

Disclaimer

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

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

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

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Overview for Request: cder_mpl1r_wp217

Request ID: cder_mpl1r_wp217_nsdv_v02_r01

Request Description: In this study we examined the trends in diagnosis of congenital cytomegalovirus disease (cCMV) or CMV infection (CMV). We also assessed clinical characteristics, laboratory tests performed for CMV diagnosis, hearing loss and hematologic outcomes among infants with CMV and those who used valganciclovir/ganciclovir treatment. A companion report contains assessment of follow-up time and distribution of valganciclovir/ganciclovir treatment in individuals with cCMV (see Sentinel_Report_cder_mpl1r_wp217_nsdv_v02_r02).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 11.0.0

Data Source: We distributed this request to 12 Sentinel Data Partners on December 9, 2021. These Data Partners are a subset of the Sentinel Distributed Database (SDD). The study period included data from January 1, 2008 through May 31, 2021. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: We identified occurrence of cCMV or CMV, as well as prevalent valganciclovir/ganciclovir treatment among infants between 0 and 45 days old. This is a Type 2 analysis in the Query Request Package (QRP) documentation.

Event of Interest: We defined three cohorts as follows:

Infants with CMV: We identified individuals with evidence of cCMV or CMV during the query period.

Infants with valganciclovir use within 45 days from CMV diagnosis: We identified individuals with evidence of valganciclovir treatment within 45 days from cCMV or CMV diagnosis.

Infants with valganciclovir use within 180 days from CMV diagnosis: We identified individuals with evidence of valganciclovir treatment within 180 days from cCMV or CMV diagnosis.

In each of the above cohorts we only included the first qualifying (index) cCMV or CMV diagnosis in any care setting for each infant; cohort re-entry was not allowed. Please see Appendix D for a list of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes used to define cCMV or CMV events in this report.

Outcome of Interest: Among the cohort of infants with CMV described above, we examined valganciclovir/ganciclovir dispensings within 180 days from cCMV or CMV diagnosis. We defined valganciclovir/ganciclovir outcome using National Drug Codes (NDCs). Please see Appendix C for a list of generic and brand names of medical products used to define valganciclovir/ganciclovir use in this report.

Cohort Eligibility Criteria: We required members to be enrolled in health plans with medical and drug coverage on the index date. We included individuals between 0 and 45 days of age. We defined four separate groups with the following requirements:

- a) ***Cohort A (Infants with CMV)***: To evaluate rates of CMV diagnosis, we identified individuals with evidence of cCMV or CMV during the query period. We also examined these individuals stratified by disease severity.
- b) ***Cohort A with valganciclovir treatment (Infants with CMV events and valganciclovir/ganciclovir outcome)***: To evaluate rates of valganciclovir/ganciclovir use in infants with CMV, we identified individuals with evidence of cCMV or CMV. Then, we assessed valganciclovir/ganciclovir use within 180 days from cCMV or CMV diagnosis.
- c) ***Two sensitivity analysis cohorts***: We performed sensitivity analyses assessing valganciclovir/ganciclovir use among infants with cCMV or CMV. We defined the analysis cohorts as follows:
 - Valganciclovir use within 45 days: We included infants with valganciclovir/ganciclovir use within 45 days from cCMV or CMV diagnosis
 - Valganciclovir use within 180 days: We included infants with valganciclovir/ganciclovir use within 180 days from cCMV or CMV diagnosis

To define disease severity for the cohort of infants with CMV, we identified four sub-cohorts based on hearing loss and selected clinical characteristics. We defined these disease severity sub-cohorts as follows:

- a) ***Hearing loss absent, clinical characteristics absent***: To be included in this cohort, we required members to have no history of hearing loss or clinical characteristics at any time prior to index date and up to 15 days after the index date.
- b) ***Hearing loss present, clinical characteristics absent***: To be included in this cohort, we required members to have a history of hearing loss, but no clinical characteristics at any time prior to the index date and up to 15 days after the index date.

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c) *Hearing loss absent, clinical characteristics present* : To be included in this cohort, we required members to have no history of hearing loss, but have a history of any of the select clinical characteristics at any time prior to the index date and up to 15 days after the index date.

d) *Hearing loss present, clinical characteristics present* : To be included in this cohort, we required members to have a history of hearing loss, and a history of any of the select clinical characteristics at any time prior to the index date and up to 15 days after the index date.

See Appendix G for specifications of parameters describing different cohorts identified in this request. See Appendix H for diagrams detailing the design for this request.

Baseline Characteristics: We assessed the following characteristics: age, year, sex, geographic region (as defined by the census bureau), race, and ethnicity. In addition, we assessed the following at any time prior to the index date and up to 30 days after the index date: head computed tomography, brain abnormality, other brain abnormality, brain magnetic resonance imaging (MRI), and head ultrasound. We assessed the following clinical tests at any time prior to the index date and up to 15 days after the index date: CMV polymerase chain reaction (PCR) lab test, CMV antigen lab test, and CMV culture lab test. We assessed the following clinical characteristics at any time prior to the index date and up to 15 days after the index date: jaundice, petechiae, splenomegaly, microcephaly, thrombocytopenia, chorioretinitis, and hepatomegaly; we also assessed the aforementioned clinical characteristics at any time prior to the index date up to and including the index date. We assessed the following clinical characteristics within 60 and 180 days from the index date: neutropenia, receipt of red blood cell (RBC) transfusion, receipt of platelet transfusion, and receipt of granulocyte colony-stimulating factor (GCSF) transfusion.

We identified disease severity cohorts using the following clinical characteristics: hearing loss, jaundice, petechiae, hepatomegaly, splenomegaly, microcephaly, thrombocytopenia, chorioretinitis, and brain abnormality; and the following hematologic outcomes: neutropenia, receipt of RBC transfusion, receipt of platelet transfusion, and receipt of GCSF transfusion.

See Appendix B for the list of states and territories included in each census bureau region.

See Appendix E for ICD-9-CM, ICD-10-CM, Current Procedural Terminology, Fourth Edition (CPT-4), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) codes used to define inclusion and exclusion criteria in this request.

See Appendix F for CPT-4, ICD-9-CM, ICD-10-CM, ICD-10-PCS and Healthcare Common Procedure Coding System, Level II (HCPCS) codes used to define baseline characteristics and hematologic outcomes in this request.

Limitations: Algorithms to define exposures, inclusion, and exclusion criteria are imperfect and may result in misclassification. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (<https://dev.sentinelssystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse>).

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

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

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 (PDX), 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, but 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.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

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

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.

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

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 Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

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

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

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

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.

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 365.25.

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 extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

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.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

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.

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

Table 1a. Aggregated Baseline Characteristics of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics		Number	
Unique patients		1,500	
Demographic Characteristics		Mean	Standard Deviation
Mean Age (Days)		7.59	11.51
Age (Days)		Number	Percent
≤ 45		1,500	100.0%
Sex			
Female		691	46.1%
Male		809	53.9%
Race ¹			
American Indian or Alaska Native		0	0.0%
Asian		13	0.9%
Black or African American		86	5.7%
Native Hawaiian or Other Pacific Islander		8	0.5%
Unknown		1,300	86.7%
White		93	6.2%
Hispanic origin			
Yes		12	0.8%
No		151	10.1%
Unknown		1,337	89.1%
Year			
2008		101	6.7%
2009		89	5.9%
2010		106	7.1%
2011		79	5.3%
2012		81	5.4%
2013		96	6.4%
2014		122	8.1%
2015		119	7.9%
2016		147	9.8%
2017		164	10.9%
2018		139	9.3%
2019		149	9.9%
2020		94	6.3%
2021		14	0.9%
Health Characteristics			
Type of CMV Diagnosis Code			
Congenital CMV (cCMV)		1,176	78.4%
Cytomegalovirus (CMV) Infection		619	41.3%
Ever, Prior to and Up to 15 Days After Index			
Jaundice		731	48.7%
Petechiae		84	5.6%
Hepatomegaly		73	4.9%
Splenomegaly		53	3.5%
Microcephaly		123	8.2%
Thrombocytopenia		542	36.1%
Chlorioretinitis		44	2.9%
Hearing Loss, Hearing Aid, Cochlear Implant		132	8.8%

Table 1a. Aggregated Baseline Characteristics of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	277	18.5%
Other Brain Abnormality	2	0.1%
Within 60 Days From Index		
Neutropenia	210	14.0%
Receipt of RBC transfusion	118	7.9%
Receipt of platelet transfusion	85	5.7%
Receipt of GCSF transfusion	6	0.4%
Hearing Loss, Hearing Aid, Cochlear Implant	204	13.6%
Within 180 Days From Index		
Neutropenia	244	16.3%
Receipt of RBC transfusion	122	8.1%
Receipt of platelet transfusion	90	6.0%
Receipt of GCSF transfusion	12	0.8%
Hearing Loss, Hearing Aid, Cochlear Implant	318	21.2%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	387	25.8%
Ever, Prior to and Up to Index Date		
Jaundice	683	45.5%
Petechiae	82	5.5%
Hepatomegaly	65	4.3%
Splenomegaly	49	3.3%
Microcephaly	112	7.5%
Thrombocytopenia	529	35.3%
Chlorioretinitis	36	2.4%
Brain Abnormality	237	15.8%
Other Brain Abnormality	2	0.1%
Hearing Loss, Hearing Aid, Cochlear Implant	93	6.2%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	741	49.4%
Petechiae	85	5.7%
Hepatomegaly	80	5.3%
Splenomegaly	59	3.9%
Microcephaly	131	8.7%
Thrombocytopenia	546	36.4%
Chlorioretinitis	53	3.5%
Brain Abnormality	283	18.9%
Other Brain Abnormality	2	0.1%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	254	16.9%
CMV Antigen or Antibody Testing	65	4.3%
CMV Culture	110	7.3%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	326	21.7%

Table 1a. Aggregated Baseline Characteristics of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Radiology Tests (Ever, Prior to and Up to 30 Days After Index)		
Head computed tomography (CT)	142	9.5%
Brain MRI	282	18.8%
Head Ultrasound	37	2.5%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1b. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Absent, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics	Number	
Unique patients	405	N/A
Demographic Characteristics	Mean	Standard Deviation
Mean Age (Days)	10.76	11.69
	Number	Percent
Age (Days)		
≤ 45	405	100.0%
Sex		
Female	216	53.3%
Male	189	46.7%
Race ¹		
American Indian or Alaska Native	0	0.0%
Asian	2	0.5%
Black or African American	31	7.7%
Native Hawaiian or Other Pacific Islander	1	0.2%
Unknown	346	85.4%
White	25	6.2%
Hispanic origin		
Yes	3	0.7%
No	50	12.3%
Unknown	352	86.9%
Year		
2008	35	8.6%
2009	29	7.2%
2010	35	8.6%
2011	31	7.7%
2012	15	3.7%
2013	29	7.2%
2014	35	8.6%
2015	24	5.9%
2016	36	8.9%
2017	38	9.4%
2018	29	7.2%
2019	38	9.4%
2020	26	6.4%
2021	5	1.2%
Health Characteristics		
Type of CMV Diagnosis Code		
Congenital CMV (cCMV)	309	76.3%
Cytomegalovirus (CMV) Infection	149	36.8%
Ever, Prior to and Up to 15 Days After Index		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Hearing loss, Hearing Aid, Cochlear Implant	0	0.0%

Table 1b. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Absent, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	4	1.0%
Other Brain Abnormality	0	0.0%
Within 60 Days From Index		
Neutropenia	18	4.4%
Receipt of RBC transfusion	6	1.5%
Receipt of platelet transfusion	0	0.0%
Receipt of GCSF transfusion	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	14	3.5%
Within 180 Days From Index		
Neutropenia	20	4.9%
Receipt of RBC transfusion	7	1.7%
Receipt of platelet transfusion	1	0.2%
Receipt of GCSF transfusion	1	0.2%
Hearing Loss, Hearing Aid, Cochlear Implant	37	9.1%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	57	14.1%
Ever, Prior to and Up to Index Date		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Brain Abnormality	0	0.0%
Other Brain Abnormality	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	0	0.0%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	5	1.2%
Petechiae	0	0.0%
Hepatomegaly	1	0.2%
Splenomegaly	0	0.0%
Microcephaly	2	0.5%
Thrombocytopenia	3	0.7%
Chlorioretinitis	2	0.5%
Brain Abnormality	5	1.2%
Other Brain Abnormality	0	0.0%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	78	19.3%
CMV Antigen or Antibody Testing	20	4.9%
CMV Culture	22	5.4%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	94	23.2%

Table 1b. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Absent, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Radiology Tests (Ever, Prior to and Up to 30 Days After Index)		
Head computed tomography (CT)	13	3.2%
Brain MRI	24	5.9%
Head Ultrasound	4	1.0%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1c. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Present, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics		Number	
Unique patients		38	
Demographic Characteristics		Mean	Standard Deviation
Mean Age (Days)		22.82	14.46
Age (Days)		Number	Percent
≤ 45		38	100.0%
Sex			
Female		19	50.0%
Male		19	50.0%
Race ¹			
American Indian or Alaska Native		0	0.0%
Asian		1	2.6%
Black or African American		0	0.0%
Native Hawaiian or Other Pacific Islander		1	2.6%
Unknown		34	89.5%
White		2	5.3%
Hispanic origin			
Yes		0	0.0%
No		4	10.5%
Unknown		34	89.5%
Year			
2008		0	0.0%
2009		3	7.9%
2010		3	7.9%
2011		0	0.0%
2012		4	10.5%
2013		2	5.3%
2014		1	2.6%
2015		2	5.3%
2016		3	7.9%
2017		6	15.8%
2018		7	18.4%
2019		3	7.9%
2020		4	10.5%
2021		0	0.0%
Health Characteristics			
Type of CMV Diagnosis Code			
Congenital CMV (cCMV)		29	76.3%
Cytomegalovirus (CMV) Infection		19	50.0%
Ever, Prior to and Up to 15 Days After Index			
Jaundice		0	0.0%
Petechiae		0	0.0%
Hepatomegaly		0	0.0%
Splenomegaly		0	0.0%
Microcephaly		0	0.0%
Thrombocytopenia		0	0.0%
Chlorioretinitis		0	0.0%
Hearing loss, Hearing Aid, Cochlear Implant		38	100.0%

Table 1c. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Present, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	0	0.0%
Other Brain Abnormality	0	0.0%
Within 60 Days From Index		
Neutropenia	3	7.9%
Receipt of RBC transfusion	0	0.0%
Receipt of platelet transfusion	0	0.0%
Receipt of GCSF transfusion	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	35	92.1%
Within 180 Days From Index		
Neutropenia	3	7.9%
Receipt of RBC transfusion	0	0.0%
Receipt of platelet transfusion	0	0.0%
Receipt of GCSF transfusion	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	37	97.4%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	37	97.4%
Ever, Prior to and Up to Index Date		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Brain Abnormality	0	0.0%
Other Brain Abnormality	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	29	76.3%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Brain Abnormality	0	0.0%
Other Brain Abnormality	0	0.0%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	13	34.2%
CMV Antigen or Antibody Testing	2	5.3%
CMV Culture	6	15.8%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	16	42.1%

Table 1c. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Present, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Head computed tomography (CT)	4	10.5%
Brain MRI	3	7.9%
Head Ultrasound	0	0.0%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1d. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Absent, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics		Number	
Unique patients		963	
Demographic Characteristics		Mean	Standard Deviation
Mean Age (Days)		5.25	10.1
Age (Days)		Number	Percent
≤ 45		963	100.0%
Sex			
Female		416	43.2%
Male		547	56.8%
Race ¹			
American Indian or Alaska Native		0	0.0%
Asian		10	1.0%
Black or African American		50	5.2%
Native Hawaiian or Other Pacific Islander		4	0.4%
Unknown		840	87.2%
White		59	6.1%
Hispanic origin			
Yes		7	0.7%
No		89	9.2%
Unknown		867	90.0%
Year			
2008		59	6.1%
2009		49	5.1%
2010		59	6.1%
2011		44	4.6%
2012		60	6.2%
2013		62	6.4%
2014		78	8.1%
2015		81	8.4%
2016		100	10.4%
2017		115	11.9%
2018		96	10.0%
2019		95	9.9%
2020		58	6.0%
2021		7	0.7%
Health Characteristics			
Type of CMV Diagnosis Code			
Congenital CMV (cCMV)		757	78.6%
Cytomegalovirus (CMV) Infection		400	41.5%
Ever, Prior to and Up to 15 Days After Index			
Jaundice		682	70.8%
Petechiae		69	7.2%
Hepatomegaly		65	6.7%
Splenomegaly		50	5.2%
Microcephaly		103	10.7%
Thrombocytopenia		500	51.9%
Chlorioretinitis		40	4.2%
Hearing loss, Hearing Aid, Cochlear Implant		0	0.0%

Table 1d. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Absent, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	227	23.6%
Other Brain Abnormality	2	0.2%
Within 60 Days From Index		
Neutropenia	173	18.0%
Receipt of RBC transfusion	105	10.9%
Receipt of platelet transfusion	82	8.5%
Receipt of GCSF transfusion	5	0.5%
Hearing Loss, Hearing Aid, Cochlear Implant	63	6.5%
Within 180 Days From Index		
Neutropenia	200	20.8%
Receipt of RBC transfusion	108	11.2%
Receipt of platelet transfusion	86	8.9%
Receipt of GCSF transfusion	10	1.0%
Hearing Loss, Hearing Aid, Cochlear Implant	152	15.8%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	200	20.8%
Ever, Prior to and Up to Index Date		
Jaundice	638	66.3%
Petechiae	67	7.0%
Hepatomegaly	58	6.0%
Splenomegaly	46	4.8%
Microcephaly	94	9.8%
Thrombocytopenia	489	50.8%
Chlorioretinitis	36	3.7%
Brain Abnormality	202	21.0%
Other Brain Abnormality	2	0.2%
Hearing Loss, Hearing Aid, Cochlear Implant	0	0.0%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	687	71.3%
Petechiae	70	7.3%
Hepatomegaly	71	7.4%
Splenomegaly	55	5.7%
Microcephaly	109	11.3%
Thrombocytopenia	501	52.0%
Chlorioretinitis	45	4.7%
Brain Abnormality	232	24.1%
Other Brain Abnormality	2	0.2%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	129	13.4%
CMV Antigen or Antibody Testing	34	3.5%
CMV Culture	67	7.0%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	177	18.4%

Table 1d. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Absent, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Head computed tomography (CT)	102	10.6%
Brain MRI	221	22.9%
Head Ultrasound	29	3.0%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1e. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Present, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics		Number	
Unique patients		94	
Demographic Characteristics		Mean	Standard Deviation
Mean Age (Days)		11.78	14.33
Age (Days)		Number	Percent
≤ 45		94	100.0%
Sex			
Female		40	42.6%
Male		54	57.4%
Race ¹			
American Indian or Alaska Native		0	0.0%
Asian		0	0.0%
Black or African American		5	5.3%
Native Hawaiian or Other Pacific Islander		2	2.1%
Unknown		80	85.1%
White		7	7.4%
Hispanic origin			
Yes		2	2.1%
No		8	8.5%
Unknown		84	89.4%
Year			
2008		7	7.4%
2009		8	8.5%
2010		9	9.6%
2011		4	4.3%
2012		2	2.1%
2013		3	3.2%
2014		8	8.5%
2015		12	12.8%
2016		8	8.5%
2017		5	5.3%
2018		7	7.4%
2019		13	13.8%
2020		6	6.4%
2021		2	2.1%
Health Characteristics			
Type of CMV Diagnosis Code			
Congenital CMV (cCMV)		81	86.2%
Cytomegalovirus (CMV) Infection		51	54.3%
Ever, Prior to and Up to 15 Days After Index			
Jaundice		49	52.1%
Petechiae		15	16.0%
Hepatomegaly		8	8.5%
Splenomegaly		3	3.2%
Microcephaly		20	21.3%
Thrombocytopenia		42	44.7%
Chlorioretinitis		4	4.3%
Hearing loss, Hearing Aid, Cochlear Implant		94	100.0%

Table 1e. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Present, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	46	48.9%
Other Brain Abnormality	0	0.0%
Within 60 Days From Index		
Neutropenia	16	17.0%
Receipt of RBC transfusion	7	7.4%
Receipt of platelet transfusion	3	3.2%
Receipt of GCSF transfusion	1	1.1%
Hearing Loss, Hearing Aid, Cochlear Implant	92	97.9%
Within 180 Days From Index		
Neutropenia	21	22.3%
Receipt of RBC transfusion	7	7.4%
Receipt of platelet transfusion	3	3.2%
Receipt of GCSF transfusion	1	1.1%
Hearing Loss, Hearing Aid, Cochlear Implant	92	97.9%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	93	98.9%
Ever, Prior to and Up to Index Date		
Jaundice	45	47.9%
Petechiae	15	16.0%
Hepatomegaly	7	7.4%
Splenomegaly	3	3.2%
Microcephaly	18	19.1%
Thrombocytopenia	40	42.6%
Chlorioretinitis	0	0.0%
Brain Abnormality	35	37.2%
Other Brain Abnormality	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	64	68.1%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	49	52.1%
Petechiae	15	16.0%
Hepatomegaly	8	8.5%
Splenomegaly	4	4.3%
Microcephaly	20	21.3%
Thrombocytopenia	42	44.7%
Chlorioretinitis	6	6.4%
Brain Abnormality	46	48.9%
Other Brain Abnormality	0	0.0%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	34	36.2%
CMV Antigen or Antibody Testing	9	9.6%
CMV Culture	15	16.0%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	39	41.5%

Table 1e. Aggregated Baseline Characteristic of Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) (Hearing Loss: Present, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Head computed tomography (CT)	23	24.5%
Brain MRI	34	36.2%
Head Ultrasound	4	4.3%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1f. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics		Number	
Unique patients		1,496	
Demographic Characteristics		Mean	Standard Deviation
Mean Age (Days)		7.55	11.48
Age (Days)		Number	Percent
≤ 45		1,496	100.0%
Sex			
Female		688	46.0%
Male		808	54.0%
Race ¹			
American Indian or Alaska Native		0	0.0%
Asian		13	0.9%
Black or African American		86	5.7%
Native Hawaiian or Other Pacific Islander		8	0.5%
Unknown		1,296	86.6%
White		93	6.2%
Hispanic origin			
Yes		12	0.8%
No		151	10.1%
Unknown		1,333	89.1%
Year			
2008		101	6.8%
2009		89	5.9%
2010		106	7.1%
2011		79	5.3%
2012		80	5.3%
2013		96	6.4%
2014		122	8.2%
2015		118	7.9%
2016		145	9.7%
2017		164	11.0%
2018		139	9.3%
2019		149	10.0%
2020		94	6.3%
2021		14	0.9%
Health Characteristics			
Type of CMV Diagnosis Code			
Congenital CMV (cCMV)		1,173	78.4%
Cytomegalovirus (CMV) Infection		616	41.2%
Ever, Prior to and Up to 15 Days After Index			
Jaundice		728	48.7%
Petechiae		83	5.5%
Hepatomegaly		73	4.9%
Splenomegaly		53	3.5%
Microcephaly		123	8.2%
Thrombocytopenia		541	36.2%
Chlorioretinitis		44	2.9%
Hearing loss, Hearing Aid, Cochlear Implant		131	8.8%

Table 1f. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	275	18.4%
Other Brain Abnormality	2	0.1%
Within 60 Days From Index		
Neutropenia	209	14.0%
Receipt of RBC transfusion	118	7.9%
Receipt of platelet transfusion	85	5.7%
Receipt of GCSF transfusion	5	0.3%
Hearing Loss, Hearing Aid, Cochlear Implant	202	13.5%
Within 180 Days From Index		
Neutropenia	243	16.2%
Receipt of RBC transfusion	122	8.2%
Receipt of platelet transfusion	90	6.0%
Receipt of GCSF transfusion	11	0.7%
Hearing Loss, Hearing Aid, Cochlear Implant	316	21.1%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	385	25.7%
Ever, Prior to and Up to Index Date		
Jaundice	680	45.5%
Petechiae	81	5.4%
Hepatomegaly	65	4.3%
Splenomegaly	49	3.3%
Microcephaly	112	7.5%
Thrombocytopenia	528	35.3%
Chlorioretinitis	36	2.4%
Brain Abnormality	235	15.7%
Other Brain Abnormality	2	0.1%
Hearing Loss, Hearing Aid, Cochlear Implant	92	6.1%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	738	49.3%
Petechiae	84	5.6%
Hepatomegaly	80	5.3%
Splenomegaly	59	3.9%
Microcephaly	131	8.8%
Thrombocytopenia	545	36.4%
Chlorioretinitis	53	3.5%
Brain Abnormality	281	18.8%
Other Brain Abnormality	2	0.1%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	253	16.9%
CMV Antigen or Antibody Testing	65	4.3%
CMV Culture	110	7.4%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	325	21.7%

Table 1f. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Head computed tomography (CT)	141	9.4%
Brain MRI	281	18.8%
Head Ultrasound	37	2.5%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1g. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Absent, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics	Number	
Unique patients	405	
Demographic Characteristics	Mean	Standard Deviation
Mean Age (Days)	10.76	11.69
	Number	Percent
Age (Days)		
≤ 45	405	100.0%
Sex		
Female	216	53.3%
Male	189	46.7%
Race ¹		
American Indian or Alaska Native	0	0.0%
Asian	2	0.5%
Black or African American	31	7.7%
Native Hawaiian or Other Pacific Islander	1	0.2%
Unknown	346	85.4%
White	25	6.2%
Hispanic origin		
Yes	3	0.7%
No	50	12.3%
Unknown	352	86.9%
Year		
2008	35	8.6%
2009	29	7.2%
2010	35	8.6%
2011	31	7.7%
2012	15	3.7%
2013	29	7.2%
2014	35	8.6%
2015	24	5.9%
2016	36	8.9%
2017	38	9.4%
2018	29	7.2%
2019	38	9.4%
2020	26	6.4%
2021	5	1.2%
Health Characteristics		
Type of CMV Diagnosis Code		
Congenital CMV (cCMV)	309	76.3%
Cytomegalovirus (CMV) Infection	149	36.8%
Ever, Prior to and Up to 15 Days After Index		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Hearing loss, Hearing Aid, Cochlear Implant	0	0.0%

Table 1g. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Absent, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	4	1.0%
Other Brain Abnormality	0	0.0%
Within 60 Days From Index		
Neutropenia	18	4.4%
Receipt of RBC transfusion	6	1.5%
Receipt of platelet transfusion	0	0.0%
Receipt of GCSF transfusion	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	14	3.5%
Within 180 Days From Index		
Neutropenia	20	4.9%
Receipt of RBC transfusion	7	1.7%
Receipt of platelet transfusion	1	0.2%
Receipt of GCSF transfusion	1	0.2%
Hearing Loss, Hearing Aid, Cochlear Implant	37	9.1%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	57	14.1%
Ever, Prior to and Up to Index Date		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Brain Abnormality	0	0.0%
Other Brain Abnormality	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	0	0.0%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	5	1.2%
Petechiae	0	0.0%
Hepatomegaly	1	0.2%
Splenomegaly	0	0.0%
Microcephaly	2	0.5%
Thrombocytopenia	3	0.7%
Chlorioretinitis	2	0.5%
Brain Abnormality	5	1.2%
Other Brain Abnormality	0	0.0%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	78	19.3%
CMV Antigen or Antibody Testing	20	4.9%
CMV Culture	22	5.4%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	94	23.2%

Table 1g. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Absent, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Medical Product Use		
Head computed tomography (CT)	13	3.2%
Brain MRI	24	5.9%
Head Ultrasound	4	1.0%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1h. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Present, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics	Number	
Unique patients	38	
Demographic Characteristics	Mean	Standard Deviation
Mean Age (Days)	22.82	14.46
	Number	Percent
Age (Days)		
≤ 45	38	100.0%
Sex		
Female	19	50.0%
Male	19	50.0%
Race ¹		
American Indian or Alaska Native	0	0.0%
Asian	1	2.6%
Black or African American	0	0.0%
Native Hawaiian or Other Pacific Islander	1	2.6%
Unknown	34	89.5%
White	2	5.3%
Hispanic origin		
Yes	0	0.0%
No	4	10.5%
Unknown	34	89.5%
Year		
2008	0	0.0%
2009	3	7.9%
2010	3	7.9%
2011	0	0.0%
2012	4	10.5%
2013	2	5.3%
2014	1	2.6%
2015	2	5.3%
2016	3	7.9%
2017	6	15.8%
2018	7	18.4%
2019	3	7.9%
2020	4	10.5%
2021	0	0.0%
Health Characteristics		
Type of CMV Diagnosis Code		
Congenital CMV (cCMV)	29	76.3%
Cytomegalovirus (CMV) Infection	19	50.0%
Ever, Prior to and Up to 15 Days After Index		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Hearing loss, Hearing Aid, Cochlear Implant	38	100.0%

Table 1h. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Present, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	0	0.0%
Other Brain Abnormality	0	0.0%
Within 60 Days From Index		
Neutropenia	3	7.9%
Receipt of RBC transfusion	0	0.0%
Receipt of platelet transfusion	0	0.0%
Receipt of GCSF transfusion	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	35	92.1%
Within 180 Days From Index		
Neutropenia	3	7.9%
Receipt of RBC transfusion	0	0.0%
Receipt of platelet transfusion	0	0.0%
Receipt of GCSF transfusion	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	37	97.4%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	37	97.4%
Ever, Prior to and Up to Index Date		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Brain Abnormality	0	0.0%
Other Brain Abnormality	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	29	76.3%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	0	0.0%
Petechiae	0	0.0%
Hepatomegaly	0	0.0%
Splenomegaly	0	0.0%
Microcephaly	0	0.0%
Thrombocytopenia	0	0.0%
Chlorioretinitis	0	0.0%
Brain Abnormality	0	0.0%
Other Brain Abnormality	0	0.0%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	13	34.2%
CMV Antigen or Antibody Testing	2	5.3%
CMV Culture	6	15.8%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	16	42.1%

Table 1h. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Present, Clinical Characteristics: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Medical Product Use		
Head computed tomography (CT)	4	10.5%
Brain MRI	3	7.9%
Head Ultrasound	0	0.0%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1i. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Absent, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics	Number	
Unique patients	960	
Demographic Characteristics	Mean	Standard Deviation
Mean Age (Days)	5.19	10.02
Age (Days)	Number	Percent
≤ 45	960	100.0%
Sex		
Female	413	43.0%
Male	547	57.0%
Race ¹		
American Indian or Alaska Native	0	0.0%
Asian	10	1.0%
Black or African American	50	5.2%
Native Hawaiian or Other Pacific Islander	4	0.4%
Unknown	837	87.2%
White	59	6.1%
Hispanic origin		
Yes	7	0.7%
No	89	9.3%
Unknown	864	90.0%
Year		
2008	59	6.1%
2009	49	5.1%
2010	59	6.1%
2011	44	4.6%
2012	59	6.1%
2013	62	6.5%
2014	78	8.1%
2015	80	8.3%
2016	99	10.3%
2017	115	12.0%
2018	96	10.0%
2019	95	9.9%
2020	58	6.0%
2021	7	0.7%
Health Characteristics		
Type of CMV Diagnosis Code		
Congenital CMV (cCMV)	755	78.6%
Cytomegalovirus (CMV) Infection	398	41.5%
Ever, Prior to and Up to 15 Days After Index		
Jaundice	680	70.8%
Petechiae	69	7.2%
Hepatomegaly	65	6.8%
Splenomegaly	50	5.2%
Microcephaly	103	10.7%
Thrombocytopenia	500	52.1%
Chlorioretinitis	40	4.2%
Hearing loss, Hearing Aid, Cochlear Implant	0	0.0%

Table 1i. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Absent, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	225	23.4%
Other Brain Abnormality	2	0.2%
Within 60 Days From Index		
Neutropenia	173	18.0%
Receipt of RBC transfusion	105	10.9%
Receipt of platelet transfusion	82	8.5%
Receipt of GCSF transfusion	5	0.5%
Hearing Loss, Hearing Aid, Cochlear Implant	62	6.5%
Within 180 Days From Index		
Neutropenia	200	20.8%
Receipt of RBC transfusion	108	11.3%
Receipt of platelet transfusion	86	9.0%
Receipt of GCSF transfusion	10	1.0%
Hearing Loss, Hearing Aid, Cochlear Implant	151	15.7%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	199	20.7%
Ever, Prior to and Up to Index Date		
Jaundice	636	66.3%
Petechiae	67	7.0%
Hepatomegaly	58	6.0%
Splenomegaly	46	4.8%
Microcephaly	94	9.8%
Thrombocytopenia	489	50.9%
Chlorioretinitis	36	3.8%
Brain Abnormality	200	20.8%
Other Brain Abnormality	2	0.2%
Hearing Loss, Hearing Aid, Cochlear Implant	0	0.0%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	685	71.4%
Petechiae	70	7.3%
Hepatomegaly	71	7.4%
Splenomegaly	55	5.7%
Microcephaly	109	11.4%
Thrombocytopenia	501	52.2%
Chlorioretinitis	45	4.7%
Brain Abnormality	230	24.0%
Other Brain Abnormality	2	0.2%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	128	13.3%
CMV Antigen or Antibody Testing	34	3.5%
CMV Culture	67	7.0%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	176	18.3%

Table 1i. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Absent, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Head computed tomography (CT)	101	10.5%
Brain MRI	220	22.9%
Head Ultrasound	29	3.0%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1j. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Present, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics	Number	
Unique patients	93	
Demographic Characteristics	Mean	Standard Deviation
Mean Age (Days)	11.73	14.40
Age (Days)	Number	Percent
≤ 45	93	100.0%
Sex		
Female	40	43.0%
Male	53	57.0%
Race ¹		
American Indian or Alaska Native	0	0.0%
Asian	0	0.0%
Black or African American	5	5.4%
Native Hawaiian or Other Pacific Islander	2	2.2%
Unknown	79	84.9%
White	7	7.5%
Hispanic origin		
Yes	2	2.2%
No	8	8.6%
Unknown	83	89.2%
Year		
2008	7	7.5%
2009	8	8.6%
2010	9	9.7%
2011	4	4.3%
2012	2	2.2%
2013	3	3.2%
2014	8	8.6%
2015	12	12.9%
2016	7	7.5%
2017	5	5.4%
2018	7	7.5%
2019	13	14.0%
2020	6	6.5%
2021	2	2.2%
Health Characteristics		
Type of CMV Diagnosis Code		
Congenital CMV (cCMV)	80	86.0%
Cytomegalovirus (CMV) Infection	50	53.8%
Ever, Prior to and Up to 15 Days After Index		
Jaundice	48	51.6%
Petechiae	14	15.1%
Hepatomegaly	8	8.6%
Splenomegaly	3	3.2%
Microcephaly	20	21.5%
Thrombocytopenia	41	44.1%
Chlorioretinitis	4	4.3%
Hearing loss, Hearing Aid, Cochlear Implant	93	100.0%

Table 1j. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Present, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	46	49.5%
Other Brain Abnormality	0	0.0%
Within 60 Days From Index		
Neutropenia	15	16.1%
Receipt of RBC transfusion	7	7.5%
Receipt of platelet transfusion	3	3.2%
Receipt of GCSF transfusion	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	91	97.8%
Within 180 Days From Index		
Neutropenia	20	21.5%
Receipt of RBC transfusion	7	7.5%
Receipt of platelet transfusion	3	3.2%
Receipt of GCSF transfusion	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	91	97.8%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	92	98.9%
Ever, Prior to and Up to Index Date		
Jaundice	44	47.3%
Petechiae	14	15.1%
Hepatomegaly	7	7.5%
Splenomegaly	3	3.2%
Microcephaly	18	19.4%
Thrombocytopenia	39	41.9%
Chlorioretinitis	0	0.0%
Brain Abnormality	35	37.6%
Other Brain Abnormality	0	0.0%
Hearing Loss, Hearing Aid, Cochlear Implant	63	67.7%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	48	51.6%
Petechiae	14	15.1%
Hepatomegaly	8	8.6%
Splenomegaly	4	4.3%
Microcephaly	20	21.5%
Thrombocytopenia	41	44.1%
Chlorioretinitis	6	6.5%
Brain Abnormality	46	49.5%
Other Brain Abnormality	0	0.0%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	34	36.6%
CMV Antigen or Antibody Testing	9	9.7%
CMV Culture	15	16.1%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	39	41.9%

Table 1j. Aggregated Baseline Characteristics of Valganciclovir Treatment for Infants with Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV), (Hearing Loss: Present, Clinical Characteristics: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Head computed tomography (CT)	23	24.7%
Brain MRI	34	36.6%
Head Ultrasound	4	4.3%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1k. Aggregated Baseline Characteristics of Infants with Valganciclovir Treatment Within 45 Days from Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) Diagnosis in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics	Number	
Unique patients	221	
Demographic Characteristics	Mean	Standard Deviation
Mean Age (Days)	8.97	12.34
Age (Days)	Number	Percent
≤ 45	221	100.0%
Sex		
Female	105	47.5%
Male	116	52.5%
Race ¹		
American Indian or Alaska Native	0	0.0%
Asian	1	0.5%
Black or African American	15	6.8%
Native Hawaiian or Other Pacific Islander	2	0.9%
Unknown	185	83.7%
White	18	8.1%
Hispanic origin		
Yes	2	0.9%
No	27	12.2%
Unknown	192	86.9%
Year		
2008	2	0.9%
2009	1	0.5%
2010	3	1.4%
2011	5	2.3%
2012	11	5.0%
2013	11	5.0%
2014	16	7.2%
2015	28	12.7%
2016	32	14.5%
2017	30	13.6%
2018	25	11.3%
2019	31	14.0%
2020	23	10.4%
2021	3	1.4%
Health Characteristics		
Type of CMV Diagnosis Code		
Congenital CMV (cCMV)	208	94.1%
Cytomegalovirus (CMV) Infection	90	40.7%
Ever, Prior to and Up to 15 Days After Index		
Jaundice	105	47.5%
Petechiae	33	14.9%
Hepatomegaly	18	8.1%
Splenomegaly	18	8.1%
Microcephaly	36	16.3%
Thrombocytopenia	97	43.9%
Chlorioretinitis	13	5.9%
Hearing loss, Hearing Aid, Cochlear Implant	49	22.2%

