## Disclaimer

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

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

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

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

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**Overview for Request: cder_mpl1r_wp217**

**Request ID:** cder_mpl1r_wp217_nsdp_v02_r02

**Request Description:** In this study we assessed follow-up time and distribution of valganciclovir or ganciclovir treatment in infants with congenital cytomegalovirus infection (cCMV). We also assessed clinical characteristics, laboratory tests performed for cytomegalovirus infection (CMV) diagnosis, hearing loss and hematologic outcomes among infants with CMV who used valganciclovir/ganciclovir treatment. A companion report contains assemment of trends in diagnosis of cCMV or CMV infection (see Sentinel_Report_cder_mpl1r_wp217_nsdp_v02_r01).

**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 individuals with incident use of valganciclovir/ganciclovir and evaluated the distribution of follow-up time from the date of incident valganciclovir use. This is a Type 2 analysis in the Query Request Package (QRP) documentation.

**Exposure of Interest:** We identified incident use of valganciclovir or gancivlovir among individuals with CMV diagnosis before or after treatment initiation and assessed the distribution of follow-up time until censoring from incident valganciclvoir/ganciclovir exposure. We identified valganciclovir/ganciclovir treatments using National Drug Codes (NDC). See Appendix C for a list of generic and brand names of medical products for valganciclovir/ganciclovir exposure in this request.

**Cohort Eligibility Criteria**: We required members to be enrolled in health plans with medical and drug coverage on the index date. The following age groups were examined: 0 - 6 months, 6 months - 1 year, 1 - 2 years, 2 - 3 years, 3 - 4 years, and 4 - 5 years. To evaluate the distribution of valganciclovir use among individuals with CMV, we identified individuals with incident use of valganciclovir or gancivlovir among individuals with CMV diagnosis at any time prior to or within 45 days after the first valganciclovir/ganciclovir dispensing. We assessed the distribution of follow-up time from the incident valganciclvoir/ganciclovir exposure until censoring. We repeated this assessment by disease severity.

To define disease severity, we identified four sub-cohorts based on hearing loss and select clinical characteristics. In addition, we identified two cohorts based on hematologic outcomes, requiring CMV diagnosis at any time prior to and up to the first valganciclovir/ganciclovir dispensing. 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 prior to and including 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 prior to and including the index date.
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 clinical characteristics prior to and including 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 have a history of any of the clinical characteristics prior to and including the index date.
e) *Hematologic outcomes absent* : To be included in this cohort, we required members to have no history of hematologic outcomes within the first 180 days of the valganciclovir/ganciclovir dispensing.
f) *Hematologic outcomes present* : To be included in this cohort, we required members to have a history of any of the hematologic outcomes within the first 180 days of the valganciclovir/ganciclovir dispensing.

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

**Follow-up Time**: We created exposure episodes based on the number of days of product supplied per dispensing in the outpatient pharmacy dispensing data. We bridged together episodes less than 30 days apart and added 30 days to the end of each episode. Follow-up for valganciclovir/ganciclovir use began on the day of the index dispensing and continued until the first occurrence of any of the following: 1) disenrollment; 2) death; 3) the end of data provided by each Data Partner; 4) the end of the query period; or 5) the end of exposure episode.

**Overview for Request: cder_mpl1r_wp217**

**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, chloriotinitis; 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 clincal 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 D for 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 inclusion criteria in this request.

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@sentinelsystem.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.sentinelsystem.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 Exposure (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
**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 Exposure 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 - i**ndicator 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 Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Patient Characteristics | Number | |
|---|---|---|
| Unique patients | 372 | |
| **Demographic Characteristics** | **Mean** | **Standard Deviation** |
| Mean Age (Days) | 77.71 | 137.66 |
| Age (Days) | **Number** | **Percent** |
| ≤ 181 | 343 | 92.2% |
| 182-364 | 22 | 5.9% |
| 365-729 | 3 | 0.8% |
| 730-1094 | 0 | 0.0% |
| 1095-1459 | 0 | 0.0% |
| 1460-1825 | 0 | 0.0% |
| Sex | | |
| Female | 178 | 47.8% |
| Male | 194 | 52.2% |
| Race[1] | | |
| American Indian or Alaska Native | 0 | 0.0% |
| Asian | 1 | 0.3% |
| Black or African American | 27 | 7.3% |
| Native Hawaiian or Other Pacific Islander | 5 | 1.3% |
| Unknown | 302 | 81.2% |
| White | 37 | 9.9% |
| Hispanic Origin | | |
| Yes | 2 | 0.5% |
| No | 55 | 14.8% |
| Unknown | 315 | 84.7% |
| Year | | |
| 2008 | 11 | 3.0% |
| 2009 | 5 | 1.3% |
| 2010 | 11 | 3.0% |
| 2011 | 14 | 3.8% |
| 2012 | 12 | 3.2% |
| 2013 | 16 | 4.3% |
| 2014 | 26 | 7.0% |
| 2015 | 46 | 12.4% |
| 2016 | 53 | 14.2% |
| 2017 | 43 | 11.6% |
| 2018 | 46 | 12.4% |
| 2019 | 49 | 13.2% |
| 2020 | 36 | 9.7% |
| 2021 | 4 | 1.1% |
| **Health Characteristics** | | |
| Type of Cytomegalovirus (CMV) Diagnosis Code | | |
| cCMV | 360 | 96.8% |
| CMV | 209 | 56.2% |

**Table 1a. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Clinical Characteristics | Number | Percent |
|---|---|---|
| **Ever, Prior to and Up to 15 Days After Index** | | |
| Jaundice | 163 | 43.8% |
| Petechiae | 40 | 10.8% |
| Hepatomegaly | 34 | 9.1% |
| Splenomegaly | 34 | 9.1% |
| Microcephaly | 62 | 16.7% |
| Thrombocytopenia | 158 | 42.5% |
| Chlorioretinitis | 25 | 6.7% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 125 | 33.6% |
| **Ever, Prior to and Up to 30 Days After Index** | | |
| Brain Abnormality | 116 | 31.2% |
| Other Brain Abnormality | 1 | 0.3% |
| **Within 60 Days From Index** | | |
| Neutropenia | 54 | 14.5% |
| Receipt of RBC transfusion | 6 | 1.6% |
| Receipt of platelet transfusion | 3 | 0.8% |
| Receipt of GCSF transfusion | 6 | 1.6% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 153 | 41.1% |
| **Within 180 Days From Index** | | |
| Neutropenia | 70 | 18.8% |
| Receipt of RBC transfusion | 6 | 1.6% |
| Receipt of platelet transfusion | 3 | 0.8% |
| Receipt of GCSF transfusion | 8 | 2.2% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 195 | 52.4% |
| **Within 365 Days From Index** | | |
| Hearing Loss, Hearing Aid, Cochlear Implant | 216 | 58.1% |
| **Ever, Prior to and Up to Index Date** | | |
| Jaundice | 157 | 42.2% |
| Petechiae | 38 | 10.2% |
| Hepatomegaly | 32 | 8.6% |
| Splenomegaly | 31 | 8.3% |
| Microcephaly | 58 | 15.6% |
| Thrombocytopenia | 157 | 42.2% |
| Chlorioretinitis | 23 | 6.2% |
| Brain Abnormality | 103 | 27.7% |
| Other Brain Abnormality | 1 | 0.3% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 100 | 26.9% |
| **Ever, Prior to and Up to 45 Days After Index** | | |
| Jaundice | 163 | 43.8% |
| Petechiae | 42 | 11.3% |
| Hepatomegaly | 38 | 10.2% |
| Splenomegaly | 34 | 9.1% |
| Microcephaly | 67 | 18.0% |
| Thrombocytopenia | 159 | 42.7% |
| Chlorioretinitis | 31 | 8.3% |
| Brain Abnormality | 119 | 32.0% |
| Other Brain Abnormality | 1 | 0.3% |

**Table 1a. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV), Overall in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Medical Product Use | Number | Percent |
|---|---|---|
| **Lab Tests (Ever, Prior to and Up to 15 Days After Index)** | | |
| CMV PCR (Blood, Urine, Saliva) | 141 | 37.9% |
| CMV Antigen or Antibody Testing | 33 | 8.9% |
| CMV Culture | 46 | 12.4% |
| CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture | 152 | 40.9% |
| **Radiology Tests (Ever, Prior to and Up to 30 Days After Index)** | | |
| Head Computed Tomography (CT) | 48 | 12.9% |
| Brain MRI | 125 | 33.6% |
| Head Ultrasound | 8 | 2.2% |

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

**Table 1b. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Absent, Clinical Characteristic: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Patient Characteristics | Number | |
|---|---|---|
| Unique patients | 62 | |
| **Demographic Characteristics** | **Mean** | **Standard Deviation** |
| Mean Age (Days) | 99.40 | 158.27 |
| Age (Days) | **Number** | **Percent** |
| ≤ 181 | 56 | 90.3% |
| 182-364 | 4 | 6.5% |
| 365-729 | 1 | 1.6% |
| 730-1094 | 0 | 0.0% |
| 1095-1459 | 0 | 0.0% |
| 1460-1825 | 0 | 0.0% |
| Sex | | |
| Female | 27 | 43.5% |
| Male | 35 | 56.5% |
| Race[1] | | |
| American Indian or Alaska Native | 0 | 0.0% |
| Asian | 0 | 0.0% |
| Black or African American | 8 | 12.9% |
| Native Hawaiian or Other Pacific Islander | 1 | 1.6% |
| Unknown | 48 | 77.4% |
| White | 5 | 8.1% |
| Hispanic Origin | | |
| Yes | 1 | 1.6% |
| No | 12 | 19.4% |
| Unknown | 49 | 79.0% |
| Year | | |
| 2008 | 2 | 3.2% |
| 2009 | 0 | 0.0% |
| 2010 | 1 | 1.6% |
| 2011 | 4 | 6.5% |
| 2012 | 3 | 4.8% |
| 2013 | 2 | 3.2% |
| 2014 | 0 | 0.0% |
| 2015 | 6 | 9.7% |
| 2016 | 8 | 12.9% |
| 2017 | 11 | 17.7% |
| 2018 | 7 | 11.3% |
| 2019 | 10 | 16.1% |
| 2020 | 7 | 11.3% |
| 2021 | 1 | 1.6% |
| **Health Characteristics** | | |
| Type of Cytomegalovirus (CMV) Diagnosis Code | | |
| cCMV | 60 | 96.8% |
| CMV | 31 | 50.0% |

**Table 1b. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Absent, Clinical Characteristic: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Clinical Characteristics | Number | Percent |
|---|---|---|
| **Ever, Prior to and Up to 15 Days After Index** | | |
| Jaundice | 2 | 3.2% |
| Petechiae | 0 | 0.0% |
| Hepatomegaly | 1 | 1.6% |
| Splenomegaly | 0 | 0.0% |
| Microcephaly | 4 | 6.5% |
| Thrombocytopenia | 1 | 1.6% |
| Chlorioretinitis | 0 | 0.0% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 8 | 12.9% |
| **Ever, Prior to and Up to 30 Days After Index** | | |
| Brain Abnormality | 5 | 8.1% |
| Other Brain Abnormality | 0 | 0.0% |
| **Within 60 Days From Index** | | |
| Neutropenia | 5 | 8.1% |
| 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 | 15 | 24.2% |
| **Within 180 Days From Index** | | |
| Neutropenia | 6 | 9.7% |
| 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 | 20 | 32.3% |
| **Within 365 Days From Index** | | |
| Hearing Loss, Hearing Aid, Cochlear Implant | 26 | 41.9% |
| **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 | 2 | 3.2% |
| Petechiae | 0 | 0.0% |
| Hepatomegaly | 1 | 1.6% |
| Splenomegaly | 0 | 0.0% |
| Microcephaly | 4 | 6.5% |
| Thrombocytopenia | 1 | 1.6% |
| Chlorioretinitis | 1 | 1.6% |
| Brain Abnormality | 6 | 9.7% |
| Other Brain Abnormality | 0 | 0.0% |

**Table 1b. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Absent, Clinical Characteristic: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Medical Product Use | Number | Percent |
|---|---|---|
| **Lab Tests (Ever, Prior to and Up to 15 Days After Index)** | | |
| CMV PCR (Blood, Urine, Saliva) | 17 | 27.4% |
| CMV Antigen or Antibody Testing | 2 | 3.2% |
| CMV Culture | 3 | 4.8% |
| CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture | 18 | 29.0% |
| **Radiology Tests (Ever, Prior to and Up to 30 Days After Index)** | | |
| Head Computed Tomography (CT) | 4 | 6.5% |
| Brain MRI | 9 | 14.5% |
| Head Ultrasound | 1 | 1.6% |

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

**Table 1c. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Present, Clinical Characteristic: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Patient Characteristics | Number | |
|---|---|---|
| Unique patients | 36 | |
| **Demographic Characteristics** | **Mean** | **Standard Deviation** |
| Mean Age (Days) | 119.78 | 104.92 |
| Age (Days) | **Number** | **Percent** |
| ≤ 181 | 27 | 75.0% |
| 182-364 | 8 | 22.2% |
| 365-729 | 1 | 2.8% |
| 730-1094 | 0 | 0.0% |
| 1095-1459 | 0 | 0.0% |
| 1460-1825 | 0 | 0.0% |
| Sex | | |
| Female | 17 | 47.2% |
| Male | 19 | 52.8% |
| Race[1] | | |
| American Indian or Alaska Native | 0 | 0.0% |
| Asian | 1 | 2.8% |
| Black or African American | 0 | 0.0% |
| Native Hawaiian or Other Pacific Islander | 1 | 2.8% |
| Unknown | 27 | 75.0% |
| White | 7 | 19.4% |
| Hispanic Origin | | |
| Yes | 0 | 0.0% |
| No | 7 | 19.4% |
| Unknown | 29 | 80.6% |
| Year | | |
| 2008 | 0 | 0.0% |
| 2009 | 2 | 5.6% |
| 2010 | 2 | 5.6% |
| 2011 | 2 | 5.6% |
| 2012 | 0 | 0.0% |
| 2013 | 3 | 8.3% |
| 2014 | 1 | 2.8% |
| 2015 | 3 | 8.3% |
| 2016 | 3 | 8.3% |
| 2017 | 5 | 13.9% |
| 2018 | 4 | 11.1% |
| 2019 | 5 | 13.9% |
| 2020 | 6 | 16.7% |
| 2021 | 0 | 0.0% |
| **Health Characteristics** | | |
| Type of Cytomegalovirus (CMV) Diagnosis Code | | |
| cCMV | 35 | 97.2% |
| CMV | 22 | 61.1% |

