	ETHACRYNIC ACID
CLD - Medication	ETHACRYNATE SODIUM
CLD - Medication	FUROSEMIDE IN 0.9 % SODIUM CHLORIDE
CLD - Medication	FUROSEMIDE/DEXTROSE 5 % IN WATER
CLD - Medication	SPIRONOLACTONE
CLD - Medication	EPLERENONE
CLD - Medication	TRIAMTERENE
CLD - Medication	AMILORIDE HCL
CLD - Medication	SPIRONOLACTONE, MICRONIZED
CHD - Medication	FOSINOPRIL SODIUM
CHD - Medication	BENAZEPRIL HCL
CHD - Medication	LISINOPRIL
CHD - Medication	ENALAPRIL MALEATE
CHD - Medication	QUINAPRIL HCL
CHD - Medication	CAPTOPRIL
CHD - Medication	RAMIPRIL
CHD - Medication	TRANDOLAPRIL
CHD - Medication	AMLODIPINE BESYLATE/BENAZEPRIL HCL
CHD - Medication	MOEXIPRIL HCL
CHD - Medication	TRANDOLAPRIL/VERAPAMIL HCL
CHD - Medication	PERINDOPRIL ERBUMINE
CHD - Medication	ENALAPRILAT DIHYDRATE
CHD - Medication	ENALAPRIL MALEATE/FELODIPINE
CHD - Medication	LISINOPRIL/DIETARY SUPPLEMENT,COMB.10
CHD - Medication	PERINDOPRIL ARGININE/AMLODIPINE BESYLATE
CHD - Medication	DIGOXIN

Appendix D: List of Diagnosis and Procedure Codes Used to Define Exposures in this Request

With Code Types: International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes, International Classification of Disease, Tenth Edition, Clinical Modification (ICD-10-CM) diagnosis codes, Healthcare Common Procedure Coding System (HCPCS) procedure codes, and Current Procedural Terminology, 4th Edition (CPT-4) procedures codes.

Condition	Code	Code Category	Code Type	Description
Respiratory Syncytial Virus (RSV)	079.6	Diagnosis	ICD-9-CM	Respiratory syncytial virus (RSV)
Respiratory Syncytial Virus (RSV)	466.11	Diagnosis	ICD-9-CM	Acute bronchiolitis due to respiratory syncytial virus (RSV)
Respiratory Syncytial Virus (RSV)	480.1	Diagnosis	ICD-9-CM	Pneumonia due to respiratory syncytial virus
Respiratory Syncytial Virus (RSV)	B974	Diagnosis	ICD-10-CM	Respiratory syncytial virus as the cause of diseases classified elsewhere
Respiratory Syncytial Virus (RSV)	J121	Diagnosis	ICD-10-CM	Respiratory syncytial virus pneumonia
Respiratory Syncytial Virus (RSV)	J205	Diagnosis	ICD-10-CM	Acute bronchitis due to respiratory syncytial virus
Respiratory Syncytial Virus (RSV)	J210	Diagnosis	ICD-10-CM	Acute bronchiolitis due to respiratory syncytial virus
Bronchiolitis	466	Diagnosis	ICD-9-CM	Acute bronchitis and bronchiolitis
Bronchiolitis	466.1	Diagnosis	ICD-9-CM	Acute bronchiolitis
Bronchiolitis	466.11	Diagnosis	ICD-9-CM	Acute bronchiolitis due to respiratory syncytial virus (RSV)
Bronchiolitis	466.19	Diagnosis	ICD-9-CM	Acute bronchiolitis due to other infectious organisms
Bronchiolitis	516.34	Diagnosis	ICD-9-CM	Respiratory bronchiolitis interstitial lung disease
Bronchiolitis	J210	Diagnosis	ICD-10-CM	Acute bronchiolitis due to respiratory syncytial virus
Bronchiolitis	J219	Diagnosis	ICD-10-CM	Acute bronchiolitis, unspecified
Bronchiolitis	J218	Diagnosis	ICD-10-CM	Acute bronchiolitis due to other specified organisms
Bronchiolitis	J84115	Diagnosis	ICD-10-CM	Respiratory bronchiolitis interstitial lung disease
Palivizumab	C9003	Procedure	HCPCS	Palivizumab-RSV-IgM, per 50 mg
Palivizumab	S9562	Procedure	HCPCS	and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
Diagnostic Assay	87280	Procedure	CPT-4	Infectious agent antigen detection by immunofluorescent technique; respiratory syncytial virus
Diagnostic Assay	87420	Procedure	CPT-4	immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step
Diagnostic Assay	87807	Procedure	CPT-4	Infectious agent antigen detection by immunoassay with direct optical observation; respiratory syncytial virus
Diagnostic Assay	87631	Procedure	CPT-4	metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when
Diagnostic Assay	87632	Procedure	CPT-4	metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when
Diagnostic Assay	87633	Procedure	CPT-4	metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when