Table 1k. Aggregated Baseline Characteristics of Infants with Valganciclovir Treatment Within 45 Days from Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) Diagnosis in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	74	33.5%
Other Brain Abnormality	1	0.5%
Within 60 Days From Index		
Neutropenia	41	18.6%
Receipt of RBC transfusion	7	3.2%
Receipt of platelet transfusion	14	6.3%
Receipt of GCSF transfusion	3	1.4%
Hearing Loss, Hearing Aid, Cochlear Implant	87	39.4%
Within 180 Days From Index		
Neutropenia	57	25.8%
Receipt of RBC transfusion	7	3.2%
Receipt of platelet transfusion	14	6.3%
Receipt of GCSF transfusion	7	3.2%
Hearing Loss, Hearing Aid, Cochlear Implant	124	56.1%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	138	62.4%
Ever, Prior to and Up to Index Date		
Jaundice	99	44.8%
Petechiae	32	14.5%
Hepatomegaly	15	6.8%
Splenomegaly	16	7.2%
Microcephaly	31	14.0%
Thrombocytopenia	95	43.0%
Chlorioretinitis	10	4.5%
Brain Abnormality	55	24.9%
Other Brain Abnormality	1	0.5%
Hearing Loss, Hearing Aid, Cochlear Implant	33	14.9%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	107	48.4%
Petechiae	34	15.4%
Hepatomegaly	19	8.6%
Splenomegaly	21	9.5%
Microcephaly	38	17.2%
Thrombocytopenia	97	43.9%
Chlorioretinitis	17	7.7%
Brain Abnormality	77	34.8%
Other Brain Abnormality	1	0.5%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	69	31.2%
CMV Antigen or Antibody Testing	10	4.5%
CMV Culture	16	7.2%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	73	33.0%

Table 1k. Aggregated Baseline Characteristics of Infants with Valganciclovir Treatment Within 45 Days from Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) Diagnosis in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Medical Product Use		
Head computed tomography (CT)	26	11.8%
Brain MRI	72	32.6%
Head Ultrasound	4	1.8%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 11. Aggregated Baseline Characteristics of Infants with Valganciclovir Treatment Within 180 Days from Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) Diagnosis in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Patient Characteristics	Number	
Unique patients	301	
Demographic Characteristics	Mean	Standard Deviation
Mean Age (Days)	8.02	11.84
Age (Days)	Number	Percent
≤ 45	301	100.0%
Sex		
Female	142	47.2%
Male	159	52.8%
Race ¹		
American Indian or Alaska Native	0	0.0%
Asian	1	0.3%
Black or African American	24	8.0%
Native Hawaiian or Other Pacific Islander	3	1.0%
Unknown	246	81.7%
White	27	9.0%
Hispanic origin		
Yes	2	0.7%
No	43	14.3%
Unknown	256	85.0%
Year		
2008	7	2.3%
2009	4	1.3%
2010	5	1.7%
2011	11	3.7%
2012	11	3.7%
2013	15	5.0%
2014	24	8.0%
2015	35	11.6%
2016	45	15.0%
2017	43	14.3%
2018	32	10.6%
2019	39	13.0%
2020	27	9.0%
2021	3	1.0%
Health Characteristics		
Type of CMV Diagnosis Code		
Congenital CMV (cCMV)	279	92.7%
Cytomegalovirus (CMV) Infection	125	41.5%
Ever, Prior to and Up to 15 Days After Index		
Jaundice	144	47.8%
Petechiae	37	12.3%
Hepatomegaly	24	8.0%
Splenomegaly	25	8.3%
Microcephaly	50	16.6%
Thrombocytopenia	141	46.8%
Chlorioretinitis	16	5.3%
Hearing loss, Hearing Aid, Cochlear Implant	58	19.3%

Table 11. Aggregated Baseline Characteristics of Infants with Valganciclovir Treatment Within 180 Days from Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) Diagnosis in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Health Characteristics	Number	Percent
Ever, Prior to and Up to 30 Days After Index		
Brain Abnormality	95	31.6%
Other Brain Abnormality	1	0.3%
Within 60 Days From Index		
Neutropenia	64	21.3%
Receipt of RBC transfusion	17	5.6%
Receipt of platelet transfusion	23	7.6%
Receipt of GCSF transfusion	4	1.3%
Hearing Loss, Hearing Aid, Cochlear Implant	103	34.2%
Within 180 Days From Index		
Neutropenia	85	28.2%
Receipt of RBC transfusion	19	6.3%
Receipt of platelet transfusion	24	8.0%
Receipt of GCSF transfusion	8	2.7%
Hearing Loss, Hearing Aid, Cochlear Implant	155	51.5%
Within 365 Days From Index		
Hearing Loss, Hearing Aid, Cochlear Implant	175	58.1%
Ever, Prior to and Up to Index Date		
Jaundice	137	45.5%
Petechiae	36	12.0%
Hepatomegaly	20	6.6%
Splenomegaly	22	7.3%
Microcephaly	45	15.0%
Thrombocytopenia	136	45.2%
Chlorioretinitis	13	4.3%
Brain Abnormality	72	23.9%
Other Brain Abnormality	1	0.3%
Hearing Loss, Hearing Aid, Cochlear Implant	39	13.0%
Ever, Prior to and Up to 45 Days After Index		
Jaundice	149	49.5%
Petechiae	38	12.6%
Hepatomegaly	25	8.3%
Splenomegaly	28	9.3%
Microcephaly	53	17.6%
Thrombocytopenia	142	47.2%
Chlorioretinitis	22	7.3%
Brain Abnormality	99	32.9%
Other Brain Abnormality	1	0.3%
Medical Product Use		
Lab Tests (Ever, Prior to and Up to 15 Days After Index)		
CMV PCR (Blood, urine, saliva)	80	26.6%
CMV Antigen or Antibody Testing	13	4.3%
CMV Culture	21	7.0%
CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture	86	28.6%

Table 1I. Aggregated Baseline Characteristics of Infants with Valganciclovir Treatment Within 180 Days from Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) Diagnosis in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

Medical Product Use	Number	Percent
Medical Product Use		
Head computed tomography (CT)	36	12.0%
Brain MRI	98	32.6%
Head Ultrasound	6	2.0%

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 2. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall	1,500	5,947,422	3,368.4	2.2	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Absent	405	4,142,341	969.4	2.4	0	0.0
Hearing Loss: Present, Clinical Characteristics: Absent	38	25,229	79.6	2.1	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Present	963	1,812,140	2,080.7	2.2	0	0.0
Hearing Loss: Present, Clinical Characteristics: Present	94	15,600	238.6	2.5	0	0.0
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall	1,496	5,947,422	506.7	0.3	295	1,971.9
Hearing Loss: Absent, Clinical Characteristics: Absent	405	4,142,341	152.6	0.4	39	963.0
Hearing Loss: Present, Clinical Characteristics: Absent	38	25,229	10.8	0.3	11	2,894.7
Hearing Loss: Absent, Clinical Characteristics: Present	960	1,812,140	320.5	0.3	199	2,072.9
Hearing Loss: Present, Clinical Characteristics: Present	93	15,600	22.8	0.2	46	4,946.2
Treatment Within 45 Days from Diagnosis	221	275	468.8	2.1	0	0.0
Treatment Within 180 Days from Diagnosis	301	474	677.7	2.3	0	0.0

¹Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

²Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 3. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex¹

Sex	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
Female	691	2,890,509	1,524.8	2.2	0	0.0
Male	809	3,056,281	1,843.6	2.3	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Absent						
Female	216	2,039,435	528.7	2.4	0	0.0
Male	189	2,102,458	440.8	2.3	0	0.0
Hearing Loss: Present, Clinical Characteristics: Absent						
Female	19	11,443	48.1	2.5	0	0.0
Male	19	13,781	31.4	1.7	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Present						
Female	416	852,826	859.4	2.1	0	0.0
Male	547	959,134	1,221.3	2.2	0	0.0
Hearing Loss: Present, Clinical Characteristics: Present						
Female	40	6,916	88.6	2.2	0	0.0
Male	54	8,680	150.1	2.8	0	0.0
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
Female	688	2,890,509	229.2	0.3	137	1,991.3
Male	808	3,056,281	277.5	0.3	158	1,955.4
Hearing Loss: Absent, Clinical Characteristics: Absent						
Female	216	2,039,435	81.1	0.4	15	694.4
Male	189	2,102,458	71.5	0.4	24	1,269.8
Hearing Loss: Present, Clinical Characteristics: Absent						
Female	19	11,443	5.6	0.3	5	2,631.6
Male	19	13,781	5.2	0.3	6	3,157.9
Hearing Loss: Absent, Clinical Characteristics: Present						
Female	413	852,826	133.4	0.3	97	2,348.7
Male	547	959,134	187.2	0.3	102	1,864.7
Hearing Loss: Present, Clinical Characteristics: Present						
Female	40	6,916	9.2	0.2	20	5,000.0
Male	53	8,680	13.6	0.3	26	4,905.7

Table 3. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex¹

Sex	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Valganciclovir Treatment for Infants with CMV or cCMV						
Treatment Within 45 Days from Diagnosis						
Female	105	134	209.1	2.0	0	0.0
Male	116	141	259.8	2.2	0	0.0
Treatment Within 180 Days from Diagnosis						
Female	142	231	298.6	2.1	0	0.0
Male	159	243	379.1	2.4	0	0.0

¹Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

²Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 4. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Year¹

Year	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
2008	101	557,288	308.5	3.1	0	0.0
2009	89	526,114	267.4	3.0	0	0.0
2010	106	466,006	362.2	3.4	0	0.0
2011	79	440,362	261.5	3.3	0	0.0
2012	81	425,161	246.2	3.0	0	0.0
2013	96	485,284	266.9	2.8	0	0.0
2014	122	505,232	328.3	2.7	0	0.0
2015	119	520,647	293.4	2.5	0	0.0
2016	147	535,835	316.2	2.2	0	0.0
2017	164	521,359	309.3	1.9	0	0.0
2018	139	504,080	207.0	1.5	0	0.0
2019	149	478,833	152.2	1.0	0	0.0
2020	94	402,715	47.1	0.5	0	0.0
2021	14	52,420	2.2	0.2	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Absent						
2008	35	400,692	119.8	3.4	0	0.0
2009	29	367,909	92.2	3.2	0	0.0
2010	35	324,206	119.6	3.4	0	0.0
2011	31	309,501	93.1	3.0	0	0.0
2012	15	299,620	43.2	2.9	0	0.0
2013	29	343,332	95.6	3.3	0	0.0
2014	35	354,217	86.6	2.5	0	0.0
2015	24	364,651	57.3	2.4	0	0.0
2016	36	369,744	84.0	2.3	0	0.0
2017	38	354,431	81.0	2.1	0	0.0
2018	29	339,615	46.6	1.6	0	0.0
2019	38	321,940	35.7	0.9	0	0.0
2020	26	268,708	14.2	0.5	0	0.0
2021	5	36,305	0.5	0.1	0	0.0

Table 4. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Year¹

Year	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Absent						
2008	0	2,965	0.0	-	0	NaN
2009	3	2,662	13.4	4.5	0	0.0
2010	3	2,357	11.3	3.8	0	0.0
2011	0	2,217	0.0	-	0	NaN
2012	4	1,958	9.4	2.4	0	0.0
2013	2	2,147	10.6	5.3	0	0.0
2014	1	2,305	0.0	0.0	0	0.0
2015	2	2,093	6.0	3.0	0	0.0
2016	3	1,840	4.3	1.4	0	0.0
2017	6	1,686	12.0	2.0	0	0.0
2018	7	1,625	10.1	1.4	0	0.0
2019	3	1,460	0.6	0.2	0	0.0
2020	4	1,313	2.0	0.5	0	0.0
2021	0	131	0.0	-	0	NaN
Hearing Loss: Absent, Clinical Characteristics: Present						
2008	59	155,995	152.8	2.6	0	0.0
2009	49	157,906	129.6	2.6	0	0.0
2010	59	141,727	218.3	3.7	0	0.0
2011	44	130,843	154.7	3.5	0	0.0
2012	60	125,743	184.2	3.1	0	0.0
2013	62	142,324	158.7	2.6	0	0.0
2014	78	151,124	204.9	2.6	0	0.0
2015	81	156,586	194.6	2.4	0	0.0
2016	100	166,822	209.2	2.1	0	0.0
2017	115	167,751	202.2	1.8	0	0.0
2018	96	165,265	140.8	1.5	0	0.0
2019	95	157,854	99.7	1.0	0	0.0
2020	58	134,778	29.8	0.5	0	0.0
2021	7	16,175	1.1	0.2	0	0.0

Table 4. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Year¹

Year	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
2008	7	1,777	35.9	5.1	0	0.0
2009	8	1,660	32.2	4.0	0	0.0
2010	9	1,434	13.0	1.4	0	0.0
2011	4	1,323	13.6	3.4	0	0.0
2012	2	1,299	9.4	4.7	0	0.0
2013	3	1,262	1.9	0.6	0	0.0
2014	8	1,426	36.8	4.6	0	0.0
2015	12	1,258	35.5	3.0	0	0.0
2016	8	1,138	18.7	2.3	0	0.0
2017	5	1,139	14.2	2.8	0	0.0
2018	7	1,055	9.5	1.4	0	0.0
2019	13	957	16.2	1.2	0	0.0
2020	6	783	1.1	0.2	0	0.0
2021	2	91	0.6	0.3	0	0.0
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
2008	101	557,288	38.3	0.4	7	693.1
2009	89	526,114	36.3	0.4	4	449.4
2010	106	466,006	43.8	0.4	5	471.7
2011	79	440,362	30.7	0.4	11	1,392.4
2012	80	425,161	30.6	0.4	10	1,250.0
2013	96	485,284	34.1	0.4	15	1,562.5
2014	122	505,232	41.9	0.3	23	1,885.2
2015	118	520,647	36.9	0.3	34	2,881.4
2016	145	535,835	43.4	0.3	42	2,896.6
2017	164	521,359	53.4	0.3	43	2,622.0
2018	139	504,080	45.1	0.3	32	2,302.2
2019	149	478,833	46.3	0.3	39	2,617.4
2020	94	402,715	24.1	0.3	27	2,872.3
2021	14	52,420	1.7	0.1	3	2,142.9

Table 4. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Year¹

Year	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Absent						
2008	35	400,692	12.2	0.3	1	285.7
2009	29	367,909	11.4	0.4	0	0.0
2010	35	324,206	14.5	0.4	0	0.0
2011	31	309,501	11.9	0.4	5	1,612.9
2012	15	299,620	6.3	0.4	0	0.0
2013	29	343,332	10.5	0.4	4	1,379.3
2014	35	354,217	14.7	0.4	0	0.0
2015	24	364,651	10.3	0.4	1	416.7
2016	36	369,744	14.0	0.4	5	1,388.9
2017	38	354,431	14.0	0.4	6	1,578.9
2018	29	339,615	10.8	0.4	4	1,379.3
2019	38	321,940	14.7	0.4	5	1,315.8
2020	26	268,708	7.0	0.3	7	2,692.3
2021	5	36,305	0.3	0.1	1	2,000.0
Hearing Loss: Present, Clinical Characteristics: Absent						
2008	0	2,965	0.0	-	0	NaN
2009	3	2,662	1.2	0.4	0	0.0
2010	3	2,357	1.5	0.5	0	0.0
2011	0	2,217	0.0	-	0	NaN
2012	4	1,958	2.0	0.5	0	0.0
2013	2	2,147	0.6	0.3	1	5,000.0
2014	1	2,305	0.0	0.0	0	0.0
2015	2	2,093	0.3	0.2	1	5,000.0
2016	3	1,840	0.6	0.2	2	6,666.7
2017	6	1,686	1.2	0.2	3	5,000.0
2018	7	1,625	2.2	0.3	2	2,857.1
2019	3	1,460	0.6	0.2	0	0.0
2020	4	1,313	0.5	0.1	2	5,000.0
2021	0	131	0.0	-	0	NaN

Table 4. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Year¹

Year	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
2008	59	155,995	23.1	0.4	5	847.5
2009	49	157,906	20.6	0.4	3	612.2
2010	59	141,727	23.6	0.4	5	847.5
2011	44	130,843	17.4	0.4	5	1,136.4
2012	59	125,743	22.2	0.4	8	1,355.9
2013	62	142,324	22.1	0.4	9	1,451.6
2014	78	151,124	26.0	0.3	16	2,051.3
2015	80	156,586	23.4	0.3	26	3,250.0
2016	99	166,822	28.0	0.3	30	3,030.3
2017	115	167,751	37.8	0.3	29	2,521.7
2018	96	165,265	30.5	0.3	22	2,291.7
2019	95	157,854	29.3	0.3	24	2,526.3
2020	58	134,778	15.8	0.3	15	2,586.2
2021	7	16,175	0.8	0.1	2	2,857.1
Hearing Loss: Present, Clinical Characteristics: Present						
2008	7	1,777	3.0	0.4	1	1,428.6
2009	8	1,660	3.1	0.4	1	1,250.0
2010	9	1,434	4.3	0.5	0	0.0
2011	4	1,323	1.4	0.3	1	2,500.0
2012	2	1,299	0.1	0.1	2	10,000.0
2013	3	1,262	0.9	0.3	1	3,333.3
2014	8	1,426	1.1	0.1	7	8,750.0
2015	12	1,258	2.9	0.2	6	5,000.0
2016	7	1,138	0.9	0.1	5	7,142.9
2017	5	1,139	0.5	0.1	5	10,000.0
2018	7	1,055	1.7	0.2	4	5,714.3
2019	13	957	1.6	0.1	10	7,692.3
2020	6	783	0.7	0.1	3	5,000.0
2021	2	91	0.6	0.3	0	0.0

Table 4. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Year¹

Year	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Treatment Within 45 Days from Diagnosis						
2008	2	3	21.7	10.9	0	0.0
2009	1	4	0.4	0.4	0	0.0
2010	3	4	7.6	2.5	0	0.0
2011	5	8	24.7	4.9	0	0.0
2012	11	12	34.4	3.1	0	0.0
2013	11	15	27.2	2.5	0	0.0
2014	16	19	45.0	2.8	0	0.0
2015	28	37	76.3	2.7	0	0.0
2016	32	40	88.6	2.8	0	0.0
2017	30	40	58.1	1.9	0	0.0
2018	25	28	36.5	1.5	0	0.0
2019	31	44	34.1	1.1	0	0.0
2020	23	27	13.6	0.6	0	0.0
2021	3	3	0.7	0.2	0	0.0
Treatment Within 180 Days from Diagnosis						
2008	7	14	38.1	5.4	0	0.0
2009	4	13	15.8	3.9	0	0.0
2010	5	17	18.5	3.7	0	0.0
2011	11	17	45.0	4.1	0	0.0
2012	11	19	34.4	3.1	0	0.0
2013	15	27	30.4	2.0	0	0.0
2014	24	39	73.3	3.1	0	0.0
2015	35	57	99.2	2.8	0	0.0
2016	45	67	122.9	2.7	0	0.0
2017	43	69	89.6	2.1	0	0.0
2018	32	45	50.3	1.6	0	0.0
2019	39	66	43.0	1.1	0	0.0
2020	27	37	16.7	0.6	0	0.0
2021	3	3	0.7	0.2	0	0.0

¹Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

²Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 5. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race^{1,2}

Race	New Users	Eligible Members ³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
American Indian or Alaska Native	0	7,426	0.0	-	0	N/A
Asian	13	49,380	30.2	2.3	0	0.0
Black or African American	86	166,054	261.8	3.0	0	0.0
Native Hawaiian or Other Pacific Islander	8	16,909	28.2	3.5	0	0.0
Unknown	1,300	5,275,903	2,674.6	2.1	0	0.0
White	93	431,750	373.5	4.0	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Absent						
American Indian or Alaska Native	0	5,211	0.0	-	0	N/A
Asian	2	27,334	2.3	1.1	0	0.0
Black or African American	31	132,973	97.2	3.1	0	0.0
Native Hawaiian or Other Pacific Islander	1	8,756	2.9	2.9	0	0.0
Unknown	346	3,670,194	763.6	2.2	0	0.0
White	25	297,873	103.5	4.1	0	0.0
Hearing Loss: Present, Clinical Characteristics: Absent						
American Indian or Alaska Native	0	38	0.0	-	0	N/A
Asian	1	219	3.8	3.8	0	0.0
Black or African American	0	492	0.0	.	0	N/A
Native Hawaiian or Other Pacific Islander	1	164	3.0	3.0	0	0.0
Unknown	34	22,827	62.7	1.8	0	0.0
White	2	1,489	10.1	5.1	0	0.0

Table 5. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race^{1,2}

Race	New Users	Eligible Members ³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
American Indian or Alaska Native	0	2,218	0.0	-	0	N/A
Asian	10	22,167	24.0	2.4	0	0.0
Black or African American	50	33,338	150.2	3.0	0	0.0
Native Hawaiian or Other Pacific Islander	4	8,133	12.3	3.1	0	0.0
Unknown	840	1,611,463	1,666.2	2.0	0	0.0
White	59	134,821	227.9	3.9	0	0.0
Hearing Loss: Present, Clinical Characteristics: Present						
American Indian or Alaska Native	0	20	0.0	-	0	N/A
Asian	0	237	0.0	-	0	N/A
Black or African American	5	285	14.4	2.9	0	0.0
Native Hawaiian or Other Pacific Islander	2	159	10.1	5.0	0	0.0
Unknown	80	13,966	182.2	2.3	0	0.0
White	7	933	32.0	4.6	0	0.0
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
American Indian or Alaska Native	0	7,426	0.0	-	0	N/A
Asian	13	49,380	5.7	0.4	1	769.2
Black or African American	86	166,054	29.0	0.3	24	2,790.7
Native Hawaiian or Other Pacific Islander	8	16,909	2.7	0.3	3	3,750.0
Unknown	1,296	5,275,903	436.6	0.3	240	1,851.9
White	93	431,750	32.8	0.4	27	2,903.2

Table 5. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race^{1,2}

Race	New Users	Eligible Members ³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Absent						
American Indian or Alaska Native	0	5,211	0.0	-	0	N/A
Asian	2	27,334	1.0	0.5	0	0.0
Black or African American	31	132,973	12.5	0.4	5	1,612.9
Native Hawaiian or Other Pacific Islander	1	8,756	0.1	0.1	1	10,000.0
Unknown	346	3,670,194	129.1	0.4	30	867.1
White	25	297,873	9.9	0.4	3	1,200.0
Hearing Loss: Present, Clinical Characteristics: Absent						
American Indian or Alaska Native	0	38	0.0	-	0	N/A
Asian	1	219	0.1	0.1	1	10,000.0
Black or African American	0	492	0.0	.	0	N/A
Native Hawaiian or Other Pacific Islander	1	164	0.1	0.1	1	10,000.0
Unknown	34	22,827	10.0	0.3	8	2,352.9
White	2	1,489	0.6	0.3	1	5,000.0
Hearing Loss: Absent, Clinical Characteristics: Present						
American Indian or Alaska Native	0	2,218	0.0	-	0	N/A
Asian	10	22,167	4.6	0.5	0	0.0
Black or African American	50	33,338	15.5	0.3	16	3,200.0
Native Hawaiian or Other Pacific Islander	4	8,133	1.9	0.5	0	0.0
Unknown	837	1,611,463	277.5	0.3	165	1,971.3
White	59	134,821	21.0	0.4	18	3,050.8

Table 5. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race^{1,2}

Race	New Users	Eligible Members ³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
American Indian or Alaska Native	0	20	0.0	-	0	N/A
Asian	0	237	0.0	-	0	N/A
Black or African American	5	285	0.9	0.2	3	6,000.0
Native Hawaiian or Other Pacific Islander	2	159	0.5	0.3	1	5,000.0
Unknown	79	13,966	20.0	0.3	37	4,683.5
White	7	933	1.3	0.2	5	7,142.9
Treatment Within 45 Days from Diagnosis						
American Indian or Alaska Native	0	0	0.0	-	0	N/A
Asian	1	2	3.8	3.8	0	0.0
Black or African American	15	18	44.8	3.0	0	0.0
Native Hawaiian or Other Pacific Islander	2	3	3.0	1.5	0	0.0
Unknown	185	227	352.7	1.9	0	0.0
White	18	25	64.6	3.6	0	0.0
Treatment Within 180 Days from Diagnosis						
American Indian or Alaska Native	0	0	0.0	-	0	N/A
Asian	1	3	3.8	3.8	0	0.0
Black or African American	24	29	72.9	3.0	0	0.0
Native Hawaiian or Other Pacific Islander	3	6	5.9	2.0	0	0.0
Unknown	246	394	497.1	2.0	0	0.0
White	27	42	98.0	3.6	0	0.0

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

²Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

³Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 6. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin¹

Hispanic Origin	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
Yes	12	56,193	31.7	2.6	0	0.0
No	151	543,509	583.9	3.9	0	0.0
Unknown	1,337	5,347,720	2,752.7	2.1	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Absent						
Yes	3	36,210	13.7	4.6	0	0.0
No	50	381,403	182.0	3.6	0	0.0
Unknown	352	3,724,728	773.7	2.2	0	0.0
Hearing Loss: Present, Clinical Characteristics: Absent						
Yes	0	228	0.0	-	0	N/A
No	4	1,872	16.9	4.2	0	0.0
Unknown	34	23,129	62.7	1.8	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Present						
Yes	7	20,040	15.4	2.2	0	0.0
No	89	163,195	338.9	3.8	0	0.0
Unknown	867	1,628,905	1,726.4	2.0	0	0.0
Hearing Loss: Present, Clinical Characteristics: Present						
Yes	2	175	2.6	1.3	0	0.0
No	8	1,270	46.1	5.8	0	0.0
Unknown	84	14,155	189.9	2.3	0	0.0
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
Yes	12	56,193	5.0	0.4	2	1,666.7
No	151	543,509	54.2	0.4	43	2,847.7
Unknown	1,333	5,347,720	447.5	0.3	250	1,875.5
Hearing Loss: Absent, Clinical Characteristics: Absent						
Yes	3	36,210	1.0	0.3	1	3,333.3
No	50	381,403	20.0	0.4	8	1,600.0
Unknown	352	3,724,728	131.6	0.4	30	852.3

Table 6. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin¹

Hispanic Origin	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Absent						
Yes	0	228	0.0	-	0	N/A
No	4	1,872	0.8	0.2	3	7,500.0
Unknown	34	23,129	10.0	0.3	8	2,352.9
Hearing Loss: Absent, Clinical Characteristics: Present						
Yes	7	20,040	3.4	0.5	0	0.0
No	89	163,195	31.4	0.4	27	3,033.7
Unknown	864	1,628,905	285.7	0.3	172	1,990.7
Hearing Loss: Present, Clinical Characteristics: Present						
Yes	2	175	0.5	0.3	1	5,000.0
No	8	1,270	2.0	0.3	5	6,250.0
Unknown	83	14,155	20.2	0.2	40	4,819.3
Treatment Within 45 Days from Diagnosis						
Yes	2	3	3.9	2.0	0	0.0
No	27	37	85.5	3.2	0	0.0
Unknown	192	235	379.4	2.0	0	0.0
Treatment Within 180 Days from Diagnosis						
Yes	2	4	3.9	2.0	0	0.0
No	43	62	138.3	3.2	0	0.0
Unknown	256	408	535.4	2.1	0	0.0

¹Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

²Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 7. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
Midwest	317	1,273,190	581.6	1.8	0	0.0
Northeast	177	706,647	325.0	1.8	0	0.0
South	753	2,558,253	1,904.4	2.5	0	0.0
West	233	1,247,290	517.4	2.2	0	0.0
Invalid	8	53,261	32.2	4.0	0	0.0
Missing	12	107,992	7.8	0.7	0	0.0
Other	0	789	0.0	-	0	N/A
Hearing Loss: Absent, Clinical Characteristics: Absent						
Midwest	70	855,895	144.6	2.1	0	0.0
Northeast	58	535,728	98.0	1.7	0	0.0
South	211	1,758,587	587.0	2.8	0	0.0
West	58	862,030	118.1	2.0	0	0.0
Invalid	2	42,226	16.1	8.1	0	0.0
Missing	6	87,215	5.5	0.9	0	0.0
Other	0	660	0.0	-	0	N/A
Hearing Loss: Present, Clinical Characteristics: Absent						
Midwest	6	5,158	12.1	2.0	0	0.0
Northeast	13	4,168	27.2	2.1	0	0.0
South	13	10,931	22.2	1.7	0	0.0
West	6	4,428	18.1	3.0	0	0.0
Invalid	0	95	0.0	-	0	N/A
Missing	0	449	0.0	-	0	N/A
Other	0	0	0.0	-	0	N/A
Hearing Loss: Absent, Clinical Characteristics: Present						
Midwest	219	419,446	369.7	1.7	0	0.0
Northeast	95	171,214	180.0	1.9	0	0.0
South	497	801,964	1,205.8	2.4	0	0.0
West	143	387,339	308.1	2.2	0	0.0
Invalid	6	11,105	16.0	2.7	0	0.0
Missing	3	20,933	1.1	0.4	0	0.0
Other	0	139	0.0	-	0	N/A

Table 7. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
Midwest	22	3,168	55.2	2.5	0	0.0
Northeast	11	2,035	19.7	1.8	0	0.0
South	32	6,963	89.4	2.8	0	0.0
West	26	3,167	73.1	2.8	0	0.0
Invalid	0	67	0.0	-	0	N/A
Missing	3	199	1.2	0.4	0	0.0
Other	0	1	0.0	-	0	N/A
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
Midwest	317	1,273,190	104.2	0.3	70	2,208.2
Northeast	176	706,647	60.3	0.3	31	1,761.4
South	752	2,558,253	255.2	0.3	152	2,021.3
West	231	1,247,290	80.8	0.3	40	1,731.6
Invalid	8	53,261	3.3	0.4	0	0.0
Missing	12	107,992	2.9	0.2	2	1,666.7
Other	0	789	0.0	-	0	N/A
Hearing Loss: Absent, Clinical Characteristics: Absent						
Midwest	70	855,895	28.3	0.4	4	571.4
Northeast	58	535,728	19.6	0.3	4	689.7
South	211	1,758,587	82.9	0.4	22	1,042.7
West	58	862,030	19.5	0.3	9	1,551.7
Invalid	2	42,226	1.0	0.5	0	0.0
Missing	6	87,215	1.4	0.2	0	0.0
Other	0	660	0.0	-	0	N/A
Hearing Loss: Present, Clinical Characteristics: Absent						
Midwest	6	5,158	1.6	0.3	3	5,000.0
Northeast	13	4,168	4.2	0.3	1	769.2
South	13	10,931	3.3	0.3	5	3,846.2
West	6	4,428	1.7	0.3	2	3,333.3
Invalid	0	95	0.0	-	0	N/A
Missing	0	449	0.0	-	0	N/A
Other	0	0	0.0	-	0	N/A

Table 7. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
Midwest	219	419,446	69.9	0.3	50	2,283.1
Northeast	94	171,214	34.5	0.4	18	1,914.9
South	496	801,964	161.0	0.3	109	2,197.6
West	142	387,339	52.0	0.4	21	1,478.9
Invalid	6	11,105	2.3	0.4	0	0.0
Missing	3	20,933	0.8	0.3	1	3,333.3
Other	0	139	0.0	-	0	N/A
Hearing Loss: Present, Clinical Characteristics: Present						
Midwest	22	3,168	4.5	0.2	13	5,909.1
Northeast	11	2,035	1.9	0.2	8	7,272.7
South	32	6,963	8.0	0.2	16	5,000.0
West	25	3,167	7.7	0.3	8	3,200.0
Invalid	0	67	0.0	-	0	N/A
Missing	3	199	0.7	0.2	1	3,333.3
Other	0	1	0.0	-	0	N/A
Treatment Within 45 Days from Diagnosis						
Midwest	55	68	104.3	1.9	0	0.0
Northeast	24	31	37.2	1.6	0	0.0
South	103	129	233.4	2.3	0	0.0
West	37	45	93.6	2.5	0	0.0
Invalid	0	0	0.0	-	0	N/A
Missing	2	2	0.3	0.1	0	0.0
Other	0	0	0.0	-	0	N/A
Treatment Within 180 Days from Diagnosis						
Midwest	70	108	139.8	2.0	0	0.0
Northeast	33	53	52.4	1.6	0	0.0
South	154	229	380.0	2.5	0	0.0
West	42	80	105.2	2.5	0	0.0
Invalid	0	1	0.0	-	0	N/A
Missing	2	3	0.3	0.1	0	0.0
Other	0	0	0.0	-	0	N/A

¹Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

²Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
Female						
2008	49	270,320	127.2	2.6	0	0.0
2009	40	255,371	141.3	3.5	0	0.0
2010	53	226,069	187.3	3.5	0	0.0
2011	41	213,394	117.2	2.9	0	0.0
2012	35	206,077	104.4	3.0	0	0.0
2013	43	235,352	127.3	3.0	0	0.0
2014	53	245,651	117.7	2.2	0	0.0
2015	55	252,935	133.1	2.4	0	0.0
2016	72	260,661	146.9	2.0	0	0.0
2017	74	253,871	139.6	1.9	0	0.0
2018	59	246,015	96.8	1.6	0	0.0
2019	68	233,144	66.2	1.0	0	0.0
2020	46	196,004	19.5	0.4	0	0.0
2021	3	25,529	0.3	0.1	0	0.0
Male						
2008	52	286,920	181.3	3.5	0	0.0
2009	49	270,695	126.1	2.6	0	0.0
2010	53	239,905	174.9	3.3	0	0.0
2011	38	226,948	144.3	3.8	0	0.0
2012	46	219,041	141.8	3.1	0	0.0
2013	53	249,897	139.6	2.6	0	0.0
2014	69	259,530	210.7	3.1	0	0.0
2015	64	267,673	160.3	2.5	0	0.0
2016	75	275,104	169.4	2.3	0	0.0
2017	90	267,436	169.7	1.9	0	0.0
2018	80	258,023	110.2	1.4	0	0.0
2019	81	245,601	86.0	1.1	0	0.0
2020	48	206,620	27.6	0.6	0	0.0
2021	11	26,884	1.8	0.2	0	0.0

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Absent						
Female						
2008	18	196,697	44.8	2.5	0	0.0
2009	16	180,926	58.0	3.6	0	0.0
2010	19	159,515	84.0	4.4	0	0.0
2011	22	151,993	60.6	2.8	0	0.0
2012	8	147,409	26.6	3.3	0	0.0
2013	15	168,487	51.7	3.4	0	0.0
2014	14	174,650	36.2	2.6	0	0.0
2015	14	179,259	39.9	2.9	0	0.0
2016	22	182,250	46.1	2.1	0	0.0
2017	20	174,957	35.0	1.7	0	0.0
2018	17	168,197	23.3	1.4	0	0.0
2019	16	158,708	15.5	1.0	0	0.0
2020	14	132,363	6.9	0.5	0	0.0
2021	1	17,940	0.0	0.0	0	0.0
Male						
2008	17	203,961	75.0	4.4	0	0.0
2009	13	186,957	34.1	2.6	0	0.0
2010	16	164,666	35.7	2.2	0	0.0
2011	9	157,489	32.5	3.6	0	0.0
2012	7	152,182	16.6	2.4	0	0.0
2013	14	174,820	43.9	3.1	0	0.0
2014	21	179,532	50.4	2.4	0	0.0
2015	10	185,362	17.4	1.7	0	0.0
2016	14	187,442	37.9	2.7	0	0.0
2017	18	179,435	46.0	2.6	0	0.0
2018	12	171,390	23.3	1.9	0	0.0
2019	22	163,170	20.2	0.9	0	0.0
2020	12	136,280	7.3	0.6	0	0.0
2021	4	18,361	0.5	0.1	0	0.0

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Absent						
Female						
2008	0	1,358	0.0	-	0	N/A
2009	2	1,208	12.3	6.2	0	0.0
2010	2	1,103	10.4	5.2	0	0.0
2011	0	1,024	0.0	-	0	N/A
2012	1	881	6.3	6.3	0	0.0
2013	0	969	0.0	-	0	N/A
2014	1	1,076	0.0	0.0	0	0.0
2015	2	928	6.0	3.0	0	0.0
2016	2	828	2.4	1.2	0	0.0
2017	1	754	0.3	0.3	0	0.0
2018	5	731	9.4	1.9	0	0.0
2019	1	671	0.3	0.3	0	0.0
2020	2	588	0.7	0.4	0	0.0
2021	0	53	0.0	-	0	N/A
Male						
2008	0	1,607	0.0	-	0	N/A
2009	1	1,453	1.1	1.1	0	0.0
2010	1	1,254	0.8	0.8	0	0.0
2011	0	1,193	0.0	-	0	N/A
2012	3	1,076	3.1	1.0	0	0.0
2013	2	1,177	10.6	5.3	0	0.0
2014	0	1,229	0.0	-	0	N/A
2015	0	1,165	0.0	-	0	N/A
2016	1	1,011	1.9	1.9	0	0.0
2017	5	931	11.7	2.3	0	0.0
2018	2	894	0.7	0.3	0	0.0
2019	2	789	0.3	0.2	0	0.0
2020	2	725	1.2	0.6	0	0.0
2021	0	78	0.0	-	0	N/A

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
Female						
2008	29	73,191	70.1	2.4	0	0.0
2009	19	74,195	60.4	3.2	0	0.0
2010	28	66,332	83.1	3.0	0	0.0
2011	17	61,309	52.9	3.1	0	0.0
2012	26	58,669	71.5	2.8	0	0.0
2013	27	66,917	74.4	2.8	0	0.0
2014	33	70,923	64.8	2.0	0	0.0
2015	35	73,848	76.2	2.2	0	0.0
2016	42	78,596	88.9	2.1	0	0.0
2017	51	79,178	99.9	2.0	0	0.0
2018	36	78,124	61.2	1.7	0	0.0
2019	46	74,775	44.6	1.0	0	0.0
2020	25	63,886	11.1	0.4	0	0.0
2021	2	7,605	0.3	0.2	0	0.0
Male						
2008	30	82,788	82.7	2.8	0	0.0
2009	30	83,690	69.3	2.3	0	0.0
2010	31	75,388	135.2	4.4	0	0.0
2011	27	69,533	101.8	3.8	0	0.0
2012	34	67,061	112.7	3.3	0	0.0
2013	35	75,399	84.4	2.4	0	0.0
2014	45	80,185	140.1	3.1	0	0.0
2015	46	82,730	118.3	2.6	0	0.0
2016	58	88,209	120.3	2.1	0	0.0
2017	64	88,560	102.3	1.6	0	0.0
2018	60	87,127	79.6	1.3	0	0.0
2019	49	83,052	55.2	1.1	0	0.0
2020	33	70,868	18.7	0.6	0	0.0
2021	5	8,567	0.8	0.2	0	0.0

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
Female						
2008	2	807	12.2	6.1	0	0.0
2009	3	740	10.6	3.5	0	0.0
2010	4	650	9.8	2.4	0	0.0
2011	2	594	3.7	1.8	0	0.0
2012	0	592	0.0	-	0	N/A
2013	1	585	1.3	1.3	0	0.0
2014	5	646	16.6	3.3	0	0.0
2015	4	542	10.9	2.7	0	0.0
2016	6	482	9.5	1.6	0	0.0
2017	2	509	4.5	2.3	0	0.0
2018	1	430	2.9	2.9	0	0.0
2019	5	415	5.8	1.2	0	0.0
2020	5	350	0.8	0.2	0	0.0
2021	0	43	0.0	-	0	N/A
Male						
2008	5	970	23.7	4.7	0	0.0
2009	5	920	21.5	4.3	0	0.0
2010	5	784	3.2	0.6	0	0.0
2011	2	729	10.0	5.0	0	0.0
2012	2	707	9.4	4.7	0	0.0
2013	2	676	0.7	0.3	0	0.0
2014	3	780	20.2	6.7	0	0.0
2015	8	715	24.6	3.1	0	0.0
2016	2	656	9.2	4.6	0	0.0
2017	3	630	9.7	3.2	0	0.0
2018	6	625	6.6	1.1	0	0.0
2019	8	542	10.4	1.3	0	0.0
2020	1	431	0.3	0.3	0	0.0
2021	2	48	0.6	0.3	0	0.0