**Table 1c. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Present, Clinical Characteristic: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Clinical Characteristics | Number | Percent |
|---|---|---|
| **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 | 1 | 2.8% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 36 | 100.0% |
| **Ever, Prior to and Up to 30 Days After Index** | | |
| Brain Abnormality | 3 | 8.3% |
| Other Brain Abnormality | 0 | 0.0% |
| **Within 60 Days From Index** | | |
| Neutropenia | 4 | 11.1% |
| Receipt of RBC transfusion | 0 | 0.0% |
| Receipt of platelet transfusion | 0 | 0.0% |
| Receipt of GCSF transfusion | 1 | 2.8% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 33 | 91.7% |
| **Within 180 Days From Index** | | |
| Neutropenia | 4 | 11.1% |
| Receipt of RBC transfusion | 0 | 0.0% |
| Receipt of platelet transfusion | 0 | 0.0% |
| Receipt of GCSF transfusion | 1 | 2.8% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 35 | 97.2% |
| **Within 365 Days From Index** | | |
| Hearing Loss, Hearing Aid, Cochlear Implant | 35 | 97.2% |
| **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 | 36 | 100.0% |
| **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 | 1 | 2.8% |
| Brain Abnormality | 3 | 8.3% |
| Other Brain Abnormality | 0 | 0.0% |

**Table 1c. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Present, Clinical Characteristic: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Medical Product Use | Number | Percent |
|---|---|---|
| **Lab Tests (Ever, Prior to and Up to 15 Days After Index)** | | |
| CMV PCR (Blood, Urine, Saliva) | 21 | 58.3% |
| CMV Antigen or Antibody Testing | 10 | 27.8% |
| CMV Culture | 7 | 19.4% |
| CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture | 23 | 63.9% |
| **Radiology Tests (Ever, Prior to and Up to 30 Days After Index)** | | |
| Head Computed Tomography (CT) | 7 | 19.4% |
| Brain MRI | 12 | 33.3% |
| Head Ultrasound | 1 | 2.8% |

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

**Table 1d. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Absent, Clinical Characteristic: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Patient Characteristics | Number | |
|---|---|---|
| Unique patients | 210 | |
| **Demographic Characteristics** | **Mean** | **Standard Deviation** |
| Mean Age (Days) | 50.98 | 53.22 |
| Age (Days) | **Number** | **Percent** |
| ≤ 181 | 203 | 96.7% |
| 182-364 | 7 | 3.3% |
| 365-729 | 0 | 0.0% |
| 730-1094 | 0 | 0.0% |
| 1095-1459 | 0 | 0.0% |
| 1460-1825 | 0 | 0.0% |
| Sex | | |
| Female | 98 | 46.7% |
| Male | 112 | 53.3% |
| Race[1] | | |
| American Indian or Alaska Native | 0 | 0.0% |
| Asian | 0 | 0.0% |
| Black or African American | 15 | 7.1% |
| Native Hawaiian or Other Pacific Islander | 0 | 0.0% |
| Unknown | 180 | 85.7% |
| White | 15 | 7.1% |
| Hispanic Origin | | |
| Yes | 0 | 0.0% |
| No | 23 | 11.0% |
| Unknown | 187 | 89.0% |
| Year | | |
| 2008 | 7 | 3.3% |
| 2009 | 2 | 1.0% |
| 2010 | 6 | 2.9% |
| 2011 | 4 | 1.9% |
| 2012 | 7 | 3.3% |
| 2013 | 8 | 3.8% |
| 2014 | 16 | 7.6% |
| 2015 | 29 | 13.8% |
| 2016 | 34 | 16.2% |
| 2017 | 23 | 11.0% |
| 2018 | 30 | 14.3% |
| 2019 | 24 | 11.4% |
| 2020 | 17 | 8.1% |
| 2021 | 3 | 1.4% |
| **Health Characteristics** | | |
| Type of Cytomegalovirus (CMV) Diagnosis Code | | |
| cCMV | 204 | 97.1% |
| CMV | 109 | 51.9% |

**Table 1d. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Absent, Clinical Characteristic: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Clinical Characteristics | Number | Percent |
|---|---|---|
| **Ever, Prior to and Up to 15 Days After Index** | | |
| Jaundice | 128 | 61.0% |
| Petechiae | 26 | 12.4% |
| Hepatomegaly | 24 | 11.4% |
| Splenomegaly | 27 | 12.9% |
| Microcephaly | 40 | 19.0% |
| Thrombocytopenia | 125 | 59.5% |
| Chlorioretinitis | 18 | 8.6% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 17 | 8.1% |
| **Ever, Prior to and Up to 30 Days After Index** | | |
| Brain Abnormality | 75 | 35.7% |
| Other Brain Abnormality | 1 | 0.5% |
| **Within 60 Days From Index** | | |
| Neutropenia | 32 | 15.2% |
| Receipt of RBC transfusion | 5 | 2.4% |
| Receipt of platelet transfusion | 3 | 1.4% |
| Receipt of GCSF transfusion | 5 | 2.4% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 57 | 27.1% |
| **Within 180 Days From Index** | | |
| Neutropenia | 43 | 20.5% |
| Receipt of RBC transfusion | 5 | 2.4% |
| Receipt of platelet transfusion | 3 | 1.4% |
| Receipt of GCSF transfusion | 7 | 3.3% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 86 | 41.0% |
| **Within 365 Days From Index** | | |
| Hearing Loss, Hearing Aid, Cochlear Implant | 101 | 48.1% |
| **Ever, Prior to and Up to Index Date** | | |
| Jaundice | 124 | 59.0% |
| Petechiae | 24 | 11.4% |
| Hepatomegaly | 23 | 11.0% |
| Splenomegaly | 24 | 11.4% |
| Microcephaly | 40 | 19.0% |
| Thrombocytopenia | 125 | 59.5% |
| Chlorioretinitis | 18 | 8.6% |
| Brain Abnormality | 70 | 33.3% |
| Other Brain Abnormality | 1 | 0.5% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 0 | 0.0% |
| **Ever, Prior to and Up to 45 Days After Index** | | |
| Jaundice | 128 | 61.0% |
| Petechiae | 28 | 13.3% |
| Hepatomegaly | 26 | 12.4% |
| Splenomegaly | 27 | 12.9% |
| Microcephaly | 45 | 21.4% |
| Thrombocytopenia | 126 | 60.0% |
| Chlorioretinitis | 22 | 10.5% |
| Brain Abnormality | 77 | 36.7% |
| Other Brain Abnormality | 1 | 0.5% |

**Table 1d. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Absent, Clinical Characteristic: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Medical Product Use | Number | Percent |
|---|---|---|
| **Lab Tests (Ever, Prior to and Up to 15 Days After Index)** | | |
| CMV PCR (Blood, Urine, Saliva) | 66 | 31.4% |
| CMV Antigen or Antibody Testing | 11 | 5.2% |
| CMV Culture | 20 | 9.5% |
| CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture | 72 | 34.3% |
| **Radiology Tests (Ever, Prior to and Up to 30 Days After Index)** | | |
| Head Computed Tomography (CT) | 22 | 10.5% |
| Brain MRI | 76 | 36.2% |
| Head Ultrasound | 5 | 2.4% |

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

**Table 1e. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Present, Clinical Characteristic: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Patient Characteristics | Number | |
|---|---|---|
| Unique patients | 64 | |
| **Demographic Characteristics** | **Mean** | **Standard Deviation** |
| Mean Age (Days) | 120.73 | 256.42 |
| Age (Days) | **Number** | **Percent** |
| ≤ 181 | 57 | 89.1% |
| 182-364 | 3 | 4.7% |
| 365-729 | 1 | 1.6% |
| 730-1094 | 0 | 0.0% |
| 1095-1459 | 0 | 0.0% |
| 1460-1825 | 0 | 0.0% |
| Sex | | |
| Female | 36 | 56.3% |
| Male | 28 | 43.8% |
| Race[1] | | |
| American Indian or Alaska Native | 0 | 0.0% |
| Asian | 0 | 0.0% |
| Black or African American | 4 | 6.3% |
| Native Hawaiian or Other Pacific Islander | 3 | 4.7% |
| Unknown | 47 | 73.4% |
| White | 10 | 15.6% |
| Hispanic Origin | | |
| Yes | 1 | 1.6% |
| No | 13 | 20.3% |
| Unknown | 50 | 78.1% |
| Year | | |
| 2008 | 2 | 3.1% |
| 2009 | 1 | 1.6% |
| 2010 | 2 | 3.1% |
| 2011 | 4 | 6.3% |
| 2012 | 2 | 3.1% |
| 2013 | 3 | 4.7% |
| 2014 | 9 | 14.1% |
| 2015 | 8 | 12.5% |
| 2016 | 8 | 12.5% |
| 2017 | 4 | 6.3% |
| 2018 | 5 | 7.8% |
| 2019 | 10 | 15.6% |
| 2020 | 6 | 9.4% |
| 2021 | 0 | 0.0% |
| **Health Characteristics** | | |
| Type of Cytomegalovirus (CMV) Diagnosis Code | | |
| cCMV | 61 | 95.3% |
| CMV | 47 | 73.4% |

**Table 1e. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Present, Clinical Characteristic: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Clinical Characteristics | Number | Percent |
|---|---|---|
| **Ever, Prior to and Up to 15 Days After Index** | | |
| Jaundice | 33 | 51.6% |
| Petechiae | 14 | 21.9% |
| Hepatomegaly | 9 | 14.1% |
| Splenomegaly | 7 | 10.9% |
| Microcephaly | 18 | 28.1% |
| Thrombocytopenia | 32 | 50.0% |
| Chlorioretinitis | 6 | 9.4% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 64 | 100.0% |
| **Ever, Prior to and Up to 30 Days After Index** | | |
| Brain Abnormality | 33 | 51.6% |
| Other Brain Abnormality | 0 | 0.0% |
| **Within 60 Days From Index** | | |
| Neutropenia | 13 | 20.3% |
| Receipt of RBC transfusion | 1 | 1.6% |
| Receipt of platelet transfusion | 0 | 0.0% |
| Receipt of GCSF transfusion | 0 | 0.0% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 48 | 75.0% |
| **Within 180 Days From Index** | | |
| Neutropenia | 17 | 26.6% |
| Receipt of RBC transfusion | 1 | 1.6% |
| Receipt of platelet transfusion | 0 | 0.0% |
| Receipt of GCSF transfusion | 0 | 0.0% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 54 | 84.4% |
| **Within 365 Days From Index** | | |
| Hearing Loss, Hearing Aid, Cochlear Implant | 54 | 84.4% |
| **Ever, Prior to and Up to Index Date** | | |
| Jaundice | 33 | 51.6% |
| Petechiae | 14 | 21.9% |
| Hepatomegaly | 9 | 14.1% |
| Splenomegaly | 7 | 10.9% |
| Microcephaly | 18 | 28.1% |
| Thrombocytopenia | 32 | 50.0% |
| Chlorioretinitis | 5 | 7.8% |
| Brain Abnormality | 33 | 51.6% |
| Other Brain Abnormality | 0 | 0.0% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 64 | 100.0% |
| **Ever, Prior to and Up to 45 Days After Index** | | |
| Jaundice | 33 | 51.6% |
| Petechiae | 14 | 21.9% |
| Hepatomegaly | 11 | 17.2% |
| Splenomegaly | 7 | 10.9% |
| Microcephaly | 18 | 28.1% |
| Thrombocytopenia | 32 | 50.0% |
| Chlorioretinitis | 7 | 10.9% |
| Brain Abnormality | 33 | 51.6% |
| Other Brain Abnormality | 0 | 0.0% |

**Table 1e. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) (Hearing Loss: Present, Clinical Characteristic: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Medical Product Use | Number | Percent |
|---|---|---|
| **Lab Tests (Ever, Prior to and Up to 15 Days After Index)** | | |
| CMV PCR (Blood, Urine, Saliva) | 37 | 57.8% |
| CMV Antigen or Antibody Testing | 10 | 15.6% |
| CMV Culture | 16 | 25.0% |
| CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture | 39 | 60.9% |
| **Radiology Tests (Ever, Prior to and Up to 30 Days After Index)** | | |
| Head Computed Tomography (CT) | 15 | 23.4% |
| Brain MRI | 28 | 43.8% |
| Head Ultrasound | 1 | 1.6% |

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

**Table 1f. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) by Disease Severity (Hematologic Outcomes: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Patient Characteristics | Number | |
|---|---|---|
| Unique patients | 270 | |
| **Demographic Characteristics** | **Mean** | **Standard Deviation** |
| Mean Age (Days) | 83.00 | 151.89 |
| Age (Days) | **Number** | **Percent** |
| ≤ 181 | 246 | 91.1% |
| 182-364 | 18 | 6.7% |
| 365-729 | 3 | 1.1% |
| 730-1094 | 0 | 0.0% |
| 1095-1459 | 0 | 0.0% |
| 1460-1825 | 0 | 0.0% |
| Sex | | |
| Female | 130 | 48.1% |
| Male | 140 | 51.9% |
| Race[1] | | |
| American Indian or Alaska Native | 0 | 0.0% |
| Asian | 1 | 0.4% |
| Black or African American | 20 | 7.4% |
| Native Hawaiian or Other Pacific Islander | 4 | 1.5% |
| Unknown | 217 | 80.4% |
| White | 28 | 10.4% |
| Hispanic Origin | | |
| Yes | 1 | 0.4% |
| No | 45 | 16.7% |
| Unknown | 224 | 83.0% |
| Year | | |
| 2008 | 9 | 3.3% |
| 2009 | 4 | 1.5% |
| 2010 | 9 | 3.3% |
| 2011 | 12 | 4.4% |
| 2012 | 8 | 3.0% |
| 2013 | 10 | 3.7% |
| 2014 | 14 | 5.2% |
| 2015 | 36 | 13.3% |
| 2016 | 40 | 14.8% |
| 2017 | 30 | 11.1% |
| 2018 | 32 | 11.9% |
| 2019 | 33 | 12.2% |
| 2020 | 29 | 10.7% |
| 2021 | 4 | 1.5% |
| **Health Characteristics** | | |
| Type of Cytomegalovirus (CMV) Diagnosis Code | | |
| cCMV | 270 | 100.0% |
| CMV | 149 | 55.2% |