Appendix E: List of Generic Names Used to Define Exposures in this Request

Condition	Generic Name
Palivizumab	PALIVIZUMAB

Appndix F: Specifications for Request ID: cder_mpl1r_wp052_nsdp_v01

The Center for Drug Evaluation and Research (CDER) has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool, version 4.0.0, to investigate background rates of baseline covariates of patients with a diagnosis of Respiratory Syncytial Virus (RSV), a diagnosis of bronchiolitis, a diagnosis of RSV or bronchiolitis, prior dosing of palivizumab, or a diagnostic assay obtained (PCR +/- Antigen), among children aged 1 month to 5 years from January 1, 2008 to June 30, 2016.

Age Groups: 1-6 months, 7-12 months, 13-24 months, 25-60 months
Six Monitoring Periods: January 1, 2008 to June 30, 2016
Coverage Requirement: Medical and Drug Coverage
Enrollment Requirement (Age 01-06 Months): 0 days
Enrollment Requirement (All Other Ages): 183 days
Enrollment Gap: 45 days
Data Partners: All Data Partners

	Exposure			Exposure Incidence				Baseline Covariates			
Scenario	Exposure	Care Setting	Cohort Definition	Incident w/ respect to	Incidence Care Setting	Washout, Age 1-6 Months	Washout, All Other Age Groups	Conditions	Care Setting	Evaluation Window Start	Evaluation Window End
1	RSV	Any	First Incident Event	RSV Diagnosis	Any	0	183	See Covariate Conditions			
2	RSV	IP	First Incident Event	RSV Diagnosis	IP, Primary or Secondary	0	183	See Covariate Conditions			
3	RSV	ED, AV	First Incident Event	RSV Diagnosis	ED, AV	0	183	See Covariate Conditions			
4	Bronchiolitis	Any	First Incident Event	Bronchiolitis	Any	0	183	See Covariate Conditions			
5	RSV or Bronchiolitis	Any	First Incident Event	RSV or Bronichiolitis	Any	0	183	See Covariate Conditions			
6	Palivizumab	N/A	First Incident Event	Palivizumab	Any	0	183	See Covariate Conditions			
7	Diagnostic Assay Obtained (PCR +/- Antigen)	Any	First Incident Event	Diagnostic Assay Obtained (PCR +/- Antigen)	Any	0	183	See Covariate Conditions			

Note: ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus"

Appendix G: Baseline Covariate Specfications for Request ID: cder_mpl1r_wp052_nsdp_v01

Condition	Care Setting	Evaluation Window Start, Age 1-6 Months	Evaluation Window Start, All Other Age Groups	Evaluation Window End
Other Exposures of Interest				
Respiratory Syncytial Virus (RSV)	Any	Entire History	3 Months (92 days)	2 Months (60 days)
Bronichiolitis	Any	Entire History	3 Months (92 days)	2 Months (60 days)
Palivizumab	Any	Entire History	3 Months (92 days)	2 Months (60 days)
Diagnostic Assay (PCR +/- Antigen)	Any	Entire History	3 Months (92 days)	2 Months (60 days)
Comorbidites				
Prematurity, GA ≤ 29 weeks	Any	Entire History	Entire History	Index Date
Prematurity, GA 29 to < 32 weeks	Any	Entire History	Entire History	Index Date
Prematurity, GA 32 to < 37 weeks	Any	Entire History	Entire History	Index Date
Congenital Heart Disease (CHD)	Any	Entire History	Entire History	2 Months (60 days)
Chronic Lung Disease (CLD)	Any	Entire History	Entire History	2 Months (60 days)
Care Settings of Cohort Entry Exposure (For all exposures)				
Intensive Care Unit (ICU)	IP	-15	-15	15
Inpatient (IP)	IP	Index Date	Index Date	Index Date
Outpatient Visit (AV, ED)	AV, ED	Index Date	Index Date	Index Date

Covariate window lengths are relative to the index date of cohort entry exposure.

Comorbidity and medical / drug utilization evaluated for the 3 months prior through 2 months post index