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
Female						
2008	49	270,320	17.6	0.4	3	612.2
2009	40	255,371	15.4	0.4	3	750.0
2010	53	226,069	21.1	0.4	2	377.4
2011	41	213,394	16.8	0.4	3	731.7
2012	34	206,077	14.2	0.4	2	588.2
2013	43	235,352	14.6	0.3	8	1,860.5
2014	53	245,651	16.6	0.3	12	2,264.2
2015	54	252,935	15.8	0.3	18	3,333.3
2016	71	260,661	20.5	0.3	18	2,535.2
2017	74	253,871	25.8	0.3	16	2,162.2
2018	59	246,015	18.9	0.3	20	3,389.8
2019	68	233,144	20.6	0.3	21	3,088.2
2020	46	196,004	10.9	0.2	11	2,391.3
2021	3	25,529	0.3	0.1	0	0.0
Male						
2008	52	286,920	20.8	0.4	4	769.2
2009	49	270,695	20.8	0.4	1	204.1
2010	53	239,905	22.7	0.4	3	566.0
2011	38	226,948	14.0	0.4	8	2,105.3
2012	46	219,041	16.4	0.4	8	1,739.1
2013	53	249,897	19.5	0.4	7	1,320.8
2014	69	259,530	25.3	0.4	11	1,594.2
2015	64	267,673	21.1	0.3	16	2,500.0
2016	74	275,104	22.9	0.3	24	3,243.2
2017	90	267,436	27.6	0.3	27	3,000.0
2018	80	258,023	26.2	0.3	12	1,500.0
2019	81	245,601	25.7	0.3	18	2,222.2
2020	48	206,620	13.2	0.3	16	3,333.3
2021	11	26,884	1.3	0.1	3	2,727.3

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Absent						
Female						
2008	18	196,697	5.7	0.3	0	0.0
2009	16	180,926	6.2	0.4	0	0.0
2010	19	159,515	7.7	0.4	0	0.0
2011	22	151,993	9.2	0.4	2	909.1
2012	8	147,409	3.7	0.5	0	0.0
2013	15	168,487	5.7	0.4	1	666.7
2014	14	174,650	5.3	0.4	0	0.0
2015	14	179,259	5.7	0.4	1	714.3
2016	22	182,250	8.3	0.4	2	909.1
2017	20	174,957	7.6	0.4	2	1,000.0
2018	17	168,197	5.5	0.3	4	2,352.9
2019	16	158,708	6.8	0.4	0	0.0
2020	14	132,363	3.6	0.3	3	2,142.9
2021	1	17,940	0.0	0.0	0	0.0
Male						
2008	17	203,961	6.5	0.4	1	588.2
2009	13	186,957	5.2	0.4	0	0.0
2010	16	164,666	6.7	0.4	0	0.0
2011	9	157,489	2.7	0.3	3	3,333.3
2012	7	152,182	2.7	0.4	0	0.0
2013	14	174,820	4.8	0.3	3	2,142.9
2014	21	179,532	9.4	0.4	0	0.0
2015	10	185,362	4.5	0.5	0	0.0
2016	14	187,442	5.7	0.4	3	2,142.9
2017	18	179,435	6.4	0.4	4	2,222.2
2018	12	171,390	5.2	0.4	0	0.0
2019	22	163,170	8.0	0.4	5	2,272.7
2020	12	136,280	3.4	0.3	4	3,333.3
2021	4	18,361	0.3	0.1	1	2,500.0

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Absent						
Female						
2008	0	1,358	0.0	-	0	N/A
2009	2	1,208	0.7	0.4	0	0.0
2010	2	1,103	1.0	0.5	0	0.0
2011	0	1,024	0.0	-	0	N/A
2012	1	881	0.5	0.5	0	0.0
2013	0	969	0.0	-	0	N/A
2014	1	1,076	0.0	0.0	0	0.0
2015	2	928	0.3	0.2	1	5,000.0
2016	2	828	0.5	0.3	1	5,000.0
2017	1	754	0.0	0.0	1	10,000.0
2018	5	731	2.1	0.4	1	2,000.0
2019	1	671	0.3	0.3	0	0.0
2020	2	588	0.0	0.0	1	5,000.0
2021	0	53	0.0	-	0	N/A
Male						
2008	0	1,607	0.0	-	0	N/A
2009	1	1,453	0.5	0.5	0	0.0
2010	1	1,254	0.5	0.5	0	0.0
2011	0	1,193	0.0	-	0	N/A
2012	3	1,076	1.5	0.5	0	0.0
2013	2	1,177	0.6	0.3	1	5,000.0
2014	0	1,229	0.0	-	0	N/A
2015	0	1,165	0.0	-	0	N/A
2016	1	1,011	0.1	0.1	1	10,000.0
2017	5	931	1.2	0.2	2	4,000.0
2018	2	894	0.1	0.1	1	5,000.0
2019	2	789	0.3	0.2	0	0.0
2020	2	725	0.5	0.2	1	5,000.0
2021	0	78	0.0	-	0	N/A

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
Female						
2008	29	73,191	10.9	0.4	3	1,034.5
2009	19	74,195	7.7	0.4	3	1,578.9
2010	28	66,332	10.4	0.4	2	714.3
2011	17	61,309	7.0	0.4	0	0.0
2012	25	58,669	10.1	0.4	2	800.0
2013	27	66,917	8.4	0.3	7	2,592.6
2014	33	70,923	10.3	0.3	8	2,424.2
2015	34	73,848	9.0	0.3	13	3,823.5
2016	41	78,596	11.0	0.3	11	2,682.9
2017	51	79,178	18.1	0.4	11	2,156.9
2018	36	78,124	10.8	0.3	15	4,166.7
2019	46	74,775	12.8	0.3	17	3,695.7
2020	25	63,886	6.5	0.3	5	2,000.0
2021	2	7,605	0.3	0.2	0	0.0
Male						
2008	30	82,788	12.3	0.4	2	666.7
2009	30	83,690	12.9	0.4	0	0.0
2010	31	75,388	13.2	0.4	3	967.7
2011	27	69,533	10.4	0.4	5	1,851.9
2012	34	67,061	12.1	0.4	6	1,764.7
2013	35	75,399	13.7	0.4	2	571.4
2014	45	80,185	15.7	0.3	8	1,777.8
2015	46	82,730	14.4	0.3	13	2,826.1
2016	58	88,209	17.0	0.3	19	3,275.9
2017	64	88,560	19.7	0.3	18	2,812.5
2018	60	87,127	19.6	0.3	7	1,166.7
2019	49	83,052	16.5	0.3	7	1,428.6
2020	33	70,868	9.3	0.3	10	3,030.3
2021	5	8,567	0.5	0.1	2	4,000.0

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
Female						
2008	2	807	1.0	0.5	0	0.0
2009	3	740	0.9	0.3	0	0.0
2010	4	650	2.0	0.5	0	0.0
2011	2	594	0.6	0.3	1	5,000.0
2012	0	592	0.0	-	0	N/A
2013	1	585	0.5	0.5	0	0.0
2014	5	646	0.9	0.2	4	8,000.0
2015	4	542	0.7	0.2	3	7,500.0
2016	6	482	0.7	0.1	4	6,666.7
2017	2	509	0.1	0.0	2	10,000.0
2018	1	430	0.5	0.5	0	0.0
2019	5	415	0.7	0.1	4	8,000.0
2020	5	350	0.7	0.1	2	4,000.0
2021	0	43	0.0	-	0	N/A
Male						
2008	5	970	2.0	0.4	1	2,000.0
2009	5	920	2.3	0.5	1	2,000.0
2010	5	784	2.3	0.5	0	0.0
2011	2	729	0.8	0.4	0	0.0
2012	2	707	0.1	0.1	2	10,000.0
2013	2	676	0.4	0.2	1	5,000.0
2014	3	780	0.2	0.1	3	10,000.0
2015	8	715	2.3	0.3	3	3,750.0
2016	1	656	0.1	0.1	1	10,000.0
2017	3	630	0.4	0.1	3	10,000.0
2018	6	625	1.2	0.2	4	6,666.7
2019	8	542	0.9	0.1	6	7,500.0
2020	1	431	0.0	0.0	1	10,000.0
2021	2	48	0.6	0.3	0	0.0

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Treatment Within 45 Days Diagnosis						
Female						
2008	1	1	10.6	10.6	0	0.0
2009	1	2	0.4	0.4	0	0.0
2010	1	1	2.7	2.7	0	0.0
2011	2	3	10.5	5.3	0	0.0
2012	3	4	9.7	3.2	0	0.0
2013	7	10	21.6	3.1	0	0.0
2014	8	11	19.3	2.4	0	0.0
2015	15	19	29.0	1.9	0	0.0
2016	15	19	43.3	2.9	0	0.0
2017	10	15	17.6	1.8	0	0.0
2018	15	17	21.0	1.4	0	0.0
2019	17	25	17.5	1.0	0	0.0
2020	10	11	5.9	0.6	0	0.0
2021	0	0	0.0	-	0	N/A
Male						
2008	1	2	11.1	11.1	0	0.0
2009	0	2	0.0	-	0	N/A
2010	2	3	4.9	2.5	0	0.0
2011	3	5	14.2	4.7	0	0.0
2012	8	8	24.7	3.1	0	0.0
2013	4	5	5.6	1.4	0	0.0
2014	8	8	25.7	3.2	0	0.0
2015	13	18	47.3	3.6	0	0.0
2016	17	21	45.3	2.7	0	0.0
2017	20	25	40.6	2.0	0	0.0
2018	10	11	15.5	1.6	0	0.0
2019	14	19	16.6	1.2	0	0.0
2020	13	16	7.7	0.6	0	0.0
2021	3	3	0.7	0.2	0	0.0

Table 8. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Treatment Within 180 Days Diagnosis						
Female						
2008	3	6	13.0	4.3	0	0.0
2009	3	4	15.2	5.1	0	0.0
2010	2	8	2.9	1.4	0	0.0
2011	3	6	11.3	3.8	0	0.0
2012	3	7	9.7	3.2	0	0.0
2013	8	17	22.0	2.7	0	0.0
2014	13	22	32.8	2.5	0	0.0
2015	19	29	42.8	2.3	0	0.0
2016	20	30	56.2	2.8	0	0.0
2017	16	31	31.7	2.0	0	0.0
2018	20	27	32.2	1.6	0	0.0
2019	21	37	21.9	1.0	0	0.0
2020	11	15	6.8	0.6	0	0.0
2021	0	0	0.0	-	0	N/A
Male						
2008	4	8	25.1	6.3	0	0.0
2009	1	9	0.6	0.6	0	0.0
2010	3	9	15.6	5.2	0	0.0
2011	8	11	33.6	4.2	0	0.0
2012	8	12	24.7	3.1	0	0.0
2013	7	10	8.4	1.2	0	0.0
2014	11	17	40.5	3.7	0	0.0
2015	16	28	56.3	3.5	0	0.0
2016	25	37	66.7	2.7	0	0.0
2017	27	38	57.8	2.1	0	0.0
2018	12	18	18.1	1.5	0	0.0
2019	18	29	21.1	1.2	0	0.0
2020	16	22	9.9	0.6	0	0.0
2021	3	3	0.7	0.2	0	0.0

¹Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

²Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
Midwest						
2008	20	112,555	41.7	2.1	0	0.0
2009	22	109,119	46.7	2.1	0	0.0
2010	16	100,340	27.4	1.7	0	0.0
2011	9	95,988	37.3	4.1	0	0.0
2012	16	93,947	42.4	2.7	0	0.0
2013	13	107,953	11.8	0.9	0	0.0
2014	27	108,780	54.2	2.0	0	0.0
2015	19	109,059	47.4	2.5	0	0.0
2016	32	111,682	82.8	2.6	0	0.0
2017	41	111,297	66.2	1.6	0	0.0
2018	33	108,977	53.1	1.6	0	0.0
2019	45	101,430	58.3	1.3	0	0.0
2020	22	95,403	12.1	0.5	0	0.0
2021	2	12,595	0.3	0.1	0	0.0
Northeast						
2008	10	60,076	36.5	3.6	0	0.0
2009	8	58,909	18.8	2.3	0	0.0
2010	11	55,832	33.0	3.0	0	0.0
2011	6	52,013	6.9	1.2	0	0.0
2012	13	49,620	32.9	2.5	0	0.0
2013	7	58,366	7.3	1.0	0	0.0
2014	17	62,169	36.0	2.1	0	0.0
2015	12	63,479	33.5	2.8	0	0.0
2016	19	64,064	29.9	1.6	0	0.0
2017	15	60,949	31.4	2.1	0	0.0
2018	21	58,656	28.0	1.3	0	0.0
2019	23	54,551	24.8	1.1	0	0.0
2020	13	51,789	5.9	0.5	0	0.0
2021	2	5,374	0.2	0.1	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
South						
2008	50	229,847	168.3	3.4	0	0.0
2009	42	221,723	153.6	3.7	0	0.0
2010	62	205,828	264.8	4.3	0	0.0
2011	55	194,561	194.2	3.5	0	0.0
2012	40	186,680	135.2	3.4	0	0.0
2013	54	207,348	176.2	3.3	0	0.0
2014	56	217,742	170.8	3.1	0	0.0
2015	63	231,296	151.3	2.4	0	0.0
2016	72	239,429	155.1	2.2	0	0.0
2017	84	234,122	168.1	2.0	0	0.0
2018	68	225,990	97.3	1.4	0	0.0
2019	67	215,567	52.5	0.8	0	0.0
2020	34	151,653	16.2	0.5	0	0.0
2021	6	16,815	0.7	0.1	0	0.0
West						
2008	16	96,392	48.4	3.0	0	0.0
2009	12	97,673	36.8	3.1	0	0.0
2010	16	97,904	36.8	2.3	0	0.0
2011	9	92,824	23.1	2.6	0	0.0
2012	12	90,078	35.6	3.0	0	0.0
2013	22	106,168	71.5	3.2	0	0.0
2014	21	110,038	62.7	3.0	0	0.0
2015	25	110,126	61.3	2.5	0	0.0
2016	23	112,879	47.8	2.1	0	0.0
2017	22	107,896	38.1	1.7	0	0.0
2018	16	103,401	25.5	1.6	0	0.0
2019	14	100,793	16.6	1.2	0	0.0
2020	23	97,239	12.7	0.6	0	0.0
2021	2	14,198	0.6	0.3	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Invalid						
2008	1	4,840	13.0	13.0	0	0.0
2009	2	4,796	10.1	5.1	0	0.0
2010	1	4,510	0.3	0.3	0	0.0
2011	0	3,547	0.0	-	0	N/A
2012	0	3,460	0.0	-	0	N/A
2013	0	3,288	0.0	-	0	N/A
2014	0	4,062	0.0	-	0	N/A
2015	0	4,190	0.0	-	0	N/A
2016	0	5,433	0.0	-	0	N/A
2017	2	5,065	5.5	2.8	0	0.0
2018	1	5,292	3.0	3.0	0	0.0
2019	0	5,043	0.0	-	0	N/A
2020	1	3,938	0.2	0.2	0	0.0
2021	0	268	0.0	-	0	N/A
Missing						
2008	4	53,519	0.7	0.2	0	0.0
2009	3	33,848	1.3	0.4	0	0.0
2010	0	1,531	0.0	-	0	N/A
2011	0	1,398	0.0	-	0	N/A
2012	0	1,345	0.0	-	0	N/A
2013	0	2,116	0.0	-	0	N/A
2014	1	2,400	4.7	4.7	0	0.0
2015	0	2,459	0.0	-	0	N/A
2016	1	2,310	0.7	0.7	0	0.0
2017	0	1,994	0.0	-	0	N/A
2018	0	1,715	0.0	-	0	N/A
2019	0	1,331	0.0	-	0	N/A
2020	1	2,460	0.1	0.1	0	0.0
2021	2	3,169	0.4	0.2	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Other						
2008	0	59	0.0	-	0	N/A
2009	0	46	0.0	-	0	N/A
2010	0	61	0.0	-	0	N/A
2011	0	31	0.0	-	0	N/A
2012	0	31	0.0	-	0	N/A
2013	0	45	0.0	-	0	N/A
2014	0	41	0.0	-	0	N/A
2015	0	38	0.0	-	0	N/A
2016	0	38	0.0	-	0	N/A
2017	0	36	0.0	-	0	N/A
2018	0	49	0.0	-	0	N/A
2019	0	118	0.0	-	0	N/A
2020	0	233	0.0	-	0	N/A
2021	0	1	0.0	-	0	N/A
Hearing Loss: Absent, Clinical Characteristics: Absent						
Midwest						
2008	3	75,883	10.1	3.4	0	0.0
2009	5	71,967	15.4	3.1	0	0.0
2010	5	66,445	4.3	0.9	0	0.0
2011	3	64,687	14.8	4.9	0	0.0
2012	2	64,129	2.2	1.1	0	0.0
2013	3	74,091	0.7	0.2	0	0.0
2014	6	74,604	19.5	3.3	0	0.0
2015	3	74,177	7.2	2.4	0	0.0
2016	8	75,246	22.6	2.8	0	0.0
2017	7	73,692	14.1	2.0	0	0.0
2018	12	71,736	24.3	2.0	0	0.0
2019	10	65,509	7.9	0.8	0	0.0
2020	3	62,395	1.3	0.4	0	0.0
2021	0	8,873	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Northeast						
2008	5	47,120	22.7	4.5	0	0.0
2009	3	45,351	13.5	4.5	0	0.0
2010	6	42,962	15.8	2.6	0	0.0
2011	4	40,056	2.3	0.6	0	0.0
2012	2	38,210	0.4	0.2	0	0.0
2013	3	44,768	1.5	0.5	0	0.0
2014	6	47,391	7.2	1.2	0	0.0
2015	6	48,438	13.4	2.2	0	0.0
2016	6	48,026	8.1	1.4	0	0.0
2017	3	44,794	4.2	1.4	0	0.0
2018	4	42,642	3.1	0.8	0	0.0
2019	3	39,445	3.0	1.0	0	0.0
2020	5	37,681	2.5	0.5	0	0.0
2021	2	4,006	0.2	0.1	0	0.0
South						
2008	14	162,263	59.8	4.3	0	0.0
2009	18	152,148	46.5	2.6	0	0.0
2010	22	142,054	98.7	4.5	0	0.0
2011	22	136,890	73.0	3.3	0	0.0
2012	10	131,490	38.9	3.9	0	0.0
2013	17	145,383	67.4	4.0	0	0.0
2014	14	150,280	41.0	2.9	0	0.0
2015	12	159,237	34.3	2.9	0	0.0
2016	15	162,608	33.0	2.2	0	0.0
2017	23	157,293	55.1	2.4	0	0.0
2018	10	150,582	13.1	1.3	0	0.0
2019	21	145,932	19.2	0.9	0	0.0
2020	10	98,170	6.8	0.7	0	0.0
2021	3	11,276	0.3	0.1	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
West						
2008	8	67,820	13.5	1.7	0	0.0
2009	2	67,738	16.5	8.3	0	0.0
2010	2	68,054	0.8	0.4	0	0.0
2011	2	63,998	3.0	1.5	0	0.0
2012	1	61,981	1.7	1.7	0	0.0
2013	6	74,891	25.9	4.3	0	0.0
2014	8	76,776	14.3	1.8	0	0.0
2015	3	77,363	2.4	0.8	0	0.0
2016	7	77,424	20.3	2.9	0	0.0
2017	4	72,833	4.4	1.1	0	0.0
2018	3	68,938	6.1	2.0	0	0.0
2019	4	65,763	5.5	1.4	0	0.0
2020	8	65,224	3.7	0.5	0	0.0
2021	0	9,834	0.0	-	0	N/A
Invalid						
2008	1	3,653	13.0	13.0	0	0.0
2009	0	3,528	0.0	-	0	N/A
2010	0	3,307	0.0	-	0	N/A
2011	0	2,640	0.0	-	0	N/A
2012	0	2,651	0.0	-	0	N/A
2013	0	2,461	0.0	-	0	N/A
2014	0	3,272	0.0	-	0	N/A
2015	0	3,495	0.0	-	0	N/A
2016	0	4,599	0.0	-	0	N/A
2017	1	4,222	3.2	3.2	0	0.0
2018	0	4,408	0.0	-	0	N/A
2019	0	4,154	0.0	-	0	N/A
2020	0	3,165	0.0	-	0	N/A
2021	0	138	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Missing						
2008	4	43,905	0.7	0.2	0	0.0
2009	1	27,139	0.2	0.2	0	0.0
2010	0	1,328	0.0	-	0	N/A
2011	0	1,203	0.0	-	0	N/A
2012	0	1,135	0.0	-	0	N/A
2013	0	1,700	0.0	-	0	N/A
2014	1	1,858	4.7	4.7	0	0.0
2015	0	1,911	0.0	-	0	N/A
2016	0	1,807	0.0	-	0	N/A
2017	0	1,568	0.0	-	0	N/A
2018	0	1,265	0.0	-	0	N/A
2019	0	1,039	0.0	-	0	N/A
2020	0	1,887	0.0	-	0	N/A
2021	0	2,178	0.0	-	0	N/A
Other						
2008	0	48	0.0	-	0	N/A
2009	0	38	0.0	-	0	N/A
2010	0	56	0.0	-	0	N/A
2011	0	27	0.0	-	0	N/A
2012	0	24	0.0	-	0	N/A
2013	0	38	0.0	-	0	N/A
2014	0	36	0.0	-	0	N/A
2015	0	30	0.0	-	0	N/A
2016	0	34	0.0	-	0	N/A
2017	0	29	0.0	-	0	N/A
2018	0	44	0.0	-	0	N/A
2019	0	98	0.0	-	0	N/A
2020	0	186	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Absent						
Midwest						
2008	0	524	0.0	-	0	N/A
2009	0	499	0.0	-	0	N/A
2010	1	537	0.8	0.8	0	0.0
2011	0	482	0.0	-	0	N/A
2012	0	421	0.0	-	0	N/A
2013	0	477	0.0	-	0	N/A
2014	0	445	0.0	-	0	N/A
2015	1	436	5.7	5.7	0	0.0
2016	0	347	0.0	-	0	N/A
2017	2	325	4.0	2.0	0	0.0
2018	0	318	0.0	-	0	N/A
2019	0	318	0.0	-	0	N/A
2020	2	286	1.6	0.8	0	0.0
2021	0	29	0.0	-	0	N/A
Northeast						
2008	0	431	0.0	-	0	N/A
2009	1	461	1.1	1.1	0	0.0
2010	2	349	10.4	5.2	0	0.0
2011	0	320	0.0	-	0	N/A
2012	2	289	8.0	4.0	0	0.0
2013	0	307	0.0	-	0	N/A
2014	1	404	0.0	0.0	0	0.0
2015	0	363	0.0	-	0	N/A
2016	0	351	0.0	-	0	N/A
2017	3	324	4.2	1.4	0	0.0
2018	3	302	3.4	1.1	0	0.0
2019	1	240	0.1	0.1	0	0.0
2020	0	268	0.0	-	0	N/A
2021	0	23	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
South						
2008	0	1,481	0.0	-	0	N/A
2009	1	1,064	12.1	12.1	0	0.0
2010	0	922	0.0	-	0	N/A
2011	0	871	0.0	-	0	N/A
2012	2	777	1.4	0.7	0	0.0
2013	1	889	2.4	2.4	0	0.0
2014	0	962	0.0	-	0	N/A
2015	0	976	0.0	-	0	N/A
2016	3	866	4.3	1.4	0	0.0
2017	0	798	0.0	-	0	N/A
2018	2	772	1.1	0.6	0	0.0
2019	2	644	0.5	0.3	0	0.0
2020	2	533	0.4	0.2	0	0.0
2021	0	50	0.0	-	0	N/A
West						
2008	0	301	0.0	-	0	N/A
2009	1	459	0.2	0.2	0	0.0
2010	0	534	0.0	-	0	N/A
2011	0	535	0.0	-	0	N/A
2012	0	457	0.0	-	0	N/A
2013	1	452	8.2	8.2	0	0.0
2014	0	472	0.0	-	0	N/A
2015	1	300	0.2	0.2	0	0.0
2016	0	269	0.0	-	0	N/A
2017	1	227	3.8	3.8	0	0.0
2018	2	225	5.5	2.8	0	0.0
2019	0	253	0.0	-	0	N/A
2020	0	209	0.0	-	0	N/A
2021	0	18	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Invalid						
2008	0	19	0.0	-	0	N/A
2009	0	12	0.0	-	0	N/A
2010	0	7	0.0	-	0	N/A
2011	0	7	0.0	-	0	N/A
2012	0	8	0.0	-	0	N/A
2013	0	9	0.0	-	0	N/A
2014	0	11	0.0	-	0	N/A
2015	0	8	0.0	-	0	N/A
2016	0	5	0.0	-	0	N/A
2017	0	3	0.0	-	0	N/A
2018	0	3	0.0	-	0	N/A
2019	0	3	0.0	-	0	N/A
2020	0	8	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Missing						
2008	0	209	0.0	-	0	N/A
2009	0	167	0.0	-	0	N/A
2010	0	8	0.0	-	0	N/A
2011	0	2	0.0	-	0	N/A
2012	0	6	0.0	-	0	N/A
2013	0	13	0.0	-	0	N/A
2014	0	11	0.0	-	0	N/A
2015	0	10	0.0	-	0	N/A
2016	0	2	0.0	-	0	N/A
2017	0	9	0.0	-	0	N/A
2018	0	5	0.0	-	0	N/A
2019	0	2	0.0	-	0	N/A
2020	0	9	0.0	-	0	N/A
2021	0	11	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Other</i>						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Hearing Loss: Absent, Clinical Characteristics: Present						
<i>Midwest</i>						
2008	16	36,705	26.4	1.7	0	0.0
2009	16	37,158	29.9	1.9	0	0.0
2010	10	33,927	22.2	2.2	0	0.0
2011	5	31,348	12.8	2.6	0	0.0
2012	13	29,919	38.8	3.0	0	0.0
2013	10	33,969	11.1	1.1	0	0.0
2014	20	34,284	34.5	1.7	0	0.0
2015	11	34,975	24.2	2.2	0	0.0
2016	21	36,632	48.0	2.3	0	0.0
2017	31	37,832	44.4	1.4	0	0.0
2018	18	37,436	24.8	1.4	0	0.0
2019	30	36,139	43.2	1.4	0	0.0
2020	16	33,257	9.1	0.6	0	0.0
2021	2	3,743	0.3	0.1	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Northeast						
2008	4	12,926	12.6	3.1	0	0.0
2009	4	13,534	4.1	1.0	0	0.0
2010	2	12,892	6.2	3.1	0	0.0
2011	2	11,999	4.6	2.3	0	0.0
2012	8	11,430	16.6	2.1	0	0.0
2013	4	13,562	5.8	1.4	0	0.0
2014	9	14,753	27.3	3.0	0	0.0
2015	6	14,988	20.0	3.3	0	0.0
2016	11	15,983	20.5	1.9	0	0.0
2017	8	16,144	19.1	2.4	0	0.0
2018	13	15,994	20.2	1.6	0	0.0
2019	17	15,141	19.8	1.2	0	0.0
2020	7	14,146	3.2	0.5	0	0.0
2021	0	1,361	0.0	-	0	N/A
South						
2008	33	66,727	87.1	2.6	0	0.0
2009	20	69,387	75.6	3.8	0	0.0
2010	37	63,787	164.0	4.4	0	0.0
2011	30	57,750	117.3	3.9	0	0.0
2012	28	55,408	94.9	3.4	0	0.0
2013	34	62,194	104.8	3.1	0	0.0
2014	39	67,595	112.5	2.9	0	0.0
2015	48	72,287	110.2	2.3	0	0.0
2016	53	77,064	117.7	2.2	0	0.0
2017	59	77,065	107.7	1.8	0	0.0
2018	54	75,695	79.3	1.5	0	0.0
2019	39	70,024	25.8	0.7	0	0.0
2020	21	53,599	8.8	0.4	0	0.0
2021	2	5,544	0.2	0.1	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
West						
2008	6	28,708	26.8	4.5	0	0.0
2009	7	29,846	9.9	1.4	0	0.0
2010	9	29,692	25.6	2.8	0	0.0
2011	7	28,630	20.1	2.9	0	0.0
2012	11	27,949	34.0	3.1	0	0.0
2013	14	31,347	37.0	2.6	0	0.0
2014	10	33,152	30.6	3.1	0	0.0
2015	16	33,080	40.0	2.5	0	0.0
2016	14	35,784	22.4	1.6	0	0.0
2017	16	35,433	28.7	1.8	0	0.0
2018	10	34,791	13.4	1.3	0	0.0
2019	9	35,344	10.9	1.2	0	0.0
2020	13	32,374	8.5	0.7	0	0.0
2021	1	4,409	0.2	0.2	0	0.0
Invalid						
2008	0	1,188	0.0	-	0	N/A
2009	2	1,270	10.1	5.1	0	0.0
2010	1	1,217	0.3	0.3	0	0.0
2011	0	913	0.0	-	0	N/A
2012	0	815	0.0	-	0	N/A
2013	0	828	0.0	-	0	N/A
2014	0	789	0.0	-	0	N/A
2015	0	697	0.0	-	0	N/A
2016	0	842	0.0	-	0	N/A
2017	1	849	2.4	2.4	0	0.0
2018	1	890	3.0	3.0	0	0.0
2019	0	894	0.0	-	0	N/A
2020	1	774	0.2	0.2	0	0.0
2021	0	130	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Missing						
2008	0	9,730	0.0	-	0	N/A
2009	0	6,702	0.0	-	0	N/A
2010	0	206	0.0	-	0	N/A
2011	0	199	0.0	-	0	N/A
2012	0	215	0.0	-	0	N/A
2013	0	417	0.0	-	0	N/A
2014	0	544	0.0	-	0	N/A
2015	0	551	0.0	-	0	N/A
2016	1	513	0.7	0.7	0	0.0
2017	0	421	0.0	-	0	N/A
2018	0	454	0.0	-	0	N/A
2019	0	292	0.0	-	0	N/A
2020	0	575	0.0	-	0	N/A
2021	2	987	0.4	0.2	0	0.0
Other						
2008	0	11	0.0	-	0	N/A
2009	0	9	0.0	-	0	N/A
2010	0	6	0.0	-	0	N/A
2011	0	4	0.0	-	0	N/A
2012	0	7	0.0	-	0	N/A
2013	0	7	0.0	-	0	N/A
2014	0	7	0.0	-	0	N/A
2015	0	8	0.0	-	0	N/A
2016	0	4	0.0	-	0	N/A
2017	0	7	0.0	-	0	N/A
2018	0	5	0.0	-	0	N/A
2019	0	20	0.0	-	0	N/A
2020	0	53	0.0	-	0	N/A
2021	0	1	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
Midwest						
2008	1	297	5.2	5.2	0	0.0
2009	1	343	1.4	1.4	0	0.0
2010	0	298	0.0	-	0	N/A
2011	1	280	9.7	9.7	0	0.0
2012	1	280	1.4	1.4	0	0.0
2013	0	245	0.0	-	0	N/A
2014	1	287	0.2	0.2	0	0.0
2015	4	272	10.2	2.5	0	0.0
2016	3	219	12.3	4.1	0	0.0
2017	1	209	3.7	3.7	0	0.0
2018	3	217	4.0	1.3	0	0.0
2019	5	207	7.1	1.4	0	0.0
2020	1	197	0.1	0.1	0	0.0
2021	0	22	0.0	-	0	N/A
Northeast						
2008	1	201	1.3	1.3	0	0.0
2009	0	174	0.0	-	0	N/A
2010	1	171	0.6	0.6	0	0.0
2011	0	152	0.0	-	0	N/A
2012	1	157	8.0	8.0	0	0.0
2013	0	176	0.0	-	0	N/A
2014	1	164	1.4	1.4	0	0.0
2015	0	195	0.0	-	0	N/A
2016	2	193	1.2	0.6	0	0.0
2017	1	175	3.9	3.9	0	0.0
2018	1	140	1.3	1.3	0	0.0
2019	2	120	1.9	1.0	0	0.0
2020	1	129	0.1	0.1	0	0.0
2021	0	13	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
South						
2008	3	942	21.4	7.1	0	0.0
2009	3	705	19.5	6.5	0	0.0
2010	3	605	2.1	0.7	0	0.0
2011	3	499	4.0	1.3	0	0.0
2012	0	472	0.0	-	0	N/A
2013	2	512	1.7	0.8	0	0.0
2014	3	605	17.4	5.8	0	0.0
2015	3	593	6.7	2.2	0	0.0
2016	1	544	0.1	0.1	0	0.0
2017	2	593	5.4	2.7	0	0.0
2018	2	539	3.7	1.8	0	0.0
2019	5	457	6.9	1.4	0	0.0
2020	1	318	0.3	0.3	0	0.0
2021	1	27	0.2	0.2	0	0.0
West						
2008	2	233	8.1	4.0	0	0.0
2009	2	345	10.1	5.1	0	0.0
2010	5	352	10.3	2.1	0	0.0
2011	0	386	0.0	-	0	N/A
2012	0	386	0.0	-	0	N/A
2013	1	323	0.3	0.3	0	0.0
2014	3	359	17.8	5.9	0	0.0
2015	5	187	18.6	3.7	0	0.0
2016	2	179	5.1	2.6	0	0.0
2017	1	159	1.1	1.1	0	0.0
2018	1	146	0.5	0.5	0	0.0
2019	1	167	0.2	0.2	0	0.0
2020	2	133	0.5	0.3	0	0.0
2021	1	25	0.4	0.4	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Invalid						
2008	0	8	0.0	-	0	N/A
2009	0	11	0.0	-	0	N/A
2010	0	7	0.0	-	0	N/A
2011	0	5	0.0	-	0	N/A
2012	0	3	0.0	-	0	N/A
2013	0	4	0.0	-	0	N/A
2014	0	8	0.0	-	0	N/A
2015	0	6	0.0	-	0	N/A
2016	0	3	0.0	-	0	N/A
2017	0	2	0.0	-	0	N/A
2018	0	9	0.0	-	0	N/A
2019	0	4	0.0	-	0	N/A
2020	0	1	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Missing						
2008	0	96	0.0	-	0	N/A
2009	2	82	1.2	0.6	0	0.0
2010	0	1	0.0	-	0	N/A
2011	0	1	0.0	-	0	N/A
2012	0	1	0.0	-	0	N/A
2013	0	2	0.0	-	0	N/A
2014	0	3	0.0	-	0	N/A
2015	0	5	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	1	0.0	-	0	N/A
2018	0	3	0.0	-	0	N/A
2019	0	2	0.0	-	0	N/A
2020	1	5	0.1	0.1	0	0.0
2021	0	4	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Other						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	1	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
Midwest						
2008	20	112,555	8.0	0.4	1	500.0
2009	22	109,119	8.5	0.4	2	909.1
2010	16	100,340	5.6	0.4	4	2,500.0
2011	9	95,988	3.6	0.4	2	2,222.2
2012	16	93,947	6.1	0.4	2	1,250.0
2013	13	107,953	4.1	0.3	1	769.2
2014	27	108,780	8.0	0.3	7	2,592.6
2015	19	109,059	5.4	0.3	5	2,631.6
2016	32	111,682	10.0	0.3	9	2,812.5
2017	41	111,297	13.1	0.3	8	1,951.2
2018	33	108,977	10.5	0.3	8	2,424.2
2019	45	101,430	15.3	0.3	13	2,888.9
2020	22	95,403	5.8	0.3	7	3,181.8
2021	2	12,595	0.1	0.0	1	5,000.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Northeast						
2008	10	60,076	4.5	0.5	0	0.0
2009	8	58,909	3.2	0.4	0	0.0
2010	11	55,832	5.0	0.5	0	0.0
2011	6	52,013	1.9	0.3	2	3,333.3
2012	12	49,620	3.9	0.3	3	2,500.0
2013	7	58,366	2.2	0.3	3	4,285.7
2014	17	62,169	5.2	0.3	2	1,176.5
2015	12	63,479	4.3	0.4	3	2,500.0
2016	19	64,064	6.8	0.4	3	1,578.9
2017	15	60,949	5.1	0.3	3	2,000.0
2018	21	58,656	6.4	0.3	4	1,904.8
2019	23	54,551	8.7	0.4	3	1,304.3
2020	13	51,789	2.8	0.2	5	3,846.2
2021	2	5,374	0.2	0.1	0	0.0
South						
2008	50	229,847	18.3	0.4	6	1,200.0
2009	42	221,723	17.6	0.4	2	476.2
2010	62	205,828	26.0	0.4	1	161.3
2011	55	194,561	22.2	0.4	6	1,090.9
2012	40	186,680	15.7	0.4	3	750.0
2013	54	207,348	21.1	0.4	5	925.9
2014	56	217,742	20.2	0.4	10	1,785.7
2015	62	231,296	19.0	0.3	20	3,225.8
2016	72	239,429	20.9	0.3	23	3,194.4
2017	84	234,122	26.7	0.3	29	3,452.4
2018	68	225,990	21.0	0.3	18	2,647.1
2019	67	215,567	17.9	0.3	19	2,835.8
2020	34	151,653	8.1	0.2	9	2,647.1
2021	6	16,815	0.5	0.1	1	1,666.7