**Table 1f. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) by Disease Severity (Hematologic Outcomes: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Clinical Characteristics | Number | Percent |
|---|---|---|
| **Ever, Prior to and Up to 15 Days After Index** | | |
| Jaundice | 114 | 42.2% |
| Petechiae | 26 | 9.6% |
| Hepatomegaly | 23 | 8.5% |
| Splenomegaly | 23 | 8.5% |
| Microcephaly | 50 | 18.5% |
| Thrombocytopenia | 105 | 38.9% |
| Chlorioretinitis | 14 | 5.2% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 87 | 32.2% |
| **Ever, Prior to and Up to 30 Days After Index** | | |
| Brain Abnormality | 72 | 26.7% |
| Other Brain Abnormality | 1 | 0.4% |
| **Within 60 Days From Index** | | |
| Neutropenia | 0 | 0.0% |
| 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 | 106 | 39.3% |
| **Within 180 Days From Index** | | |
| Neutropenia | 0 | 0.0% |
| 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 | 134 | 49.6% |
| **Within 365 Days From Index** | | |
| Hearing Loss, Hearing Aid, Cochlear Implant | 152 | 56.3% |
| **Ever, Prior to and Up to Index Date** | | |
| Jaundice | 111 | 41.1% |
| Petechiae | 25 | 9.3% |
| Hepatomegaly | 22 | 8.1% |
| Splenomegaly | 21 | 7.8% |
| Microcephaly | 47 | 17.4% |
| Thrombocytopenia | 105 | 38.9% |
| Chlorioretinitis | 14 | 5.2% |
| Brain Abnormality | 67 | 24.8% |
| Other Brain Abnormality | 1 | 0.4% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 70 | 25.9% |
| **Ever, Prior to and Up to 45 Days After Index** | | |
| Jaundice | 114 | 42.2% |
| Petechiae | 26 | 9.6% |
| Hepatomegaly | 25 | 9.3% |
| Splenomegaly | 23 | 8.5% |
| Microcephaly | 52 | 19.3% |
| Thrombocytopenia | 105 | 38.9% |
| Chlorioretinitis | 16 | 5.9% |
| Brain Abnormality | 74 | 27.4% |
| Other Brain Abnormality | 1 | 0.4% |

**Table 1f. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) by Disease Severity (Hematologic Outcomes: Absent) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Medical Product Use | Number | Percent |
|---|---|---|
| **Lab Tests (Ever, Prior to and Up to 15 Days After Index)** | | |
| CMV PCR (Blood, Urine, Saliva) | 98 | 36.3% |
| CMV Antigen or Antibody Testing | 24 | 8.9% |
| CMV Culture | 23 | 8.5% |
| CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture | 106 | 39.3% |
| **Radiology Tests (Ever, Prior to and Up to 30 Days After Index)** | | |
| Head Computed Tomography (CT) | 37 | 13.7% |
| Brain MRI | 84 | 31.1% |
| Head Ultrasound | 5 | 1.9% |

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

**Table 1g. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) by Disease Severity (Hematologic Outcomes: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Patient Characteristics | Number | |
|---|---|---|
| Unique patients | 68 | |
| **Demographic Characteristics** | **Mean** | **Standard Deviation** |
| Mean Age (Days) | 42.18 | 29.68 |
| Age (Days) | **Number** | **Percent** |
| ≤ 181 | 68 | 100.0% |
| 182-364 | 0 | 0.0% |
| 365-729 | 0 | 0.0% |
| 730-1094 | 0 | 0.0% |
| 1095-1459 | 0 | 0.0% |
| 1460-1825 | 0 | 0.0% |
| Sex | | |
| Female | 31 | 45.6% |
| Male | 37 | 54.4% |
| Race[1] | | |
| American Indian or Alaska Native | 0 | 0.0% |
| Asian | 0 | 0.0% |
| Black or African American | 5 | 7.4% |
| Native Hawaiian or Other Pacific Islander | 1 | 1.5% |
| Unknown | 57 | 83.8% |
| White | 5 | 7.4% |
| Hispanic Origin | | |
| Yes | 1 | 1.5% |
| No | 6 | 8.8% |
| Unknown | 61 | 89.7% |
| Year | | |
| 2008 | 2 | 2.9% |
| 2009 | 0 | 0.0% |
| 2010 | 1 | 1.5% |
| 2011 | 0 | 0.0% |
| 2012 | 2 | 2.9% |
| 2013 | 5 | 7.4% |
| 2014 | 10 | 14.7% |
| 2015 | 8 | 11.8% |
| 2016 | 9 | 13.2% |
| 2017 | 8 | 11.8% |
| 2018 | 11 | 16.2% |
| 2019 | 8 | 11.8% |
| 2020 | 4 | 5.9% |
| 2021 | 0 | 0.0% |
| **Health Characteristics** | | |
| Type of Cytomegalovirus (CMV) Diagnosis Code | | |
| cCMV | 68 | 100.0% |
| CMV | 35 | 51.5% |

**Table 1g. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) by Disease Severity (Hematologic Outcomes: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Clinical Characteristics | Number | Percent |
|---|---|---|
| **Ever, Prior to and Up to 15 Days After Index** | | |
| Jaundice | 39 | 57.4% |
| Petechiae | 13 | 19.1% |
| Hepatomegaly | 10 | 14.7% |
| Splenomegaly | 9 | 13.2% |
| Microcephaly | 10 | 14.7% |
| Thrombocytopenia | 43 | 63.2% |
| Chlorioretinitis | 9 | 13.2% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 25 | 36.8% |
| **Ever, Prior to and Up to 30 Days After Index** | | |
| Brain Abnormality | 33 | 48.5% |
| Other Brain Abnormality | 0 | 0.0% |
| **Within 60 Days From Index** | | |
| Neutropenia | 48 | 70.6% |
| Receipt of RBC transfusion | 5 | 7.4% |
| Receipt of platelet transfusion | 3 | 4.4% |
| Receipt of GCSF transfusion | 4 | 5.9% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 30 | 44.1% |
| **Within 180 Days From Index** | | |
| Neutropenia | 64 | 94.1% |
| Receipt of RBC transfusion | 5 | 7.4% |
| Receipt of platelet transfusion | 3 | 4.4% |
| Receipt of GCSF transfusion | 6 | 8.8% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 43 | 63.2% |
| **Within 365 Days From Index** | | |
| Hearing Loss, Hearing Aid, Cochlear Implant | 44 | 64.7% |
| **Ever, Prior to and Up to Index Date** | | |
| Jaundice | 38 | 55.9% |
| Petechiae | 12 | 17.6% |
| Hepatomegaly | 9 | 13.2% |
| Splenomegaly | 8 | 11.8% |
| Microcephaly | 10 | 14.7% |
| Thrombocytopenia | 43 | 63.2% |
| Chlorioretinitis | 9 | 13.2% |
| Brain Abnormality | 31 | 45.6% |
| Other Brain Abnormality | 0 | 0.0% |
| Hearing Loss, Hearing Aid, Cochlear Implant | 20 | 29.4% |
| **Ever, Prior to and Up to 45 Days After Index** | | |
| Jaundice | 39 | 57.4% |
| Petechiae | 15 | 22.1% |
| Hepatomegaly | 12 | 17.6% |
| Splenomegaly | 9 | 13.2% |
| Microcephaly | 13 | 19.1% |
| Thrombocytopenia | 44 | 64.7% |
| Chlorioretinitis | 11 | 16.2% |
| Brain Abnormality | 34 | 50.0% |
| Other Brain Abnormality | 0 | 0.0% |

**Table 1g. Aggregated Baseline Characteristics of Valganciclovir (VGCV) Use Among Infants with Congenital Cytomegalovirus (cCMV) by Disease Severity (Hematologic Outcomes: Present) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Medical Product Use | Number | Percent |
|---|---|---|
| **Lab Tests (Ever, Prior to and Up to 15 Days After Index)** | | |
| CMV PCR (Blood, Urine, Saliva) | 28 | 41.2% |
| CMV Antigen or Antibody Testing | 3 | 4.4% |
| CMV Culture | 17 | 25.0% |
| CMV PCR, CMV Antigen/Antibody Testing, or CMV Culture | 30 | 44.1% |
| **Radiology Tests (Ever, Prior to and Up to 30 Days After Index)** | | |
| Head Computed Tomography (CT) | 7 | 10.3% |
| Brain MRI | 31 | 45.6% |
| Head Ultrasound | 1 | 1.5% |

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

**Table 2. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | |
| **Overall** | | | |
| 372 | 2,125 | 142.3 | 0.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | |
| 62 | 1,043 | 20.6 | 0.3 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | |
| 36 | 304 | 14.6 | 0.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | |
| 210 | 1,149 | 81.1 | 0.4 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | |
| 64 | 425 | 26.0 | 0.4 |
| **Hematologic Outcomes: Absent** | | | |
| 270 | 2,011 | 102.1 | 0.4 |
| **Hematologic Outcomes: Present** | | | |
| 68 | 322 | 27.2 | 0.4 |

[1]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| Female | 178 | 1,024 | 69.0 | 0.4 |
| Male | 194 | 1,101 | 73.3 | 0.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| Female | 27 | 517 | 8.1 | 0.3 |
| Male | 35 | 526 | 12.5 | 0.4 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| Female | 17 | 162 | 6.3 | 0.4 |
| Male | 19 | 142 | 8.3 | 0.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| Female | 98 | 509 | 38.7 | 0.4 |
| Male | 112 | 640 | 42.5 | 0.4 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| Female | 36 | 209 | 16.0 | 0.4 |
| Male | 28 | 216 | 10.1 | 0.4 |
| **Hematologic Outcomes: Absent** | | | | |
| Female | 130 | 972 | 51.7 | 0.4 |
| Male | 140 | 1,039 | 50.3 | 0.4 |
| **Hematologic Outcomes: Present** | | | | |
| Female | 31 | 131 | 11.0 | 0.4 |
| Male | 37 | 191 | 16.2 | 0.4 |

[1]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Year**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| 2008 | 11 | 289 | 2.4 | 0.2 |
| 2009 | 5 | 310 | 1.1 | 0.2 |
| 2010 | 11 | 353 | 2.8 | 0.3 |
| 2011 | 14 | 341 | 4.4 | 0.3 |
| 2012 | 12 | 349 | 3.2 | 0.3 |
| 2013 | 16 | 368 | 5.9 | 0.4 |
| 2014 | 26 | 382 | 10.2 | 0.4 |
| 2015 | 46 | 400 | 18.4 | 0.4 |
| 2016 | 53 | 430 | 24.1 | 0.5 |
| 2017 | 43 | 493 | 16.7 | 0.4 |
| 2018 | 46 | 496 | 20.5 | 0.4 |
| 2019 | 49 | 533 | 20.1 | 0.4 |
| 2020 | 36 | 415 | 11.8 | 0.3 |
| 2021 | 4 | 131 | 0.7 | 0.2 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| 2008 | 2 | 130 | 0.3 | 0.1 |
| 2009 | 0 | 121 | 0.0 | - |
| 2010 | 1 | 124 | 0.2 | 0.2 |
| 2011 | 4 | 129 | 1.7 | 0.4 |
| 2012 | 3 | 132 | 0.9 | 0.3 |
| 2013 | 2 | 134 | 0.7 | 0.4 |
| 2014 | 0 | 147 | 0.0 | - |
| 2015 | 6 | 140 | 2.1 | 0.4 |
| 2016 | 8 | 144 | 2.8 | 0.4 |
| 2017 | 11 | 187 | 3.4 | 0.3 |
| 2018 | 7 | 165 | 2.5 | 0.4 |
| 2019 | 10 | 186 | 2.7 | 0.3 |
| 2020 | 7 | 167 | 3.1 | 0.4 |
| 2021 | 1 | 46 | 0.2 | 0.2 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| 2008 | 0 | 27 | 0.0 | - |
| 2009 | 2 | 28 | 0.5 | 0.2 |
| 2010 | 2 | 27 | 0.4 | 0.2 |
| 2011 | 2 | 26 | 0.6 | 0.3 |
| 2012 | 0 | 25 | 0.0 | - |
| 2013 | 3 | 30 | 1.2 | 0.4 |
| 2014 | 1 | 30 | 0.3 | 0.3 |
| 2015 | 3 | 30 | 0.9 | 0.3 |
| 2016 | 3 | 35 | 1.1 | 0.4 |
| 2017 | 5 | 60 | 1.6 | 0.3 |
| 2018 | 4 | 72 | 2.0 | 0.5 |
| 2019 | 5 | 75 | 3.7 | 0.7 |
| 2020 | 6 | 78 | 2.2 | 0.4 |
| 2021 | 0 | 23 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| 2008 | 7 | 139 | 1.6 | 0.2 |
| 2009 | 2 | 142 | 0.3 | 0.2 |
| 2010 | 6 | 166 | 1.8 | 0.3 |
| 2011 | 4 | 142 | 0.8 | 0.2 |
| 2012 | 7 | 165 | 1.9 | 0.3 |
| 2013 | 8 | 176 | 3.0 | 0.4 |
| 2014 | 16 | 171 | 6.0 | 0.4 |
| 2015 | 29 | 201 | 11.8 | 0.4 |
| 2016 | 34 | 229 | 16.3 | 0.5 |
| 2017 | 23 | 239 | 9.6 | 0.4 |
| 2018 | 30 | 232 | 14.1 | 0.5 |
| 2019 | 24 | 236 | 8.4 | 0.4 |
| 2020 | 17 | 160 | 5.0 | 0.3 |
| 2021 | 3 | 50 | 0.5 | 0.2 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| 2008 | 2 | 47 | 0.5 | 0.2 |
| 2009 | 1 | 64 | 0.3 | 0.3 |
| 2010 | 2 | 84 | 0.4 | 0.2 |
| 2011 | 4 | 79 | 1.3 | 0.3 |
| 2012 | 2 | 78 | 0.4 | 0.2 |
| 2013 | 3 | 90 | 0.9 | 0.3 |
| 2014 | 9 | 90 | 3.9 | 0.4 |
| 2015 | 8 | 86 | 3.7 | 0.5 |
| 2016 | 8 | 90 | 3.9 | 0.5 |
| 2017 | 4 | 101 | 2.1 | 0.5 |
| 2018 | 5 | 97 | 1.9 | 0.4 |
| 2019 | 10 | 115 | 5.3 | 0.5 |
| 2020 | 6 | 74 | 1.5 | 0.3 |
| 2021 | 0 | 24 | 0.0 | - |
| **Hematologic Outcomes: Absent** | | | | |
| 2008 | 9 | 280 | 2.1 | 0.2 |
| 2009 | 4 | 300 | 0.8 | 0.2 |
| 2010 | 9 | 344 | 2.2 | 0.2 |
| 2011 | 12 | 331 | 4.1 | 0.3 |
| 2012 | 8 | 339 | 1.6 | 0.2 |
| 2013 | 10 | 356 | 3.4 | 0.3 |
| 2014 | 14 | 367 | 5.3 | 0.4 |
| 2015 | 36 | 385 | 15.1 | 0.4 |
| 2016 | 40 | 406 | 18.9 | 0.5 |
| 2017 | 30 | 468 | 11.3 | 0.4 |
| 2018 | 32 | 472 | 14.4 | 0.5 |
| 2019 | 33 | 506 | 12.2 | 0.4 |
| 2020 | 29 | 399 | 9.8 | 0.3 |
| 2021 | 4 | 131 | 0.7 | 0.2 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Present** | | | | |
| 2008 | 2 | 25 | 0.2 | 0.1 |
| 2009 | 0 | 12 | 0.0 | - |
| 2010 | 1 | 26 | 0.2 | 0.2 |
| 2011 | 0 | 24 | 0.0 | - |
| 2012 | 2 | 20 | 0.8 | 0.4 |
| 2013 | 5 | 27 | 2.0 | 0.4 |
| 2014 | 10 | 32 | 3.8 | 0.4 |
| 2015 | 8 | 29 | 2.6 | 0.3 |
| 2016 | 9 | 30 | 3.4 | 0.4 |
| 2017 | 8 | 36 | 3.6 | 0.4 |
| 2018 | 11 | 31 | 5.4 | 0.5 |
| 2019 | 8 | 35 | 3.9 | 0.5 |
| 2020 | 4 | 23 | 1.2 | 0.3 |
| 2021 | 0 | 1 | 0.0 | - |