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
West						
2008	16	96,392	6.4	0.4	0	0.0
2009	12	97,673	5.3	0.4	0	0.0
2010	16	97,904	6.9	0.4	0	0.0
2011	9	92,824	3.1	0.3	1	1,111.1
2012	12	90,078	4.8	0.4	2	1,666.7
2013	22	106,168	6.7	0.3	6	2,727.3
2014	21	110,038	8.0	0.4	4	1,904.8
2015	25	110,126	8.1	0.3	6	2,400.0
2016	21	112,879	5.2	0.2	7	3,333.3
2017	22	107,896	7.5	0.3	3	1,363.6
2018	16	103,401	6.7	0.4	2	1,250.0
2019	14	100,793	4.3	0.3	4	2,857.1
2020	23	97,239	7.1	0.3	5	2,173.9
2021	2	14,198	0.6	0.3	0	0.0
Invalid						
2008	1	4,840	0.5	0.5	0	0.0
2009	2	4,796	0.8	0.4	0	0.0
2010	1	4,510	0.3	0.3	0	0.0
2011	0	3,547	0.0	-	0	N/A
2012	0	3,460	0.0	-	0	N/A
2013	0	3,288	0.0	-	0	N/A
2014	0	4,062	0.0	-	0	N/A
2015	0	4,190	0.0	-	0	N/A
2016	0	5,433	0.0	-	0	N/A
2017	2	5,065	1.0	0.5	0	0.0
2018	1	5,292	0.5	0.5	0	0.0
2019	0	5,043	0.0	-	0	N/A
2020	1	3,938	0.2	0.2	0	0.0
2021	0	268	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Missing						
2008	4	53,519	0.7	0.2	0	0.0
2009	3	33,848	0.9	0.3	0	0.0
2010	0	1,531	0.0	-	0	N/A
2011	0	1,398	0.0	-	0	N/A
2012	0	1,345	0.0	-	0	N/A
2013	0	2,116	0.0	-	0	N/A
2014	1	2,400	0.5	0.5	0	0.0
2015	0	2,459	0.0	-	0	N/A
2016	1	2,310	0.5	0.5	0	0.0
2017	0	1,994	0.0	-	0	N/A
2018	0	1,715	0.0	-	0	N/A
2019	0	1,331	0.0	-	0	N/A
2020	1	2,460	0.0	0.0	1	10,000.0
2021	2	3,169	0.3	0.2	1	5,000.0
Other						
2008	0	59	0.0	-	0	N/A
2009	0	46	0.0	-	0	N/A
2010	0	61	0.0	-	0	N/A
2011	0	31	0.0	-	0	N/A
2012	0	31	0.0	-	0	N/A
2013	0	45	0.0	-	0	N/A
2014	0	41	0.0	-	0	N/A
2015	0	38	0.0	-	0	N/A
2016	0	38	0.0	-	0	N/A
2017	0	36	0.0	-	0	N/A
2018	0	49	0.0	-	0	N/A
2019	0	118	0.0	-	0	N/A
2020	0	233	0.0	-	0	N/A
2021	0	1	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Absent						
Midwest						
2008	3	75,883	1.5	0.5	0	0.0
2009	5	71,967	1.6	0.3	0	0.0
2010	5	66,445	2.1	0.4	0	0.0
2011	3	64,687	1.0	0.3	1	3,333.3
2012	2	64,129	1.0	0.5	0	0.0
2013	3	74,091	0.7	0.2	0	0.0
2014	6	74,604	3.0	0.5	0	0.0
2015	3	74,177	1.1	0.4	0	0.0
2016	8	75,246	3.7	0.5	0	0.0
2017	7	73,692	3.0	0.4	0	0.0
2018	12	71,736	4.4	0.4	3	2,500.0
2019	10	65,509	4.1	0.4	0	0.0
2020	3	62,395	1.1	0.4	0	0.0
2021	0	8,873	0.0	-	0	N/A
Northeast						
2008	5	47,120	2.1	0.4	0	0.0
2009	3	45,351	1.2	0.4	0	0.0
2010	6	42,962	2.5	0.4	0	0.0
2011	4	40,056	1.4	0.4	1	2,500.0
2012	2	38,210	0.4	0.2	0	0.0
2013	3	44,768	0.9	0.3	1	3,333.3
2014	6	47,391	2.1	0.3	0	0.0
2015	6	48,438	2.5	0.4	0	0.0
2016	6	48,026	2.1	0.3	0	0.0
2017	3	44,794	0.6	0.2	1	3,333.3
2018	4	42,642	0.9	0.2	0	0.0
2019	3	39,445	1.3	0.4	0	0.0
2020	5	37,681	1.5	0.3	1	2,000.0
2021	2	4,006	0.2	0.1	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
South						
2008	14	162,263	4.6	0.3	1	714.3
2009	18	152,148	7.4	0.4	0	0.0
2010	22	142,054	9.4	0.4	0	0.0
2011	22	136,890	9.3	0.4	2	909.1
2012	10	131,490	4.5	0.5	0	0.0
2013	17	145,383	7.3	0.4	1	588.2
2014	14	150,280	6.0	0.4	0	0.0
2015	12	159,237	5.6	0.5	1	833.3
2016	15	162,608	6.1	0.4	2	1,333.3
2017	23	157,293	8.7	0.4	5	2,173.9
2018	10	150,582	3.9	0.4	1	1,000.0
2019	21	145,932	7.9	0.4	4	1,904.8
2020	10	98,170	2.1	0.2	4	4,000.0
2021	3	11,276	0.1	0.0	1	3,333.3
West						
2008	8	67,820	2.9	0.4	0	0.0
2009	2	67,738	1.0	0.5	0	0.0
2010	2	68,054	0.5	0.3	0	0.0
2011	2	63,998	0.1	0.1	1	5,000.0
2012	1	61,981	0.5	0.5	0	0.0
2013	6	74,891	1.6	0.3	2	3,333.3
2014	8	76,776	3.2	0.4	0	0.0
2015	3	77,363	1.1	0.4	0	0.0
2016	7	77,424	2.1	0.3	3	4,285.7
2017	4	72,833	1.1	0.3	0	0.0
2018	3	68,938	1.5	0.5	0	0.0
2019	4	65,763	1.5	0.4	1	2,500.0
2020	8	65,224	2.3	0.3	2	2,500.0
2021	0	9,834	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Invalid						
2008	1	3,653	0.5	0.5	0	0.0
2009	0	3,528	0.0	-	0	N/A
2010	0	3,307	0.0	-	0	N/A
2011	0	2,640	0.0	-	0	N/A
2012	0	2,651	0.0	-	0	N/A
2013	0	2,461	0.0	-	0	N/A
2014	0	3,272	0.0	-	0	N/A
2015	0	3,495	0.0	-	0	N/A
2016	0	4,599	0.0	-	0	N/A
2017	1	4,222	0.5	0.5	0	0.0
2018	0	4,408	0.0	-	0	N/A
2019	0	4,154	0.0	-	0	N/A
2020	0	3,165	0.0	-	0	N/A
2021	0	138	0.0	-	0	N/A
Missing						
2008	4	43,905	0.7	0.2	0	0.0
2009	1	27,139	0.2	0.2	0	0.0
2010	0	1,328	0.0	-	0	N/A
2011	0	1,203	0.0	-	0	N/A
2012	0	1,135	0.0	-	0	N/A
2013	0	1,700	0.0	-	0	N/A
2014	1	1,858	0.5	0.5	0	0.0
2015	0	1,911	0.0	-	0	N/A
2016	0	1,807	0.0	-	0	N/A
2017	0	1,568	0.0	-	0	N/A
2018	0	1,265	0.0	-	0	N/A
2019	0	1,039	0.0	-	0	N/A
2020	0	1,887	0.0	-	0	N/A
2021	0	2,178	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Other</i>						
2008	0	48	0.0	-	0	N/A
2009	0	38	0.0	-	0	N/A
2010	0	56	0.0	-	0	N/A
2011	0	27	0.0	-	0	N/A
2012	0	24	0.0	-	0	N/A
2013	0	38	0.0	-	0	N/A
2014	0	36	0.0	-	0	N/A
2015	0	30	0.0	-	0	N/A
2016	0	34	0.0	-	0	N/A
2017	0	29	0.0	-	0	N/A
2018	0	44	0.0	-	0	N/A
2019	0	98	0.0	-	0	N/A
2020	0	186	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Hearing Loss: Present, Clinical Characteristics: Absent						
<i>Midwest</i>						
2008	0	524	0.0	-	0	N/A
2009	0	499	0.0	-	0	N/A
2010	1	537	0.5	0.5	0	0.0
2011	0	482	0.0	-	0	N/A
2012	0	421	0.0	-	0	N/A
2013	0	477	0.0	-	0	N/A
2014	0	445	0.0	-	0	N/A
2015	1	436	0.1	0.1	1	10,000.0
2016	0	347	0.0	-	0	N/A
2017	2	325	0.5	0.3	1	5,000.0
2018	0	318	0.0	-	0	N/A
2019	0	318	0.0	-	0	N/A
2020	2	286	0.5	0.3	1	5,000.0
2021	0	29	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Northeast</i>						
2008	0	431	0.0	-	0	N/A
2009	1	461	0.5	0.5	0	0.0
2010	2	349	1.0	0.5	0	0.0
2011	0	320	0.0	-	0	N/A
2012	2	289	1.0	0.5	0	0.0
2013	0	307	0.0	-	0	N/A
2014	1	404	0.0	0.0	0	0.0
2015	0	363	0.0	-	0	N/A
2016	0	351	0.0	-	0	N/A
2017	3	324	0.6	0.2	1	3,333.3
2018	3	302	1.1	0.4	0	0.0
2019	1	240	0.1	0.1	0	0.0
2020	0	268	0.0	-	0	N/A
2021	0	23	0.0	-	0	N/A
<i>South</i>						
2008	0	1,481	0.0	-	0	N/A
2009	1	1,064	0.5	0.5	0	0.0
2010	0	922	0.0	-	0	N/A
2011	0	871	0.0	-	0	N/A
2012	2	777	1.0	0.5	0	0.0
2013	1	889	0.1	0.1	1	10,000.0
2014	0	962	0.0	-	0	N/A
2015	0	976	0.0	-	0	N/A
2016	3	866	0.6	0.2	2	6,666.7
2017	0	798	0.0	-	0	N/A
2018	2	772	0.5	0.3	1	5,000.0
2019	2	644	0.5	0.3	0	0.0
2020	2	533	0.0	0.0	1	5,000.0
2021	0	50	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
West						
2008	0	301	0.0	-	0	N/A
2009	1	459	0.2	0.2	0	0.0
2010	0	534	0.0	-	0	N/A
2011	0	535	0.0	-	0	N/A
2012	0	457	0.0	-	0	N/A
2013	1	452	0.5	0.5	0	0.0
2014	0	472	0.0	-	0	N/A
2015	1	300	0.2	0.2	0	0.0
2016	0	269	0.0	-	0	N/A
2017	1	227	0.1	0.1	1	10,000.0
2018	2	225	0.6	0.3	1	5,000.0
2019	0	253	0.0	-	0	N/A
2020	0	209	0.0	-	0	N/A
2021	0	18	0.0	-	0	N/A
Invalid						
2008	0	19	0.0	-	0	N/A
2009	0	12	0.0	-	0	N/A
2010	0	7	0.0	-	0	N/A
2011	0	7	0.0	-	0	N/A
2012	0	8	0.0	-	0	N/A
2013	0	9	0.0	-	0	N/A
2014	0	11	0.0	-	0	N/A
2015	0	8	0.0	-	0	N/A
2016	0	5	0.0	-	0	N/A
2017	0	3	0.0	-	0	N/A
2018	0	3	0.0	-	0	N/A
2019	0	3	0.0	-	0	N/A
2020	0	8	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Missing						
2008	0	209	0.0	-	0	N/A
2009	0	167	0.0	-	0	N/A
2010	0	8	0.0	-	0	N/A
2011	0	2	0.0	-	0	N/A
2012	0	6	0.0	-	0	N/A
2013	0	13	0.0	-	0	N/A
2014	0	11	0.0	-	0	N/A
2015	0	10	0.0	-	0	N/A
2016	0	2	0.0	-	0	N/A
2017	0	9	0.0	-	0	N/A
2018	0	5	0.0	-	0	N/A
2019	0	2	0.0	-	0	N/A
2020	0	9	0.0	-	0	N/A
2021	0	11	0.0	-	0	N/A
Other						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
Midwest						
2008	16	36,705	6.0	0.4	1	625.0
2009	16	37,158	6.4	0.4	2	1,250.0
2010	10	33,927	3.1	0.3	4	4,000.0
2011	5	31,348	2.1	0.4	1	2,000.0
2012	13	29,919	5.1	0.4	1	769.2
2013	10	33,969	3.3	0.3	1	1,000.0
2014	20	34,284	5.0	0.3	6	3,000.0
2015	11	34,975	3.2	0.3	3	2,727.3
2016	21	36,632	6.2	0.3	6	2,857.1
2017	31	37,832	9.2	0.3	6	1,935.5
2018	18	37,436	5.5	0.3	3	1,666.7
2019	30	36,139	10.5	0.4	9	3,000.0
2020	16	33,257	4.1	0.3	6	3,750.0
2021	2	3,743	0.1	0.0	1	5,000.0
Northeast						
2008	4	12,926	2.0	0.5	0	0.0
2009	4	13,534	1.6	0.4	0	0.0
2010	2	12,892	1.0	0.5	0	0.0
2011	2	11,999	0.5	0.2	1	5,000.0
2012	7	11,430	2.5	0.4	2	2,857.1
2013	4	13,562	1.3	0.3	2	5,000.0
2014	9	14,753	2.9	0.3	1	1,111.1
2015	6	14,988	1.8	0.3	3	5,000.0
2016	11	15,983	4.6	0.4	1	909.1
2017	8	16,144	3.9	0.5	0	0.0
2018	13	15,994	3.9	0.3	4	3,076.9
2019	17	15,141	7.3	0.4	1	588.2
2020	7	14,146	1.3	0.2	3	4,285.7
2021	0	1,361	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
South						
2008	33	66,727	12.7	0.4	4	1,212.1
2009	20	69,387	8.4	0.4	1	500.0
2010	37	63,787	15.2	0.4	1	270.3
2011	30	57,750	11.9	0.4	3	1,000.0
2012	28	55,408	10.2	0.4	3	1,071.4
2013	34	62,194	12.8	0.4	3	882.4
2014	39	67,595	13.5	0.3	8	2,051.3
2015	47	72,287	12.8	0.3	17	3,617.0
2016	53	77,064	14.1	0.3	19	3,584.9
2017	59	77,065	17.9	0.3	22	3,728.8
2018	54	75,695	16.5	0.3	14	2,592.6
2019	39	70,024	8.9	0.2	11	2,820.5
2020	21	53,599	5.9	0.3	3	1,428.6
2021	2	5,544	0.2	0.1	0	0.0
West						
2008	6	28,708	2.5	0.4	0	0.0
2009	7	29,846	3.4	0.5	0	0.0
2010	9	29,692	4.0	0.4	0	0.0
2011	7	28,630	2.9	0.4	0	0.0
2012	11	27,949	4.4	0.4	2	1,818.2
2013	14	31,347	4.6	0.3	3	2,142.9
2014	10	33,152	4.5	0.5	1	1,000.0
2015	16	33,080	5.6	0.4	3	1,875.0
2016	13	35,784	2.6	0.2	4	3,076.9
2017	16	35,433	6.2	0.4	1	625.0
2018	10	34,791	4.1	0.4	1	1,000.0
2019	9	35,344	2.6	0.3	3	3,333.3
2020	13	32,374	4.3	0.3	3	2,307.7
2021	1	4,409	0.2	0.2	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Invalid						
2008	0	1,188	0.0	-	0	N/A
2009	2	1,270	0.8	0.4	0	0.0
2010	1	1,217	0.3	0.3	0	0.0
2011	0	913	0.0	-	0	N/A
2012	0	815	0.0	-	0	N/A
2013	0	828	0.0	-	0	N/A
2014	0	789	0.0	-	0	N/A
2015	0	697	0.0	-	0	N/A
2016	0	842	0.0	-	0	N/A
2017	1	849	0.5	0.5	0	0.0
2018	1	890	0.5	0.5	0	0.0
2019	0	894	0.0	-	0	N/A
2020	1	774	0.2	0.2	0	0.0
2021	0	130	0.0	-	0	N/A
Missing						
2008	0	9,730	0.0	-	0	N/A
2009	0	6,702	0.0	-	0	N/A
2010	0	206	0.0	-	0	N/A
2011	0	199	0.0	-	0	N/A
2012	0	215	0.0	-	0	N/A
2013	0	417	0.0	-	0	N/A
2014	0	544	0.0	-	0	N/A
2015	0	551	0.0	-	0	N/A
2016	1	513	0.5	0.5	0	0.0
2017	0	421	0.0	-	0	N/A
2018	0	454	0.0	-	0	N/A
2019	0	292	0.0	-	0	N/A
2020	0	575	0.0	-	0	N/A
2021	2	987	0.3	0.2	1	5,000.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Other</i>						
2008	0	11	0.0	-	0	N/A
2009	0	9	0.0	-	0	N/A
2010	0	6	0.0	-	0	N/A
2011	0	4	0.0	-	0	N/A
2012	0	7	0.0	-	0	N/A
2013	0	7	0.0	-	0	N/A
2014	0	7	0.0	-	0	N/A
2015	0	8	0.0	-	0	N/A
2016	0	4	0.0	-	0	N/A
2017	0	7	0.0	-	0	N/A
2018	0	5	0.0	-	0	N/A
2019	0	20	0.0	-	0	N/A
2020	0	53	0.0	-	0	N/A
2021	0	1	0.0	-	0	N/A
Hearing Loss: Present, Clinical Characteristics: Present						
<i>Midwest</i>						
2008	1	297	0.5	0.5	0	0.0
2009	1	343	0.5	0.5	0	0.0
2010	0	298	0.0	-	0	N/A
2011	1	280	0.5	0.5	0	0.0
2012	1	280	0.1	0.1	1	10,000.0
2013	0	245	0.0	-	0	N/A
2014	1	287	0.0	0.0	1	10,000.0
2015	4	272	1.1	0.3	1	2,500.0
2016	3	219	0.2	0.1	3	10,000.0
2017	1	209	0.3	0.3	1	10,000.0
2018	3	217	0.6	0.2	2	6,666.7
2019	5	207	0.7	0.1	4	8,000.0
2020	1	197	0.1	0.1	0	0.0
2021	0	22	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Northeast</i>						
2008	1	201	0.5	0.5	0	0.0
2009	0	174	0.0	-	0	N/A
2010	1	171	0.5	0.5	0	0.0
2011	0	152	0.0	-	0	N/A
2012	1	157	0.1	0.1	1	10,000.0
2013	0	176	0.0	-	0	N/A
2014	1	164	0.1	0.1	1	10,000.0
2015	0	195	0.0	-	0	N/A
2016	2	193	0.1	0.1	2	10,000.0
2017	1	175	0.0	0.0	1	10,000.0
2018	1	140	0.5	0.5	0	0.0
2019	2	120	0.0	0.0	2	10,000.0
2020	1	129	0.1	0.1	1	10,000.0
2021	0	13	0.0	-	0	N/A
<i>South</i>						
2008	3	942	1.1	0.4	1	3,333.3
2009	3	705	1.3	0.4	1	3,333.3
2010	3	605	1.4	0.5	0	0.0
2011	3	499	0.9	0.3	1	3,333.3
2012	0	472	0.0	-	0	N/A
2013	2	512	0.9	0.4	0	0.0
2014	3	605	0.7	0.2	2	6,666.7
2015	3	593	0.6	0.2	2	6,666.7
2016	1	544	0.1	0.1	0	0.0
2017	2	593	0.1	0.1	2	10,000.0
2018	2	539	0.1	0.0	2	10,000.0
2019	5	457	0.6	0.1	4	8,000.0
2020	1	318	0.0	0.0	1	10,000.0
2021	1	27	0.2	0.2	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
West						
2008	2	233	1.0	0.5	0	0.0
2009	2	345	0.7	0.3	0	0.0
2010	5	352	2.4	0.5	0	0.0
2011	0	386	0.0	-	0	N/A
2012	0	386	0.0	-	0	N/A
2013	1	323	0.0	0.0	1	10,000.0
2014	3	359	0.2	0.1	3	10,000.0
2015	5	187	1.2	0.2	3	6,000.0
2016	1	179	0.5	0.5	0	0.0
2017	1	159	0.1	0.1	1	10,000.0
2018	1	146	0.5	0.5	0	0.0
2019	1	167	0.2	0.2	0	0.0
2020	2	133	0.5	0.3	0	0.0
2021	1	25	0.4	0.4	0	0.0
Invalid						
2008	0	8	0.0	-	0	N/A
2009	0	11	0.0	-	0	N/A
2010	0	7	0.0	-	0	N/A
2011	0	5	0.0	-	0	N/A
2012	0	3	0.0	-	0	N/A
2013	0	4	0.0	-	0	N/A
2014	0	8	0.0	-	0	N/A
2015	0	6	0.0	-	0	N/A
2016	0	3	0.0	-	0	N/A
2017	0	2	0.0	-	0	N/A
2018	0	9	0.0	-	0	N/A
2019	0	4	0.0	-	0	N/A
2020	0	1	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Missing						
2008	0	96	0.0	-	0	N/A
2009	2	82	0.7	0.3	0	0.0
2010	0	1	0.0	-	0	N/A
2011	0	1	0.0	-	0	N/A
2012	0	1	0.0	-	0	N/A
2013	0	2	0.0	-	0	N/A
2014	0	3	0.0	-	0	N/A
2015	0	5	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	1	0.0	-	0	N/A
2018	0	3	0.0	-	0	N/A
2019	0	2	0.0	-	0	N/A
2020	1	5	0.0	0.0	1	10,000.0
2021	0	4	0.0	-	0	N/A
Other						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	1	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Treatment Within 45 Days from Diagnosis						
Midwest						
2008	0	0	0.0	-	0	N/A
2009	1	2	0.4	0.4	0	0.0
2010	2	3	4.9	2.5	0	0.0
2011	1	3	3.0	3.0	0	0.0
2012	2	2	4.0	2.0	0	0.0
2013	0	1	0.0	-	0	N/A
2014	7	8	11.0	1.6	0	0.0
2015	5	8	21.1	4.2	0	0.0
2016	6	8	23.2	3.9	0	0.0
2017	6	7	10.6	1.8	0	0.0
2018	8	11	7.9	1.0	0	0.0
2019	10	12	13.8	1.4	0	0.0
2020	6	6	4.2	0.7	0	0.0
2021	1	1	0.2	0.2	0	0.0
Northeast						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	4	4	10.9	2.7	0	0.0
2013	1	1	1.6	1.6	0	0.0
2014	1	1	6.2	6.2	0	0.0
2015	2	5	2.0	1.0	0	0.0
2016	3	4	1.9	0.6	0	0.0
2017	3	4	5.5	1.8	0	0.0
2018	2	2	2.8	1.4	0	0.0
2019	3	5	3.5	1.2	0	0.0
2020	5	7	2.7	0.5	0	0.0
2021	0	0	0.0	.	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
South						
2008	2	3	21.7	10.9	0	0.0
2009	0	2	0.0	-	0	N/A
2010	1	1	2.7	2.7	0	0.0
2011	3	3	18.8	6.3	0	0.0
2012	3	4	17.0	5.7	0	0.0
2013	4	5	10.9	2.7	0	0.0
2014	5	7	16.2	3.2	0	0.0
2015	15	17	33.9	2.3	0	0.0
2016	15	19	35.7	2.4	0	0.0
2017	18	25	35.9	2.0	0	0.0
2018	14	14	24.3	1.7	0	0.0
2019	14	21	12.1	0.9	0	0.0
2020	8	9	4.1	0.5	0	0.0
2021	1	1	0.2	0.2	0	0.0
West						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	1	2	2.9	2.9	0	0.0
2012	2	2	2.5	1.2	0	0.0
2013	6	8	14.7	2.5	0	0.0
2014	3	3	11.6	3.9	0	0.0
2015	6	7	19.3	3.2	0	0.0
2016	8	9	27.8	3.5	0	0.0
2017	3	4	6.1	2.0	0	0.0
2018	1	1	1.5	1.5	0	0.0
2019	4	6	4.8	1.2	0	0.0
2020	3	4	2.4	0.8	0	0.0
2021	0	0	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Invalid						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Missing						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	1	1	0.1	0.1	0	0.0
2021	1	1	0.2	0.2	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Other						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Treatment Within 180 Days from Diagnosis						
Midwest						
2008	1	2	1.8	1.8	0	0.0
2009	2	4	5.1	2.5	0	0.0
2010	4	10	15.8	4.0	0	0.0
2011	2	5	3.9	1.9	0	0.0
2012	2	3	4.0	2.0	0	0.0
2013	1	6	0.4	0.4	0	0.0
2014	7	12	11.0	1.6	0	0.0
2015	5	12	21.1	4.2	0	0.0
2016	9	14	30.3	3.4	0	0.0
2017	8	10	14.9	1.9	0	0.0
2018	8	11	7.9	1.0	0	0.0
2019	13	16	18.5	1.4	0	0.0
2020	7	8	5.1	0.7	0	0.0
2021	1	1	0.2	0.2	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Northeast</i>						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	1	0.0	-	0	N/A
2011	2	3	5.2	2.6	0	0.0
2012	4	6	10.9	2.7	0	0.0
2013	3	4	2.3	0.8	0	0.0
2014	3	4	7.6	2.5	0	0.0
2015	3	8	6.3	2.1	0	0.0
2016	3	5	1.9	0.6	0	0.0
2017	3	5	5.5	1.8	0	0.0
2018	4	4	6.4	1.6	0	0.0
2019	3	7	3.5	1.2	0	0.0
2020	5	8	2.7	0.5	0	0.0
2021	0	0	0.0	-	0	N/A
<i>South</i>						
2008	6	12	36.3	6.1	0	0.0
2009	2	6	10.7	5.3	0	0.0
2010	1	4	2.7	2.7	0	0.0
2011	6	7	33.0	5.5	0	0.0
2012	3	6	17.0	5.7	0	0.0
2013	5	6	13.1	2.6	0	0.0
2014	10	15	36.2	3.6	0	0.0
2015	21	29	52.5	2.5	0	0.0
2016	24	34	62.2	2.6	0	0.0
2017	29	44	63.0	2.2	0	0.0
2018	18	24	31.5	1.8	0	0.0
2019	19	34	16.3	0.9	0	0.0
2020	9	13	5.4	0.6	0	0.0
2021	1	1	0.2	0.2	0	0.0

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
West						
2008	0	0	0.0	-	0	N/A
2009	0	3	0.0	-	0	N/A
2010	0	2	0.0	-	0	N/A
2011	1	2	2.9	2.9	0	0.0
2012	2	3	2.5	1.2	0	0.0
2013	6	11	14.7	2.5	0	0.0
2014	4	7	18.4	4.6	0	0.0
2015	6	8	19.3	3.2	0	0.0
2016	9	14	28.6	3.2	0	0.0
2017	3	10	6.1	2.0	0	0.0
2018	2	6	4.5	2.2	0	0.0
2019	4	9	4.8	1.2	0	0.0
2020	5	7	3.4	0.7	0	0.0
2021	0	0	0.0	-	0	N/A
Invalid						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	1	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 9. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Missing						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	1	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	1	1	0.1	0.1	0	0.0
2021	1	1	0.2	0.2	0	0.0
Other						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

¹Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

²Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
American Indian or Alaska Native						
2008	0	641	0.0	-	0	N/A
2009	0	569	0.0	-	0	N/A
2010	0	779	0.0	-	0	N/A
2011	0	951	0.0	-	0	N/A
2012	0	1,229	0.0	-	0	N/A
2013	0	1,234	0.0	-	0	N/A
2014	0	675	0.0	-	0	N/A
2015	0	395	0.0	-	0	N/A
2016	0	337	0.0	-	0	N/A
2017	0	345	0.0	-	0	N/A
2018	0	299	0.0	-	0	N/A
2019	0	311	0.0	-	0	N/A
2020	0	231	0.0	-	0	N/A
2021	0	47	0.0	-	0	N/A
Asian						
2008	0	4,679	0.0	-	0	N/A
2009	1	3,761	9.8	9.8	0	0.0
2010	1	3,631	0.3	0.3	0	0.0
2011	3	3,721	4.5	1.5	0	0.0
2012	0	3,979	0.0	-	0	N/A
2013	0	3,601	0.0	-	0	N/A
2014	1	3,841	5.6	5.6	0	0.0
2015	1	3,909	2.1	2.1	0	0.0
2016	0	4,329	0.0	-	0	N/A
2017	3	4,944	4.7	1.6	0	0.0
2018	0	4,865	0.0	-	0	N/A
2019	2	4,558	2.6	1.3	0	0.0
2020	1	3,787	0.6	0.6	0	0.0
2021	0	700	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	3	16,073	12.6	4.2	0	0.0
2009	4	15,812	4.9	1.2	0	0.0
2010	8	15,408	63.2	7.9	0	0.0
2011	4	16,040	21.4	5.3	0	0.0
2012	5	16,502	13.9	2.8	0	0.0
2013	3	16,271	15.2	5.1	0	0.0
2014	7	15,241	31.3	4.5	0	0.0
2015	8	15,170	29.2	3.6	0	0.0
2016	10	15,346	23.8	2.4	0	0.0
2017	12	15,091	27.1	2.3	0	0.0
2018	12	11,385	13.5	1.1	0	0.0
2019	7	10,100	4.6	0.7	0	0.0
2020	3	5,406	1.1	0.4	0	0.0
2021	0	554	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	1,587	0.0	-	0	N/A
2009	1	1,486	10.0	10.0	0	0.0
2010	0	1,409	0.0	-	0	N/A
2011	1	1,470	2.9	2.9	0	0.0
2012	2	1,500	9.7	4.8	0	0.0
2013	0	1,412	0.0	-	0	N/A
2014	0	1,293	0.0	-	0	N/A
2015	0	1,352	0.0	-	0	N/A
2016	0	1,496	0.0	-	0	N/A
2017	0	1,391	0.0	-	0	N/A
2018	1	1,389	3.0	3.0	0	0.0
2019	1	1,362	2.2	2.2	0	0.0
2020	2	1,245	0.5	0.3	0	0.0
2021	0	236	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	85	483,458	210.7	2.5	0	0.0
2009	77	459,818	209.7	2.7	0	0.0
2010	89	402,103	263.7	3.0	0	0.0
2011	66	374,433	201.5	3.1	0	0.0
2012	66	359,065	185.9	2.8	0	0.0
2013	87	421,917	216.0	2.5	0	0.0
2014	107	445,819	264.2	2.5	0	0.0
2015	102	463,196	227.7	2.2	0	0.0
2016	124	477,378	262.4	2.1	0	0.0
2017	141	464,688	263.0	1.9	0	0.0
2018	122	459,840	184.5	1.5	0	0.0
2019	136	440,690	140.6	1.0	0	0.0
2020	86	380,697	43.3	0.5	0	0.0
2021	12	48,332	1.6	0.1	0	0.0
White						
2008	13	50,850	85.1	6.5	0	0.0
2009	6	44,668	33.0	5.5	0	0.0
2010	8	42,676	35.0	4.4	0	0.0
2011	5	43,747	31.2	6.2	0	0.0
2012	8	42,886	36.7	4.6	0	0.0
2013	6	40,849	35.7	5.9	0	0.0
2014	7	38,363	27.3	3.9	0	0.0
2015	8	36,625	34.4	4.3	0	0.0
2016	13	36,949	30.0	2.3	0	0.0
2017	8	34,900	14.5	1.8	0	0.0
2018	4	26,302	6.1	1.5	0	0.0
2019	3	21,812	2.1	0.7	0	0.0
2020	2	11,349	1.7	0.8	0	0.0
2021	2	2,551	0.6	0.3	0	0.0

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Absent						
<i>American Indian or Alaska Native</i>						
2008	0	471	0.0	-	0	N/A
2009	0	411	0.0	-	0	N/A
2010	0	576	0.0	-	0	N/A
2011	0	690	0.0	-	0	N/A
2012	0	907	0.0	-	0	N/A
2013	0	888	0.0	-	0	N/A
2014	0	458	0.0	-	0	N/A
2015	0	228	0.0	-	0	N/A
2016	0	213	0.0	-	0	N/A
2017	0	217	0.0	-	0	N/A
2018	0	187	0.0	-	0	N/A
2019	0	193	0.0	-	0	N/A
2020	0	141	0.0	-	0	N/A
2021	0	26	0.0	-	0	N/A
<i>Asian</i>						
2008	0	2,962	0.0	-	0	N/A
2009	0	2,200	0.0	-	0	N/A
2010	0	2,006	0.0	-	0	N/A
2011	1	2,086	1.3	1.3	0	0.0
2012	0	2,101	0.0	-	0	N/A
2013	0	1,918	0.0	-	0	N/A
2014	0	1,902	0.0	-	0	N/A
2015	0	2,106	0.0	-	0	N/A
2016	0	2,221	0.0	-	0	N/A
2017	0	2,694	0.0	-	0	N/A
2018	0	2,729	0.0	-	0	N/A
2019	1	2,523	1.0	1.0	0	0.0
2020	0	1,993	0.0	-	0	N/A
2021	0	364	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	1	13,692	2.2	2.2	0	0.0
2009	2	13,144	3.1	1.5	0	0.0
2010	4	12,740	31.2	7.8	0	0.0
2011	1	13,423	8.3	8.3	0	0.0
2012	4	13,670	8.1	2.0	0	0.0
2013	1	13,239	6.7	6.7	0	0.0
2014	1	12,036	5.7	5.7	0	0.0
2015	1	11,695	3.0	3.0	0	0.0
2016	5	11,716	10.2	2.0	0	0.0
2017	5	11,389	11.7	2.3	0	0.0
2018	2	8,719	3.8	1.9	0	0.0
2019	4	7,879	3.3	0.8	0	0.0
2020	0	3,988	0.0	-	0	N/A
2021	0	374	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	984	0.0	-	0	N/A
2009	0	884	0.0	-	0	N/A
2010	0	732	0.0	-	0	N/A
2011	1	677	2.9	2.9	0	0.0
2012	0	602	0.0	-	0	N/A
2013	0	599	0.0	-	0	N/A
2014	0	519	0.0	-	0	N/A
2015	0	727	0.0	-	0	N/A
2016	0	731	0.0	-	0	N/A
2017	0	695	0.0	-	0	N/A
2018	0	750	0.0	-	0	N/A
2019	0	852	0.0	-	0	N/A
2020	0	730	0.0	-	0	N/A
2021	0	128	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	31	344,719	87.0	2.8	0	0.0
2009	22	318,914	66.2	3.0	0	0.0
2010	29	278,052	87.6	3.0	0	0.0
2011	25	261,035	67.8	2.7	0	0.0
2012	9	252,114	26.5	2.9	0	0.0
2013	28	298,390	88.9	3.2	0	0.0
2014	33	314,003	78.4	2.4	0	0.0
2015	22	325,851	49.8	2.3	0	0.0
2016	27	330,909	61.1	2.3	0	0.0
2017	31	316,975	65.6	2.1	0	0.0
2018	25	310,047	38.7	1.5	0	0.0
2019	33	295,794	31.4	1.0	0	0.0
2020	26	254,816	14.2	0.5	0	0.0
2021	5	33,832	0.5	0.1	0	0.0
White						
2008	3	37,864	30.6	10.2	0	0.0
2009	5	32,356	22.9	4.6	0	0.0
2010	2	30,100	0.9	0.4	0	0.0
2011	3	31,590	12.9	4.3	0	0.0
2012	2	30,226	8.6	4.3	0	0.0
2013	0	28,298	0.0	-	0	N/A
2014	1	25,299	2.6	2.6	0	0.0
2015	1	24,044	4.6	4.6	0	0.0
2016	4	23,954	12.7	3.2	0	0.0
2017	2	22,461	3.6	1.8	0	0.0
2018	2	17,183	4.1	2.1	0	0.0
2019	0	14,699	0.0	-	0	N/A
2020	0	7,040	0.0	-	0	N/A
2021	0	1,581	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Absent						
<i>American Indian or Alaska Native</i>						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	4	0.0	-	0	N/A
2011	0	5	0.0	-	0	N/A
2012	0	11	0.0	-	0	N/A
2013	0	6	0.0	-	0	N/A
2014	0	4	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	3	0.0	-	0	N/A
2017	0	2	0.0	-	0	N/A
2018	0	2	0.0	-	0	N/A
2019	0	5	0.0	-	0	N/A
2020	0	1	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Asian</i>						
2008	0	25	0.0	-	0	N/A
2009	0	23	0.0	-	0	N/A
2010	0	24	0.0	-	0	N/A
2011	0	28	0.0	-	0	N/A
2012	0	13	0.0	-	0	N/A
2013	0	24	0.0	-	0	N/A
2014	0	14	0.0	-	0	N/A
2015	0	9	0.0	-	0	N/A
2016	0	13	0.0	-	0	N/A
2017	1	11	3.8	3.8	0	0.0
2018	0	15	0.0	-	0	N/A
2019	0	26	0.0	-	0	N/A
2020	0	9	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	0	32	0.0	-	0	N/A
2009	0	50	0.0	-	0	N/A
2010	0	63	0.0	-	0	N/A
2011	0	45	0.0	-	0	N/A
2012	0	44	0.0	-	0	N/A
2013	0	35	0.0	-	0	N/A
2014	0	43	0.0	-	0	N/A
2015	0	62	0.0	-	0	N/A
2016	0	49	0.0	-	0	N/A
2017	0	31	0.0	-	0	N/A
2018	0	28	0.0	-	0	N/A
2019	0	24	0.0	-	0	N/A
2020	0	12	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	6	0.0	-	0	N/A
2009	0	12	0.0	-	0	N/A
2010	0	19	0.0	-	0	N/A
2011	0	13	0.0	-	0	N/A
2012	0	12	0.0	-	0	N/A
2013	0	9	0.0	-	0	N/A
2014	0	10	0.0	-	0	N/A
2015	0	10	0.0	-	0	N/A
2016	0	13	0.0	-	0	N/A
2017	0	16	0.0	-	0	N/A
2018	1	12	3.0	3.0	0	0.0
2019	0	26	0.0	-	0	N/A
2020	0	17	0.0	-	0	N/A
2021	0	3	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	0	2,701	0.0	-	0	N/A
2009	3	2,364	13.4	4.5	0	0.0
2010	3	2,056	11.3	3.8	0	0.0
2011	0	1,959	0.0	-	0	N/A
2012	4	1,704	9.4	2.4	0	0.0
2013	1	1,916	2.4	2.4	0	0.0
2014	1	2,137	0.0	0.0	0	0.0
2015	2	1,913	6.0	3.0	0	0.0
2016	2	1,678	2.4	1.2	0	0.0
2017	5	1,557	8.1	1.6	0	0.0
2018	6	1,498	7.1	1.2	0	0.0
2019	3	1,337	0.6	0.2	0	0.0
2020	4	1,257	2.0	0.5	0	0.0
2021	0	123	0.0	-	0	N/A
White						
2008	0	201	0.0	-	0	N/A
2009	0	213	0.0	-	0	N/A
2010	0	191	0.0	-	0	N/A
2011	0	167	0.0	-	0	N/A
2012	0	174	0.0	-	0	N/A
2013	1	157	8.2	8.2	0	0.0
2014	0	97	0.0	-	0	N/A
2015	0	99	0.0	-	0	N/A
2016	1	84	1.9	1.9	0	0.0
2017	0	69	0.0	-	0	N/A
2018	0	70	0.0	-	0	N/A
2019	0	42	0.0	-	0	N/A
2020	0	17	0.0	-	0	N/A
2021	0	5	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
<i>American Indian or Alaska Native</i>						
2008	0	170	0.0	-	0	N/A
2009	0	159	0.0	-	0	N/A
2010	0	201	0.0	-	0	N/A
2011	0	262	0.0	-	0	N/A
2012	0	317	0.0	-	0	N/A
2013	0	348	0.0	-	0	N/A
2014	0	216	0.0	-	0	N/A
2015	0	167	0.0	-	0	N/A
2016	0	123	0.0	-	0	N/A
2017	0	130	0.0	-	0	N/A
2018	0	110	0.0	-	0	N/A
2019	0	114	0.0	-	0	N/A
2020	0	95	0.0	-	0	N/A
2021	0	21	0.0	-	0	N/A
<i>Asian</i>						
2008	0	1,735	0.0	-	0	N/A
2009	1	1,559	9.8	9.8	0	0.0
2010	1	1,614	0.3	0.3	0	0.0
2011	2	1,619	3.2	1.6	0	0.0
2012	0	1,877	0.0	-	0	N/A
2013	0	1,680	0.0	-	0	N/A
2014	1	1,946	5.6	5.6	0	0.0
2015	1	1,810	2.1	2.1	0	0.0
2016	0	2,122	0.0	-	0	N/A
2017	2	2,267	0.8	0.4	0	0.0
2018	0	2,148	0.0	-	0	N/A
2019	1	2,050	1.6	1.6	0	0.0
2020	1	1,819	0.6	0.6	0	0.0
2021	0	336	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	2	2,412	10.5	5.2	0	0.0
2009	2	2,691	1.8	0.9	0	0.0
2010	4	2,680	32.0	8.0	0	0.0
2011	3	2,634	13.1	4.4	0	0.0
2012	1	2,852	5.9	5.9	0	0.0
2013	1	3,061	7.2	7.2	0	0.0
2014	5	3,225	19.8	4.0	0	0.0
2015	5	3,486	20.9	4.2	0	0.0
2016	5	3,629	13.6	2.7	0	0.0
2017	6	3,713	13.4	2.2	0	0.0
2018	10	2,688	9.7	1.0	0	0.0
2019	3	2,231	1.4	0.5	0	0.0
2020	3	1,419	1.1	0.4	0	0.0
2021	0	181	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	606	0.0	-	0	N/A
2009	0	595	0.0	-	0	N/A
2010	0	674	0.0	-	0	N/A
2011	0	785	0.0	-	0	N/A
2012	2	887	9.7	4.8	0	0.0
2013	0	797	0.0	-	0	N/A
2014	0	775	0.0	-	0	N/A
2015	0	631	0.0	-	0	N/A
2016	0	761	0.0	-	0	N/A
2017	0	693	0.0	-	0	N/A
2018	0	641	0.0	-	0	N/A
2019	1	497	2.2	2.2	0	0.0
2020	1	522	0.4	0.4	0	0.0
2021	0	106	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	48	138,008	98.9	2.1	0	0.0
2009	45	140,540	107.9	2.4	0	0.0
2010	48	123,933	151.8	3.2	0	0.0
2011	37	113,332	120.0	3.2	0	0.0
2012	51	107,092	140.6	2.8	0	0.0
2013	56	123,833	124.1	2.2	0	0.0
2014	68	131,840	166.8	2.5	0	0.0
2015	69	137,830	146.4	2.1	0	0.0
2016	87	147,118	180.3	2.1	0	0.0
2017	102	148,426	180.4	1.8	0	0.0
2018	85	150,515	129.6	1.5	0	0.0
2019	87	145,796	92.4	1.1	0	0.0
2020	51	126,580	26.0	0.5	0	0.0
2021	6	14,561	0.9	0.2	0	0.0
White						
2008	9	13,064	43.4	4.8	0	0.0
2009	1	12,362	10.1	10.1	0	0.0
2010	6	12,625	34.1	5.7	0	0.0
2011	2	12,211	18.3	9.2	0	0.0
2012	6	12,718	28.1	4.7	0	0.0
2013	5	12,605	27.5	5.5	0	0.0
2014	4	13,122	12.7	3.2	0	0.0
2015	6	12,662	25.1	4.2	0	0.0
2016	8	13,069	15.4	1.9	0	0.0
2017	5	12,522	7.6	1.5	0	0.0
2018	1	9,163	1.5	1.5	0	0.0
2019	3	7,166	2.1	0.7	0	0.0
2020	2	4,343	1.7	0.8	0	0.0
2021	1	970	0.2	0.2	0	0.0

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
<i>American Indian or Alaska Native</i>						
2008	0	3	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	2	0.0	-	0	N/A
2011	0	5	0.0	-	0	N/A
2012	0	3	0.0	-	0	N/A
2013	0	3	0.0	-	0	N/A
2014	0	2	0.0	-	0	N/A
2015	0	4	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Asian</i>						
2008	0	20	0.0	-	0	N/A
2009	0	19	0.0	-	0	N/A
2010	0	30	0.0	-	0	N/A
2011	0	25	0.0	-	0	N/A
2012	0	34	0.0	-	0	N/A
2013	0	26	0.0	-	0	N/A
2014	0	18	0.0	-	0	N/A
2015	0	23	0.0	-	0	N/A
2016	0	16	0.0	-	0	N/A
2017	0	14	0.0	-	0	N/A
2018	0	10	0.0	-	0	N/A
2019	0	10	0.0	-	0	N/A
2020	0	10	0.0	-	0	N/A
2021	0	3	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	0	12	0.0	-	0	N/A
2009	0	25	0.0	-	0	N/A
2010	0	21	0.0	-	0	N/A
2011	0	18	0.0	-	0	N/A
2012	0	24	0.0	-	0	N/A
2013	1	19	1.3	1.3	0	0.0
2014	1	40	5.8	5.8	0	0.0
2015	2	36	5.3	2.6	0	0.0
2016	0	33	0.0	-	0	N/A
2017	1	41	2.0	2.0	0	0.0
2018	0	22	0.0	-	0	N/A
2019	0	11	0.0	-	0	N/A
2020	0	4	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	8	0.0	-	0	N/A
2009	1	5	10.0	10.0	0	0.0
2010	0	17	0.0	-	0	N/A
2011	0	17	0.0	-	0	N/A
2012	0	21	0.0	-	0	N/A
2013	0	31	0.0	-	0	N/A
2014	0	13	0.0	-	0	N/A
2015	0	10	0.0	-	0	N/A
2016	0	14	0.0	-	0	N/A
2017	0	9	0.0	-	0	N/A
2018	0	3	0.0	-	0	N/A
2019	0	14	0.0	-	0	N/A
2020	1	9	0.1	0.1	0	0.0
2021	0	1	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	6	1,643	24.8	4.1	0	0.0
2009	7	1,505	22.2	3.2	0	0.0
2010	9	1,257	13.0	1.4	0	0.0
2011	4	1,160	13.6	3.4	0	0.0
2012	2	1,101	9.4	4.7	0	0.0
2013	2	1,083	0.7	0.3	0	0.0
2014	5	1,280	18.9	3.8	0	0.0
2015	9	1,119	25.5	2.8	0	0.0
2016	8	1,024	18.7	2.3	0	0.0
2017	3	1,020	8.8	2.9	0	0.0
2018	6	957	9.1	1.5	0	0.0
2019	13	881	16.2	1.2	0	0.0
2020	5	732	1.1	0.2	0	0.0
2021	1	83	0.2	0.2	0	0.0
White						
2008	1	91	11.1	11.1	0	0.0
2009	0	106	0.0	-	0	N/A
2010	0	107	0.0	-	0	N/A
2011	0	98	0.0	-	0	N/A
2012	0	116	0.0	-	0	N/A
2013	0	100	0.0	-	0	N/A
2014	2	73	12.0	6.0	0	0.0
2015	1	66	4.7	4.7	0	0.0
2016	0	51	0.0	-	0	N/A
2017	1	55	3.4	3.4	0	0.0
2018	1	63	0.4	0.4	0	0.0
2019	0	41	0.0	-	0	N/A
2020	0	28	0.0	-	0	N/A
2021	1	4	0.4	0.4	0	0.0

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members ³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
<i>American Indian or Alaska Native</i>						
2008	0	641	0.0	-	0	N/A
2009	0	569	0.0	-	0	N/A
2010	0	779	0.0	-	0	N/A
2011	0	951	0.0	-	0	N/A
2012	0	1,229	0.0	-	0	N/A
2013	0	1,234	0.0	-	0	N/A
2014	0	675	0.0	-	0	N/A
2015	0	395	0.0	-	0	N/A
2016	0	337	0.0	-	0	N/A
2017	0	345	0.0	-	0	N/A
2018	0	299	0.0	-	0	N/A
2019	0	311	0.0	-	0	N/A
2020	0	231	0.0	-	0	N/A
2021	0	47	0.0	-	0	N/A
<i>Asian</i>						
2008	0	4,679	0.0	-	0	N/A
2009	1	3,761	0.5	0.5	0	0.0
2010	1	3,631	0.3	0.3	0	0.0
2011	3	3,721	1.5	0.5	0	0.0
2012	0	3,979	0.0	-	0	N/A
2013	0	3,601	0.0	-	0	N/A
2014	1	3,841	0.5	0.5	0	0.0
2015	1	3,909	0.5	0.5	0	0.0
2016	0	4,329	0.0	-	0	N/A
2017	3	4,944	0.9	0.3	1	3,333.3
2018	0	4,865	0.0	-	0	N/A
2019	2	4,558	1.0	0.5	0	0.0
2020	1	3,787	0.5	0.5	0	0.0
2021	0	700	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	3	16,073	1.5	0.5	0	0.0
2009	4	15,812	2.0	0.5	0	0.0
2010	8	15,408	3.9	0.5	0	0.0
2011	4	16,040	1.1	0.3	1	2,500.0
2012	5	16,502	2.1	0.4	0	0.0
2013	3	16,271	1.5	0.5	0	0.0
2014	7	15,241	2.2	0.3	3	4,285.7
2015	8	15,170	1.8	0.2	4	5,000.0
2016	10	15,346	3.4	0.3	4	4,000.0
2017	12	15,091	3.5	0.3	5	4,166.7
2018	12	11,385	3.7	0.3	3	2,500.0
2019	7	10,100	1.6	0.2	4	5,714.3
2020	3	5,406	0.6	0.2	0	0.0
2021	0	554	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	1,587	0.0	-	0	N/A
2009	1	1,486	0.5	0.5	0	0.0
2010	0	1,409	0.0	-	0	N/A
2011	1	1,470	0.1	0.1	1	10,000.0
2012	2	1,500	1.0	0.5	0	0.0
2013	0	1,412	0.0	-	0	N/A
2014	0	1,293	0.0	-	0	N/A
2015	0	1,352	0.0	-	0	N/A
2016	0	1,496	0.0	-	0	N/A
2017	0	1,391	0.0	-	0	N/A
2018	1	1,389	0.1	0.1	1	10,000.0
2019	1	1,362	0.5	0.5	0	0.0
2020	2	1,245	0.5	0.2	1	5,000.0
2021	0	236	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	85	483,458	31.5	0.4	3	352.9
2009	77	459,818	31.2	0.4	4	519.5
2010	89	402,103	36.1	0.4	4	449.4
2011	66	374,433	25.9	0.4	9	1,363.6
2012	65	359,065	24.9	0.4	8	1,230.8
2013	87	421,917	29.9	0.3	15	1,724.1
2014	107	445,819	37.0	0.3	18	1,682.2
2015	101	463,196	31.3	0.3	28	2,772.3
2016	122	477,378	36.8	0.3	30	2,459.0
2017	141	464,688	46.0	0.3	34	2,411.3
2018	122	459,840	40.1	0.3	26	2,131.1
2019	136	440,690	42.5	0.3	34	2,500.0
2020	86	380,697	22.4	0.3	24	2,790.7
2021	12	48,332	1.1	0.1	3	2,500.0
White						
2008	13	50,850	5.4	0.4	4	3,076.9
2009	6	44,668	2.2	0.4	0	0.0
2010	8	42,676	3.5	0.4	1	1,250.0
2011	5	43,747	2.2	0.4	0	0.0
2012	8	42,886	2.7	0.3	2	2,500.0
2013	6	40,849	2.8	0.5	0	0.0
2014	7	38,363	2.2	0.3	2	2,857.1
2015	8	36,625	3.3	0.4	2	2,500.0
2016	13	36,949	3.1	0.2	8	6,153.8
2017	8	34,900	2.9	0.4	3	3,750.0
2018	4	26,302	1.2	0.3	2	5,000.0
2019	3	21,812	0.7	0.2	1	3,333.3
2020	2	11,349	0.1	0.1	2	10,000.0
2021	2	2,551	0.6	0.3	0	0.0

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Absent						
<i>American Indian or Alaska Native</i>						
2008	0	471	0.0	-	0	N/A
2009	0	411	0.0	-	0	N/A
2010	0	576	0.0	-	0	N/A
2011	0	690	0.0	-	0	N/A
2012	0	907	0.0	-	0	N/A
2013	0	888	0.0	-	0	N/A
2014	0	458	0.0	-	0	N/A
2015	0	228	0.0	-	0	N/A
2016	0	213	0.0	-	0	N/A
2017	0	217	0.0	-	0	N/A
2018	0	187	0.0	-	0	N/A
2019	0	193	0.0	-	0	N/A
2020	0	141	0.0	-	0	N/A
2021	0	26	0.0	-	0	N/A
<i>Asian</i>						
2008	0	2,962	0.0	-	0	N/A
2009	0	2,200	0.0	-	0	N/A
2010	0	2,006	0.0	-	0	N/A
2011	1	2,086	0.5	0.5	0	0.0
2012	0	2,101	0.0	-	0	N/A
2013	0	1,918	0.0	-	0	N/A
2014	0	1,902	0.0	-	0	N/A
2015	0	2,106	0.0	-	0	N/A
2016	0	2,221	0.0	-	0	N/A
2017	0	2,694	0.0	-	0	N/A
2018	0	2,729	0.0	-	0	N/A
2019	1	2,523	0.5	0.5	0	0.0
2020	0	1,993	0.0	-	0	N/A
2021	0	364	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	1	13,692	0.5	0.5	0	0.0
2009	2	13,144	1.0	0.5	0	0.0
2010	4	12,740	2.0	0.5	0	0.0
2011	1	13,423	0.1	0.1	1	10,000.0
2012	4	13,670	1.6	0.4	0	0.0
2013	1	13,239	0.5	0.5	0	0.0
2014	1	12,036	0.5	0.5	0	0.0
2015	1	11,695	0.5	0.5	0	0.0
2016	5	11,716	2.2	0.4	0	0.0
2017	5	11,389	2.1	0.4	1	2,000.0
2018	2	8,719	0.6	0.3	1	5,000.0
2019	4	7,879	1.1	0.3	2	5,000.0
2020	0	3,988	0.0	-	0	N/A
2021	0	374	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	984	0.0	-	0	N/A
2009	0	884	0.0	-	0	N/A
2010	0	732	0.0	-	0	N/A
2011	1	677	0.1	0.1	1	10,000.0
2012	0	602	0.0	-	0	N/A
2013	0	599	0.0	-	0	N/A
2014	0	519	0.0	-	0	N/A
2015	0	727	0.0	-	0	N/A
2016	0	731	0.0	-	0	N/A
2017	0	695	0.0	-	0	N/A
2018	0	750	0.0	-	0	N/A
2019	0	852	0.0	-	0	N/A
2020	0	730	0.0	-	0	N/A
2021	0	128	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	31	344,719	10.2	0.3	1	322.6
2009	22	318,914	8.7	0.4	0	0.0
2010	29	278,052	11.7	0.4	0	0.0
2011	25	261,035	10.1	0.4	3	1,200.0
2012	9	252,114	3.8	0.4	0	0.0
2013	28	298,390	10.0	0.4	4	1,428.6
2014	33	314,003	13.7	0.4	0	0.0
2015	22	325,851	9.3	0.4	1	454.5
2016	27	330,909	11.0	0.4	2	740.7
2017	31	316,975	10.9	0.4	5	1,612.9
2018	25	310,047	9.2	0.4	3	1,200.0
2019	33	295,794	13.2	0.4	3	909.1
2020	26	254,816	7.0	0.3	7	2,692.3
2021	5	33,832	0.3	0.1	1	2,000.0
White						
2008	3	37,864	1.5	0.5	0	0.0
2009	5	32,356	1.7	0.3	0	0.0
2010	2	30,100	0.8	0.4	0	0.0
2011	3	31,590	1.2	0.4	0	0.0
2012	2	30,226	1.0	0.5	0	0.0
2013	0	28,298	0.0	-	0	N/A
2014	1	25,299	0.5	0.5	0	0.0
2015	1	24,044	0.5	0.5	0	0.0
2016	4	23,954	0.8	0.2	3	7,500.0
2017	2	22,461	1.0	0.5	0	0.0
2018	2	17,183	1.0	0.5	0	0.0
2019	0	14,699	0.0	-	0	N/A
2020	0	7,040	0.0	-	0	N/A
2021	0	1,581	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Absent						
<i>American Indian or Alaska Native</i>						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	4	0.0	-	0	N/A
2011	0	5	0.0	-	0	N/A
2012	0	11	0.0	-	0	N/A
2013	0	6	0.0	-	0	N/A
2014	0	4	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	3	0.0	-	0	N/A
2017	0	2	0.0	-	0	N/A
2018	0	2	0.0	-	0	N/A
2019	0	5	0.0	-	0	N/A
2020	0	1	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Asian</i>						
2008	0	25	0.0	-	0	N/A
2009	0	23	0.0	-	0	N/A
2010	0	24	0.0	-	0	N/A
2011	0	28	0.0	-	0	N/A
2012	0	13	0.0	-	0	N/A
2013	0	24	0.0	-	0	N/A
2014	0	14	0.0	-	0	N/A
2015	0	9	0.0	-	0	N/A
2016	0	13	0.0	-	0	N/A
2017	1	11	0.1	0.1	1	10,000.0
2018	0	15	0.0	-	0	N/A
2019	0	26	0.0	-	0	N/A
2020	0	9	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	0	32	0.0	-	0	N/A
2009	0	50	0.0	-	0	N/A
2010	0	63	0.0	-	0	N/A
2011	0	45	0.0	-	0	N/A
2012	0	44	0.0	-	0	N/A
2013	0	35	0.0	-	0	N/A
2014	0	43	0.0	-	0	N/A
2015	0	62	0.0	-	0	N/A
2016	0	49	0.0	-	0	N/A
2017	0	31	0.0	-	0	N/A
2018	0	28	0.0	-	0	N/A
2019	0	24	0.0	-	0	N/A
2020	0	12	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	6	0.0	-	0	N/A
2009	0	12	0.0	-	0	N/A
2010	0	19	0.0	-	0	N/A
2011	0	13	0.0	-	0	N/A
2012	0	12	0.0	-	0	N/A
2013	0	9	0.0	-	0	N/A
2014	0	10	0.0	-	0	N/A
2015	0	10	0.0	-	0	N/A
2016	0	13	0.0	-	0	N/A
2017	0	16	0.0	-	0	N/A
2018	1	12	0.1	0.1	1	10,000.0
2019	0	26	0.0	-	0	N/A
2020	0	17	0.0	-	0	N/A
2021	0	3	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	0	2,701	0.0	-	0	N/A
2009	3	2,364	1.2	0.4	0	0.0
2010	3	2,056	1.5	0.5	0	0.0
2011	0	1,959	0.0	-	0	N/A
2012	4	1,704	2.0	0.5	0	0.0
2013	1	1,916	0.1	0.1	1	10,000.0
2014	1	2,137	0.0	0.0	0	0.0
2015	2	1,913	0.3	0.2	1	5,000.0
2016	2	1,678	0.5	0.3	1	5,000.0
2017	5	1,557	1.1	0.2	2	4,000.0
2018	6	1,498	2.1	0.3	1	1,666.7
2019	3	1,337	0.6	0.2	0	0.0
2020	4	1,257	0.5	0.1	2	5,000.0
2021	0	123	0.0	-	0	N/A
White						
2008	0	201	0.0	-	0	N/A
2009	0	213	0.0	-	0	N/A
2010	0	191	0.0	-	0	N/A
2011	0	167	0.0	-	0	N/A
2012	0	174	0.0	-	0	N/A
2013	1	157	0.5	0.5	0	0.0
2014	0	97	0.0	-	0	N/A
2015	0	99	0.0	-	0	N/A
2016	1	84	0.1	0.1	1	10,000.0
2017	0	69	0.0	-	0	N/A
2018	0	70	0.0	-	0	N/A
2019	0	42	0.0	-	0	N/A
2020	0	17	0.0	-	0	N/A
2021	0	5	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
<i>American Indian or Alaska Native</i>						
2008	0	170	0.0	-	0	N/A
2009	0	159	0.0	-	0	N/A
2010	0	201	0.0	-	0	N/A
2011	0	262	0.0	-	0	N/A
2012	0	317	0.0	-	0	N/A
2013	0	348	0.0	-	0	N/A
2014	0	216	0.0	-	0	N/A
2015	0	167	0.0	-	0	N/A
2016	0	123	0.0	-	0	N/A
2017	0	130	0.0	-	0	N/A
2018	0	110	0.0	-	0	N/A
2019	0	114	0.0	-	0	N/A
2020	0	95	0.0	-	0	N/A
2021	0	21	0.0	-	0	N/A
<i>Asian</i>						
2008	0	1,735	0.0	-	0	N/A
2009	1	1,559	0.5	0.5	0	0.0
2010	1	1,614	0.3	0.3	0	0.0
2011	2	1,619	1.0	0.5	0	0.0
2012	0	1,877	0.0	-	0	N/A
2013	0	1,680	0.0	-	0	N/A
2014	1	1,946	0.5	0.5	0	0.0
2015	1	1,810	0.5	0.5	0	0.0
2016	0	2,122	0.0	-	0	N/A
2017	2	2,267	0.8	0.4	0	0.0
2018	0	2,148	0.0	-	0	N/A
2019	1	2,050	0.5	0.5	0	0.0
2020	1	1,819	0.5	0.5	0	0.0
2021	0	336	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	2	2,412	1.0	0.5	0	0.0
2009	2	2,691	1.0	0.5	0	0.0
2010	4	2,680	2.0	0.5	0	0.0
2011	3	2,634	1.0	0.3	0	0.0
2012	1	2,852	0.5	0.5	0	0.0
2013	1	3,061	0.5	0.5	0	0.0
2014	5	3,225	1.5	0.3	2	4,000.0
2015	5	3,486	1.2	0.2	3	6,000.0
2016	5	3,629	1.2	0.2	4	8,000.0
2017	6	3,713	1.3	0.2	3	5,000.0
2018	10	2,688	3.2	0.3	2	2,000.0
2019	3	2,231	0.6	0.2	2	6,666.7
2020	3	1,419	0.6	0.2	0	0.0
2021	0	181	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	606	0.0	-	0	N/A
2009	0	595	0.0	-	0	N/A
2010	0	674	0.0	-	0	N/A
2011	0	785	0.0	-	0	N/A
2012	2	887	1.0	0.5	0	0.0
2013	0	797	0.0	-	0	N/A
2014	0	775	0.0	-	0	N/A
2015	0	631	0.0	-	0	N/A
2016	0	761	0.0	-	0	N/A
2017	0	693	0.0	-	0	N/A
2018	0	641	0.0	-	0	N/A
2019	1	497	0.5	0.5	0	0.0
2020	1	522	0.4	0.4	0	0.0
2021	0	106	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	48	138,008	18.3	0.4	2	416.7
2009	45	140,540	18.6	0.4	3	666.7
2010	48	123,933	18.7	0.4	4	833.3
2011	37	113,332	14.4	0.4	5	1,351.4
2012	50	107,092	19.0	0.4	6	1,200.0
2013	56	123,833	19.3	0.3	9	1,607.1
2014	68	131,840	22.9	0.3	13	1,911.8
2015	68	137,830	19.1	0.3	22	3,235.3
2016	86	147,118	24.4	0.3	22	2,558.1
2017	102	148,426	33.7	0.3	24	2,352.9
2018	85	150,515	27.2	0.3	19	2,235.3
2019	87	145,796	27.1	0.3	21	2,413.8
2020	51	126,580	14.1	0.3	13	2,549.0
2021	6	14,561	0.6	0.1	2	3,333.3
White						
2008	9	13,064	3.8	0.4	3	3,333.3
2009	1	12,362	0.5	0.5	0	0.0
2010	6	12,625	2.6	0.4	1	1,666.7
2011	2	12,211	1.0	0.5	0	0.0
2012	6	12,718	1.7	0.3	2	3,333.3
2013	5	12,605	2.3	0.5	0	0.0
2014	4	13,122	1.0	0.3	1	2,500.0
2015	6	12,662	2.7	0.4	1	1,666.7
2016	8	13,069	2.3	0.3	4	5,000.0
2017	5	12,522	1.9	0.4	2	4,000.0
2018	1	9,163	0.1	0.1	1	10,000.0
2019	3	7,166	0.7	0.2	1	3,333.3
2020	2	4,343	0.1	0.1	2	10,000.0
2021	1	970	0.2	0.2	0	0.0

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
<i>American Indian or Alaska Native</i>						
2008	0	3	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	2	0.0	-	0	N/A
2011	0	5	0.0	-	0	N/A
2012	0	3	0.0	-	0	N/A
2013	0	3	0.0	-	0	N/A
2014	0	2	0.0	-	0	N/A
2015	0	4	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Asian</i>						
2008	0	20	0.0	-	0	N/A
2009	0	19	0.0	-	0	N/A
2010	0	30	0.0	-	0	N/A
2011	0	25	0.0	-	0	N/A
2012	0	34	0.0	-	0	N/A
2013	0	26	0.0	-	0	N/A
2014	0	18	0.0	-	0	N/A
2015	0	23	0.0	-	0	N/A
2016	0	16	0.0	-	0	N/A
2017	0	14	0.0	-	0	N/A
2018	0	10	0.0	-	0	N/A
2019	0	10	0.0	-	0	N/A
2020	0	10	0.0	-	0	N/A
2021	0	3	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	0	12	0.0	-	0	N/A
2009	0	25	0.0	-	0	N/A
2010	0	21	0.0	-	0	N/A
2011	0	18	0.0	-	0	N/A
2012	0	24	0.0	-	0	N/A
2013	1	19	0.5	0.5	0	0.0
2014	1	40	0.2	0.2	1	10,000.0
2015	2	36	0.1	0.1	1	5,000.0
2016	0	33	0.0	-	0	N/A
2017	1	41	0.1	0.1	1	10,000.0
2018	0	22	0.0	-	0	N/A
2019	0	11	0.0	-	0	N/A
2020	0	4	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	8	0.0	-	0	N/A
2009	1	5	0.5	0.5	0	0.0
2010	0	17	0.0	-	0	N/A
2011	0	17	0.0	-	0	N/A
2012	0	21	0.0	-	0	N/A
2013	0	31	0.0	-	0	N/A
2014	0	13	0.0	-	0	N/A
2015	0	10	0.0	-	0	N/A
2016	0	14	0.0	-	0	N/A
2017	0	9	0.0	-	0	N/A
2018	0	3	0.0	-	0	N/A
2019	0	14	0.0	-	0	N/A
2020	1	9	0.0	0.0	1	10,000.0
2021	0	1	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	6	1,643	3.0	0.5	0	0.0
2009	7	1,505	2.6	0.4	1	1,428.6
2010	9	1,257	4.3	0.5	0	0.0
2011	4	1,160	1.4	0.3	1	2,500.0
2012	2	1,101	0.1	0.1	2	10,000.0
2013	2	1,083	0.4	0.2	1	5,000.0
2014	5	1,280	0.3	0.1	5	10,000.0
2015	9	1,119	2.7	0.3	4	4,444.4
2016	7	1,024	0.9	0.1	5	7,142.9
2017	3	1,020	0.4	0.1	3	10,000.0
2018	6	957	1.6	0.3	3	5,000.0
2019	13	881	1.6	0.1	10	7,692.3
2020	5	732	0.7	0.1	2	4,000.0
2021	1	83	0.2	0.2	0	0.0
White						
2008	1	91	0.1	0.1	1	10,000.0
2009	0	106	0.0	-	0	N/A
2010	0	107	0.0	-	0	N/A
2011	0	98	0.0	-	0	N/A
2012	0	116	0.0	-	0	N/A
2013	0	100	0.0	-	0	N/A
2014	2	73	0.6	0.3	1	5,000.0
2015	1	66	0.1	0.1	1	10,000.0
2016	0	51	0.0	-	0	N/A
2017	1	55	0.0	0.0	1	10,000.0
2018	1	63	0.1	0.1	1	10,000.0
2019	0	41	0.0	-	0	N/A
2020	0	28	0.0	-	0	N/A
2021	1	4	0.4	0.4	0	0.0

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Treatment Within 45 Days from Diagnosis						
American Indian or Alaska Native						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Asian						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	1	0.0	-	0	N/A
2017	1	1	3.8	3.8	0	0.0
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	1	2	8.3	8.3	0	0.0
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	4	4	19.9	5.0	0	0.0
2016	2	2	6.2	3.1	0	0.0
2017	3	5	6.6	2.2	0	0.0
2018	2	2	1.9	0.9	0	0.0
2019	3	3	2.0	0.7	0	0.0
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	1	1	2.9	2.9	0	0.0
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	1	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	1	1	0.1	0.1	0	0.0
2021	0	0	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	0	1	0.0	-	0	N/A
2009	1	3	0.4	0.4	0	0.0
2010	3	4	7.6	2.5	0	0.0
2011	3	5	13.5	4.5	0	0.0
2012	9	10	24.5	2.7	0	0.0
2013	11	14	27.2	2.5	0	0.0
2014	15	17	39.1	2.6	0	0.0
2015	24	32	56.4	2.3	0	0.0
2016	24	30	63.7	2.7	0	0.0
2017	24	31	43.3	1.8	0	0.0
2018	21	24	32.7	1.6	0	0.0
2019	27	38	31.7	1.2	0	0.0
2020	20	24	11.8	0.6	0	0.0
2021	3	3	0.7	0.2	0	0.0
White						
2008	2	2	21.7	10.9	0	0.0
2009	0	1	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	2	2	9.9	5.0	0	0.0
2013	0	1	0.0	-	0	N/A
2014	1	2	5.9	5.9	0	0.0
2015	0	1	0.0	-	0	N/A
2016	6	7	18.7	3.1	0	0.0
2017	2	2	4.4	2.2	0	0.0
2018	2	2	1.9	1.0	0	0.0
2019	1	3	0.4	0.4	0	0.0
2020	2	2	1.7	0.8	0	0.0
2021	0	0	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Treatment Within 180 Days from Diagnosis						
American Indian or Alaska Native						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
Asian						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	1	0.0	-	0	N/A
2016	0	1	0.0	-	0	N/A
2017	1	1	3.8	3.8	0	0.0
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
<i>Black or African American</i>						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	1	2	8.3	8.3	0	0.0
2012	0	1	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	3	3	16.4	5.5	0	0.0
2015	4	4	19.9	5.0	0	0.0
2016	4	4	10.4	2.6	0	0.0
2017	5	8	11.5	2.3	0	0.0
2018	3	3	3.8	1.3	0	0.0
2019	4	4	2.6	0.6	0	0.0
2020	0	0	0.0	-	0	N/A
2021	0	0	0.0	-	0	N/A
<i>Native Hawaiian or Other Pacific Islander</i>						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	1	1	2.9	2.9	0	0.0
2012	0	0	0.0	-	0	N/A
2013	0	1	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	0	0.0	-	0	N/A
2016	0	0	0.0	-	0	N/A
2017	0	2	0.0	-	0	N/A
2018	1	1	3.0	3.0	0	0.0
2019	0	0	0.0	-	0	N/A
2020	1	1	0.1	0.1	0	0.0
2021	0	0	0.0	-	0	N/A

Table 10. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year^{1,2}

	New Users	Eligible Members ³	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	3	8	14.0	4.7	0	0.0
2009	4	11	15.8	3.9	0	0.0
2010	4	15	7.8	1.9	0	0.0
2011	9	14	33.8	3.8	0	0.0
2012	9	16	24.5	2.7	0	0.0
2013	15	25	30.4	2.0	0	0.0
2014	19	33	44.2	2.3	0	0.0
2015	29	48	70.0	2.4	0	0.0
2016	33	52	90.2	2.7	0	0.0
2017	34	54	69.3	2.0	0	0.0
2018	26	38	41.5	1.6	0	0.0
2019	34	58	40.0	1.2	0	0.0
2020	24	33	14.9	0.6	0	0.0
2021	3	3	0.7	0.2	0	0.0
White						
2008	4	6	24.1	6.0	0	0.0
2009	0	2	0.0	-	0	N/A
2010	1	2	10.7	10.7	0	0.0
2011	0	0	0.0	-	0	N/A
2012	2	2	9.9	5.0	0	0.0
2013	0	1	0.0	-	0	N/A
2014	2	3	12.7	6.4	0	0.0
2015	2	4	9.2	4.6	0	0.0
2016	8	10	22.3	2.8	0	0.0
2017	3	4	4.9	1.6	0	0.0
2018	2	3	1.9	1.0	0	0.0
2019	1	4	0.4	0.4	0	0.0
2020	2	3	1.7	0.8	0	0.0
2021	0	0	0.0	-	0	N/A

¹Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

²Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

³Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV)						
Overall						
Yes						
2008	0	7,652	0.0	-	0	N/A
2009	0	5,645	0.0	-	0	N/A
2010	1	4,911	2.6	2.6	0	0.0
2011	0	4,668	0.0	-	0	N/A
2012	2	4,596	5.5	2.7	0	0.0
2013	2	3,988	9.9	4.9	0	0.0
2014	0	3,687	0.0	-	0	N/A
2015	0	3,985	0.0	-	0	N/A
2016	1	4,209	3.9	3.9	0	0.0
2017	1	4,195	1.9	1.9	0	0.0
2018	1	4,447	2.9	2.9	0	0.0
2019	2	4,598	3.9	2.0	0	0.0
2020	2	3,813	1.2	0.6	0	0.0
2021	0	585	0.0	-	0	N/A
No						
2008	14	53,464	93.4	6.7	0	0.0
2009	11	54,068	57.5	5.2	0	0.0
2010	13	53,505	76.7	5.9	0	0.0
2011	12	55,640	55.5	4.6	0	0.0
2012	12	55,600	44.2	3.7	0	0.0
2013	6	53,372	42.1	7.0	0	0.0
2014	13	50,306	57.1	4.4	0	0.0
2015	14	48,597	54.2	3.9	0	0.0
2016	17	49,278	41.8	2.5	0	0.0
2017	17	47,111	36.7	2.2	0	0.0
2018	8	34,994	16.4	2.1	0	0.0
2019	9	29,031	5.7	0.6	0	0.0
2020	4	13,637	2.2	0.5	0	0.0
2021	1	2,473	0.4	0.4	0	0.0

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	87	496,172	215.1	2.5	0	0.0
2009	78	466,401	209.9	2.7	0	0.0
2010	92	407,590	282.9	3.1	0	0.0
2011	67	380,054	206.0	3.1	0	0.0
2012	67	364,965	196.6	2.9	0	0.0
2013	88	427,924	214.9	2.4	0	0.0
2014	109	451,239	271.2	2.5	0	0.0
2015	105	468,065	239.2	2.3	0	0.0
2016	129	482,348	270.6	2.1	0	0.0
2017	146	470,053	270.7	1.9	0	0.0
2018	130	464,639	187.7	1.4	0	0.0
2019	138	445,204	142.5	1.0	0	0.0
2020	88	385,265	43.7	0.5	0	0.0
2021	13	49,362	1.8	0.1	0	0.0
Hearing Loss: Absent, Clinical Characteristics: Absent						
Yes						
2008	0	5,424	0.0	-	0	N/A
2009	0	3,791	0.0	-	0	N/A
2010	0	3,256	0.0	-	0	N/A
2011	0	2,966	0.0	-	0	N/A
2012	0	2,848	0.0	-	0	N/A
2013	2	2,336	9.9	4.9	0	0.0
2014	0	2,117	0.0	-	0	N/A
2015	0	2,425	0.0	-	0	N/A
2016	1	2,539	3.9	3.9	0	0.0
2017	0	2,614	0.0	-	0	N/A
2018	0	2,840	0.0	-	0	N/A
2019	0	2,983	0.0	-	0	N/A
2020	0	2,522	0.0	-	0	N/A
2021	0	321	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
No						
2008	4	40,083	32.7	8.2	0	0.0
2009	6	40,087	25.8	4.3	0	0.0
2010	4	38,804	21.2	5.3	0	0.0
2011	5	41,204	20.8	4.2	0	0.0
2012	6	40,159	16.7	2.8	0	0.0
2013	1	38,067	6.7	6.7	0	0.0
2014	2	34,058	8.2	4.1	0	0.0
2015	2	32,757	7.6	3.8	0	0.0
2016	7	32,683	18.0	2.6	0	0.0
2017	6	31,032	14.0	2.3	0	0.0
2018	4	23,212	7.9	2.0	0	0.0
2019	3	19,831	2.2	0.7	0	0.0
2020	0	8,056	0.0	-	0	N/A
2021	0	1,516	0.0	-	0	N/A
Unknown						
2008	31	355,185	87.0	2.8	0	0.0
2009	23	324,031	66.3	2.9	0	0.0
2010	31	282,146	98.4	3.2	0	0.0
2011	26	265,331	72.3	2.8	0	0.0
2012	9	256,613	26.5	2.9	0	0.0
2013	26	302,929	79.0	3.0	0	0.0
2014	33	318,042	78.4	2.4	0	0.0
2015	22	329,469	49.8	2.3	0	0.0
2016	28	334,522	62.2	2.2	0	0.0
2017	32	320,785	66.9	2.1	0	0.0
2018	25	313,563	38.7	1.5	0	0.0
2019	35	299,126	33.5	1.0	0	0.0
2020	26	258,130	14.2	0.5	0	0.0
2021	5	34,468	0.5	0.1	0	0.0