[1]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race[1]**

| | New Users | Eligible Members[2] | Years at Risk | Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| American Indian or Alaska Native | 0 | 3 | 0.0 | - |
| Asian | 1 | 23 | 0.4 | 0.4 |
| Black or African American | 27 | 116 | 8.5 | 0.3 |
| Native Hawaiian or Other Pacific Islander | 5 | 10 | 1.3 | 0.3 |
| Unknown | 302 | 1,805 | 118.5 | 0.4 |
| White | 37 | 168 | 13.6 | 0.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| American Indian or Alaska Native | 0 | 2 | 0.0 | - |
| Asian | 0 | 9 | 0.0 | - |
| Black or African American | 8 | 51 | 1.8 | 0.2 |
| Native Hawaiian or Other Pacific Islander | 1 | 4 | 0.2 | 0.2 |
| Unknown | 48 | 908 | 16.9 | 0.4 |
| White | 5 | 69 | 1.8 | 0.4 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| American Indian or Alaska Native | 0 | 2 | 0.0 | - |
| Asian | 1 | 3 | 0.4 | 0.4 |
| Black or African American | 0 | 9 | 0.0 | - |
| Native Hawaiian or Other Pacific Islander | 1 | 2 | 0.4 | 0.4 |
| Unknown | 27 | 266 | 11.0 | 0.4 |
| White | 7 | 22 | 2.8 | 0.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| American Indian or Alaska Native | 0 | 0 | 0.0 | - |
| Asian | 0 | 13 | 0.0 | - |
| Black or African American | 15 | 66 | 5.7 | 0.4 |
| Native Hawaiian or Other Pacific Islander | 0 | 3 | 0.0 | - |
| Unknown | 180 | 965 | 70.2 | 0.4 |
| White | 15 | 102 | 5.2 | 0.3 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| American Indian or Alaska Native | 0 | 0 | 0.0 | - |
| Asian | 0 | 5 | 0.0 | - |
| Black or African American | 4 | 12 | 1.1 | 0.3 |
| Native Hawaiian or Other Pacific Islander | 3 | 5 | 0.7 | 0.2 |
| Unknown | 47 | 358 | 20.4 | 0.4 |
| White | 10 | 45 | 3.8 | 0.4 |
| **Hematologic Outcomes: Absent** | | | | |
| American Indian or Alaska Native | 0 | 3 | 0.0 | - |
| Asian | 1 | 22 | 0.4 | 0.4 |
| Black or African American | 20 | 109 | 6.4 | 0.3 |
| Native Hawaiian or Other Pacific Islander | 4 | 9 | 1.3 | 0.3 |
| Unknown | 217 | 1,710 | 82.8 | 0.4 |
| White | 28 | 158 | 11.2 | 0.4 |

**Table 5. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race[1]**

| | New Users | Eligible Members[2] | Years at Risk | Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Present** | | | | |
| American Indian or Alaska Native | 0 | 0 | 0.0 | - |
| Asian | 0 | 3 | 0.0 | - |
| Black or African American | 5 | 23 | 1.8 | 0.4 |
| Native Hawaiian or Other Pacific Islander | 1 | 2 | 0.0 | 0.0 |
| Unknown | 57 | 266 | 24.1 | 0.4 |
| White | 5 | 28 | 1.3 | 0.3 |

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

[2]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| Yes | 2 | 17 | 0.2 | 0.1 |
| No | 55 | 232 | 19.8 | 0.4 |
| Unknown | 315 | 1,876 | 122.4 | 0.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| Yes | 1 | 9 | 0.2 | 0.2 |
| No | 12 | 102 | 3.4 | 0.3 |
| Unknown | 49 | 932 | 17.1 | 0.3 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| Yes | 0 | 3 | 0.0 | - |
| No | 7 | 27 | 2.8 | 0.4 |
| Unknown | 29 | 274 | 11.8 | 0.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| Yes | 0 | 7 | 0.0 | - |
| No | 23 | 132 | 8.5 | 0.4 |
| Unknown | 187 | 1,010 | 72.6 | 0.4 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| Yes | 1 | 3 | 0.0 | 0.0 |
| No | 13 | 52 | 5.1 | 0.4 |
| Unknown | 50 | 370 | 20.9 | 0.4 |
| **Hematologic Outcomes: Absent** | | | | |
| Yes | 1 | 16 | 0.2 | 0.2 |
| No | 45 | 220 | 17.1 | 0.4 |
| Unknown | 224 | 1,775 | 84.8 | 0.4 |
| **Hematologic Outcomes: Present** | | | | |
| Yes | 1 | 3 | 0.0 | 0.0 |
| No | 6 | 37 | 1.6 | 0.3 |
| Unknown | 61 | 282 | 25.5 | 0.4 |

[1]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| Midwest | 87 | 459 | 33.6 | 0.4 |
| Northeast | 41 | 231 | 14.8 | 0.4 |
| South | 193 | 1,083 | 72.8 | 0.4 |
| West | 49 | 320 | 21.0 | 0.4 |
| Invalid | 0 | 11 | 0.0 | - |
| Missing | 2 | 19 | 0.1 | 0.1 |
| Other | 0 | 2 | 0.0 | - |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| Midwest | 15 | 214 | 4.1 | 0.3 |
| Northeast | 9 | 143 | 2.1 | 0.2 |
| South | 37 | 530 | 13.2 | 0.4 |
| West | 13 | 174 | 4.5 | 0.3 |
| Invalid | 0 | 4 | 0.0 | - |
| Missing | 0 | 15 | 0.0 | - |
| Other | 0 | 2 | 0.0 | - |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| Midwest | 6 | 61 | 3.4 | 0.6 |
| Northeast | 3 | 21 | 0.8 | 0.3 |
| South | 12 | 96 | 5.2 | 0.4 |
| West | 3 | 27 | 1.8 | 0.6 |
| Invalid | 0 | 1 | 0.0 | - |
| Missing | 0 | 1 | 0.0 | - |
| Other | 0 | 1 | 0.0 | - |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| Midwest | 57 | 266 | 21.5 | 0.4 |
| Northeast | 23 | 121 | 9.4 | 0.4 |
| South | 130 | 667 | 48.5 | 0.4 |
| West | 29 | 187 | 12.6 | 0.4 |
| Invalid | 0 | 8 | 0.0 | - |
| Missing | 1 | 7 | 0.1 | 0.1 |
| Other | 0 | 1 | 0.0 | - |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| Midwest | 9 | 59 | 4.5 | 0.5 |
| Northeast | 6 | 29 | 2.5 | 0.4 |
| South | 14 | 105 | 6.0 | 0.4 |
| West | 4 | 39 | 2.0 | 0.5 |
| Invalid | 0 | 1 | 0.0 | - |
| Missing | 1 | 1 | 0.0 | 0.0 |
| Other | 0 | 0 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Absent** | | | | |
| Midwest | 65 | 436 | 23.3 | 0.4 |
| Northeast | 32 | 220 | 12.1 | 0.4 |
| South | 140 | 1,023 | 53.5 | 0.4 |
| West | 32 | 302 | 13.1 | 0.4 |
| Invalid | 0 | 10 | 0.0 | - |
| Missing | 1 | 18 | 0.1 | 0.1 |
| Other | 0 | 2 | 0.0 | - |
| **Hematologic Outcomes: Present** | | | | |
| Midwest | 14 | 84 | 6.8 | 0.5 |
| Northeast | 8 | 16 | 2.6 | 0.3 |
| South | 36 | 172 | 13.7 | 0.4 |
| West | 9 | 46 | 4.1 | 0.5 |
| Invalid | 0 | 2 | 0.0 | - |
| Missing | 1 | 2 | 0.0 | 0.0 |
| Other | 0 | 0 | 0.0 | - |