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Absent						
Yes						
2008	0	29	0.0	-	0	N/A
2009	0	20	0.0	-	0	N/A
2010	0	26	0.0	-	0	N/A
2011	0	31	0.0	-	0	N/A
2012	0	22	0.0	-	0	N/A
2013	0	22	0.0	-	0	N/A
2014	0	11	0.0	-	0	N/A
2015	0	9	0.0	-	0	N/A
2016	0	14	0.0	-	0	N/A
2017	0	11	0.0	-	0	N/A
2018	0	18	0.0	-	0	N/A
2019	0	19	0.0	-	0	N/A
2020	0	12	0.0	-	0	N/A
2021	0	1	0.0	-	0	N/A
No						
2008	0	157	0.0	-	0	N/A
2009	0	226	0.0	-	0	N/A
2010	0	241	0.0	-	0	N/A
2011	0	199	0.0	-	0	N/A
2012	0	211	0.0	-	0	N/A
2013	1	192	8.2	8.2	0	0.0
2014	0	137	0.0	-	0	N/A
2015	0	152	0.0	-	0	N/A
2016	1	133	1.9	1.9	0	0.0
2017	1	112	3.8	3.8	0	0.0
2018	1	103	3.0	3.0	0	0.0
2019	0	95	0.0	-	0	N/A
2020	0	37	0.0	-	0	N/A
2021	0	7	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	0	2,779	0.0	-	0	N/A
2009	3	2,416	13.4	4.5	0	0.0
2010	3	2,090	11.3	3.8	0	0.0
2011	0	1,987	0.0	-	0	N/A
2012	4	1,725	9.4	2.4	0	0.0
2013	1	1,933	2.4	2.4	0	0.0
2014	1	2,157	0.0	0.0	0	0.0
2015	2	1,932	6.0	3.0	0	0.0
2016	2	1,693	2.4	1.2	0	0.0
2017	5	1,563	8.1	1.6	0	0.0
2018	6	1,504	7.1	1.2	0	0.0
2019	3	1,346	0.6	0.2	0	0.0
2020	4	1,264	2.0	0.5	0	0.0
2021	0	123	0.0	-	0	N/A
Hearing Loss: Absent, Clinical Characteristics: Present						
Yes						
2008	0	2,234	0.0	-	0	N/A
2009	0	1,863	0.0	-	0	N/A
2010	0	1,670	0.0	-	0	N/A
2011	0	1,686	0.0	-	0	N/A
2012	2	1,743	5.5	2.7	0	0.0
2013	0	1,645	0.0	-	0	N/A
2014	0	1,575	0.0	-	0	N/A
2015	0	1,565	0.0	-	0	N/A
2016	0	1,672	0.0	-	0	N/A
2017	1	1,578	1.9	1.9	0	0.0
2018	1	1,607	2.9	2.9	0	0.0
2019	2	1,613	3.9	2.0	0	0.0
2020	1	1,305	1.2	1.2	0	0.0
2021	0	266	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
No						
2008	9	13,456	49.6	5.5	0	0.0
2009	4	14,046	21.7	5.4	0	0.0
2010	9	14,727	55.5	6.2	0	0.0
2011	7	14,493	34.7	5.0	0	0.0
2012	6	15,499	27.5	4.6	0	0.0
2013	4	15,369	27.2	6.8	0	0.0
2014	8	16,327	31.0	3.9	0	0.0
2015	11	15,934	41.9	3.8	0	0.0
2016	9	16,676	21.9	2.4	0	0.0
2017	9	16,166	16.8	1.9	0	0.0
2018	3	11,843	5.5	1.8	0	0.0
2019	6	9,251	3.5	0.6	0	0.0
2020	4	5,640	2.2	0.5	0	0.0
2021	0	953	0.0	-	0	N/A
Unknown						
2008	50	140,305	103.2	2.1	0	0.0
2009	45	141,997	107.9	2.4	0	0.0
2010	50	125,330	162.8	3.3	0	0.0
2011	37	114,664	120.0	3.2	0	0.0
2012	52	108,501	151.3	2.9	0	0.0
2013	58	125,310	131.5	2.3	0	0.0
2014	70	133,222	173.9	2.5	0	0.0
2015	70	139,087	152.7	2.2	0	0.0
2016	91	148,474	187.4	2.1	0	0.0
2017	105	150,007	183.4	1.7	0	0.0
2018	92	151,815	132.4	1.4	0	0.0
2019	87	146,990	92.3	1.1	0	0.0
2020	53	127,833	26.5	0.5	0	0.0
2021	7	14,956	1.1	0.2	0	0.0

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Present, Clinical Characteristics: Present						
Yes						
2008	0	26	0.0	-	0	N/A
2009	0	16	0.0	-	0	N/A
2010	1	10	2.6	2.6	0	0.0
2011	0	14	0.0	-	0	N/A
2012	0	27	0.0	-	0	N/A
2013	0	17	0.0	-	0	N/A
2014	0	7	0.0	-	0	N/A
2015	0	12	0.0	-	0	N/A
2016	0	10	0.0	-	0	N/A
2017	0	15	0.0	-	0	N/A
2018	0	9	0.0	-	0	N/A
2019	0	16	0.0	-	0	N/A
2020	1	8	0.1	0.1	0	0.0
2021	0	1	0.0	-	0	N/A
No						
2008	1	90	11.1	11.1	0	0.0
2009	1	109	10.0	10.0	0	0.0
2010	0	144	0.0	-	0	N/A
2011	0	129	0.0	-	0	N/A
2012	0	147	0.0	-	0	N/A
2013	0	143	0.0	-	0	N/A
2014	3	120	17.9	6.0	0	0.0
2015	1	120	4.7	4.7	0	0.0
2016	0	95	0.0	-	0	N/A
2017	1	99	2.0	2.0	0	0.0
2018	0	75	0.0	-	0	N/A
2019	0	53	0.0	-	0	N/A
2020	0	35	0.0	-	0	N/A
2021	1	5	0.4	0.4	0	0.0

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members ²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	6	1,661	24.8	4.1	0	0.0
2009	7	1,535	22.2	3.2	0	0.0
2010	8	1,280	10.5	1.3	0	0.0
2011	4	1,180	13.6	3.4	0	0.0
2012	2	1,125	9.4	4.7	0	0.0
2013	3	1,102	1.9	0.6	0	0.0
2014	5	1,299	18.9	3.8	0	0.0
2015	11	1,126	30.8	2.8	0	0.0
2016	8	1,033	18.7	2.3	0	0.0
2017	4	1,025	12.2	3.0	0	0.0
2018	7	971	9.5	1.4	0	0.0
2019	13	888	16.2	1.2	0	0.0
2020	5	740	1.1	0.2	0	0.0
2021	1	85	0.2	0.2	0	0.0
Valganciclovir Treatment for Infants with CMV or cCMV						
Overall						
Yes						
2008	0	7,652	0.0	-	0	N/A
2009	0	5,645	0.0	-	0	N/A
2010	1	4,911	0.5	0.5	0	0.0
2011	0	4,668	0.0	-	0	N/A
2012	2	4,596	1.0	0.5	0	0.0
2013	2	3,988	1.0	0.5	0	0.0
2014	0	3,687	0.0	-	0	N/A
2015	0	3,985	0.0	-	0	N/A
2016	1	4,209	0.1	0.1	1	10,000.0
2017	1	4,195	0.5	0.5	0	0.0
2018	1	4,447	0.5	0.5	0	0.0
2019	2	4,598	1.0	0.5	0	0.0
2020	2	3,813	0.5	0.3	1	5,000.0
2021	0	585	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
No						
2008	14	53,464	5.9	0.4	4	2,857.1
2009	11	54,068	5.0	0.5	0	0.0
2010	13	53,505	6.2	0.5	0	0.0
2011	12	55,640	4.4	0.4	2	1,666.7
2012	12	55,600	4.2	0.4	2	1,666.7
2013	6	53,372	3.0	0.5	0	0.0
2014	13	50,306	4.4	0.3	4	3,076.9
2015	14	48,597	5.4	0.4	4	2,857.1
2016	17	49,278	5.0	0.3	9	5,294.1
2017	17	47,111	5.5	0.3	7	4,117.6
2018	8	34,994	2.4	0.3	4	5,000.0
2019	9	29,031	1.8	0.2	5	5,555.6
2020	4	13,637	0.6	0.2	2	5,000.0
2021	1	2,473	0.4	0.4	0	0.0
Unknown						
2008	87	496,172	32.5	0.4	3	344.8
2009	78	466,401	31.3	0.4	4	512.8
2010	92	407,590	37.1	0.4	5	543.5
2011	67	380,054	26.4	0.4	9	1,343.3
2012	66	364,965	25.4	0.4	8	1,212.1
2013	88	427,924	30.2	0.3	15	1,704.5
2014	109	451,239	37.5	0.3	19	1,743.1
2015	104	468,065	31.5	0.3	30	2,884.6
2016	127	482,348	38.4	0.3	32	2,519.7
2017	146	470,053	47.4	0.3	36	2,465.8
2018	130	464,639	42.2	0.3	28	2,153.8
2019	138	445,204	43.5	0.3	34	2,463.8
2020	88	385,265	22.9	0.3	24	2,727.3
2021	13	49,362	1.3	0.1	3	2,307.7

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Absent						
Yes						
2008	0	5,424	0.0	-	0	N/A
2009	0	3,791	0.0	-	0	N/A
2010	0	3,256	0.0	-	0	N/A
2011	0	2,966	0.0	-	0	N/A
2012	0	2,848	0.0	-	0	N/A
2013	2	2,336	1.0	0.5	0	0.0
2014	0	2,117	0.0	-	0	N/A
2015	0	2,425	0.0	-	0	N/A
2016	1	2,539	0.1	0.1	1	10,000.0
2017	0	2,614	0.0	-	0	N/A
2018	0	2,840	0.0	-	0	N/A
2019	0	2,983	0.0	-	0	N/A
2020	0	2,522	0.0	-	0	N/A
2021	0	321	0.0	-	0	N/A
No						
2008	4	40,083	2.0	0.5	0	0.0
2009	6	40,087	2.5	0.4	0	0.0
2010	4	38,804	2.0	0.5	0	0.0
2011	5	41,204	1.4	0.3	2	4,000.0
2012	6	40,159	2.5	0.4	0	0.0
2013	1	38,067	0.5	0.5	0	0.0
2014	2	34,058	1.0	0.5	0	0.0
2015	2	32,757	1.0	0.5	0	0.0
2016	7	32,683	2.4	0.3	2	2,857.1
2017	6	31,032	2.6	0.4	1	1,666.7
2018	4	23,212	1.5	0.4	1	2,500.0
2019	3	19,831	0.6	0.2	2	6,666.7
2020	0	8,056	0.0	-	0	N/A
2021	0	1,516	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	31	355,185	10.2	0.3	1	322.6
2009	23	324,031	8.9	0.4	0	0.0
2010	31	282,146	12.5	0.4	0	0.0
2011	26	265,331	10.6	0.4	3	1,153.8
2012	9	256,613	3.8	0.4	0	0.0
2013	26	302,929	9.0	0.3	4	1,538.5
2014	33	318,042	13.7	0.4	0	0.0
2015	22	329,469	9.3	0.4	1	454.5
2016	28	334,522	11.5	0.4	2	714.3
2017	32	320,785	11.4	0.4	5	1,562.5
2018	25	313,563	9.2	0.4	3	1,200.0
2019	35	299,126	14.2	0.4	3	857.1
2020	26	258,130	7.0	0.3	7	2,692.3
2021	5	34,468	0.3	0.1	1	2,000.0
Hearing Loss: Present, Clinical Characteristics: Absent						
Yes						
2008	0	29	0.0	-	0	N/A
2009	0	20	0.0	-	0	N/A
2010	0	26	0.0	-	0	N/A
2011	0	31	0.0	-	0	N/A
2012	0	22	0.0	-	0	N/A
2013	0	22	0.0	-	0	N/A
2014	0	11	0.0	-	0	N/A
2015	0	9	0.0	-	0	N/A
2016	0	14	0.0	-	0	N/A
2017	0	11	0.0	-	0	N/A
2018	0	18	0.0	-	0	N/A
2019	0	19	0.0	-	0	N/A
2020	0	12	0.0	-	0	N/A
2021	0	1	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
No						
2008	0	157	0.0	-	0	N/A
2009	0	226	0.0	-	0	N/A
2010	0	241	0.0	-	0	N/A
2011	0	199	0.0	-	0	N/A
2012	0	211	0.0	-	0	N/A
2013	1	192	0.5	0.5	0	0.0
2014	0	137	0.0	-	0	N/A
2015	0	152	0.0	-	0	N/A
2016	1	133	0.1	0.1	1	10,000.0
2017	1	112	0.1	0.1	1	10,000.0
2018	1	103	0.1	0.1	1	10,000.0
2019	0	95	0.0	-	0	N/A
2020	0	37	0.0	-	0	N/A
2021	0	7	0.0	-	0	N/A
Unknown						
2008	0	2,779	0.0	-	0	N/A
2009	3	2,416	1.2	0.4	0	0.0
2010	3	2,090	1.5	0.5	0	0.0
2011	0	1,987	0.0	-	0	N/A
2012	4	1,725	2.0	0.5	0	0.0
2013	1	1,933	0.1	0.1	1	10,000.0
2014	1	2,157	0.0	0.0	0	0.0
2015	2	1,932	0.3	0.2	1	5,000.0
2016	2	1,693	0.5	0.3	1	5,000.0
2017	5	1,563	1.1	0.2	2	4,000.0
2018	6	1,504	2.1	0.3	1	1,666.7
2019	3	1,346	0.6	0.2	0	0.0
2020	4	1,264	0.5	0.1	2	5,000.0
2021	0	123	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Hearing Loss: Absent, Clinical Characteristics: Present						
Yes						
2008	0	2,234	0.0	-	0	N/A
2009	0	1,863	0.0	-	0	N/A
2010	0	1,670	0.0	-	0	N/A
2011	0	1,686	0.0	-	0	N/A
2012	2	1,743	1.0	0.5	0	0.0
2013	0	1,645	0.0	-	0	N/A
2014	0	1,575	0.0	-	0	N/A
2015	0	1,565	0.0	-	0	N/A
2016	0	1,672	0.0	-	0	N/A
2017	1	1,578	0.5	0.5	0	0.0
2018	1	1,607	0.5	0.5	0	0.0
2019	2	1,613	1.0	0.5	0	0.0
2020	1	1,305	0.5	0.5	0	0.0
2021	0	266	0.0	-	0	N/A
No						
2008	9	13,456	3.8	0.4	3	3,333.3
2009	4	14,046	2.0	0.5	0	0.0
2010	9	14,727	4.2	0.5	0	0.0
2011	7	14,493	3.0	0.4	0	0.0
2012	6	15,499	1.7	0.3	2	3,333.3
2013	4	15,369	2.0	0.5	0	0.0
2014	8	16,327	2.5	0.3	2	2,500.0
2015	11	15,934	4.3	0.4	3	2,727.3
2016	9	16,676	2.5	0.3	6	6,666.7
2017	9	16,166	2.7	0.3	4	4,444.4
2018	3	11,843	0.8	0.3	2	6,666.7
2019	6	9,251	1.3	0.2	3	5,000.0
2020	4	5,640	0.6	0.2	2	5,000.0
2021	0	953	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	50	140,305	19.3	0.4	2	400.0
2009	45	141,997	18.6	0.4	3	666.7
2010	50	125,330	19.3	0.4	5	1,000.0
2011	37	114,664	14.4	0.4	5	1,351.4
2012	51	108,501	19.5	0.4	6	1,176.5
2013	58	125,310	20.1	0.3	9	1,551.7
2014	70	133,222	23.5	0.3	14	2,000.0
2015	69	139,087	19.1	0.3	23	3,333.3
2016	90	148,474	25.5	0.3	24	2,666.7
2017	105	150,007	34.5	0.3	25	2,381.0
2018	92	151,815	29.2	0.3	20	2,173.9
2019	87	146,990	27.1	0.3	21	2,413.8
2020	53	127,833	14.7	0.3	13	2,452.8
2021	7	14,956	0.8	0.1	2	2,857.1
Hearing Loss: Present, Clinical Characteristics: Present						
Yes						
2008	0	26	0.0	-	0	N/A
2009	0	16	0.0	-	0	N/A
2010	1	10	0.5	0.5	0	0.0
2011	0	14	0.0	-	0	N/A
2012	0	27	0.0	-	0	N/A
2013	0	17	0.0	-	0	N/A
2014	0	7	0.0	-	0	N/A
2015	0	12	0.0	-	0	N/A
2016	0	10	0.0	-	0	N/A
2017	0	15	0.0	-	0	N/A
2018	0	9	0.0	-	0	N/A
2019	0	16	0.0	-	0	N/A
2020	1	8	0.0	0.0	1	10,000.0
2021	0	1	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
No						
2008	1	90	0.1	0.1	1	10,000.0
2009	1	109	0.5	0.5	0	0.0
2010	0	144	0.0	-	0	N/A
2011	0	129	0.0	-	0	N/A
2012	0	147	0.0	-	0	N/A
2013	0	143	0.0	-	0	N/A
2014	3	120	0.8	0.3	2	6,666.7
2015	1	120	0.1	0.1	1	10,000.0
2016	0	95	0.0	-	0	N/A
2017	1	99	0.1	0.1	1	10,000.0
2018	0	75	0.0	-	0	N/A
2019	0	53	0.0	-	0	N/A
2020	0	35	0.0	-	0	N/A
2021	1	5	0.4	0.4	0	0.0
Unknown						
2008	6	1,661	3.0	0.5	0	0.0
2009	7	1,535	2.6	0.4	1	1,428.6
2010	8	1,280	3.8	0.5	0	0.0
2011	4	1,180	1.4	0.3	1	2,500.0
2012	2	1,125	0.1	0.1	2	10,000.0
2013	3	1,102	0.9	0.3	1	3,333.3
2014	5	1,299	0.3	0.1	5	10,000.0
2015	11	1,126	2.8	0.3	5	4,545.5
2016	7	1,033	0.9	0.1	5	7,142.9
2017	4	1,025	0.4	0.1	4	10,000.0
2018	7	971	1.7	0.2	4	5,714.3
2019	13	888	1.6	0.1	10	7,692.3
2020	5	740	0.7	0.1	2	4,000.0
2021	1	85	0.2	0.2	0	0.0

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Treatment Within 45 Days from Diagnosis						
Yes						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	1	0.0	-	0	N/A
2016	1	1	3.9	3.9	0	0.0
2017	0	0	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	1	1	0.1	0.1	0	0.0
2021	0	0	0.0	-	0	N/A
No						
2008	2	2	21.7	10.9	0	0.0
2009	0	1	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	2	2	11.1	5.6	0	0.0
2012	2	2	9.9	5.0	0	0.0
2013	0	1	0.0	-	0	N/A
2014	0	1	0.0	-	0	N/A
2015	2	2	8.4	4.2	0	0.0
2016	6	8	15.9	2.7	0	0.0
2017	5	8	11.4	2.3	0	0.0
2018	2	2	2.9	1.4	0	0.0
2019	4	6	2.4	0.6	0	0.0
2020	2	2	1.7	0.8	0	0.0
2021	0	0	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
Unknown						
2008	0	1	0.0	-	0	N/A
2009	1	3	0.4	0.4	0	0.0
2010	3	4	7.6	2.5	0	0.0
2011	3	6	13.5	4.5	0	0.0
2012	9	10	24.5	2.7	0	0.0
2013	11	14	27.2	2.5	0	0.0
2014	16	18	45.0	2.8	0	0.0
2015	26	34	67.9	2.6	0	0.0
2016	25	31	68.8	2.8	0	0.0
2017	25	32	46.7	1.9	0	0.0
2018	23	26	33.6	1.5	0	0.0
2019	27	38	31.7	1.2	0	0.0
2020	20	24	11.8	0.6	0	0.0
2021	3	3	0.7	0.2	0	0.0
Treatment Within 180 Days from Diagnosis						
Yes						
2008	0	0	0.0	-	0	N/A
2009	0	0	0.0	-	0	N/A
2010	0	0	0.0	-	0	N/A
2011	0	0	0.0	-	0	N/A
2012	0	0	0.0	-	0	N/A
2013	0	0	0.0	-	0	N/A
2014	0	0	0.0	-	0	N/A
2015	0	1	0.0	-	0	N/A
2016	1	1	3.9	3.9	0	0.0
2017	0	1	0.0	-	0	N/A
2018	0	0	0.0	-	0	N/A
2019	0	0	0.0	-	0	N/A
2020	1	1	0.1	0.1	0	0.0
2021	0	0	0.0	-	0	N/A

Table 11. Summary of Exposures of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year¹

	New Users	Eligible Members²	Years at Risk	Average Person-Years at Risk	New Episodes with an Event	Events per 10,000 New Infants
No						
2008	4	6	24.1	6.0	0	0.0
2009	0	2	0.0	-	0	N/A
2010	0	1	0.0	-	0	N/A
2011	2	2	11.1	5.6	0	0.0
2012	2	2	9.9	5.0	0	0.0
2013	0	2	0.0	-	0	N/A
2014	4	5	23.3	5.8	0	0.0
2015	4	6	17.6	4.4	0	0.0
2016	9	12	23.3	2.6	0	0.0
2017	7	12	16.4	2.3	0	0.0
2018	4	4	7.8	2.0	0	0.0
2019	5	8	3.0	0.6	0	0.0
2020	2	2	1.7	0.8	0	0.0
2021	0	0	0.0	-	0	N/A
Unknown						
2008	3	8	14.0	4.7	0	0.0
2009	4	11	15.8	3.9	0	0.0
2010	5	16	18.5	3.7	0	0.0
2011	9	15	33.8	3.8	0	0.0
2012	9	17	24.5	2.7	0	0.0
2013	15	25	30.4	2.0	0	0.0
2014	20	34	50.0	2.5	0	0.0
2015	31	50	81.6	2.6	0	0.0
2016	35	54	95.7	2.7	0	0.0
2017	36	56	73.2	2.0	0	0.0
2018	28	41	42.4	1.5	0	0.0
2019	34	58	40.0	1.2	0	0.0
2020	24	34	14.9	0.6	0	0.0
2021	3	3	0.7	0.2	0	0.0

¹Counts of events and proportions of events per 10,000 new infants were not estimated (reported as 0) in cohorts examining clinical characteristics of infants with CMV at ≤45 days of age and VGCV treatment within 45/180 days from CMV diagnosis.

²Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Appendix A. Start and End Dates for Each Data Partner (DP) as of Request Distribution Date (December 9, 2021)

DP ID	Start Date	End Date
DP01	01/01/2008	12/31/2020
DP02	01/01/2000	04/30/2021
DP03	01/01/2000	06/30/2020
DP04	01/01/2004	05/31/2021
DP05	01/01/2007	02/28/2021
DP06	01/01/2000	12/31/2019
DP07	01/01/2005	10/31/2020
DP08	01/01/2000	02/28/2021
DP09	01/01/2000	05/31/2021
DP10	01/01/2006	03/31/2021
DP11	01/01/2008	12/31/2020
DP12	01/01/2000	02/28/2021

The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of States and Territories Included in Each Census Bureau Region

Census Bureau Region	States and Territories
Northeast	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, Pennsylvania
Midwest	Illinois, Indiana, Michigan, Ohio, Wisconsin, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
South	Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia, Alabama, Kentucky, Mississippi, Tennessee, Arkansas, Louisiana, Oklahoma, Texas
West	Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming, Alaska, California, Hawaii, Washington, Oregon
Other	Northern Mariana Islands, Marshall Islands, Puerto Rico, US Virgin Islands, American Samoa, Micronesia, Guam, Palau
Missing	Missing
Invalid	Recorded geographic location does not match any identifiers per the Sentinel Common Data Model definition

Appendix C. List of Generic and Brand Names of Medical Products Used to Define Outcome and Inclusion Criteria in this Request

Generic Name	Brand Name
Valganciclovir/Ganciclovir	
ganciclovir	Cytovene
ganciclovir	ganciclovir
ganciclovir sodium	Cytovene
ganciclovir sodium	ganciclovir sodium
valganciclovir HCl	Valcyte
valganciclovir HCl	valganciclovir

Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Cytomegalovirus (CMV) Infection or Congenital CMV (cCMV) Events in this Request

Code	Description	Code Category	Code Type
Cytomegalovirus Infection (CMV)			
078.5	Cytomegaloviral disease	Diagnosis	ICD-9-CM
B25.0	Cytomegaloviral pneumonitis	Diagnosis	ICD-10-CM
B25.1	Cytomegaloviral hepatitis	Diagnosis	ICD-10-CM
B25.2	Cytomegaloviral pancreatitis	Diagnosis	ICD-10-CM
B25.8	Other cytomegaloviral diseases	Diagnosis	ICD-10-CM
B25.9	Cytomegaloviral disease, unspecified	Diagnosis	ICD-10-CM
Congenital Cytomegalovirus (cCMV)			
771.1	Congenital cytomegalovirus infection	Diagnosis	ICD-9-CM
P35.1	Congenital cytomegalovirus infection	Diagnosis	ICD-10-CM

Appendix E. List of Current Procedural Terminology, Fourth Edition (CPT-4), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
Hearing Loss			
388.01	Presbycusis	Diagnosis	ICD-9-CM
388.2	Unspecified sudden hearing loss	Diagnosis	ICD-9-CM
389.1	Sensorineural hearing loss	Diagnosis	ICD-9-CM
389.10	Unspecified sensorineural hearing loss	Diagnosis	ICD-9-CM
389.11	Sensory hearing loss, bilateral	Diagnosis	ICD-9-CM
389.12	Neural hearing loss, bilateral	Diagnosis	ICD-9-CM
389.13	Neural hearing loss, unilateral	Diagnosis	ICD-9-CM
389.14	Central hearing loss	Diagnosis	ICD-9-CM
389.15	Sensorineural hearing loss, unilateral	Diagnosis	ICD-9-CM
389.16	Sensorineural hearing loss, asymmetrical	Diagnosis	ICD-9-CM
389.17	Sensory hearing loss, unilateral	Diagnosis	ICD-9-CM
389.18	Sensorineural hearing loss, bilateral	Diagnosis	ICD-9-CM
389.2	Mixed conductive and sensorineural hearing loss	Diagnosis	ICD-9-CM
389.20	Mixed hearing loss, unspecified	Diagnosis	ICD-9-CM
389.21	Mixed hearing loss, unilateral	Diagnosis	ICD-9-CM
389.22	Mixed hearing loss, bilateral	Diagnosis	ICD-9-CM
389.7	Deaf, nonspeaking, not elsewhere classifiable	Diagnosis	ICD-9-CM
389.8	Other specified forms of hearing loss	Diagnosis	ICD-9-CM
389.9	Unspecified hearing loss	Diagnosis	ICD-9-CM
69710	IMPLANT/REPLACE HEARING AID	Procedure	CPT-4
69930	IMPLANT COCHLEAR DEVICE	Procedure	CPT-4
92510	AURAL REHABILITATION FOLLOWING COCHLEAR IMPLANT (INCLUDES EVALUATION OF AURAL REHABILITATION STATUS	Procedure	CPT-4
92601	COCHLEAR IMPLT F/UP EXAM <7	Procedure	CPT-4
92602	REPROGRAM COCHLEAR IMPLT <7	Procedure	CPT-4
92630	AUD REHAB PRE-LING HEAR LOSS	Procedure	CPT-4
92633	AUD REHAB POSTLING HEAR LOSS	Procedure	CPT-4
95.48	Fitting of hearing aid	Procedure	ICD-9-CM
F0DZ05Z	Tinnitus Masker Device Fitting using Hearing Aid Selection / Fitting / Test Equipment	Procedure	ICD-10-PCS
F0DZ0ZZ	Tinnitus Masker Device Fitting	Procedure	ICD-10-PCS
F0DZ11Z	Monaural Hearing Aid Device Fitting using Audiometer	Procedure	ICD-10-PCS
F0DZ12Z	Monaural Hearing Aid Device Fitting using Sound Field / Booth	Procedure	ICD-10-PCS
F0DZ15Z	Monaural Hearing Aid Device Fitting using Hearing Aid Selection / Fitting / Test Equipmen	Procedure	ICD-10-PCS
F0DZ1KZ	Monaural Hearing Aid Device Fitting using Audiovisual Equipment	Procedure	ICD-10-PCS
F0DZ1LZ	Monaural Hearing Aid Device Fitting using Assistive Listening Equipment	Procedure	ICD-10-PCS
F0DZ1ZZ	Monaural Hearing Aid Device Fitting	Procedure	ICD-10-PCS
F0DZ21Z	Binaural Hearing Aid Device Fitting using Audiometer	Procedure	ICD-10-PCS
F0DZ22Z	Binaural Hearing Aid Device Fitting using Sound Field / Booth	Procedure	ICD-10-PCS
F0DZ25Z	Binaural Hearing Aid Device Fitting using Hearing Aid Selection / Fitting / Test Equipment	Procedure	ICD-10-PCS
F0DZ2KZ	Binaural Hearing Aid Device Fitting using Audiovisual Equipment	Procedure	ICD-10-PCS
F0DZ2LZ	Binaural Hearing Aid Device Fitting using Assistive Listening Equipment	Procedure	ICD-10-PCS
F0DZ2ZZ	Binaural Hearing Aid Device Fitting	Procedure	ICD-10-PCS
F0DZ51Z	Assistive Listening Device Device Fitting using Audiometer	Procedure	ICD-10-PCS

Appendix E. List of Current Procedural Terminology, Fourth Edition (CPT-4), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
F0DZ52Z	Assistive Listening Device Device Fitting using Sound Field / Booth	Procedure	ICD-10-PCS
F0DZ55Z	Assistive Listening Device Device Fitting using Hearing Aid Selection / Fitting / Test Equipn	Procedure	ICD-10-PCS
F0DZ5KZ	Assistive Listening Device Device Fitting using Audiovisual Equipment	Procedure	ICD-10-PCS
F0DZ5LZ	Assistive Listening Device Device Fitting using Assistive Listening Equipment	Procedure	ICD-10-PCS
F0DZ5ZZ	Assistive Listening Device Device Fitting	Procedure	ICD-10-PCS
H90.3	Sensorineural hearing loss, bilateral	Diagnosis	ICD-10-CM
H90.4	Sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.5	Unspecified sensorineural hearing loss	Diagnosis	ICD-10-CM
H90.6	Mixed conductive and sensorineural hearing loss, bilateral	Diagnosis	ICD-10-CM
H90.7	Mixed conductive and sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.71	Mixed conductive and sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.72	Mixed conductive and sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.8	Mixed conductive and sensorineural hearing loss, unspecified	Diagnosis	ICD-10-CM
H90.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.A22	Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.A31	Mixed conductive and sensorineural hearing loss, unilateral, right ear with restricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.A32	Mixed conductive and sensorineural hearing loss, unilateral, left ear with restricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H91.0	Ototoxic hearing loss	Diagnosis	ICD-10-CM
H91.01	Ototoxic hearing loss, right ear	Diagnosis	ICD-10-CM
H91.02	Ototoxic hearing loss, left ear	Diagnosis	ICD-10-CM
H91.03	Ototoxic hearing loss, bilateral	Diagnosis	ICD-10-CM
H91.09	Ototoxic hearing loss, unspecified ear	Diagnosis	ICD-10-CM
H91.1	Presbycusis	Diagnosis	ICD-10-CM
H91.10	Presbycusis, unspecified ear	Diagnosis	ICD-10-CM
H91.11	Presbycusis, right ear	Diagnosis	ICD-10-CM
H91.12	Presbycusis, left ear	Diagnosis	ICD-10-CM
H91.13	Presbycusis, bilateral	Diagnosis	ICD-10-CM
H91.2	Sudden idiopathic hearing loss	Diagnosis	ICD-10-CM
H91.20	Sudden idiopathic hearing loss, unspecified ear	Diagnosis	ICD-10-CM
H91.21	Sudden idiopathic hearing loss, right ear	Diagnosis	ICD-10-CM
H91.22	Sudden idiopathic hearing loss, left ear	Diagnosis	ICD-10-CM
H91.23	Sudden idiopathic hearing loss, bilateral	Diagnosis	ICD-10-CM
H91.3	Deaf nonspeaking, not elsewhere classified	Diagnosis	ICD-10-CM
H91.8	Other specified hearing loss	Diagnosis	ICD-10-CM

Appendix E. List of Current Procedural Terminology, Fourth Edition (CPT-4), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
H91.8X	Other specified hearing loss	Diagnosis	ICD-10-CM
H91.8X1	Other specified hearing loss, right ear	Diagnosis	ICD-10-CM
H91.8X2	Other specified hearing loss, left ear	Diagnosis	ICD-10-CM
H91.8X3	Other specified hearing loss, bilateral	Diagnosis	ICD-10-CM
H91.8X9	Other specified hearing loss, unspecified ear	Diagnosis	ICD-10-CM
H91.9	Unspecified hearing loss	Diagnosis	ICD-10-CM
H91.90	Unspecified hearing loss, unspecified ear	Diagnosis	ICD-10-CM
H91.91	Unspecified hearing loss, right ear	Diagnosis	ICD-10-CM
H91.92	Unspecified hearing loss, left ear	Diagnosis	ICD-10-CM
H91.93	Unspecified hearing loss, bilateral	Diagnosis	ICD-10-CM
V53.2	Adjustment hearing aid	Procedure	ICD-9-CM
Z46.1	Encounter for fitting and adjustment of hearing aid	Procedure	ICD-10-PCS
Jaundice			
774	Other perinatal jaundice	Diagnosis	ICD-9-CM
774.0	Perinatal jaundice from hereditary hemolytic anemias	Diagnosis	ICD-9-CM
774.1	Perinatal jaundice from other excessive hemolysis	Diagnosis	ICD-9-CM
774.2	Neonatal jaundice associated with preterm delivery	Diagnosis	ICD-9-CM
774.3	Neonatal jaundice due to delayed conjugation from other causes	Diagnosis	ICD-9-CM
774.30	Neonatal jaundice due to delayed conjugation, cause unspecified	Diagnosis	ICD-9-CM
774.31	Neonatal jaundice due to delayed conjugation in diseases classified elsewhere	Diagnosis	ICD-9-CM
774.39	Other neonatal jaundice due to delayed conjugation from other causes	Diagnosis	ICD-9-CM
774.4	Perinatal jaundice due to hepatocellular damage	Diagnosis	ICD-9-CM
774.5	Perinatal jaundice from other causes	Diagnosis	ICD-9-CM
774.6	Unspecified fetal and neonatal jaundice	Diagnosis	ICD-9-CM
P58.0	Neonatal jaundice due to bruising	Diagnosis	ICD-10-CM
P58.1	Neonatal jaundice due to bleeding	Diagnosis	ICD-10-CM
P58.2	Neonatal jaundice due to infection	Diagnosis	ICD-10-CM
P58.3	Neonatal jaundice due to polycythemia	Diagnosis	ICD-10-CM
P58.41	Neonatal jaundice due to drugs or toxins transmitted from mother	Diagnosis	ICD-10-CM
P58.42	Neonatal jaundice due to drugs or toxins given to newborn	Diagnosis	ICD-10-CM
P58.5	Neonatal jaundice due to swallowed maternal blood	Diagnosis	ICD-10-CM
P58.8	Neonatal jaundice due to other specified excessive hemolysis	Diagnosis	ICD-10-CM
P58.9	Neonatal jaundice due to excessive hemolysis, unspecified	Diagnosis	ICD-10-CM
P59.0	Neonatal jaundice associated with preterm delivery	Diagnosis	ICD-10-CM
P59.1	Inspissated bile syndrome	Diagnosis	ICD-10-CM
P59.20	Neonatal jaundice from unspecified hepatocellular damage	Diagnosis	ICD-10-CM
P59.29	Neonatal jaundice from other hepatocellular damage	Diagnosis	ICD-10-CM
P59.3	Neonatal jaundice from breast milk inhibitor	Diagnosis	ICD-10-CM
P59.8	Neonatal jaundice from other specified causes	Diagnosis	ICD-10-CM
P59.9	Neonatal jaundice, unspecified	Diagnosis	ICD-10-CM
Petechiae			
772.6	Fetal and neonatal cutaneous hemorrhage	Diagnosis	ICD-9-CM
782.7	Spontaneous ecchymoses	Diagnosis	ICD-9-CM
P54.5	Neonatal cutaneous hemorrhage	Diagnosis	ICD-10-CM
R23.3	Spontaneous ecchymoses	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Hepatomegaly			
573.1	Hepatitis in viral diseases classified elsewhere	Diagnosis	ICD-9-CM
789.1	Hepatomegaly	Diagnosis	ICD-9-CM
B25.1	Cytomegaloviral hepatitis	Diagnosis	ICD-10-CM
R16.0	Hepatomegaly, not elsewhere classified	Diagnosis	ICD-10-CM
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified	Diagnosis	ICD-10-CM
Splenomegaly			
289.51	Chronic congestive splenomegaly	Diagnosis	ICD-9-CM
289.53	Neutropenic splenomegaly	Diagnosis	ICD-9-CM
789.2	Splenomegaly	Diagnosis	ICD-9-CM
D73.2	Chronic congestive splenomegaly	Diagnosis	ICD-10-CM
D73.81	Neutropenic splenomegaly	Diagnosis	ICD-10-CM
R16.1	Splenomegaly, not elsewhere classified	Diagnosis	ICD-10-CM
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified	Diagnosis	ICD-10-CM
Microcephaly			
742.1	Microcephalus	Diagnosis	ICD-9-CM
Q02	Microcephaly	Diagnosis	ICD-10-CM
Thrombocytopenia			
287.3	Primary thrombocytopenia	Diagnosis	ICD-9-CM
287.30	Primary thrombocytopenia, unspecified	Diagnosis	ICD-9-CM
287.31	Immune thrombocytopenic purpura	Diagnosis	ICD-9-CM
287.33	Congenital and hereditary thrombocytopenic purpura	Diagnosis	ICD-9-CM
287.39	Other primary thrombocytopenia	Diagnosis	ICD-9-CM
287.4	Secondary thrombocytopenia	Diagnosis	ICD-9-CM
287.49	Other secondary thrombocytopenia	Diagnosis	ICD-9-CM
287.5	Unspecified thrombocytopenia	Diagnosis	ICD-9-CM
776.1	Transient neonatal thrombocytopenia	Diagnosis	ICD-9-CM
776.2	Disseminated intravascular coagulation in newborn	Diagnosis	ICD-9-CM
D69.42	Congenital and hereditary thrombocytopenia purpura	Diagnosis	ICD-10-CM
D69.49	Other primary thrombocytopenia	Diagnosis	ICD-10-CM
D69.51	Posttransfusion purpura	Diagnosis	ICD-10-CM
D69.59	Other secondary thrombocytopenia	Diagnosis	ICD-10-CM
D69.6	Thrombocytopenia, unspecified	Diagnosis	ICD-10-CM
P60	Disseminated intravascular coagulation of newborn	Diagnosis	ICD-10-CM
P61.0	Transient neonatal thrombocytopenia	Diagnosis	ICD-10-CM
Chorioretinitis			
363.0	Focal chorioretinitis and focal retinochoroiditis	Diagnosis	ICD-9-CM
363.00	Unspecified focal chorioretinitis	Diagnosis	ICD-9-CM
363.01	Focal choroiditis and chorioretinitis, juxtapapillary	Diagnosis	ICD-9-CM
363.03	Focal choroiditis and chorioretinitis of other posterior pole	Diagnosis	ICD-9-CM
363.04	Focal choroiditis and chorioretinitis, peripheral	Diagnosis	ICD-9-CM
363.05	Focal retinitis and retinochoroiditis, juxtapapillary	Diagnosis	ICD-9-CM
363.06	Focal retinitis and retinochoroiditis, macular or paramacular	Diagnosis	ICD-9-CM
363.07	Focal retinitis and retinochoroiditis of other posterior pole	Diagnosis	ICD-9-CM
363.08	Focal retinitis and retinochoroiditis, peripheral	Diagnosis	ICD-9-CM

Appendix E. List of Current Procedural Terminology, Fourth Edition (CPT-4), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
363.1	Disseminated chorioretinitis and disseminated retino-choroiditis	Diagnosis	ICD-9-CM
363.10	Unspecified disseminated chorioretinitis	Diagnosis	ICD-9-CM
363.11	Disseminated choroiditis and chorioretinitis, posterior pole	Diagnosis	ICD-9-CM
363.12	Disseminated choroiditis and chorioretinitis, peripheral	Diagnosis	ICD-9-CM
363.13	Disseminated choroiditis and chorioretinitis, generalized	Diagnosis	ICD-9-CM
363.14	Disseminated retinitis and retinochoroiditis, metastatic	Diagnosis	ICD-9-CM
363.15	Disseminated retinitis and retinochoroiditis, pigment epitheliopathy	Diagnosis	ICD-9-CM
363.2	Other and unspecified forms of chorioretinitis and retinochoroiditis	Diagnosis	ICD-9-CM
363.20	Unspecified chorioretinitis	Diagnosis	ICD-9-CM
363.21	Pars planitis	Diagnosis	ICD-9-CM
363.22	Harada's disease	Diagnosis	ICD-9-CM
363.3	Chorioretinal scars	Diagnosis	ICD-9-CM
363.30	Unspecified chorioretinal scar	Diagnosis	ICD-9-CM
363.31	Solar retinopathy	Diagnosis	ICD-9-CM
363.32	Other macular chorioretinal scars	Diagnosis	ICD-9-CM
363.33	Other chorioretinal scars of posterior pole	Diagnosis	ICD-9-CM
363.34	Peripheral chorioretinal scars	Diagnosis	ICD-9-CM
363.35	Disseminated chorioretinal scars	Diagnosis	ICD-9-CM
H30.0	Focal chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.00	Unspecified focal chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.001	Unspecified focal chorioretinal inflammation, right eye	Diagnosis	ICD-10-CM
H30.002	Unspecified focal chorioretinal inflammation, left eye	Diagnosis	ICD-10-CM
H30.003	Unspecified focal chorioretinal inflammation, bilateral	Diagnosis	ICD-10-CM
H30.009	Unspecified focal chorioretinal inflammation, unspecified eye	Diagnosis	ICD-10-CM
H30.01	Focal chorioretinal inflammation, juxtapapillary	Diagnosis	ICD-10-CM
H30.011	Focal chorioretinal inflammation, juxtapapillary, right eye	Diagnosis	ICD-10-CM
H30.012	Focal chorioretinal inflammation, juxtapapillary, left eye	Diagnosis	ICD-10-CM
H30.013	Focal chorioretinal inflammation, juxtapapillary, bilateral	Diagnosis	ICD-10-CM
H30.019	Focal chorioretinal inflammation, juxtapapillary, unspecified eye	Diagnosis	ICD-10-CM
H30.02	Focal chorioretinal inflammation of posterior pole	Diagnosis	ICD-10-CM
H30.021	Focal chorioretinal inflammation of posterior pole, right eye	Diagnosis	ICD-10-CM
H30.022	Focal chorioretinal inflammation of posterior pole, left eye	Diagnosis	ICD-10-CM
H30.023	Focal chorioretinal inflammation of posterior pole, bilateral	Diagnosis	ICD-10-CM
H30.029	Focal chorioretinal inflammation of posterior pole, unspecified eye	Diagnosis	ICD-10-CM
H30.03	Focal chorioretinal inflammation, peripheral	Diagnosis	ICD-10-CM
H30.031	Focal chorioretinal inflammation, peripheral, right eye	Diagnosis	ICD-10-CM
H30.032	Focal chorioretinal inflammation, peripheral, left eye	Diagnosis	ICD-10-CM
H30.033	Focal chorioretinal inflammation, peripheral, bilateral	Diagnosis	ICD-10-CM
H30.039	Focal chorioretinal inflammation, peripheral, unspecified eye	Diagnosis	ICD-10-CM
H30.04	Focal chorioretinal inflammation, macular or paramacular	Diagnosis	ICD-10-CM
H30.041	Focal chorioretinal inflammation, macular or paramacular, right eye	Diagnosis	ICD-10-CM
H30.042	Focal chorioretinal inflammation, macular or paramacular, left eye	Diagnosis	ICD-10-CM
H30.043	Focal chorioretinal inflammation, macular or paramacular, bilateral	Diagnosis	ICD-10-CM
H30.049	Focal chorioretinal inflammation, macular or paramacular, unspecified eye	Diagnosis	ICD-10-CM
H30.1	Disseminated chorioretinal inflammation	Diagnosis	ICD-10-CM

Appendix E. List of Current Procedural Terminology, Fourth Edition (CPT-4), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
H30.10	Unspecified disseminated chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.101	Unspecified disseminated chorioretinal inflammation, right eye	Diagnosis	ICD-10-CM
H30.102	Unspecified disseminated chorioretinal inflammation, left eye	Diagnosis	ICD-10-CM
H30.103	Unspecified disseminated chorioretinal inflammation, bilateral	Diagnosis	ICD-10-CM
H30.109	Unspecified disseminated chorioretinal inflammation, unspecified eye	Diagnosis	ICD-10-CM
H30.11	Disseminated chorioretinal inflammation of posterior pole	Diagnosis	ICD-10-CM
H30.111	Disseminated chorioretinal inflammation of posterior pole, right eye	Diagnosis	ICD-10-CM
H30.112	Disseminated chorioretinal inflammation of posterior pole, left eye	Diagnosis	ICD-10-CM
H30.113	Disseminated chorioretinal inflammation of posterior pole, bilateral	Diagnosis	ICD-10-CM
H30.119	Disseminated chorioretinal inflammation of posterior pole, unspecified eye	Diagnosis	ICD-10-CM
H30.12	Disseminated chorioretinal inflammation, peripheral	Diagnosis	ICD-10-CM
H30.121	Disseminated chorioretinal inflammation, peripheral right eye	Diagnosis	ICD-10-CM
H30.122	Disseminated chorioretinal inflammation, peripheral, left eye	Diagnosis	ICD-10-CM
H30.123	Disseminated chorioretinal inflammation, peripheral, bilateral	Diagnosis	ICD-10-CM
H30.129	Disseminated chorioretinal inflammation, peripheral, unspecified eye	Diagnosis	ICD-10-CM
H30.13	Disseminated chorioretinal inflammation, generalized	Diagnosis	ICD-10-CM
H30.131	Disseminated chorioretinal inflammation, generalized, right eye	Diagnosis	ICD-10-CM
H30.132	Disseminated chorioretinal inflammation, generalized, left eye	Diagnosis	ICD-10-CM
H30.133	Disseminated chorioretinal inflammation, generalized, bilateral	Diagnosis	ICD-10-CM
H30.139	Disseminated chorioretinal inflammation, generalized, unspecified eye	Diagnosis	ICD-10-CM
H30.14	Acute posterior multifocal placoid pigment epitheliopathy	Diagnosis	ICD-10-CM
H30.141	Acute posterior multifocal placoid pigment epitheliopathy, right eye	Diagnosis	ICD-10-CM
H30.142	Acute posterior multifocal placoid pigment epitheliopathy, left eye	Diagnosis	ICD-10-CM
H30.143	Acute posterior multifocal placoid pigment epitheliopathy, bilateral	Diagnosis	ICD-10-CM
H30.149	Acute posterior multifocal placoid pigment epitheliopathy, unspecified eye	Diagnosis	ICD-10-CM
H30.89	Other chorioretinal inflammations	Diagnosis	ICD-10-CM
H30.891	Other chorioretinal inflammations, right eye	Diagnosis	ICD-10-CM
H30.892	Other chorioretinal inflammations, left eye	Diagnosis	ICD-10-CM
H30.893	Other chorioretinal inflammations, bilateral	Diagnosis	ICD-10-CM
H30.899	Other chorioretinal inflammations, unspecified eye	Diagnosis	ICD-10-CM
H30.9	Unspecified chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.90	Unspecified chorioretinal inflammation, unspecified eye	Diagnosis	ICD-10-CM
H30.91	Unspecified chorioretinal inflammation, right eye	Diagnosis	ICD-10-CM
H30.92	Unspecified chorioretinal inflammation, left eye	Diagnosis	ICD-10-CM
H30.93	Unspecified chorioretinal inflammation, bilateral	Diagnosis	ICD-10-CM
H31.00	Unspecified chorioretinal scars	Diagnosis	ICD-10-CM
H31.001	Unspecified chorioretinal scars, right eye	Diagnosis	ICD-10-CM
H31.002	Unspecified chorioretinal scars, left eye	Diagnosis	ICD-10-CM
H31.003	Unspecified chorioretinal scars, bilateral	Diagnosis	ICD-10-CM
H31.009	Unspecified chorioretinal scars, unspecified eye	Diagnosis	ICD-10-CM
H31.011	Macula scars of posterior pole (postinflammatory) (post-traumatic), right eye	Diagnosis	ICD-10-CM
H31.012	Macula scars of posterior pole (postinflammatory) (post-traumatic), left eye	Diagnosis	ICD-10-CM
H31.013	Macula scars of posterior pole (postinflammatory) (post-traumatic), bilateral	Diagnosis	ICD-10-CM
H31.019	Macula scars of posterior pole (postinflammatory) (post-traumatic), unspecified eye	Diagnosis	ICD-10-CM
H31.021	Solar retinopathy, right eye	Diagnosis	ICD-10-CM

Appendix E. List of Current Procedural Terminology, Fourth Edition (CPT-4), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
H31.022	Solar retinopathy, left eye	Diagnosis	ICD-10-CM
H31.023	Solar retinopathy, bilateral	Diagnosis	ICD-10-CM
H31.029	Solar retinopathy, unspecified eye	Diagnosis	ICD-10-CM
H31.091	Other chorioretinal scars, right eye	Diagnosis	ICD-10-CM
H31.092	Other chorioretinal scars, left eye	Diagnosis	ICD-10-CM
H31.093	Other chorioretinal scars, bilateral	Diagnosis	ICD-10-CM
H31.099	Other chorioretinal scars, unspecified eye	Diagnosis	ICD-10-CM
Brain Abnormality			
330.3	Cerebral degeneration of childhood in other diseases classified elsewhere	Diagnosis	ICD-9-CM
331.3	Communicating hydrocephalus	Diagnosis	ICD-9-CM
331.4	Obstructive hydrocephalus	Diagnosis	ICD-9-CM
331.5	Idiopathic normal pressure hydrocephalus [INPH]	Diagnosis	ICD-9-CM
331.7	Cerebral degeneration in diseases classified elsewhere	Diagnosis	ICD-9-CM
348.89	Other conditions of brain	Diagnosis	ICD-9-CM
348.9	Unspecified condition of brain	Diagnosis	ICD-9-CM
742.2	Congenital reduction deformities of brain	Diagnosis	ICD-9-CM
742.3	Congenital hydrocephalus	Diagnosis	ICD-9-CM
742.4	Other specified congenital anomalies of brain	Diagnosis	ICD-9-CM
742.9	Unspecified congenital anomaly of brain, spinal cord, and nervous system	Diagnosis	ICD-9-CM
793.0	Nonspecific (abnormal) findings on radiological and other examination of skull and head	Diagnosis	ICD-9-CM
G91.0	Communicating hydrocephalus	Diagnosis	ICD-10-CM
G91.1	Obstructive hydrocephalus	Diagnosis	ICD-10-CM
G91.2	(Idiopathic) normal pressure hydrocephalus	Diagnosis	ICD-10-CM
G91.4	Hydrocephalus in diseases classified elsewhere	Diagnosis	ICD-10-CM
G91.8	Other hydrocephalus	Diagnosis	ICD-10-CM
G91.9	Hydrocephalus, unspecified	Diagnosis	ICD-10-CM
G93.89	Other specified disorders of brain	Diagnosis	ICD-10-CM
G93.9	Disorder of brain, unspecified	Diagnosis	ICD-10-CM
Q03.8	Other congenital hydrocephalus	Diagnosis	ICD-10-CM
Q03.9	Congenital hydrocephalus, unspecified	Diagnosis	ICD-10-CM
Q04.0	Congenital malformations of corpus callosum	Diagnosis	ICD-10-CM
Q04.3	Other reduction deformities of brain	Diagnosis	ICD-10-CM
Q04.4	Septo-optic dysplasia of brain	Diagnosis	ICD-10-CM
Q04.5	Megalencephaly	Diagnosis	ICD-10-CM
Q04.6	Congenital cerebral cysts	Diagnosis	ICD-10-CM
Q04.8	Other specified congenital malformations of brain	Diagnosis	ICD-10-CM
Q04.9	Congenital malformation of brain, unspecified	Diagnosis	ICD-10-CM
R90.82	White matter disease, unspecified	Diagnosis	ICD-10-CM
R93.0	Abnormal findings on diagnostic imaging of skull and head, not elsewhere classified	Diagnosis	ICD-10-CM
Other Brain Abnormality			
G91.3	Post-traumatic hydrocephalus, unspecified	Diagnosis	ICD-10-CM
Q03.0	Malformations of aqueduct of Sylvius	Diagnosis	ICD-10-CM
Q03.1	Atresia of foramina of Magendie and Luschka	Diagnosis	ICD-10-CM
Q04.1	Arhinencephaly	Diagnosis	ICD-10-CM
Q04.2	Holoprosencephaly	Diagnosis	ICD-10-CM

Appendix E. List of Current Procedural Terminology, Fourth Edition (CPT-4), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
Cytomegalovirus Infection (CMV)			
078.5	Cytomegaloviral disease	Diagnosis	ICD-9-CM
B25.0	Cytomegaloviral pneumonitis	Diagnosis	ICD-10-CM
B25.1	Cytomegaloviral hepatitis	Diagnosis	ICD-10-CM
B25.2	Cytomegaloviral pancreatitis	Diagnosis	ICD-10-CM
B25.8	Other cytomegaloviral diseases	Diagnosis	ICD-10-CM
B25.9	Cytomegaloviral disease, unspecified	Diagnosis	ICD-10-CM
Congenital Cytomegalovirus (cCMV)			
771.1	Congenital cytomegalovirus infection	Diagnosis	ICD-9-CM
P35.1	Congenital cytomegalovirus infection	Diagnosis	ICD-10-CM

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Baseline Characteristics and Hematologic Outcomes in this Request

Code	Description	Code Category	Code Type
Hearing Loss			
388.01	Presbycusis	Diagnosis	ICD-9-CM
388.2	Unspecified sudden hearing loss	Diagnosis	ICD-9-CM
389.1	Sensorineural hearing loss	Diagnosis	ICD-9-CM
389.10	Unspecified sensorineural hearing loss	Diagnosis	ICD-9-CM
389.11	Sensory hearing loss, bilateral	Diagnosis	ICD-9-CM
389.12	Neural hearing loss, bilateral	Diagnosis	ICD-9-CM
389.13	Neural hearing loss, unilateral	Diagnosis	ICD-9-CM
389.14	Central hearing loss	Diagnosis	ICD-9-CM
389.15	Sensorineural hearing loss, unilateral	Diagnosis	ICD-9-CM
389.16	Sensorineural hearing loss, asymmetrical	Diagnosis	ICD-9-CM
389.17	Sensory hearing loss, unilateral	Diagnosis	ICD-9-CM
389.18	Sensorineural hearing loss, bilateral	Diagnosis	ICD-9-CM
389.2	Mixed conductive and sensorineural hearing loss	Diagnosis	ICD-9-CM
389.20	Mixed hearing loss, unspecified	Diagnosis	ICD-9-CM
389.21	Mixed hearing loss, unilateral	Diagnosis	ICD-9-CM
389.22	Mixed hearing loss, bilateral	Diagnosis	ICD-9-CM
389.7	Deaf, nonspeaking, not elsewhere classifiable	Diagnosis	ICD-9-CM
389.8	Other specified forms of hearing loss	Diagnosis	ICD-9-CM
389.9	Unspecified hearing loss	Diagnosis	ICD-9-CM
69710	IMPLANT/REPLACE HEARING AID	Procedure	CPT-4
69930	IMPLANT COCHLEAR DEVICE	Procedure	CPT-4
92510	AURAL REHABILITATION FOLLOWING COCHLEAR IMPLANT (INCLUDES EVALUATION OF AURAL REHABILITATION STATUS	Procedure	CPT-4
92601	COCHLEAR IMPLT F/UP EXAM <7	Procedure	CPT-4
92602	REPROGRAM COCHLEAR IMPLT <7	Procedure	CPT-4
92630	AUD REHAB PRE-LING HEAR LOSS	Procedure	CPT-4
92633	AUD REHAB POSTLING HEAR LOSS	Procedure	CPT-4
95.48	Fitting of hearing aid	Procedure	ICD-9-CM
F0DZ05Z	Tinnitus Masker Device Fitting using Hearing Aid Selection / Fitting / Test Equipment	Procedure	ICD-10-PCS
F0DZ0ZZ	Tinnitus Masker Device Fitting	Procedure	ICD-10-PCS
F0DZ11Z	Monaural Hearing Aid Device Fitting using Audiometer	Procedure	ICD-10-PCS
F0DZ12Z	Monaural Hearing Aid Device Fitting using Sound Field / Booth	Procedure	ICD-10-PCS
F0DZ15Z	Monaural Hearing Aid Device Fitting using Hearing Aid Selection / Fitting / Test Equipment	Procedure	ICD-10-PCS
F0DZ1KZ	Monaural Hearing Aid Device Fitting using Audiovisual Equipment	Procedure	ICD-10-PCS
F0DZ1LZ	Monaural Hearing Aid Device Fitting using Assistive Listening Equipment	Procedure	ICD-10-PCS
F0DZ1ZZ	Monaural Hearing Aid Device Fitting	Procedure	ICD-10-PCS
F0DZ21Z	Binaural Hearing Aid Device Fitting using Audiometer	Procedure	ICD-10-PCS
F0DZ22Z	Binaural Hearing Aid Device Fitting using Sound Field / Booth	Procedure	ICD-10-PCS
F0DZ25Z	Binaural Hearing Aid Device Fitting using Hearing Aid Selection / Fitting / Test Equipment	Procedure	ICD-10-PCS
F0DZ2KZ	Binaural Hearing Aid Device Fitting using Audiovisual Equipment	Procedure	ICD-10-PCS
F0DZ2LZ	Binaural Hearing Aid Device Fitting using Assistive Listening Equipment	Procedure	ICD-10-PCS
F0DZ2ZZ	Binaural Hearing Aid Device Fitting	Procedure	ICD-10-PCS

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Baseline Characteristics and Hematologic Outcomes in this Request

Code	Description	Code Category	Code Type
F0DZ51Z	Assistive Listening Device Device Fitting using Audiometer	Procedure	ICD-10-PCS
F0DZ52Z	Assistive Listening Device Device Fitting using Sound Field / Booth	Procedure	ICD-10-PCS
F0DZ55Z	Assistive Listening Device Device Fitting using Hearing Aid Selection / Fitting / Test Equipment	Procedure	ICD-10-PCS
F0DZ5KZ	Assistive Listening Device Device Fitting using Audiovisual Equipment	Procedure	ICD-10-PCS
F0DZ5LZ	Assistive Listening Device Device Fitting using Assistive Listening Equipment	Procedure	ICD-10-PCS
F0DZ5ZZ	Assistive Listening Device Device Fitting	Procedure	ICD-10-PCS
H90.3	Sensorineural hearing loss, bilateral	Diagnosis	ICD-10-CM
H90.4	Sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.5	Unspecified sensorineural hearing loss	Diagnosis	ICD-10-CM
H90.6	Mixed conductive and sensorineural hearing loss, bilateral	Diagnosis	ICD-10-CM
H90.7	Mixed conductive and sensorineural hearing loss, unilateral with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.71	Mixed conductive and sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.72	Mixed conductive and sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.8	Mixed conductive and sensorineural hearing loss, unspecified	Diagnosis	ICD-10-CM
H90.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.A22	Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.A31	Mixed conductive and sensorineural hearing loss, unilateral, right ear with restricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H90.A32	Mixed conductive and sensorineural hearing loss, unilateral, left ear with restricted hearing on the contralateral side	Diagnosis	ICD-10-CM
H91.0	Ototoxic hearing loss	Diagnosis	ICD-10-CM
H91.01	Ototoxic hearing loss, right ear	Diagnosis	ICD-10-CM
H91.02	Ototoxic hearing loss, left ear	Diagnosis	ICD-10-CM
H91.03	Ototoxic hearing loss, bilateral	Diagnosis	ICD-10-CM
H91.09	Ototoxic hearing loss, unspecified ear	Diagnosis	ICD-10-CM
H91.1	Presbycusis	Diagnosis	ICD-10-CM
H91.10	Presbycusis, unspecified ear	Diagnosis	ICD-10-CM
H91.11	Presbycusis, right ear	Diagnosis	ICD-10-CM
H91.12	Presbycusis, left ear	Diagnosis	ICD-10-CM
H91.13	Presbycusis, bilateral	Diagnosis	ICD-10-CM
H91.2	Sudden idiopathic hearing loss	Diagnosis	ICD-10-CM
H91.20	Sudden idiopathic hearing loss, unspecified ear	Diagnosis	ICD-10-CM
H91.21	Sudden idiopathic hearing loss, right ear	Diagnosis	ICD-10-CM
H91.22	Sudden idiopathic hearing loss, left ear	Diagnosis	ICD-10-CM
H91.23	Sudden idiopathic hearing loss, bilateral	Diagnosis	ICD-10-CM
H91.3	Deaf nonspeaking, not elsewhere classified	Diagnosis	ICD-10-CM
H91.8	Other specified hearing loss	Diagnosis	ICD-10-CM
H91.8X	Other specified hearing loss	Diagnosis	ICD-10-CM
H91.8X1	Other specified hearing loss, right ear	Diagnosis	ICD-10-CM

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Baseline Characteristics and Hematologic Outcomes in this Request

Code	Description	Code Category	Code Type
H91.8X2	Other specified hearing loss, left ear	Diagnosis	ICD-10-CM
H91.8X3	Other specified hearing loss, bilateral	Diagnosis	ICD-10-CM
H91.8X9	Other specified hearing loss, unspecified ear	Diagnosis	ICD-10-CM
H91.9	Unspecified hearing loss	Diagnosis	ICD-10-CM
H91.90	Unspecified hearing loss, unspecified ear	Diagnosis	ICD-10-CM
H91.91	Unspecified hearing loss, right ear	Diagnosis	ICD-10-CM
H91.92	Unspecified hearing loss, left ear	Diagnosis	ICD-10-CM
H91.93	Unspecified hearing loss, bilateral	Diagnosis	ICD-10-CM
V53.2	Adjustment hearing aid	Procedure	ICD-9-CM
Z46.1	Encounter for fitting and adjustment of hearing aid	Procedure	ICD-10-PCS
Jaundice			
774	Other perinatal jaundice	Diagnosis	ICD-9-CM
774.0	Perinatal jaundice from hereditary hemolytic anemias	Diagnosis	ICD-9-CM
774.1	Perinatal jaundice from other excessive hemolysis	Diagnosis	ICD-9-CM
774.2	Neonatal jaundice associated with preterm delivery	Diagnosis	ICD-9-CM
774.3	Neonatal jaundice due to delayed conjugation from other causes	Diagnosis	ICD-9-CM
774.30	Neonatal jaundice due to delayed conjugation, cause unspecified	Diagnosis	ICD-9-CM
774.31	Neonatal jaundice due to delayed conjugation in diseases classified elsewhere	Diagnosis	ICD-9-CM
774.39	Other neonatal jaundice due to delayed conjugation from other causes	Diagnosis	ICD-9-CM
774.4	Perinatal jaundice due to hepatocellular damage	Diagnosis	ICD-9-CM
774.5	Perinatal jaundice from other causes	Diagnosis	ICD-9-CM
774.6	Unspecified fetal and neonatal jaundice	Diagnosis	ICD-9-CM
P58.0	Neonatal jaundice due to bruising	Diagnosis	ICD-10-CM
P58.1	Neonatal jaundice due to bleeding	Diagnosis	ICD-10-CM
P58.2	Neonatal jaundice due to infection	Diagnosis	ICD-10-CM
P58.3	Neonatal jaundice due to polycythemia	Diagnosis	ICD-10-CM
P58.41	Neonatal jaundice due to drugs or toxins transmitted from mother	Diagnosis	ICD-10-CM
P58.42	Neonatal jaundice due to drugs or toxins given to newborn	Diagnosis	ICD-10-CM
P58.5	Neonatal jaundice due to swallowed maternal blood	Diagnosis	ICD-10-CM
P58.8	Neonatal jaundice due to other specified excessive hemolysis	Diagnosis	ICD-10-CM
P58.9	Neonatal jaundice due to excessive hemolysis, unspecified	Diagnosis	ICD-10-CM
P59.0	Neonatal jaundice associated with preterm delivery	Diagnosis	ICD-10-CM
P59.1	Inspissated bile syndrome	Diagnosis	ICD-10-CM
P59.20	Neonatal jaundice from unspecified hepatocellular damage	Diagnosis	ICD-10-CM
P59.29	Neonatal jaundice from other hepatocellular damage	Diagnosis	ICD-10-CM
P59.3	Neonatal jaundice from breast milk inhibitor	Diagnosis	ICD-10-CM
P59.8	Neonatal jaundice from other specified causes	Diagnosis	ICD-10-CM
P59.9	Neonatal jaundice, unspecified	Diagnosis	ICD-10-CM
Petechiae			
772.6	Fetal and neonatal cutaneous hemorrhage	Diagnosis	ICD-9-CM
782.7	Spontaneous ecchymoses	Diagnosis	ICD-9-CM
P54.5	Neonatal cutaneous hemorrhage	Diagnosis	ICD-10-CM
R23.3	Spontaneous ecchymoses	Diagnosis	ICD-10-CM
Hepatomegaly			

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Code	Description	Code Category	Code Type
573.1	Hepatitis in viral diseases classified elsewhere	Diagnosis	ICD-9-CM
789.1	Hepatomegaly	Diagnosis	ICD-9-CM
B25.1	Cytomegaloviral hepatitis	Diagnosis	ICD-10-CM
R16.0	Hepatomegaly, not elsewhere classified	Diagnosis	ICD-10-CM
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified	Diagnosis	ICD-10-CM
Splenomegaly			
289.51	Chronic congestive splenomegaly	Diagnosis	ICD-9-CM
289.53	Neutropenic splenomegaly	Diagnosis	ICD-9-CM
789.2	Splenomegaly	Diagnosis	ICD-9-CM
D73.2	Chronic congestive splenomegaly	Diagnosis	ICD-10-CM
D73.81	Neutropenic splenomegaly	Diagnosis	ICD-10-CM
R16.1	Splenomegaly, not elsewhere classified	Diagnosis	ICD-10-CM
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified	Diagnosis	ICD-10-CM
Microcephaly			
742.1	Microcephalus	Diagnosis	ICD-9-CM
Q02	Microcephaly	Diagnosis	ICD-10-CM
Thrombocytopenia			
287.3	Primary thrombocytopenia	Diagnosis	ICD-9-CM
287.30	Primary thrombocytopenia, unspecified	Diagnosis	ICD-9-CM
287.31	Immune thrombocytopenic purpura	Diagnosis	ICD-9-CM
287.33	Congenital and hereditary thrombocytopenic purpura	Diagnosis	ICD-9-CM
287.39	Other primary thrombocytopenia	Diagnosis	ICD-9-CM
287.4	Secondary thrombocytopenia	Diagnosis	ICD-9-CM
287.49	Other secondary thrombocytopenia	Diagnosis	ICD-9-CM
287.5	Unspecified thrombocytopenia	Diagnosis	ICD-9-CM
776.1	Transient neonatal thrombocytopenia	Diagnosis	ICD-9-CM
776.2	Disseminated intravascular coagulation in newborn	Diagnosis	ICD-9-CM
D69.42	Congenital and hereditary thrombocytopenia purpura	Diagnosis	ICD-10-CM
D69.49	Other primary thrombocytopenia	Diagnosis	ICD-10-CM
D69.51	Posttransfusion purpura	Diagnosis	ICD-10-CM
D69.59	Other secondary thrombocytopenia	Diagnosis	ICD-10-CM
D69.6	Thrombocytopenia, unspecified	Diagnosis	ICD-10-CM
P60	Disseminated intravascular coagulation of newborn	Diagnosis	ICD-10-CM
P61.0	Transient neonatal thrombocytopenia	Diagnosis	ICD-10-CM
Chorioretinitis			
363.0	Focal chorioretinitis and focal retinochoroiditis	Diagnosis	ICD-9-CM
363.00	Unspecified focal chorioretinitis	Diagnosis	ICD-9-CM
363.01	Focal choroiditis and chorioretinitis, juxtapapillary	Diagnosis	ICD-9-CM
363.03	Focal choroiditis and chorioretinitis of other posterior pole	Diagnosis	ICD-9-CM
363.04	Focal choroiditis and chorioretinitis, peripheral	Diagnosis	ICD-9-CM
363.05	Focal retinitis and retinochoroiditis, juxtapapillary	Diagnosis	ICD-9-CM
363.06	Focal retinitis and retinochoroiditis, macular or paramacular	Diagnosis	ICD-9-CM
363.07	Focal retinitis and retinochoroiditis of other posterior pole	Diagnosis	ICD-9-CM
363.08	Focal retinitis and retinochoroiditis, peripheral	Diagnosis	ICD-9-CM

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Code	Description	Code Category	Code Type
363.1	Disseminated chorioretinitis and disseminated retino-choroiditis	Diagnosis	ICD-9-CM
363.10	Unspecified disseminated chorioretinitis	Diagnosis	ICD-9-CM
363.11	Disseminated choroiditis and chorioretinitis, posterior pole	Diagnosis	ICD-9-CM
363.12	Disseminated choroiditis and chorioretinitis, peripheral	Diagnosis	ICD-9-CM
363.13	Disseminated choroiditis and chorioretinitis, generalized	Diagnosis	ICD-9-CM
363.14	Disseminated retinitis and retinochoroiditis, metastatic	Diagnosis	ICD-9-CM
363.15	Disseminated retinitis and retinochoroiditis, pigment epitheliopathy	Diagnosis	ICD-9-CM
363.2	Other and unspecified forms of chorioretinitis and retinochoroiditis	Diagnosis	ICD-9-CM
363.20	Unspecified chorioretinitis	Diagnosis	ICD-9-CM
363.21	Pars planitis	Diagnosis	ICD-9-CM
363.22	Harada's disease	Diagnosis	ICD-9-CM
363.3	Chorioretinal scars	Diagnosis	ICD-9-CM
363.30	Unspecified chorioretinal scar	Diagnosis	ICD-9-CM
363.31	Solar retinopathy	Diagnosis	ICD-9-CM
363.32	Other macular chorioretinal scars	Diagnosis	ICD-9-CM
363.33	Other chorioretinal scars of posterior pole	Diagnosis	ICD-9-CM
363.34	Peripheral chorioretinal scars	Diagnosis	ICD-9-CM
363.35	Disseminated chorioretinal scars	Diagnosis	ICD-9-CM
H30.0	Focal chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.00	Unspecified focal chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.001	Unspecified focal chorioretinal inflammation, right eye	Diagnosis	ICD-10-CM
H30.002	Unspecified focal chorioretinal inflammation, left eye	Diagnosis	ICD-10-CM
H30.003	Unspecified focal chorioretinal inflammation, bilateral	Diagnosis	ICD-10-CM
H30.009	Unspecified focal chorioretinal inflammation, unspecified eye	Diagnosis	ICD-10-CM
H30.01	Focal chorioretinal inflammation, juxtapapillary	Diagnosis	ICD-10-CM
H30.011	Focal chorioretinal inflammation, juxtapapillary, right eye	Diagnosis	ICD-10-CM
H30.012	Focal chorioretinal inflammation, juxtapapillary, left eye	Diagnosis	ICD-10-CM
H30.013	Focal chorioretinal inflammation, juxtapapillary, bilateral	Diagnosis	ICD-10-CM
H30.019	Focal chorioretinal inflammation, juxtapapillary, unspecified eye	Diagnosis	ICD-10-CM
H30.02	Focal chorioretinal inflammation of posterior pole	Diagnosis	ICD-10-CM
H30.021	Focal chorioretinal inflammation of posterior pole, right eye	Diagnosis	ICD-10-CM
H30.022	Focal chorioretinal inflammation of posterior pole, left eye	Diagnosis	ICD-10-CM
H30.023	Focal chorioretinal inflammation of posterior pole, bilateral	Diagnosis	ICD-10-CM
H30.029	Focal chorioretinal inflammation of posterior pole, unspecified eye	Diagnosis	ICD-10-CM
H30.03	Focal chorioretinal inflammation, peripheral	Diagnosis	ICD-10-CM
H30.031	Focal chorioretinal inflammation, peripheral, right eye	Diagnosis	ICD-10-CM
H30.032	Focal chorioretinal inflammation, peripheral, left eye	Diagnosis	ICD-10-CM
H30.033	Focal chorioretinal inflammation, peripheral, bilateral	Diagnosis	ICD-10-CM
H30.039	Focal chorioretinal inflammation, peripheral, unspecified eye	Diagnosis	ICD-10-CM
H30.04	Focal chorioretinal inflammation, macular or paramacular	Diagnosis	ICD-10-CM
H30.041	Focal chorioretinal inflammation, macular or paramacular, right eye	Diagnosis	ICD-10-CM
H30.042	Focal chorioretinal inflammation, macular or paramacular, left eye	Diagnosis	ICD-10-CM
H30.043	Focal chorioretinal inflammation, macular or paramacular, bilateral	Diagnosis	ICD-10-CM
H30.049	Focal chorioretinal inflammation, macular or paramacular, unspecified eye	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
H30.1	Disseminated chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.10	Unspecified disseminated chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.101	Unspecified disseminated chorioretinal inflammation, right eye	Diagnosis	ICD-10-CM
H30.102	Unspecified disseminated chorioretinal inflammation, left eye	Diagnosis	ICD-10-CM
H30.103	Unspecified disseminated chorioretinal inflammation, bilateral	Diagnosis	ICD-10-CM
H30.109	Unspecified disseminated chorioretinal inflammation, unspecified eye	Diagnosis	ICD-10-CM
H30.11	Disseminated chorioretinal inflammation of posterior pole	Diagnosis	ICD-10-CM
H30.111	Disseminated chorioretinal inflammation of posterior pole, right eye	Diagnosis	ICD-10-CM
H30.112	Disseminated chorioretinal inflammation of posterior pole, left eye	Diagnosis	ICD-10-CM
H30.113	Disseminated chorioretinal inflammation of posterior pole, bilateral	Diagnosis	ICD-10-CM
H30.119	Disseminated chorioretinal inflammation of posterior pole, unspecified eye	Diagnosis	ICD-10-CM
H30.12	Disseminated chorioretinal inflammation, peripheral	Diagnosis	ICD-10-CM
H30.121	Disseminated chorioretinal inflammation, peripheral right eye	Diagnosis	ICD-10-CM
H30.122	Disseminated chorioretinal inflammation, peripheral, left eye	Diagnosis	ICD-10-CM
H30.123	Disseminated chorioretinal inflammation, peripheral, bilateral	Diagnosis	ICD-10-CM
H30.129	Disseminated chorioretinal inflammation, peripheral, unspecified eye	Diagnosis	ICD-10-CM
H30.13	Disseminated chorioretinal inflammation, generalized	Diagnosis	ICD-10-CM
H30.131	Disseminated chorioretinal inflammation, generalized, right eye	Diagnosis	ICD-10-CM
H30.132	Disseminated chorioretinal inflammation, generalized, left eye	Diagnosis	ICD-10-CM
H30.133	Disseminated chorioretinal inflammation, generalized, bilateral	Diagnosis	ICD-10-CM
H30.139	Disseminated chorioretinal inflammation, generalized, unspecified eye	Diagnosis	ICD-10-CM
H30.14	Acute posterior multifocal placoid pigment epitheliopathy	Diagnosis	ICD-10-CM
H30.141	Acute posterior multifocal placoid pigment epitheliopathy, right eye	Diagnosis	ICD-10-CM
H30.142	Acute posterior multifocal placoid pigment epitheliopathy, left eye	Diagnosis	ICD-10-CM
H30.143	Acute posterior multifocal placoid pigment epitheliopathy, bilateral	Diagnosis	ICD-10-CM
H30.149	Acute posterior multifocal placoid pigment epitheliopathy, unspecified eye	Diagnosis	ICD-10-CM
H30.89	Other chorioretinal inflammations	Diagnosis	ICD-10-CM
H30.891	Other chorioretinal inflammations, right eye	Diagnosis	ICD-10-CM
H30.892	Other chorioretinal inflammations, left eye	Diagnosis	ICD-10-CM
H30.893	Other chorioretinal inflammations, bilateral	Diagnosis	ICD-10-CM
H30.899	Other chorioretinal inflammations, unspecified eye	Diagnosis	ICD-10-CM
H30.9	Unspecified chorioretinal inflammation	Diagnosis	ICD-10-CM
H30.90	Unspecified chorioretinal inflammation, unspecified eye	Diagnosis	ICD-10-CM
H30.91	Unspecified chorioretinal inflammation, right eye	Diagnosis	ICD-10-CM
H30.92	Unspecified chorioretinal inflammation, left eye	Diagnosis	ICD-10-CM
H30.93	Unspecified chorioretinal inflammation, bilateral	Diagnosis	ICD-10-CM
H31.00	Unspecified chorioretinal scars	Diagnosis	ICD-10-CM
H31.001	Unspecified chorioretinal scars, right eye	Diagnosis	ICD-10-CM
H31.002	Unspecified chorioretinal scars, left eye	Diagnosis	ICD-10-CM
H31.003	Unspecified chorioretinal scars, bilateral	Diagnosis	ICD-10-CM
H31.009	Unspecified chorioretinal scars, unspecified eye	Diagnosis	ICD-10-CM
H31.011	Macula scars of posterior pole (postinflammatory) (post-traumatic), right eye	Diagnosis	ICD-10-CM
H31.012	Macula scars of posterior pole (postinflammatory) (post-traumatic), left eye	Diagnosis	ICD-10-CM
H31.013	Macula scars of posterior pole (postinflammatory) (post-traumatic), bilateral	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
H31.019	Macula scars of posterior pole (postinflammatory) (post-traumatic), unspecified eye	Diagnosis	ICD-10-CM
H31.021	Solar retinopathy, right eye	Diagnosis	ICD-10-CM
H31.022	Solar retinopathy, left eye	Diagnosis	ICD-10-CM
H31.023	Solar retinopathy, bilateral	Diagnosis	ICD-10-CM
H31.029	Solar retinopathy, unspecified eye	Diagnosis	ICD-10-CM
H31.091	Other chorioretinal scars, right eye	Diagnosis	ICD-10-CM
H31.092	Other chorioretinal scars, left eye	Diagnosis	ICD-10-CM
H31.093	Other chorioretinal scars, bilateral	Diagnosis	ICD-10-CM
H31.099	Other chorioretinal scars, unspecified eye	Diagnosis	ICD-10-CM
Brain Abnormality			
330.3	Cerebral degeneration of childhood in other diseases classified elsewhere	Diagnosis	ICD-9-CM
331.3	Communicating hydrocephalus	Diagnosis	ICD-9-CM
331.4	Obstructive hydrocephalus	Diagnosis	ICD-9-CM
331.5	Idiopathic normal pressure hydrocephalus [INPH]	Diagnosis	ICD-9-CM
331.7	Cerebral degeneration in diseases classified elsewhere	Diagnosis	ICD-9-CM
348.89	Other conditions of brain	Diagnosis	ICD-9-CM
348.9	Unspecified condition of brain	Diagnosis	ICD-9-CM
742.2	Congenital reduction deformities of brain	Diagnosis	ICD-9-CM
742.3	Congenital hydrocephalus	Diagnosis	ICD-9-CM
742.4	Other specified congenital anomalies of brain	Diagnosis	ICD-9-CM
742.9	Unspecified congenital anomaly of brain, spinal cord, and nervous system	Diagnosis	ICD-9-CM
793.0	Nonspecific (abnormal) findings on radiological and other examination of skull and head	Diagnosis	ICD-9-CM
G91.0	Communicating hydrocephalus	Diagnosis	ICD-10-CM
G91.1	Obstructive hydrocephalus	Diagnosis	ICD-10-CM
G91.2	(Idiopathic) normal pressure hydrocephalus	Diagnosis	ICD-10-CM
G91.4	Hydrocephalus in diseases classified elsewhere	Diagnosis	ICD-10-CM
G91.8	Other hydrocephalus	Diagnosis	ICD-10-CM
G91.9	Hydrocephalus, unspecified	Diagnosis	ICD-10-CM
G93.89	Other specified disorders of brain	Diagnosis	ICD-10-CM
G93.9	Disorder of brain, unspecified	Diagnosis	ICD-10-CM
Q03.8	Other congenital hydrocephalus	Diagnosis	ICD-10-CM
Q03.9	Congenital hydrocephalus, unspecified	Diagnosis	ICD-10-CM
Q04.0	Congenital malformations of corpus callosum	Diagnosis	ICD-10-CM
Q04.3	Other reduction deformities of brain	Diagnosis	ICD-10-CM
Q04.4	Septo-optic dysplasia of brain	Diagnosis	ICD-10-CM
Q04.5	Megalencephaly	Diagnosis	ICD-10-CM
Q04.6	Congenital cerebral cysts	Diagnosis	ICD-10-CM
Q04.8	Other specified congenital malformations of brain	Diagnosis	ICD-10-CM
Q04.9	Congenital malformation of brain, unspecified	Diagnosis	ICD-10-CM
R90.82	White matter disease, unspecified	Diagnosis	ICD-10-CM
R93.0	Abnormal findings on diagnostic imaging of skull and head, not elsewhere classified	Diagnosis	ICD-10-CM
Other Brain Abnormality			
G91.3	Post-traumatic hydrocephalus, unspecified	Diagnosis	ICD-10-CM
Q03.0	Malformations of aqueduct of Sylvius	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Q03.1	Atresia of foramina of Magendie and Luschka	Diagnosis	ICD-10-CM
Q04.1	Arhinencephaly	Diagnosis	ICD-10-CM
Q04.2	Holoprosencephaly	Diagnosis	ICD-10-CM
Cytomegalovirus Infection (CMV)			
078.5	Cytomegaloviral disease	Diagnosis	ICD-9-CM
B25.0	Cytomegaloviral pneumonitis	Diagnosis	ICD-10-CM
B25.1	Cytomegaloviral hepatitis	Diagnosis	ICD-10-CM
B25.2	Cytomegaloviral pancreatitis	Diagnosis	ICD-10-CM
B25.8	Other cytomegaloviral diseases	Diagnosis	ICD-10-CM
B25.9	Cytomegaloviral disease, unspecified	Diagnosis	ICD-10-CM
Congenital Cytomegalovirus (cCMV)			
771.1	Congenital cytomegalovirus infection	Diagnosis	ICD-9-CM
P35.1	Congenital cytomegalovirus infection	Diagnosis	ICD-10-CM
CMV PCR Test (Blood, Urine, Saliva)			
87483	Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes simplex virus type 1 and 2, human herpesvirus 6, cytomegalovirus, varicella zoster virus, Cryptococcus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets	Procedure	CPT-4
87495	Infectious agent detection by nucleic acid (DNA or RNA); cytomegalovirus, direct probe technique	Procedure	CPT-4
87496	Infectious agent detection by nucleic acid (DNA or RNA); cytomegalovirus, amplified probe technique	Procedure	CPT-4
87497	Infectious agent detection by nucleic acid (DNA or RNA); cytomegalovirus, quantification	Procedure	CPT-4
87910	Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus	Procedure	CPT-4
CMV Antigen or Antibody Testing			
86644	Antibody; cytomegalovirus (CMV)	Procedure	CPT-4
86645	Antibody; cytomegalovirus (CMV), IgM	Procedure	CPT-4
87198	Cytomegalovirus, direct fluorescent antibody (DFA)	Procedure	CPT-4
87271	Infectious agent antigen detection by immunofluorescent technique; Cytomegalovirus, direct fluorescent antibody (DFA)	Procedure	CPT-4
87332	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step	Procedure	CPT-4
CMV Culture			
87252	Virus isolation; tissue culture inoculation, observation, and presumptive identification by cytopathic effect	Procedure	CPT-4
87254	Virus isolation; centrifuge enhanced (shell vial) technique, includes identification with immunofluorescence stain, each virus	Procedure	CPT-4
Head Computed Tomography (CT)			
70450	Computed tomography, head or brain; without contrast material	Procedure	CPT-4
70460	Computed tomography, head or brain; with contrast material(s)	Procedure	CPT-4