[1]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Sex and Year**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| ***Female*** | | | | |
| 2008 | 4 | 148 | 0.6 | 0.1 |
| 2009 | 3 | 156 | 0.6 | 0.2 |
| 2010 | 5 | 181 | 1.4 | 0.3 |
| 2011 | 4 | 179 | 1.3 | 0.3 |
| 2012 | 5 | 177 | 1.4 | 0.3 |
| 2013 | 9 | 175 | 3.4 | 0.4 |
| 2014 | 15 | 178 | 5.1 | 0.3 |
| 2015 | 26 | 192 | 10.2 | 0.4 |
| 2016 | 22 | 199 | 11.6 | 0.5 |
| 2017 | 17 | 222 | 6.6 | 0.4 |
| 2018 | 25 | 222 | 11.9 | 0.5 |
| 2019 | 27 | 242 | 10.0 | 0.4 |
| 2020 | 16 | 204 | 5.0 | 0.3 |
| 2021 | 0 | 59 | 0.0 | - |
| ***Male*** | | | | |
| 2008 | 7 | 141 | 1.8 | 0.3 |
| 2009 | 2 | 154 | 0.5 | 0.2 |
| 2010 | 6 | 172 | 1.4 | 0.2 |
| 2011 | 10 | 162 | 3.1 | 0.3 |
| 2012 | 7 | 172 | 1.8 | 0.3 |
| 2013 | 7 | 193 | 2.5 | 0.4 |
| 2014 | 11 | 204 | 5.1 | 0.5 |
| 2015 | 20 | 208 | 8.2 | 0.4 |
| 2016 | 31 | 231 | 12.5 | 0.4 |
| 2017 | 26 | 271 | 10.1 | 0.4 |
| 2018 | 21 | 274 | 8.6 | 0.4 |
| 2019 | 22 | 291 | 10.2 | 0.5 |
| 2020 | 20 | 211 | 6.8 | 0.3 |
| 2021 | 4 | 72 | 0.7 | 0.2 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| ***Female*** | | | | |
| 2008 | 1 | 70 | 0.2 | 0.2 |
| 2009 | 0 | 62 | 0.0 | - |
| 2010 | 0 | 65 | 0.0 | - |
| 2011 | 1 | 77 | 0.2 | 0.2 |
| 2012 | 3 | 73 | 0.9 | 0.3 |
| 2013 | 1 | 72 | 0.3 | 0.3 |
| 2014 | 0 | 79 | 0.0 | - |
| 2015 | 3 | 71 | 0.6 | 0.2 |
| 2016 | 2 | 78 | 0.7 | 0.3 |
| 2017 | 4 | 91 | 0.8 | 0.2 |
| 2018 | 5 | 83 | 2.2 | 0.4 |
| 2019 | 4 | 90 | 1.0 | 0.3 |
| 2020 | 3 | 86 | 1.3 | 0.4 |
| 2021 | 0 | 24 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Male*** | | | | |
| 2008 | 1 | 60 | 0.1 | 0.1 |
| 2009 | 0 | 59 | 0.0 | - |
| 2010 | 1 | 59 | 0.2 | 0.2 |
| 2011 | 3 | 52 | 1.6 | 0.5 |
| 2012 | 0 | 59 | 0.0 | - |
| 2013 | 1 | 62 | 0.4 | 0.4 |
| 2014 | 0 | 68 | 0.0 | - |
| 2015 | 3 | 69 | 1.5 | 0.5 |
| 2016 | 6 | 66 | 2.1 | 0.4 |
| 2017 | 7 | 96 | 2.6 | 0.4 |
| 2018 | 2 | 82 | 0.3 | 0.2 |
| 2019 | 6 | 96 | 1.6 | 0.3 |
| 2020 | 4 | 81 | 1.9 | 0.5 |
| 2021 | 1 | 22 | 0.2 | 0.2 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| ***Female*** | | | | |
| 2008 | 0 | 14 | 0.0 | - |
| 2009 | 1 | 18 | 0.2 | 0.2 |
| 2010 | 1 | 17 | 0.3 | 0.3 |
| 2011 | 0 | 14 | 0.0 | - |
| 2012 | 0 | 14 | 0.0 | - |
| 2013 | 1 | 13 | 0.6 | 0.6 |
| 2014 | 1 | 16 | 0.3 | 0.3 |
| 2015 | 2 | 16 | 0.3 | 0.2 |
| 2016 | 2 | 18 | 1.0 | 0.5 |
| 2017 | 3 | 31 | 1.1 | 0.4 |
| 2018 | 2 | 34 | 1.3 | 0.6 |
| 2019 | 1 | 37 | 0.3 | 0.3 |
| 2020 | 3 | 46 | 0.9 | 0.3 |
| 2021 | 0 | 15 | 0.0 | - |
| ***Male*** | | | | |
| 2008 | 0 | 13 | 0.0 | - |
| 2009 | 1 | 10 | 0.2 | 0.2 |
| 2010 | 1 | 10 | 0.2 | 0.2 |
| 2011 | 2 | 12 | 0.6 | 0.3 |
| 2012 | 0 | 11 | 0.0 | - |
| 2013 | 2 | 17 | 0.6 | 0.3 |
| 2014 | 0 | 14 | 0.0 | - |
| 2015 | 1 | 14 | 0.6 | 0.6 |
| 2016 | 1 | 17 | 0.2 | 0.2 |
| 2017 | 2 | 29 | 0.5 | 0.3 |
| 2018 | 2 | 38 | 0.7 | 0.4 |
| 2019 | 4 | 38 | 3.4 | 0.9 |
| 2020 | 3 | 32 | 1.3 | 0.4 |
| 2021 | 0 | 8 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| ***Female*** | | | | |
| 2008 | 3 | 69 | 0.4 | 0.1 |
| 2009 | 2 | 63 | 0.3 | 0.2 |
| 2010 | 3 | 83 | 0.8 | 0.3 |
| 2011 | 0 | 67 | 0.0 | - |
| 2012 | 2 | 74 | 0.5 | 0.2 |
| 2013 | 7 | 72 | 2.5 | 0.4 |
| 2014 | 8 | 66 | 2.8 | 0.3 |
| 2015 | 17 | 89 | 7.3 | 0.4 |
| 2016 | 12 | 99 | 6.7 | 0.6 |
| 2017 | 8 | 99 | 3.6 | 0.5 |
| 2018 | 16 | 91 | 7.6 | 0.5 |
| 2019 | 15 | 96 | 4.6 | 0.3 |
| 2020 | 5 | 65 | 1.7 | 0.3 |
| 2021 | 0 | 14 | 0.0 | - |
| ***Male*** | | | | |
| 2008 | 4 | 70 | 1.2 | 0.3 |
| 2009 | 0 | 79 | 0.0 | - |
| 2010 | 3 | 83 | 0.9 | 0.3 |
| 2011 | 4 | 75 | 0.8 | 0.2 |
| 2012 | 5 | 91 | 1.5 | 0.3 |
| 2013 | 1 | 104 | 0.5 | 0.5 |
| 2014 | 8 | 105 | 3.2 | 0.4 |
| 2015 | 12 | 112 | 4.5 | 0.4 |
| 2016 | 22 | 130 | 9.6 | 0.4 |
| 2017 | 15 | 140 | 6.0 | 0.4 |
| 2018 | 14 | 141 | 6.5 | 0.5 |
| 2019 | 9 | 140 | 3.9 | 0.4 |
| 2020 | 12 | 95 | 3.3 | 0.3 |
| 2021 | 3 | 36 | 0.5 | 0.2 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| ***Female*** | | | | |
| 2008 | 0 | 23 | 0.0 | - |
| 2009 | 0 | 30 | 0.0 | - |
| 2010 | 1 | 40 | 0.2 | 0.2 |
| 2011 | 3 | 39 | 1.1 | 0.4 |
| 2012 | 0 | 39 | 0.0 | - |
| 2013 | 0 | 44 | 0.0 | - |
| 2014 | 6 | 47 | 2.1 | 0.3 |
| 2015 | 4 | 43 | 2.0 | 0.5 |
| 2016 | 6 | 39 | 3.3 | 0.5 |
| 2017 | 2 | 43 | 1.1 | 0.5 |
| 2018 | 2 | 44 | 0.9 | 0.4 |
| 2019 | 7 | 52 | 4.1 | 0.6 |
| 2020 | 5 | 39 | 1.2 | 0.2 |
| 2021 | 0 | 14 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Male*** | | | | |
| 2008 | 2 | 24 | 0.5 | 0.2 |
| 2009 | 1 | 34 | 0.3 | 0.3 |
| 2010 | 1 | 44 | 0.2 | 0.2 |
| 2011 | 1 | 40 | 0.2 | 0.2 |
| 2012 | 2 | 39 | 0.4 | 0.2 |
| 2013 | 3 | 46 | 0.9 | 0.3 |
| 2014 | 3 | 43 | 1.8 | 0.6 |
| 2015 | 4 | 43 | 1.7 | 0.4 |
| 2016 | 2 | 51 | 0.6 | 0.3 |
| 2017 | 2 | 58 | 1.0 | 0.5 |
| 2018 | 3 | 53 | 1.0 | 0.3 |
| 2019 | 3 | 63 | 1.2 | 0.4 |
| 2020 | 1 | 35 | 0.3 | 0.3 |
| 2021 | 0 | 10 | 0.0 | - |
| **Hematologic Outcomes: Absent** | | | | |
| ***Female*** | | | | |
| 2008 | 2 | 142 | 0.3 | 0.2 |
| 2009 | 2 | 151 | 0.3 | 0.2 |
| 2010 | 3 | 176 | 0.8 | 0.3 |
| 2011 | 2 | 171 | 0.9 | 0.5 |
| 2012 | 2 | 170 | 0.3 | 0.2 |
| 2013 | 6 | 169 | 2.2 | 0.4 |
| 2014 | 7 | 169 | 2.4 | 0.3 |
| 2015 | 23 | 188 | 9.4 | 0.4 |
| 2016 | 18 | 189 | 10.0 | 0.6 |
| 2017 | 15 | 215 | 5.7 | 0.4 |
| 2018 | 18 | 212 | 8.7 | 0.5 |
| 2019 | 19 | 229 | 6.1 | 0.3 |
| 2020 | 13 | 196 | 4.6 | 0.4 |
| 2021 | 0 | 59 | 0.0 | - |
| ***Male*** | | | | |
| 2008 | 7 | 138 | 1.8 | 0.3 |
| 2009 | 2 | 149 | 0.5 | 0.2 |
| 2010 | 6 | 168 | 1.4 | 0.2 |
| 2011 | 10 | 160 | 3.1 | 0.3 |
| 2012 | 6 | 169 | 1.3 | 0.2 |
| 2013 | 4 | 187 | 1.2 | 0.3 |
| 2014 | 7 | 198 | 2.9 | 0.4 |
| 2015 | 13 | 197 | 5.7 | 0.4 |
| 2016 | 22 | 217 | 8.9 | 0.4 |
| 2017 | 15 | 253 | 5.7 | 0.4 |
| 2018 | 14 | 260 | 5.8 | 0.4 |
| 2019 | 14 | 277 | 6.1 | 0.4 |
| 2020 | 16 | 203 | 5.2 | 0.3 |
| 2021 | 4 | 72 | 0.7 | 0.2 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Present** | | | | |
| ***Female*** | | | | |
| 2008 | 2 | 7 | 0.2 | 0.1 |
| 2009 | 0 | 3 | 0.0 | - |
| 2010 | 1 | 15 | 0.2 | 0.2 |
| 2011 | 0 | 10 | 0.0 | - |
| 2012 | 1 | 7 | 0.3 | 0.3 |
| 2013 | 2 | 11 | 0.7 | 0.4 |
| 2014 | 6 | 13 | 1.6 | 0.3 |
| 2015 | 2 | 12 | 0.4 | 0.2 |
| 2016 | 2 | 9 | 0.7 | 0.3 |
| 2017 | 1 | 11 | 0.4 | 0.4 |
| 2018 | 6 | 12 | 3.0 | 0.5 |
| 2019 | 6 | 17 | 3.3 | 0.5 |
| 2020 | 2 | 13 | 0.2 | 0.1 |
| 2021 | 0 | 1 | 0.0 | - |
| ***Male*** | | | | |
| 2008 | 0 | 18 | 0.0 | - |
| 2009 | 0 | 9 | 0.0 | - |
| 2010 | 0 | 11 | 0.0 | - |
| 2011 | 0 | 14 | 0.0 | - |
| 2012 | 1 | 13 | 0.5 | 0.5 |
| 2013 | 3 | 16 | 1.2 | 0.4 |
| 2014 | 4 | 19 | 2.2 | 0.5 |
| 2015 | 6 | 17 | 2.2 | 0.4 |
| 2016 | 7 | 21 | 2.8 | 0.4 |
| 2017 | 7 | 25 | 3.2 | 0.5 |
| 2018 | 5 | 19 | 2.5 | 0.5 |
| 2019 | 2 | 18 | 0.6 | 0.3 |
| 2020 | 2 | 10 | 1.0 | 0.5 |
| 2021 | 0 | 0 | 0.0 | - |