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Baseline Characteristics and Hematologic Outcomes in this Request

Code	Description	Code Category	Code Type
70470	Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections	Procedure	CPT-4
70480	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material	Procedure	CPT-4
70481	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material(s)	Procedure	CPT-4
70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material, followed by contrast material(s) and further sections	Procedure	CPT-4
0351	CT Scan-Head Scan	Procedure	Revenue
Brain MRI			
70551	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material	Procedure	CPT-4
70552	Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)	Procedure	CPT-4
70553	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences	Procedure	CPT-4
0611	Magnetic Resonance Technology-MRI-Brain/Brain Stem	Procedure	Revenue
88.91	Magnetic resonance imaging of brain and brain stem	Procedure	ICD-9-PCS
B030Y0Z	Magnetic Resonance Imaging (MRI) of Brain using Other Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
B030YZZ	Magnetic Resonance Imaging (MRI) of Brain using Other Contrast	Procedure	ICD-10-PCS
B030ZZZ	Magnetic Resonance Imaging (MRI) of Brain	Procedure	ICD-10-PCS
B33RY0Z	Magnetic Resonance Imaging (MRI) of Intracranial Arteries using Other Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
B33RYZZ	Magnetic Resonance Imaging (MRI) of Intracranial Arteries using Other Contrast	Procedure	ICD-10-PCS
B33RZZZ	Magnetic Resonance Imaging (MRI) of Intracranial Arteries	Procedure	ICD-10-PCS
Head Ultrasound			
76536	Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation	Procedure	HCPCS
76536	US SOFT TISSUE HEAD & NECK REAL TIME IMGE DOCM	Procedure	CPT-4
88.71	DIAGNOSTIC ULTRASOUND OF HEAD AND NECK	Procedure	ICD-9-PCS
B040ZZZ	Ultrasonography of Brain	Procedure	ICD-10-PCS
BH4CZZZ	Ultrasonography of Head and Neck	Procedure	ICD-10-PCS
BW4FZZZ	Ultrasonography of Neck	Procedure	ICD-10-PCS
Neutropenia			
288.0	Neutropenia	Diagnosis	ICD-9-CM
288.00	Neutropenia, unspecified	Diagnosis	ICD-9-CM
288.01	Congenital neutropenia	Diagnosis	ICD-9-CM
288.03	Drug induced neutropenia	Diagnosis	ICD-9-CM
288.04	Neutropenia due to infection	Diagnosis	ICD-9-CM
288.09	Other neutropenia	Diagnosis	ICD-9-CM
776.7	Transient neonatal neutropenia	Diagnosis	ICD-9-CM
D70	Neutropenia	Diagnosis	ICD-10-CM
D70.0	Congenital agranulocytosis	Diagnosis	ICD-10-CM

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Baseline Characteristics and Hematologic Outcomes in this Request

Code	Description	Code Category	Code Type
D70.2	Other drug-induced agranulocytosis	Diagnosis	ICD-10-CM
D70.3	Neutropenia due to infection	Diagnosis	ICD-10-CM
D70.8	Other neutropenia	Diagnosis	ICD-10-CM
D70.9	Neutropenia, unspecified	Diagnosis	ICD-10-CM
P61.5	Transient neonatal neutropenia	Diagnosis	ICD-10-CM
Receipt of RBC Transfusion			
30230N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30230P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30233N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30233P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30240N1	Transfusion of Nonautologous Red Blood Cells into Central Vein, Open Approach	Procedure	ICD-10-PCS
30240P1	Transfusion of Nonautologous Frozen Red Cells into Central Vein, Open Approach	Procedure	ICD-10-PCS
30243N1	Transfusion of Nonautologous Red Blood Cells into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30243P1	Transfusion of Nonautologous Frozen Red Cells into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30250N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Artery, Open Approach	Procedure	ICD-10-PCS
30250P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Artery, Open Approach	Procedure	ICD-10-PCS
30253N1	Transfusion of Nonautologous Red Blood Cells into Peripheral Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30253P1	Transfusion of Nonautologous Frozen Red Cells into Peripheral Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30260N1	Transfusion of Nonautologous Red Blood Cells into Central Artery, Open Approach	Procedure	ICD-10-PCS
30260P1	Transfusion of Nonautologous Frozen Red Cells into Central Artery, Open Approach	Procedure	ICD-10-PCS
30263N1	Transfusion of Nonautologous Red Blood Cells into Central Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30263P1	Transfusion of Nonautologous Frozen Red Cells into Central Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30273N	Administration @ Circulatory @ Transfusion @ Products of Conception, Circulatory @ Percutaneous @ Red Blood Cells	Procedure	ICD-10-PCS
30273N1	Transfusion of Nonautologous Red Blood Cells into Products of Conception, Circulatory, Percutaneous Approach	Procedure	ICD-10-PCS
30273P	Administration @ Circulatory @ Transfusion @ Products of Conception, Circulatory @ Percutaneous @ Frozen Red Cells	Procedure	ICD-10-PCS
30273P1	Transfusion of Nonautologous Frozen Red Cells into Products of Conception, Circulatory, Percutaneous Approach	Procedure	ICD-10-PCS
30277N	Administration @ Circulatory @ Transfusion @ Products of Conception, Circulatory @ Via Natural or Artificial Opening @ Red Blood Cells	Procedure	ICD-10-PCS
30277N1	Transfusion of Nonautologous Red Blood Cells into Products of Conception, Circulatory, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
30277P	Administration @ Circulatory @ Transfusion @ Products of Conception, Circulatory @ Via Natural or Artificial Opening @ Frozen Red Cells	Procedure	ICD-10-PCS
30277P1	Transfusion of Nonautologous Frozen Red Cells into Products of Conception, Circulatory, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
9904	Transfusion of packed cells	Procedure	ICD-9-CM
C1010	Whole blood or red blood cells, leukoreduced, cmv negative, each unit	Procedure	HCPCS
C1016	Whole blood or red blood cells, leukoreduced, frozen, deglycerol, washed, each unit	Procedure	HCPCS
C1020	Each unit red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, irradiated	Procedure	HCPCS

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Baseline Characteristics and Hematologic Outcomes in this Request

Code	Description	Code Category	Code Type
C1021	Red blood cells, leukocyte-reduced, cmv negative, irradiated, each unit	Procedure	HCPCS
C9504	RED BLD CELLS DEGLYCEROLIZED EA UNI	Procedure	HCPCS
C9505	Red blood cells, irradiated, each unit	Procedure	HCPCS
P9016	Red blood cells, leukocytes reduced, each unit	Procedure	HCPCS
P9021	Red blood cells, each unit	Procedure	HCPCS
P9022	Red blood cells, washed, each unit	Procedure	HCPCS
P9038	Red blood cells, irradiated, each unit	Procedure	HCPCS
P9039	RBCS DEGLYCEROLIZED EACH UNIT	Procedure	HCPCS
P9040	Red blood cells, leukocytes reduced, irradiated, each unit	Procedure	HCPCS
P9051	Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit	Procedure	HCPCS
P9054	Each unit whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed	Procedure	HCPCS
P9057	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit	Procedure	HCPCS
P9058	Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit	Procedure	HCPCS
Receipt of Platelet Transfusion			
30230R	Administration @ Circulatory @ Transfusion @ Peripheral Vein @ Open @ Platelets	Procedure	ICD-10-PCS
30230R1	Transfusion of Nonautologous Platelets into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30233R	Administration @ Circulatory @ Transfusion @ Peripheral Vein @ Percutaneous @ Platelet	Procedure	ICD-10-PCS
30233R1	Transfusion of Nonautologous Platelets into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30240R	Administration @ Circulatory @ Transfusion @ Central Vein @ Open @ Platelets	Procedure	ICD-10-PCS
30240R1	Transfusion of Nonautologous Platelets into Central Vein, Open Approach	Procedure	ICD-10-PCS
30243R	Administration @ Circulatory @ Transfusion @ Central Vein @ Percutaneous @ Platelets	Procedure	ICD-10-PCS
30243R1	Transfusion of Nonautologous Platelets into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30250R	Administration @ Circulatory @ Transfusion @ Peripheral Artery @ Open @ Platelets	Procedure	ICD-10-PCS
30250R1	Transfusion of Nonautologous Platelets into Peripheral Artery, Open Approach	Procedure	ICD-10-PCS
30253R	Administration @ Circulatory @ Transfusion @ Peripheral Artery @ Percutaneous @ Platelet	Procedure	ICD-10-PCS
30253R1	Transfusion of Nonautologous Platelets into Peripheral Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30260R	Administration @ Circulatory @ Transfusion @ Central Artery @ Open @ Platelets	Procedure	ICD-10-PCS
30260R1	Transfusion of Nonautologous Platelets into Central Artery, Open Approach	Procedure	ICD-10-PCS
30263R	Administration @ Circulatory @ Transfusion @ Central Artery @ Percutaneous @ Platelets	Procedure	ICD-10-PCS
30263R1	Transfusion of Nonautologous Platelets into Central Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30273R	Administration @ Circulatory @ Transfusion @ Products of Conception, Circulatory @ Percutaneous @ Platelets	Procedure	ICD-10-PCS
30273R1	Transfusion of Nonautologous Platelets into Products of Conception, Circulatory, Percutaneous Approach	Procedure	ICD-10-PCS
30277R	Administration @ Circulatory @ Transfusion @ Products of Conception, Circulatory @ Via Natural or Artificial Opening @ Platelets	Procedure	ICD-10-PCS
30277R1	Transfusion of Nonautologous Platelets into Products of Conception, Circulatory, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
9905	Platelet transfusion	Procedure	ICD-9-CM
C1011	Platelet, hla-matched leukoreduced, apheresis/pheresis, each unit	Procedure	HCPCS
C1012	Platelet concentrate, leukoreduced, irradiated, each unit	Procedure	HCPCS
C1013	Platelet, hla-matched leukoreduced, apheresis/pheresis, each unitytes reduced	Procedure	HCPCS
C1014	Platelet, leukoreduced, apheresis/pheresis, each unit	Procedure	HCPCS
C1015	Platelets, pheresis, leukocyte-reduced, CMV negative, irradiated, each unit	Procedure	HCPCS

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) Codes Used to Define Baseline Characteristics and Hematologic Outcomes in this Request

Code	Description	Code Category	Code Type
C1017	Platelet, leukoreduced, cmv-negative, apheresis/pheresis, each unit	Procedure	HCPCS
C1019	Platelet, leukoreduced, irradiated, apheresis/pheresis, each unit	Procedure	HCPCS
C9500	Platelets, irradiated, each unit	Procedure	HCPCS
C9501	Platelets, pheresis, each unit	Procedure	HCPCS
C9502	PLATELETS PHERESIS IRRADIATED EA UN	Procedure	HCPCS
P9019	Platelets, each unit	Procedure	HCPCS
P9031	Platelets, leukocytes reduced, each unit	Procedure	HCPCS
P9032	Platelets, irradiated, each unit	Procedure	HCPCS
P9033	Platelets, leukocytes reduced, irradiated, each unit	Procedure	HCPCS
P9034	Platelets, pheresis, each unit	Procedure	HCPCS
P9035	Platelets, pheresis, leukocytes reduced, each unit	Procedure	HCPCS
P9036	PLATELETS PHERESIS IRRADATD EA UNIT	Procedure	HCPCS
P9037	Platelets, pheresis, leukocytes reduced, irradiated, each unit	Procedure	HCPCS
P9052	PLT HLA-MATCHD LEUKOCYTES RDUC EACH	Procedure	HCPCS
P9053	PLT PHERES LEUKOCYT RDUC CMV-NEG EA	Procedure	HCPCS
P9055	PLT LEUKOCYT RDUC CMV-NEG APH/PHERS	Procedure	HCPCS
P9072	PLT PHRS PATH RDUC/RPD BACT TST E U	Procedure	HCPCS
Q9988	PLATELETS PATHOGEN REDUCED EA UNIT	Procedure	HCPCS
Receipt of GCSF Transfusion			
C9058	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	Procedure	HCPCS
C9119	Injection, pegfilgrastim, per 6 mg single dose vial	Procedure	HCPCS
J1440	Injection, filgrastim (G-CSF), 300 mcg	Procedure	HCPCS
J1441	Injection, filgrastim (G-CSF), 480 mcg	Procedure	HCPCS
J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 mcg	Procedure	HCPCS
J1446	Injection, TBO-filgrastim, 5 micrograms	Procedure	HCPCS
J1447	Injection, tbo-filgrastim, 1 mcg	Procedure	HCPCS
J2505	Injection, pegfilgrastim, 6 mg	Procedure	HCPCS
Q4053	Injection, pegfilgrastim, 1 mg	Procedure	HCPCS
Q5101	Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 mcg	Procedure	HCPCS
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 mg	Procedure	HCPCS
Q5110	Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg	Procedure	HCPCS
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg	Procedure	HCPCS
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ZIEXTENZO), 0.5 mg	Procedure	HCPCS
S0135	Injection pegfilgrastim, 6 mg	Procedure	HCPCS

Appendix G. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool, version 11.0.0, to estimate rates of Valganciclovir (VGVC) or Ganciclovir (GGVC) use in children with Congenital Cytomegalovirus Infection (cCMV) and Cytomegalovirus Infection (CMV) in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2008 - May 31, 2021
Coverage Requirement: Medical and Drug Coverage
Pre-Index Enrollment Requirement: No pre-enrollment requirement
Post-Index Enrollment Requirement: 0 days
Enrollment Gap: 0 days
Age Groups: ≤45 days (**For CMV index**); 0 < 6 months, 6 months < 1 year, 1 < 2 years, 2 < 3 years, 3 < 4 years, 4 - 5 years (**For VGCV index**)
Distribution of Index-Defining Codes: Valganciclovir, Ganciclovir
Censor Output Category: Yes (Overall, censor days by 1-14, 15 - 30, 31 - 90, 91 - 180, 181 - 365, and >365) - For valganciclovir assessments only
Stratifications: Sex, Year, Ethnicity, Region, Sex & Year, Ethnicity & Year, Race & Year, Region & Year
Freeze Data: Yes

Exposure

Scenario	Index	Cohort Definition	Build Episodes on Point Exposure?	Maximum Exposure Episode Duration	Care Setting	Treatment Episode Gap	Exposure Episode Extension	Minimum Exposure Episode Duration	Minimum Days Supplied	Censor Episode at Evidence of:	Treatment Evidence of:	Flag for PEPR
1	cCMV or CMV	First valid exposure episodes during query period;	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes
2	cCMV or CMV	First valid exposure episodes during query period;	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
3	cCMV or CMV	First valid exposure episodes during query period;	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
4	cCMV or CMV	First valid exposure episodes during query period;	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
5	cCMV or CMV	First valid exposure episodes during query period;	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	

Appendix G. Specifications Defining Parameters for this Request

Scenario	Index	Cohort Definition	Exposure									
			Build Episodes on Point Exposure?	Maximum Exposure Episode Duration	Care Setting	Treatment Episode Gap	Exposure Episode Extension	Minimum Exposure Episode Duration	Minimum Days Supplied	Censor Treatment Episode at Evidence of:	Flag for PEPR	
6	cCMV or CMV	First valid exposure episodes during query period;	Yes	180	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes
7	cCMV or CMV	First valid exposure episodes during query period;	Yes	180	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
8	cCMV or CMV	First valid exposure episodes during query period;	Yes	180	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
9	cCMV or CMV	First valid exposure episodes during query period;	Yes	180	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
10	cCMV or CMV	First valid exposure episodes during query period;	Yes	180	Any care setting	N/A	N/A	N/A	N/A	N/A	N/A	
11	cCMV or CMV	First valid exposure episodes during query period;	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes
12	cCMV or CMV	First valid exposure episodes during query period;	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes
13	VGVC or GGVC	First valid exposure episodes during query period;		N/A	Any care setting	30 days	30 days	1 day	1 day		*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	Yes

Appendix G. Specifications Defining Parameters for this Request

Exposure											
Scenario	Index	Cohort Definition	Build Episodes on Point Exposure?	Maximum Exposure Episode Duration	Care Setting	Treatment Episode Gap	Exposure Episode Extension	Minimum Exposure Episode Duration	Minimum Days Supplied	Censor Episode at Evidence of:	Treatment Flag for PEPR
14	VGVC or GGVC	First valid exposure episodes during query period;		N/A	Any care setting	30 days	30 days	1 day	1 day	*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	Yes
15	VGVC or GGVC	First valid exposure episodes during query period;		N/A	Any care setting	30 days	30 days	1 day	1 day	*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	Yes
16	VGVC or GGVC	First valid exposure episodes during query period;		N/A	Any care setting	30 days	30 days	1 day	1 day	*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	Yes
17	VGVC or GGVC	First valid exposure episodes during query period;		N/A	Any care setting	30 days	30 days	1 day	1 day	*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	Yes
18	VGVC or GGVC	First valid exposure episodes during query period;		N/A	Any care setting	30 days	30 days	1 day	1 day	*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	Yes
19	VGVC or GGVC	First valid exposure episodes during query period;		N/A	Any care setting	30 days	30 days	1 day	1 day	*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	Yes

Appendix G. Specifications Defining Parameters for this Request

Exposure											
Scenario	Index	Cohort Definition	Build Episodes on Point Exposure?	Maximum Exposure Episode Duration	Care Setting	Treatment Episode Gap	Exposure Episode Extension	Minimum Exposure Episode Duration	Minimum Days Supplied	Censor Episode at Evidence of:	Treatment Flag for PEPR
20	VGVC or GGVC	First valid exposure episodes during query period;	N/A		Any care setting					*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	
21	VGVC or GGVC	First valid exposure episodes during query period;	N/A		Any care setting					*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	
22	VGVC or GGVC	First valid exposure episodes during query period;	N/A		Any care setting					*Death; *DP end date; *Query end date; *Episode End Date *Disenrollment	

Appendix G. Specifications Defining Parameters for this Request

Inclusion/Exclusion Criteria				
Scenario	Inclusion/ Exclusion Group	Criteria	Evaluation Period Start	Evaluation Period End
1	N/A	N/A	N/A	N/A
2	Hearing Loss	Exclusion	Ever (prior to index)	15 days
	Clinical Characteristics	Exclusion	Ever (prior to index)	15 days
3	Hearing Loss	Inclusion	Ever (prior to index)	15 days
	Clinical Characteristics	Exclusion	Ever (prior to index)	15 days
4	Hearing Loss	Exclusion	Ever (prior to index)	15 days
	Clinical Characteristics	Inclusion	Ever (prior to index)	15 days
5	Hearing Loss	Inclusion	Ever (prior to index)	15 days
	Clinical Characteristics	Inclusion	Ever (prior to index)	15 days
6	N/A	N/A	N/A	N/A
7	Hearing Loss	Exclusion	Ever (prior to index)	15 days
	Clinical Characteristics	Exclusion		
8	Hearing Loss	Inclusion	Ever (prior to index)	15 days
	Clinical Characteristics	Exclusion		
9	Hearing Loss	Exclusion	Ever (prior to index)	15 days
	Clinical Characteristics	Inclusion		
10	Hearing Loss	Inclusion	Ever (prior to index)	15 days
	Clinical Characteristics	Inclusion		
11	VGVC or GGVC	Inclusion	0 days	45 days
12	VGVC or GGVC	Inclusion	0 days	180 days
13	cCMV	Inclusion	Ever (prior to index)	45 days
14	cCMV	Inclusion	Ever (prior to index)	45 days
	Hearing Loss	Exclusion	Ever (prior to index)	0 days
	Clinical Characteristics	Exclusion	Ever (prior to index)	0 days

Appendix G. Specifications Defining Parameters for this Request

Inclusion/Exclusion Criteria				
Scenario	Inclusion/ Exclusion Group	Criteria	Evaluation Period Start	Evaluation Period End
15	cCMV	Inclusion	Ever (prior to index)	45 days
	Hearing Loss	Inclusion	Ever (prior to index)	0 days
	Clinical Characteristics	Exclusion	Ever (prior to index)	0 days
16	cCMV	Inclusion	Ever (prior to index)	45 days
	Hearing Loss	Exclusion	Ever (prior to index)	0 days
	Clinical Characteristics	Inclusion	Ever (prior to index)	0 days
17	cCMV	Inclusion	Ever (prior to index)	45 days
	Hearing Loss	Inclusion	Ever (prior to index)	0 days
	Clinical Characteristics	Inclusion	Ever (prior to index)	0 days
18	cCMV	Inclusion	Ever (prior to index)	0 days
	No Hematologic Outcomes	Exclusion	0 days	180 days
19	cCMV	Inclusion	Ever (prior to index)	0 days
	Any Hematologic Outcomes	Inclusion	0 days	180 days
20	cCMV or CMV	Inclusion	-45 days	0 days
21	cCMV or CMV	Inclusion	-45 days	0 days
22	cCMV or CMV	Inclusion	-45 days	0 days

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
1	Clinical characteristics, Lab tests, Radiology, CMV culture	N/A	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
2	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
3	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
4	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
5	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
6	Clinical characteristics, Lab tests, Radiology, CMV culture	N/A	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
		Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
7	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	N/A	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
		Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
8	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
9	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
10	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
11	Clinical characteristics, Lab tests, Radiology, CMV culture	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
		Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
12	Clinical characteristics, Lab tests, Radiology, CMV culture	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
		Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
13	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
		Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
14	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
15	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
16	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
17	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

Appendix G. Specifications Defining Parameters for this Request

Covariates						
Scenario	Covariates	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Forced Supply to Attach to Dispensings	Blackout Period
18	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
19	N/A	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified
	Selected clinical characteristics include Jaundice, Petechiae, Hepatomegaly, Splenomegaly, Microcephaly, Thrombocytopenia, Chorioretinitis, Brain abnormality	Only applicable for Inpatient and Institutional stays: *Principal; *Secondary; *Unknown	*Washout lookback period should search for evidence of days supply; *Washout lookback period should search for only evidence of a dispensing date	*Count all occurrences of an HOI during exposure period *De-duplicates occurrences of the same event code and code type on the same day *De-duplicates occurrences of the same event group on the same day	Numeric specified; Indicates a forced supply that should be attached to the NDC to replace the event code's RxSup value	Numeric specified

International Classification of Diseases, Ninth Revision (ICD-9) and Tenth Revision (ICD-10), Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes are provided by Optum360.

National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix H. Diagrams Detailing the Design for this Request

Trends in Rates of Congenital CMV Overall and by Selected Demographic Characteristics

Cohort A

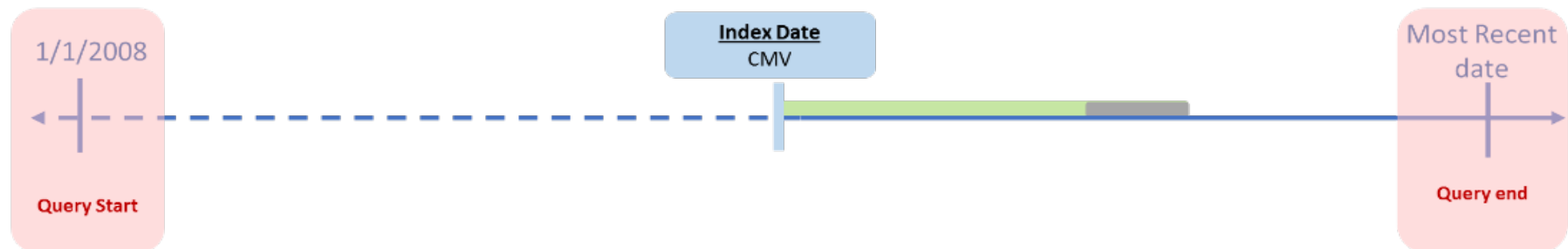
- Index on date of CMV diagnosis
- Restricted to infants 45 days old or younger
- No pre-index enrollment requirement
- Repeat, with stratification by Disease Severity

Cohort Definition

First valid exposure episode; no cohort re-entry

Stratifications

Year, Sex, Ethnicity, Race, Geographic location,
Sex*Year, Geographic location*Year, Race*Year,
Ethnicity*Year



Appendix H. Diagrams Detailing the Design for this Request

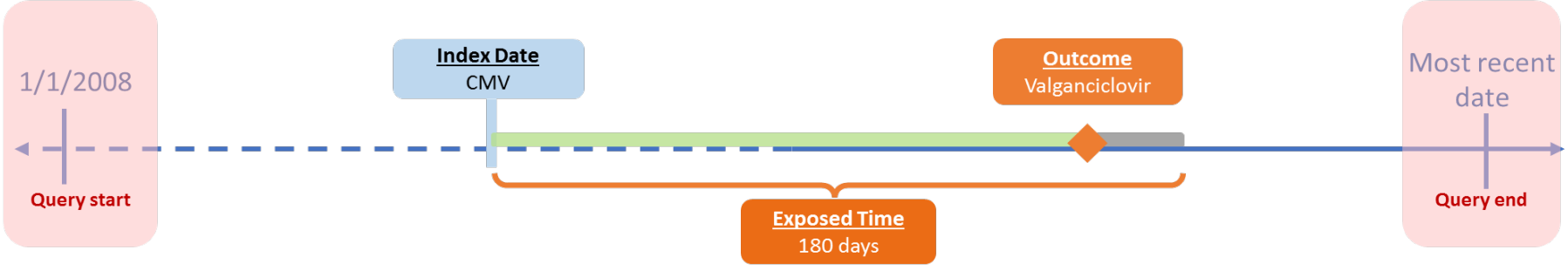
Trends in Prevalence of Valganciclovir Use Among Infants With Congenital CMV Overall and by Selected Demographic Characteristics

Cohort A with Valganciclovir Treatment

- Index on date of CMV diagnosis
- Restricted to infants 45 days old or younger
- No Pre-index requirement
- Event: Valganciclovir/Ganciclovir Treatment

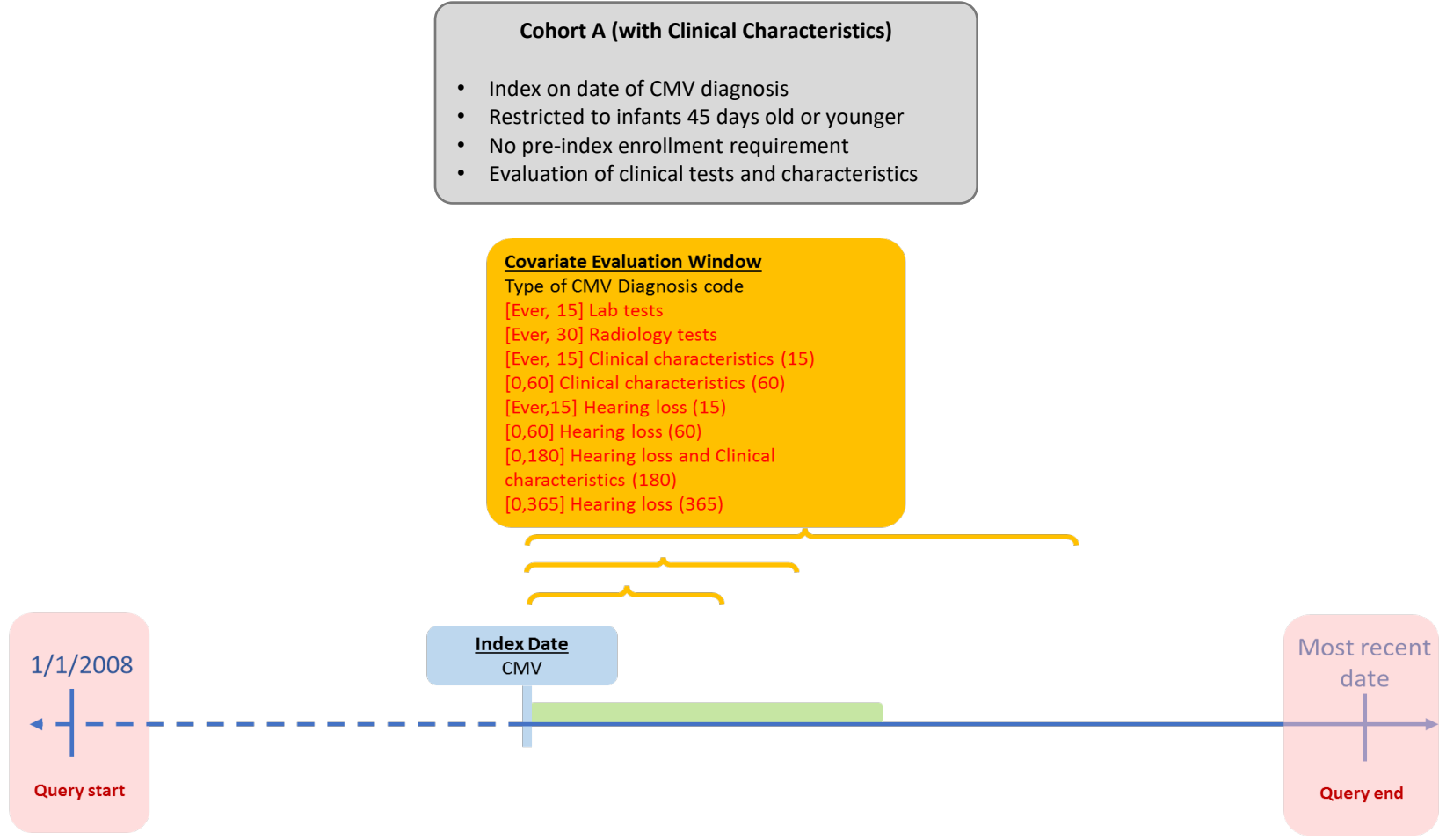
Cohort Definition
First valid exposure episode; no cohort re-entry

Stratifications
Year, Sex, Ethnicity, Race, Geographic location,
Sex*year, Ethnicity*year, Race*year, Geographic location*year



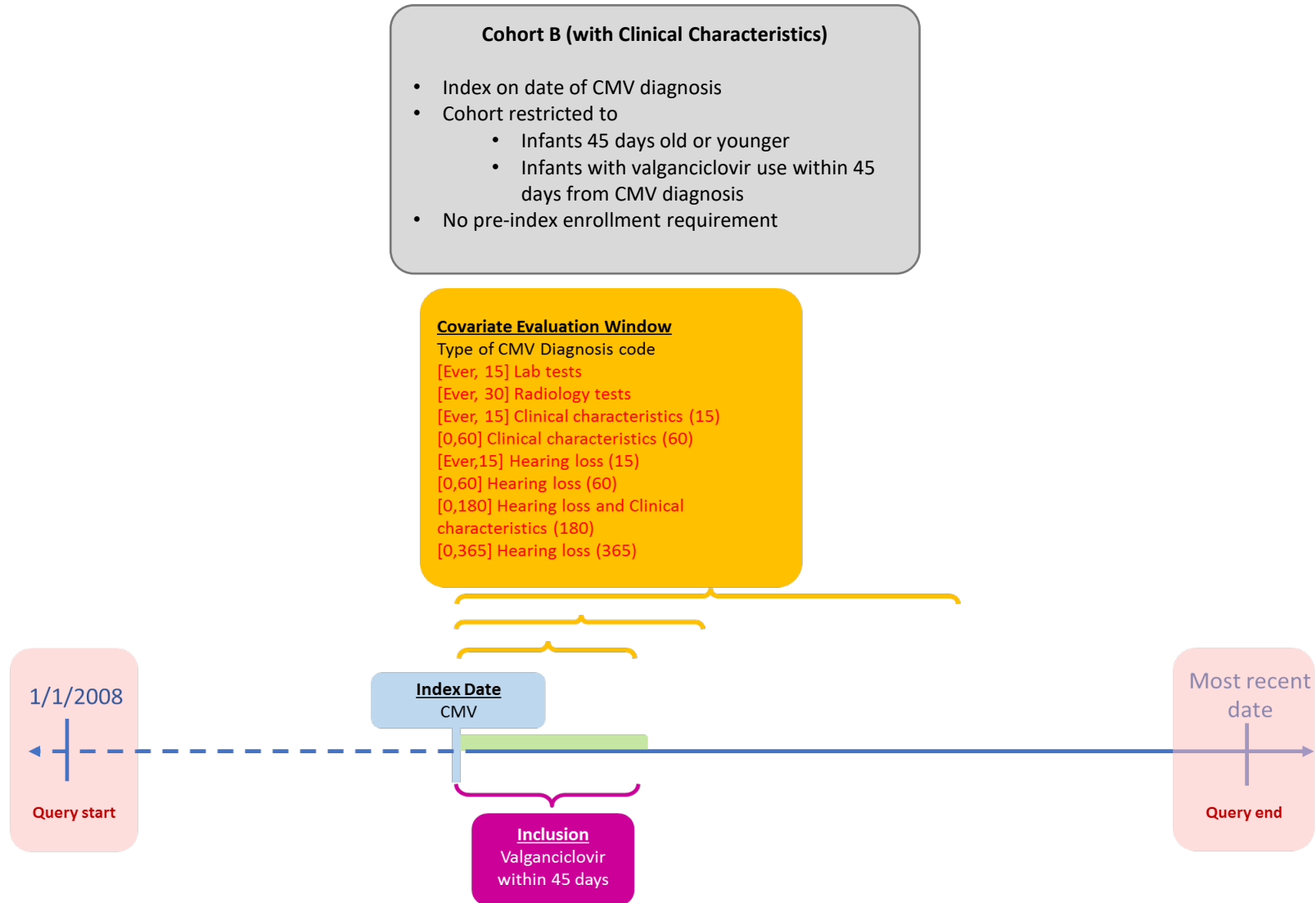
Appendix H. Diagrams Detailing the Design for this Request

Clinical Testing and Clinical Characteristics of Infants With Congenital CMV Disease



Appendix H. Diagrams Detailing the Design for this Request

Clinical Testing and Clinical Characteristics of Infants with Valganciclovir-Treated Congenital CMV Disease
(Sensitivity Analysis: Valganciclovir Use Within the First 45 Days from CMV Diagnosis)



Appendix H. Diagrams Detailing the Design for this Request

Clinical Testing and Clinical Characteristics of Infants with Valganciclovir-Treated Congenital CMV Disease
(Sensitivity Analysis: Valganciclovir Use Within the First 180 Days from CMV Diagnosis)