[1]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Census Bureau Region and Year**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| ***Midwest*** | | | | |
| 2008 | 2 | 52 | 0.5 | 0.2 |
| 2009 | 3 | 60 | 0.5 | 0.2 |
| 2010 | 7 | 64 | 1.7 | 0.2 |
| 2011 | 2 | 50 | 0.3 | 0.1 |
| 2012 | 2 | 54 | 0.7 | 0.3 |
| 2013 | 2 | 56 | 0.8 | 0.4 |
| 2014 | 8 | 57 | 2.9 | 0.4 |
| 2015 | 6 | 55 | 2.8 | 0.5 |
| 2016 | 12 | 71 | 5.8 | 0.5 |
| 2017 | 9 | 99 | 4.2 | 0.5 |
| 2018 | 12 | 100 | 3.8 | 0.3 |
| 2019 | 12 | 120 | 6.4 | 0.5 |
| 2020 | 8 | 128 | 3.0 | 0.4 |
| 2021 | 2 | 51 | 0.4 | 0.2 |
| ***Northeast*** | | | | |
| 2008 | 0 | 19 | 0.0 | - |
| 2009 | 0 | 27 | 0.0 | - |
| 2010 | 0 | 31 | 0.0 | - |
| 2011 | 4 | 33 | 1.1 | 0.3 |
| 2012 | 4 | 42 | 0.7 | 0.2 |
| 2013 | 4 | 40 | 0.8 | 0.2 |
| 2014 | 2 | 42 | 0.6 | 0.3 |
| 2015 | 8 | 37 | 3.1 | 0.4 |
| 2016 | 3 | 36 | 1.7 | 0.6 |
| 2017 | 3 | 44 | 1.0 | 0.3 |
| 2018 | 4 | 47 | 2.2 | 0.5 |
| 2019 | 3 | 58 | 1.8 | 0.6 |
| 2020 | 6 | 55 | 1.8 | 0.3 |
| 2021 | 0 | 13 | 0.0 | - |
| ***South*** | | | | |
| 2008 | 9 | 162 | 1.9 | 0.2 |
| 2009 | 1 | 166 | 0.3 | 0.3 |
| 2010 | 2 | 201 | 0.8 | 0.4 |
| 2011 | 5 | 206 | 2.3 | 0.5 |
| 2012 | 5 | 204 | 1.6 | 0.3 |
| 2013 | 4 | 217 | 1.7 | 0.4 |
| 2014 | 11 | 214 | 4.3 | 0.4 |
| 2015 | 25 | 230 | 9.8 | 0.4 |
| 2016 | 29 | 246 | 11.9 | 0.4 |
| 2017 | 28 | 279 | 10.1 | 0.4 |
| 2018 | 28 | 280 | 13.7 | 0.5 |
| 2019 | 29 | 282 | 9.3 | 0.3 |
| 2020 | 16 | 154 | 4.9 | 0.3 |
| 2021 | 1 | 34 | 0.2 | 0.2 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***West*** | | | | |
| 2008 | 0 | 42 | 0.0 | - |
| 2009 | 1 | 49 | 0.2 | 0.2 |
| 2010 | 2 | 53 | 0.3 | 0.2 |
| 2011 | 3 | 48 | 0.7 | 0.2 |
| 2012 | 1 | 46 | 0.3 | 0.3 |
| 2013 | 6 | 54 | 2.5 | 0.4 |
| 2014 | 5 | 67 | 2.4 | 0.5 |
| 2015 | 7 | 76 | 2.7 | 0.4 |
| 2016 | 9 | 74 | 4.7 | 0.5 |
| 2017 | 3 | 68 | 1.4 | 0.5 |
| 2018 | 2 | 66 | 0.9 | 0.4 |
| 2019 | 5 | 69 | 2.6 | 0.5 |
| 2020 | 5 | 73 | 2.1 | 0.4 |
| 2021 | 0 | 29 | 0.0 | - |
| ***Invalid*** | | | | |
| 2008 | 0 | 2 | 0.0 | - |
| 2009 | 0 | 3 | 0.0 | - |
| 2010 | 0 | 4 | 0.0 | - |
| 2011 | 0 | 4 | 0.0 | - |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 1 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 0 | 2 | 0.0 | - |
| 2019 | 0 | 3 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Missing*** | | | | |
| 2008 | 0 | 12 | 0.0 | - |
| 2009 | 0 | 5 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 2 | 0.0 | - |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 1 | 1 | 0.0 | 0.0 |
| 2021 | 1 | 2 | 0.1 | 0.1 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Other*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| ***Midwest*** | | | | |
| 2008 | 0 | 20 | 0.0 | - |
| 2009 | 0 | 15 | 0.0 | - |
| 2010 | 0 | 15 | 0.0 | - |
| 2011 | 1 | 10 | 0.2 | 0.2 |
| 2012 | 0 | 14 | 0.0 | - |
| 2013 | 0 | 15 | 0.0 | - |
| 2014 | 0 | 20 | 0.0 | - |
| 2015 | 0 | 20 | 0.0 | . |
| 2016 | 2 | 24 | 0.5 | - |
| 2017 | 1 | 39 | 0.3 | 0.3 |
| 2018 | 5 | 36 | 1.5 | 0.3 |
| 2019 | 0 | 40 | 0.0 | - |
| 2020 | 0 | 46 | 0.0 | - |
| 2021 | 0 | 17 | 0.0 | - |
| ***Northeast*** | | | | |
| 2008 | 0 | 12 | 0.0 | - |
| 2009 | 0 | 16 | 0.0 | - |
| 2010 | 0 | 19 | 0.0 | - |
| 2011 | 0 | 20 | 0.0 | - |
| 2012 | 2 | 25 | 0.3 | 0.2 |
| 2013 | 0 | 22 | 0.0 | - |
| 2014 | 0 | 21 | 0.0 | - |
| 2015 | 1 | 16 | 0.1 | 0.1 |
| 2016 | 0 | 18 | 0.0 | - |
| 2017 | 1 | 21 | 0.2 | 0.2 |
| 2018 | 1 | 18 | 0.5 | 0.5 |
| 2019 | 0 | 21 | 0.0 | - |
| 2020 | 1 | 20 | 0.4 | 0.4 |
| 2021 | 0 | 4 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***South*** | | | | |
| 2008 | 2 | 67 | 0.3 | 0.1 |
| 2009 | 0 | 68 | 0.0 | - |
| 2010 | 0 | 72 | 0.0 | - |
| 2011 | 2 | 80 | 1.4 | 0.7 |
| 2012 | 1 | 75 | 0.6 | 0.6 |
| 2013 | 0 | 72 | 0.0 | - |
| 2014 | 0 | 78 | 0.0 | - |
| 2015 | 4 | 79 | 1.5 | 0.4 |
| 2016 | 3 | 80 | 1.2 | 0.4 |
| 2017 | 8 | 103 | 2.4 | 0.3 |
| 2018 | 1 | 87 | 0.5 | 0.5 |
| 2019 | 9 | 99 | 2.5 | 0.3 |
| 2020 | 5 | 69 | 2.1 | 0.4 |
| 2021 | 1 | 14 | 0.2 | 0.2 |
| ***West*** | | | | |
| 2008 | 0 | 20 | 0.0 | - |
| 2009 | 0 | 18 | 0.0 | - |
| 2010 | 1 | 18 | 0.2 | 0.2 |
| 2011 | 1 | 19 | 0.2 | 0.2 |
| 2012 | 0 | 18 | 0.0 | - |
| 2013 | 2 | 25 | 0.7 | 0.4 |
| 2014 | 0 | 27 | 0.0 | - |
| 2015 | 1 | 24 | 0.5 | 0.5 |
| 2016 | 3 | 22 | 1.1 | 0.4 |
| 2017 | 1 | 24 | 0.6 | 0.6 |
| 2018 | 0 | 24 | 0.0 | - |
| 2019 | 1 | 25 | 0.2 | 0.2 |
| 2020 | 1 | 29 | 0.7 | 0.7 |
| 2021 | 0 | 11 | 0.0 | - |
| ***Invalid*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 2 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Missing*** | | | | |
| 2008 | 0 | 11 | 0.0 | - |
| 2009 | 0 | 2 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Other*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| ***Midwest*** | | | | |
| 2008 | 0 | 8 | 0.0 | - |
| 2009 | 1 | 6 | 0.2 | 0.2 |
| 2010 | 2 | 9 | 0.4 | 0.2 |
| 2011 | 0 | 5 | 0.0 | - |
| 2012 | 0 | 5 | 0.0 | - |
| 2013 | 1 | 8 | 0.6 | 0.6 |
| 2014 | 1 | 8 | 0.3 | 0.3 |
| 2015 | 1 | 9 | 0.2 | 0.2 |
| 2016 | 0 | 5 | 0.0 | - |
| 2017 | 2 | 19 | 0.8 | 0.4 |
| 2018 | 1 | 15 | 0.2 | 0.2 |
| 2019 | 2 | 19 | 1.8 | 0.9 |
| 2020 | 1 | 27 | 0.7 | 0.7 |
| 2021 | 0 | 9 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Northeast*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 2 | 0.0 | - |
| 2010 | 0 | 2 | 0.0 | - |
| 2011 | 2 | 6 | 0.6 | 0.3 |
| 2012 | 0 | 5 | 0.0 | - |
| 2013 | 1 | 6 | 0.0 | 0.0 |
| 2014 | 0 | 7 | 0.0 | - |
| 2015 | 1 | 4 | 0.6 | 0.6 |
| 2016 | 0 | 2 | 0.0 | - |
| 2017 | 1 | 6 | 0.2 | 0.2 |
| 2018 | 0 | 8 | 0.0 | - |
| 2019 | 0 | 8 | 0.0 | - |
| 2020 | 1 | 13 | 0.1 | 0.1 |
| 2021 | 0 | 2 | 0.0 | - |
| ***South*** | | | | |
| 2008 | 0 | 10 | 0.0 | - |
| 2009 | 0 | 13 | 0.0 | - |
| 2010 | 0 | 14 | 0.0 | - |
| 2011 | 0 | 11 | 0.0 | - |
| 2012 | 0 | 14 | 0.0 | - |
| 2013 | 1 | 13 | 0.5 | 0.5 |
| 2014 | 0 | 11 | 0.0 | - |
| 2015 | 0 | 11 | 0.0 | - |
| 2016 | 3 | 24 | 1.1 | 0.4 |
| 2017 | 1 | 28 | 0.3 | 0.3 |
| 2018 | 2 | 40 | 1.5 | 0.7 |
| 2019 | 2 | 37 | 0.8 | 0.4 |
| 2020 | 4 | 27 | 1.5 | 0.4 |
| 2021 | 0 | 6 | 0.0 | - |
| ***West*** | | | | |
| 2008 | 0 | 3 | 0.0 | - |
| 2009 | 1 | 5 | 0.2 | 0.2 |
| 2010 | 0 | 2 | 0.0 | - |
| 2011 | 0 | 3 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 3 | 0.0 | - |
| 2014 | 0 | 4 | 0.0 | - |
| 2015 | 1 | 6 | 0.1 | 0.1 |
| 2016 | 0 | 4 | 0.0 | - |
| 2017 | 1 | 7 | 0.4 | 0.4 |
| 2018 | 1 | 9 | 0.4 | 0.4 |
| 2019 | 1 | 11 | 1.0 | 1.0 |
| 2020 | 0 | 10 | 0.0 | - |
| 2021 | 0 | 5 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Invalid*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Missing*** | | | | |
| 2008 | 0 | 5 | 0.0 | - |
| 2009 | 0 | 2 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Other*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| ***Midwest*** | | | | |
| 2008 | 2 | 30 | 0.5 | 0.2 |
| 2009 | 2 | 35 | 0.3 | 0.2 |
| 2010 | 4 | 30 | 1.0 | 0.2 |
| 2011 | 1 | 20 | 0.1 | 0.1 |
| 2012 | 1 | 26 | 0.5 | 0.5 |
| 2013 | 1 | 24 | 0.1 | 0.1 |
| 2014 | 6 | 28 | 2.4 | 0.4 |
| 2015 | 4 | 28 | 2.0 | 0.5 |
| 2016 | 6 | 35 | 3.3 | 0.5 |
| 2017 | 5 | 48 | 2.7 | 0.5 |
| 2018 | 5 | 41 | 1.9 | 0.4 |
| 2019 | 7 | 54 | 2.7 | 0.4 |
| 2020 | 7 | 47 | 2.4 | 0.3 |
| 2021 | 2 | 18 | 0.4 | 0.2 |
| ***Northeast*** | | | | |
| 2008 | 0 | 7 | 0.0 | - |
| 2009 | 0 | 7 | 0.0 | - |
| 2010 | 0 | 6 | 0.0 | - |
| 2011 | 1 | 5 | 0.2 | 0.2 |
| 2012 | 2 | 10 | 0.4 | 0.2 |
| 2013 | 1 | 13 | 0.2 | 0.2 |
| 2014 | 1 | 16 | 0.5 | 0.5 |
| 2015 | 5 | 15 | 2.3 | 0.5 |
| 2016 | 1 | 18 | 0.6 | 0.6 |
| 2017 | 0 | 19 | 0.0 | - |
| 2018 | 2 | 22 | 1.2 | 0.6 |
| 2019 | 3 | 29 | 1.8 | 0.6 |
| 2020 | 3 | 21 | 1.3 | 0.4 |
| 2021 | 0 | 5 | 0.0 | - |
| ***South*** | | | | |
| 2008 | 5 | 82 | 1.1 | 0.2 |
| 2009 | 0 | 77 | 0.0 | - |
| 2010 | 2 | 99 | 0.8 | 0.4 |
| 2011 | 2 | 96 | 0.4 | 0.2 |
| 2012 | 3 | 100 | 0.8 | 0.3 |
| 2013 | 3 | 110 | 1.2 | 0.4 |
| 2014 | 8 | 97 | 2.6 | 0.3 |
| 2015 | 17 | 115 | 6.5 | 0.4 |
| 2016 | 22 | 133 | 9.4 | 0.4 |
| 2017 | 18 | 137 | 6.9 | 0.4 |
| 2018 | 23 | 136 | 10.9 | 0.5 |
| 2019 | 11 | 122 | 2.5 | 0.2 |
| 2020 | 4 | 62 | 0.5 | 0.1 |
| 2021 | 0 | 12 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***West*** | | | | |
| 2008 | 0 | 18 | 0.0 | - |
| 2009 | 0 | 19 | 0.0 | - |
| 2010 | 0 | 27 | 0.0 | - |
| 2011 | 0 | 18 | 0.0 | - |
| 2012 | 1 | 26 | 0.3 | 0.3 |
| 2013 | 3 | 28 | 1.5 | 0.5 |
| 2014 | 1 | 29 | 0.5 | 0.5 |
| 2015 | 3 | 41 | 1.0 | 0.3 |
| 2016 | 5 | 40 | 3.0 | 0.6 |
| 2017 | 0 | 32 | 0.0 | - |
| 2018 | 0 | 30 | 0.0 | - |
| 2019 | 3 | 29 | 1.4 | 0.5 |
| 2020 | 3 | 27 | 0.9 | 0.3 |
| 2021 | 0 | 12 | 0.0 | - |
| ***Invalid*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 3 | 0.0 | - |
| 2010 | 0 | 4 | 0.0 | - |
| 2011 | 0 | 3 | 0.0 | - |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 1 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 0 | 2 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Missing*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 2 | 0.0 | - |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 1 | 2 | 0.1 | 0.1 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Other*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| ***Midwest*** | | | | |
| 2008 | 0 | 12 | 0.0 | - |
| 2009 | 0 | 18 | 0.0 | - |
| 2010 | 1 | 22 | 0.2 | 0.2 |
| 2011 | 0 | 19 | 0.0 | - |
| 2012 | 1 | 19 | 0.1 | 0.1 |
| 2013 | 0 | 15 | 0.0 | - |
| 2014 | 1 | 13 | 0.2 | 0.2 |
| 2015 | 1 | 14 | 0.6 | 0.6 |
| 2016 | 4 | 15 | 2.1 | 0.5 |
| 2017 | 1 | 18 | 0.4 | 0.4 |
| 2018 | 1 | 21 | 0.2 | 0.2 |
| 2019 | 3 | 30 | 1.8 | 0.6 |
| 2020 | 0 | 29 | 0.0 | - |
| 2021 | 0 | 11 | 0.0 | - |
| ***Northeast*** | | | | |
| 2008 | 0 | 3 | 0.0 | - |
| 2009 | 0 | 7 | 0.0 | - |
| 2010 | 0 | 9 | 0.0 | - |
| 2011 | 1 | 7 | 0.2 | 0.2 |
| 2012 | 0 | 7 | 0.0 | - |
| 2013 | 2 | 10 | 0.6 | 0.3 |
| 2014 | 1 | 8 | 0.1 | 0.1 |
| 2015 | 1 | 7 | 0.2 | 0.2 |
| 2016 | 2 | 7 | 1.1 | 0.6 |
| 2017 | 1 | 9 | 0.6 | 0.6 |
| 2018 | 1 | 10 | 0.4 | 0.4 |
| 2019 | 0 | 12 | 0.0 | - |
| 2020 | 1 | 7 | 0.1 | 0.1 |
| 2021 | 0 | 3 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***South*** | | | | |
| 2008 | 2 | 25 | 0.5 | 0.2 |
| 2009 | 1 | 29 | 0.3 | 0.3 |
| 2010 | 0 | 41 | 0.0 | - |
| 2011 | 1 | 41 | 0.5 | 0.5 |
| 2012 | 1 | 43 | 0.2 | 0.2 |
| 2013 | 0 | 50 | 0.0 | - |
| 2014 | 3 | 50 | 1.7 | 0.6 |
| 2015 | 4 | 46 | 1.8 | 0.5 |
| 2016 | 1 | 51 | 0.2 | 0.2 |
| 2017 | 1 | 56 | 0.6 | 0.6 |
| 2018 | 2 | 49 | 0.8 | 0.4 |
| 2019 | 7 | 59 | 3.5 | 0.5 |
| 2020 | 3 | 21 | 0.9 | 0.3 |
| 2021 | 0 | 6 | 0.0 | - |
| ***West*** | | | | |
| 2008 | 0 | 6 | 0.0 | - |
| 2009 | 0 | 9 | 0.0 | - |
| 2010 | 1 | 12 | 0.2 | 0.2 |
| 2011 | 2 | 12 | 0.6 | 0.3 |
| 2012 | 0 | 9 | 0.0 | - |
| 2013 | 1 | 15 | 0.2 | 0.2 |
| 2014 | 4 | 19 | 1.9 | 0.5 |
| 2015 | 2 | 19 | 1.0 | 0.5 |
| 2016 | 1 | 17 | 0.5 | 0.5 |
| 2017 | 1 | 18 | 0.5 | 0.5 |
| 2018 | 1 | 16 | 0.5 | 0.5 |
| 2019 | 0 | 13 | 0.0 | - |
| 2020 | 1 | 16 | 0.5 | 0.5 |
| 2021 | 0 | 4 | 0.0 | - |
| ***Invalid*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Missing*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 1 | 1 | 0.0 | 0.0 |
| 2021 | 0 | 0 | 0.0 | - |
| ***Other*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| **Hematologic Outcomes: Absent** | | | | |
| ***Midwest*** | | | | |
| 2008 | 2 | 50 | 0.5 | 0.2 |
| 2009 | 3 | 60 | 0.5 | 0.2 |
| 2010 | 5 | 61 | 1.1 | 0.2 |
| 2011 | 2 | 48 | 0.3 | 0.1 |
| 2012 | 1 | 51 | 0.1 | 0.1 |
| 2013 | 2 | 55 | 0.8 | 0.4 |
| 2014 | 6 | 54 | 1.9 | 0.3 |
| 2015 | 6 | 53 | 2.8 | 0.5 |
| 2016 | 8 | 66 | 4.4 | 0.6 |
| 2017 | 5 | 90 | 2.1 | 0.4 |
| 2018 | 7 | 92 | 2.2 | 0.3 |
| 2019 | 8 | 113 | 3.2 | 0.4 |
| 2020 | 8 | 127 | 3.0 | 0.4 |
| 2021 | 2 | 51 | 0.4 | 0.2 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Northeast*** | | | | |
| 2008 | 0 | 19 | 0.0 | - |
| 2009 | 0 | 26 | 0.0 | - |
| 2010 | 0 | 30 | 0.0 | - |
| 2011 | 4 | 32 | 1.1 | 0.3 |
| 2012 | 3 | 41 | 0.5 | 0.2 |
| 2013 | 3 | 38 | 0.7 | 0.2 |
| 2014 | 0 | 40 | 0.0 | - |
| 2015 | 6 | 35 | 2.4 | 0.4 |
| 2016 | 1 | 33 | 1.1 | 1.1 |
| 2017 | 3 | 43 | 1.0 | 0.3 |
| 2018 | 3 | 45 | 1.7 | 0.6 |
| 2019 | 3 | 57 | 1.8 | 0.6 |
| 2020 | 6 | 53 | 1.8 | 0.3 |
| 2021 | 0 | 13 | 0.0 | - |
| ***South*** | | | | |
| 2008 | 7 | 156 | 1.7 | 0.2 |
| 2009 | 1 | 159 | 0.3 | 0.3 |
| 2010 | 2 | 198 | 0.8 | 0.4 |
| 2011 | 4 | 202 | 2.2 | 0.5 |
| 2012 | 4 | 199 | 1.0 | 0.2 |
| 2013 | 2 | 213 | 0.7 | 0.4 |
| 2014 | 5 | 206 | 1.8 | 0.4 |
| 2015 | 19 | 221 | 8.2 | 0.4 |
| 2016 | 24 | 236 | 9.8 | 0.4 |
| 2017 | 20 | 266 | 7.4 | 0.4 |
| 2018 | 20 | 267 | 9.7 | 0.5 |
| 2019 | 20 | 269 | 6.3 | 0.3 |
| 2020 | 11 | 145 | 3.5 | 0.3 |
| 2021 | 1 | 34 | 0.2 | 0.2 |
| ***West*** | | | | |
| 2008 | 0 | 41 | 0.0 | - |
| 2009 | 0 | 47 | 0.0 | - |
| 2010 | 2 | 51 | 0.3 | 0.2 |
| 2011 | 2 | 47 | 0.6 | 0.3 |
| 2012 | 0 | 45 | 0.0 | - |
| 2013 | 3 | 49 | 1.3 | 0.4 |
| 2014 | 3 | 65 | 1.6 | 0.5 |
| 2015 | 5 | 74 | 1.8 | 0.4 |
| 2016 | 7 | 68 | 3.5 | 0.5 |
| 2017 | 2 | 66 | 0.9 | 0.4 |
| 2018 | 2 | 65 | 0.9 | 0.4 |
| 2019 | 2 | 63 | 0.9 | 0.4 |
| 2020 | 4 | 70 | 1.4 | 0.4 |
| 2021 | 0 | 29 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Invalid*** | | | | |
| 2008 | 0 | 2 | 0.0 | - |
| 2009 | 0 | 3 | 0.0 | - |
| 2010 | 0 | 4 | 0.0 | - |
| 2011 | 0 | 2 | 0.0 | - |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 1 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 0 | 2 | 0.0 | - |
| 2019 | 0 | 3 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Missing*** | | | | |
| 2008 | 0 | 12 | 0.0 | - |
| 2009 | 0 | 5 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 2 | 0.0 | - |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 1 | 2 | 0.1 | 0.1 |
| ***Other*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Present** | | | | |
| ***Midwest*** | | | | |
| 2008 | 0 | 8 | 0.0 | - |
| 2009 | 0 | 6 | 0.0 | - |
| 2010 | 1 | 6 | 0.2 | 0.2 |
| 2011 | 0 | 4 | 0.0 | - |
| 2012 | 1 | 7 | 0.5 | 0.5 |
| 2013 | 0 | 4 | 0.0 | - |
| 2014 | 2 | 5 | 1.0 | 0.5 |
| 2015 | 0 | 6 | 0.0 | - |
| 2016 | 3 | 8 | 1.1 | 0.4 |
| 2017 | 2 | 11 | 1.3 | 0.7 |
| 2018 | 3 | 7 | 1.2 | 0.4 |
| 2019 | 2 | 13 | 1.3 | 0.7 |
| 2020 | 0 | 5 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Northeast*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 1 | 1 | 0.2 | 0.2 |
| 2014 | 2 | 3 | 0.6 | 0.3 |
| 2015 | 2 | 2 | 0.7 | 0.4 |
| 2016 | 2 | 2 | 0.6 | 0.3 |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 1 | 2 | 0.4 | 0.4 |
| 2019 | 0 | 3 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***South*** | | | | |
| 2008 | 2 | 15 | 0.2 | 0.1 |
| 2009 | 0 | 4 | 0.0 | - |
| 2010 | 0 | 14 | 0.0 | - |
| 2011 | 0 | 15 | 0.0 | - |
| 2012 | 0 | 7 | 0.0 | - |
| 2013 | 1 | 15 | 0.5 | 0.5 |
| 2014 | 4 | 18 | 1.4 | 0.3 |
| 2015 | 5 | 17 | 1.4 | 0.3 |
| 2016 | 4 | 15 | 1.7 | 0.4 |
| 2017 | 6 | 23 | 2.3 | 0.4 |
| 2018 | 7 | 20 | 3.8 | 0.5 |
| 2019 | 5 | 15 | 2.0 | 0.4 |
| 2020 | 2 | 11 | 0.5 | 0.2 |
| 2021 | 0 | 1 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***West*** | | | | |
| 2008 | 0 | 2 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 4 | 0.0 | - |
| 2011 | 0 | 3 | 0.0 | - |
| 2012 | 1 | 5 | 0.3 | 0.3 |
| 2013 | 3 | 7 | 1.3 | 0.4 |
| 2014 | 2 | 6 | 0.8 | 0.4 |
| 2015 | 1 | 4 | 0.5 | 0.5 |
| 2016 | 0 | 4 | 0.0 | - |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 0 | 2 | 0.0 | - |
| 2019 | 1 | 4 | 0.6 | 0.6 |
| 2020 | 1 | 6 | 0.7 | 0.7 |
| 2021 | 0 | 0 | 0.0 | - |
| ***Invalid*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 2 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Missing*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 1 | 1 | 0.0 | 0.0 |
| 2021 | 0 | 0 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Other*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |

[1]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| ***American Indian or Alaska Native*** | | | | |
| 2008 | 0 | 2 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Asian*** | | | | |
| 2008 | 0 | 6 | 0.0 | - |
| 2009 | 0 | 5 | 0.0 | - |
| 2010 | 0 | 6 | 0.0 | - |
| 2011 | 0 | 7 | 0.0 | - |
| 2012 | 0 | 5 | 0.0 | - |
| 2013 | 0 | 3 | 0.0 | - |
| 2014 | 0 | 5 | 0.0 | - |
| 2015 | 0 | 6 | 0.0 | - |
| 2016 | 0 | 7 | 0.0 | - |
| 2017 | 1 | 7 | 0.4 | 0.4 |
| 2018 | 0 | 3 | 0.0 | - |
| 2019 | 0 | 3 | 0.0 | - |
| 2020 | 0 | 4 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Black or African American*** | | | | |
| 2008 | 1 | 20 | 0.2 | 0.2 |
| 2009 | 0 | 20 | 0.0 | - |
| 2010 | 0 | 26 | 0.0 | - |
| 2011 | 1 | 25 | 0.2 | 0.2 |
| 2012 | 0 | 27 | 0.0 | - |
| 2013 | 0 | 27 | 0.0 | - |
| 2014 | 2 | 25 | 0.8 | 0.4 |
| 2015 | 4 | 29 | 1.5 | 0.4 |
| 2016 | 5 | 29 | 1.9 | 0.4 |
| 2017 | 6 | 39 | 1.8 | 0.3 |
| 2018 | 4 | 40 | 1.6 | 0.4 |
| 2019 | 4 | 34 | 0.6 | 0.1 |
| 2020 | 0 | 14 | 0.0 | - |
| 2021 | 0 | 5 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Native Hawaiian or Other Pacific Islander*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 1 | 1 | 0.2 | 0.2 |
| 2011 | 1 | 1 | 0.2 | 0.2 |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 4 | 0.0 | - |
| 2014 | 1 | 4 | 0.5 | 0.5 |
| 2015 | 0 | 3 | 0.0 | - |
| 2016 | 0 | 2 | 0.0 | - |
| 2017 | 0 | 3 | 0.0 | - |
| 2018 | 1 | 3 | 0.4 | 0.4 |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 1 | 2 | 0.0 | 0.0 |
| 2021 | 0 | 1 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 5 | 220 | 1.3 | 0.3 |
| 2009 | 5 | 245 | 1.1 | 0.2 |
| 2010 | 7 | 274 | 2.0 | 0.3 |
| 2011 | 12 | 268 | 4.1 | 0.3 |
| 2012 | 11 | 279 | 3.0 | 0.3 |
| 2013 | 15 | 303 | 5.2 | 0.3 |
| 2014 | 20 | 316 | 7.6 | 0.4 |
| 2015 | 40 | 327 | 15.8 | 0.4 |
| 2016 | 38 | 346 | 17.9 | 0.5 |
| 2017 | 34 | 401 | 13.6 | 0.4 |
| 2018 | 39 | 404 | 17.9 | 0.5 |
| 2019 | 40 | 449 | 17.7 | 0.4 |
| 2020 | 32 | 377 | 10.7 | 0.3 |
| 2021 | 4 | 113 | 0.7 | 0.2 |
| ***White*** | | | | |
| 2008 | 5 | 41 | 0.9 | 0.2 |
| 2009 | 0 | 38 | 0.0 | - |
| 2010 | 3 | 45 | 0.6 | 0.2 |
| 2011 | 0 | 39 | 0.0 | - |
| 2012 | 1 | 35 | 0.2 | 0.2 |
| 2013 | 1 | 31 | 0.6 | 0.6 |
| 2014 | 3 | 32 | 1.3 | 0.4 |
| 2015 | 2 | 35 | 1.1 | 0.6 |
| 2016 | 10 | 46 | 4.3 | 0.4 |
| 2017 | 2 | 43 | 1.0 | 0.5 |
| 2018 | 2 | 45 | 0.6 | 0.3 |
| 2019 | 5 | 45 | 1.8 | 0.4 |
| 2020 | 3 | 17 | 1.1 | 0.4 |
| 2021 | 0 | 10 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| ***American Indian or Alaska Native*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Asian*** | | | | |
| 2008 | 0 | 3 | 0.0 | - |
| 2009 | 0 | 2 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 3 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Black or African American*** | | | | |
| 2008 | 1 | 8 | 0.2 | 0.2 |
| 2009 | 0 | 9 | 0.0 | - |
| 2010 | 0 | 12 | 0.0 | - |
| 2011 | 1 | 11 | 0.2 | 0.2 |
| 2012 | 0 | 12 | 0.0 | - |
| 2013 | 0 | 12 | 0.0 | - |
| 2014 | 0 | 9 | 0.0 | - |
| 2015 | 0 | 7 | 0.0 | - |
| 2016 | 0 | 9 | 0.0 | - |
| 2017 | 3 | 20 | 0.7 | 0.2 |
| 2018 | 1 | 13 | 0.5 | 0.5 |
| 2019 | 2 | 15 | 0.3 | 0.1 |
| 2020 | 0 | 4 | 0.0 | - |
| 2021 | 0 | 4 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Native Hawaiian or Other Pacific Islander*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 1 | 1 | 0.2 | 0.2 |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 0 | 2 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 1 | 103 | 0.1 | 0.1 |
| 2009 | 0 | 99 | 0.0 | - |
| 2010 | 1 | 99 | 0.2 | 0.2 |
| 2011 | 2 | 102 | 1.4 | 0.7 |
| 2012 | 3 | 108 | 0.9 | 0.3 |
| 2013 | 2 | 112 | 0.7 | 0.4 |
| 2014 | 0 | 126 | 0.0 | - |
| 2015 | 6 | 121 | 2.1 | 0.4 |
| 2016 | 5 | 120 | 1.6 | 0.3 |
| 2017 | 8 | 155 | 2.7 | 0.3 |
| 2018 | 6 | 137 | 2.0 | 0.3 |
| 2019 | 6 | 155 | 1.8 | 0.3 |
| 2020 | 7 | 156 | 3.1 | 0.4 |
| 2021 | 1 | 39 | 0.2 | 0.2 |
| ***White*** | | | | |
| 2008 | 0 | 15 | 0.0 | - |
| 2009 | 0 | 11 | 0.0 | - |
| 2010 | 0 | 12 | 0.0 | - |
| 2011 | 0 | 12 | 0.0 | - |
| 2012 | 0 | 12 | 0.0 | - |
| 2013 | 0 | 10 | 0.0 | - |
| 2014 | 0 | 10 | 0.0 | - |
| 2015 | 0 | 10 | 0.0 | - |
| 2016 | 3 | 13 | 1.2 | 0.4 |
| 2017 | 0 | 9 | 0.0 | - |
| 2018 | 0 | 11 | 0.0 | - |
| 2019 | 2 | 14 | 0.6 | 0.3 |
| 2020 | 0 | 5 | 0.0 | - |
| 2021 | 0 | 3 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| ***American Indian or Alaska Native*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Asian*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 1 | 1 | 0.4 | 0.4 |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Black or African American*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 1 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 2 | 0.0 | - |
| 2016 | 0 | 2 | 0.0 | - |
| 2017 | 0 | 4 | 0.0 | - |
| 2018 | 0 | 5 | 0.0 | - |
| 2019 | 0 | 4 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Native Hawaiian or Other Pacific Islander*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 1 | 2 | 0.4 | 0.4 |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 0 | 20 | 0.0 | - |
| 2009 | 2 | 22 | 0.5 | 0.2 |
| 2010 | 0 | 21 | 0.0 | - |
| 2011 | 2 | 20 | 0.6 | 0.3 |
| 2012 | 0 | 23 | 0.0 | - |
| 2013 | 2 | 27 | 0.6 | 0.3 |
| 2014 | 1 | 28 | 0.3 | 0.3 |
| 2015 | 3 | 25 | 0.9 | 0.3 |
| 2016 | 1 | 29 | 0.3 | 0.3 |
| 2017 | 4 | 52 | 1.2 | 0.3 |
| 2018 | 3 | 61 | 1.6 | 0.5 |
| 2019 | 3 | 64 | 2.8 | 0.9 |
| 2020 | 6 | 74 | 2.2 | 0.4 |
| 2021 | 0 | 21 | 0.0 | - |
| ***White*** | | | | |
| 2008 | 0 | 5 | 0.0 | - |
| 2009 | 0 | 4 | 0.0 | - |
| 2010 | 2 | 4 | 0.4 | 0.2 |
| 2011 | 0 | 3 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 1 | 2 | 0.6 | 0.6 |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 3 | 0.0 | - |
| 2016 | 2 | 4 | 0.8 | 0.4 |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 4 | 0.0 | - |
| 2019 | 2 | 5 | 0.8 | 0.4 |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| ***American Indian or Alaska Native*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Asian*** | | | | |
| 2008 | 0 | 3 | 0.0 | - |
| 2009 | 0 | 3 | 0.0 | - |
| 2010 | 0 | 4 | 0.0 | - |
| 2011 | 0 | 5 | 0.0 | - |
| 2012 | 0 | 4 | 0.0 | - |
| 2013 | 0 | 3 | 0.0 | - |
| 2014 | 0 | 4 | 0.0 | - |
| 2015 | 0 | 4 | 0.0 | - |
| 2016 | 0 | 5 | 0.0 | - |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 2 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Black or African American*** | | | | |
| 2008 | 0 | 10 | 0.0 | - |
| 2009 | 0 | 10 | 0.0 | - |
| 2010 | 0 | 13 | 0.0 | - |
| 2011 | 0 | 13 | 0.0 | - |
| 2012 | 0 | 16 | 0.0 | - |
| 2013 | 0 | 15 | 0.0 | - |
| 2014 | 1 | 14 | 0.4 | 0.4 |
| 2015 | 3 | 18 | 1.3 | 0.4 |
| 2016 | 4 | 16 | 1.8 | 0.4 |
| 2017 | 3 | 17 | 1.1 | 0.4 |
| 2018 | 2 | 20 | 0.8 | 0.4 |
| 2019 | 2 | 15 | 0.3 | 0.1 |
| 2020 | 0 | 10 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Native Hawaiian or Other Pacific Islander*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 2 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 4 | 100 | 1.2 | 0.3 |
| 2009 | 2 | 106 | 0.3 | 0.2 |
| 2010 | 5 | 121 | 1.6 | 0.3 |
| 2011 | 4 | 106 | 0.8 | 0.2 |
| 2012 | 7 | 127 | 1.9 | 0.3 |
| 2013 | 8 | 143 | 3.0 | 0.4 |
| 2014 | 13 | 139 | 5.0 | 0.4 |
| 2015 | 26 | 162 | 10.5 | 0.4 |
| 2016 | 26 | 183 | 12.7 | 0.5 |
| 2017 | 18 | 192 | 7.5 | 0.4 |
| 2018 | 28 | 192 | 13.3 | 0.5 |
| 2019 | 21 | 201 | 7.8 | 0.4 |
| 2020 | 15 | 141 | 4.1 | 0.3 |
| 2021 | 3 | 44 | 0.5 | 0.2 |
| ***White*** | | | | |
| 2008 | 3 | 26 | 0.4 | 0.1 |
| 2009 | 0 | 23 | 0.0 | - |
| 2010 | 1 | 28 | 0.2 | 0.2 |
| 2011 | 0 | 18 | 0.0 | - |
| 2012 | 0 | 15 | 0.0 | - |
| 2013 | 0 | 13 | 0.0 | - |
| 2014 | 2 | 13 | 0.7 | 0.3 |
| 2015 | 0 | 16 | 0.0 | - |
| 2016 | 4 | 25 | 1.8 | 0.4 |
| 2017 | 2 | 28 | 1.0 | 0.5 |
| 2018 | 0 | 19 | 0.0 | - |
| 2019 | 1 | 18 | 0.4 | 0.4 |
| 2020 | 2 | 7 | 0.9 | 0.4 |
| 2021 | 0 | 4 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| ***American Indian or Alaska Native*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Asian*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 2 | 0.0 | - |
| 2017 | 0 | 3 | 0.0 | - |
| 2018 | 0 | 1 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Black or African American*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 2 | 0.0 | - |
| 2014 | 1 | 4 | 0.4 | 0.4 |
| 2015 | 1 | 5 | 0.2 | 0.2 |
| 2016 | 1 | 2 | 0.2 | 0.2 |
| 2017 | 0 | 3 | 0.0 | - |
| 2018 | 1 | 3 | 0.3 | 0.3 |
| 2019 | 0 | 2 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Native Hawaiian or Other Pacific Islander*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 1 | 1 | 0.2 | 0.2 |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 3 | 0.0 | - |
| 2014 | 1 | 2 | 0.5 | 0.5 |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 1 | 1 | 0.0 | 0.0 |
| 2021 | 0 | 0 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 0 | 41 | 0.0 | - |
| 2009 | 1 | 58 | 0.3 | 0.3 |
| 2010 | 1 | 72 | 0.2 | 0.2 |
| 2011 | 4 | 69 | 1.3 | 0.3 |
| 2012 | 1 | 64 | 0.1 | 0.1 |
| 2013 | 3 | 76 | 0.9 | 0.3 |
| 2014 | 6 | 72 | 2.3 | 0.4 |
| 2015 | 5 | 66 | 2.3 | 0.5 |
| 2016 | 6 | 73 | 3.2 | 0.5 |
| 2017 | 4 | 79 | 2.1 | 0.5 |
| 2018 | 2 | 77 | 1.0 | 0.5 |
| 2019 | 10 | 102 | 5.3 | 0.5 |
| 2020 | 4 | 68 | 1.3 | 0.3 |
| 2021 | 0 | 20 | 0.0 | . |
| ***White*** | | | | |
| 2008 | 2 | 4 | 0.5 | 0.2 |
| 2009 | 0 | 3 | 0.0 | - |
| 2010 | 0 | 9 | 0.0 | - |
| 2011 | 0 | 8 | 0.0 | - |
| 2012 | 1 | 12 | 0.2 | 0.2 |
| 2013 | 0 | 9 | 0.0 | - |
| 2014 | 1 | 12 | 0.7 | 0.7 |
| 2015 | 2 | 13 | 1.1 | 0.6 |
| 2016 | 1 | 12 | 0.5 | 0.5 |
| 2017 | 0 | 15 | 0.0 | - |
| 2018 | 2 | 16 | 0.6 | 0.3 |
| 2019 | 0 | 11 | 0.0 | - |
| 2020 | 1 | 5 | 0.2 | 0.2 |
| 2021 | 0 | 4 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Absent** | | | | |
| ***American Indian or Alaska Native*** | | | | |
| 2008 | 0 | 2 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Asian*** | | | | |
| 2008 | 0 | 6 | 0.0 | - |
| 2009 | 0 | 5 | 0.0 | - |
| 2010 | 0 | 6 | 0.0 | - |
| 2011 | 0 | 7 | 0.0 | - |
| 2012 | 0 | 5 | 0.0 | - |
| 2013 | 0 | 3 | 0.0 | - |
| 2014 | 0 | 5 | 0.0 | - |
| 2015 | 0 | 4 | 0.0 | - |
| 2016 | 0 | 7 | 0.0 | - |
| 2017 | 1 | 7 | 0.4 | 0.4 |
| 2018 | 0 | 3 | 0.0 | - |
| 2019 | 0 | 3 | 0.0 | - |
| 2020 | 0 | 3 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Black or African American*** | | | | |
| 2008 | 1 | 20 | 0.2 | 0.2 |
| 2009 | 0 | 20 | 0.0 | - |
| 2010 | 0 | 26 | 0.0 | - |
| 2011 | 0 | 24 | 0.0 | - |
| 2012 | 0 | 27 | 0.0 | - |
| 2013 | 0 | 27 | 0.0 | - |
| 2014 | 1 | 24 | 0.4 | 0.4 |
| 2015 | 4 | 28 | 1.5 | 0.4 |
| 2016 | 3 | 27 | 1.1 | 0.4 |
| 2017 | 6 | 39 | 1.8 | 0.3 |
| 2018 | 3 | 38 | 1.2 | 0.4 |
| 2019 | 2 | 32 | 0.2 | 0.1 |
| 2020 | 0 | 14 | 0.0 | - |
| 2021 | 0 | 5 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Native Hawaiian or Other Pacific Islander*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 1 | 1 | 0.2 | 0.2 |
| 2011 | 1 | 1 | 0.2 | 0.2 |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 3 | 0.0 | - |
| 2014 | 1 | 4 | 0.5 | 0.5 |
| 2015 | 0 | 3 | 0.0 | - |
| 2016 | 0 | 2 | 0.0 | - |
| 2017 | 0 | 3 | 0.0 | - |
| 2018 | 1 | 3 | 0.4 | 0.4 |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 1 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 5 | 213 | 1.3 | 0.3 |
| 2009 | 4 | 235 | 0.8 | 0.2 |
| 2010 | 6 | 266 | 1.8 | 0.3 |
| 2011 | 11 | 260 | 3.9 | 0.4 |
| 2012 | 7 | 270 | 1.4 | 0.2 |
| 2013 | 9 | 294 | 2.8 | 0.3 |
| 2014 | 12 | 305 | 4.4 | 0.4 |
| 2015 | 31 | 316 | 12.7 | 0.4 |
| 2016 | 27 | 326 | 13.4 | 0.5 |
| 2017 | 21 | 376 | 8.2 | 0.4 |
| 2018 | 26 | 384 | 12.2 | 0.5 |
| 2019 | 27 | 426 | 10.3 | 0.4 |
| 2020 | 27 | 364 | 8.9 | 0.3 |
| 2021 | 4 | 113 | 0.7 | 0.2 |
| ***White*** | | | | |
| 2008 | 3 | 39 | 0.7 | 0.2 |
| 2009 | 0 | 38 | 0.0 | - |
| 2010 | 2 | 44 | 0.3 | 0.2 |
| 2011 | 0 | 38 | 0.0 | - |
| 2012 | 1 | 34 | 0.2 | 0.2 |
| 2013 | 1 | 29 | 0.6 | 0.6 |
| 2014 | 0 | 29 | 0.0 | - |
| 2015 | 1 | 34 | 0.9 | 0.9 |
| 2016 | 10 | 44 | 4.3 | 0.4 |
| 2017 | 2 | 43 | 1.0 | 0.5 |
| 2018 | 2 | 44 | 0.6 | 0.3 |
| 2019 | 4 | 43 | 1.7 | 0.4 |
| 2020 | 2 | 16 | 0.9 | 0.4 |
| 2021 | 0 | 10 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Present** | | | | |
| ***American Indian or Alaska Native*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Asian*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 2 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Black or African American*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 2 | 0.0 | - |
| 2013 | 0 | 2 | 0.0 | - |
| 2014 | 1 | 2 | 0.4 | 0.4 |
| 2015 | 0 | 3 | 0.0 | - |
| 2016 | 2 | 3 | 0.8 | 0.4 |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 1 | 4 | 0.4 | 0.4 |
| 2019 | 1 | 2 | 0.2 | 0.2 |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |

**Table 10. Summary of Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Race and Year[1]**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| ***Native Hawaiian or Other Pacific Islander*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 1 | 1 | 0.0 | 0.0 |
| 2021 | 0 | 0 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 0 | 18 | 0.0 | - |
| 2009 | 0 | 11 | 0.0 | - |
| 2010 | 1 | 22 | 0.2 | 0.2 |
| 2011 | 0 | 19 | 0.0 | - |
| 2012 | 2 | 15 | 0.8 | 0.4 |
| 2013 | 5 | 22 | 2.0 | 0.4 |
| 2014 | 7 | 27 | 2.6 | 0.4 |
| 2015 | 7 | 22 | 2.4 | 0.3 |
| 2016 | 7 | 22 | 2.6 | 0.4 |
| 2017 | 8 | 33 | 3.6 | 0.4 |
| 2018 | 10 | 27 | 5.0 | 0.5 |
| 2019 | 7 | 31 | 3.7 | 0.5 |
| 2020 | 3 | 20 | 1.2 | 0.4 |
| 2021 | 0 | 1 | 0.0 | - |
| ***White*** | | | | |
| 2008 | 2 | 6 | 0.2 | 0.1 |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 3 | 0.0 | - |
| 2011 | 0 | 2 | 0.0 | - |
| 2012 | 0 | 2 | 0.0 | - |
| 2013 | 0 | 3 | 0.0 | - |
| 2014 | 2 | 3 | 0.9 | 0.4 |
| 2015 | 1 | 4 | 0.2 | 0.2 |
| 2016 | 0 | 4 | 0.0 | - |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 2 | 0.0 | - |
| 2020 | 0 | 0 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |

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

[2]Eligible 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 Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021, by Hispanic Origin and Year**

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | |
| **Overall** | | | | |
| ***Yes*** | | | | |
| 2008 | 0 | 6 | 0.0 | - |
| 2009 | 0 | 3 | 0.0 | - |
| 2010 | 0 | 3 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 4 | 0.0 | - |
| 2014 | 0 | 4 | 0.0 | - |
| 2015 | 0 | 4 | 0.0 | - |
| 2016 | 1 | 5 | 0.2 | 0.2 |
| 2017 | 0 | 4 | 0.0 | - |
| 2018 | 0 | 4 | 0.0 | - |
| 2019 | 0 | 5 | 0.0 | - |
| 2020 | 1 | 5 | 0.0 | 0.0 |
| 2021 | 0 | 2 | 0.0 | - |
| ***No*** | | | | |
| 2008 | 6 | 47 | 1.0 | 0.2 |
| 2009 | 0 | 47 | 0.0 | - |
| 2010 | 2 | 58 | 0.5 | 0.2 |
| 2011 | 2 | 56 | 0.3 | 0.2 |
| 2012 | 1 | 55 | 0.2 | 0.2 |
| 2013 | 1 | 54 | 0.6 | 0.6 |
| 2014 | 5 | 54 | 2.4 | 0.5 |
| 2015 | 5 | 61 | 2.1 | 0.4 |
| 2016 | 11 | 69 | 5.3 | 0.5 |
| 2017 | 8 | 72 | 2.7 | 0.3 |
| 2018 | 5 | 68 | 2.0 | 0.4 |
| 2019 | 7 | 65 | 1.6 | 0.2 |
| 2020 | 2 | 17 | 0.9 | 0.4 |
| 2021 | 0 | 11 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 5 | 236 | 1.3 | 0.3 |
| 2009 | 5 | 260 | 1.1 | 0.2 |
| 2010 | 9 | 292 | 2.3 | 0.3 |
| 2011 | 12 | 284 | 4.1 | 0.3 |
| 2012 | 11 | 291 | 3.0 | 0.3 |
| 2013 | 15 | 310 | 5.2 | 0.3 |
| 2014 | 21 | 324 | 7.8 | 0.4 |
| 2015 | 41 | 335 | 16.3 | 0.4 |
| 2016 | 41 | 356 | 18.7 | 0.5 |
| 2017 | 35 | 417 | 14.0 | 0.4 |
| 2018 | 41 | 424 | 18.4 | 0.4 |
| 2019 | 42 | 463 | 18.5 | 0.4 |
| 2020 | 33 | 393 | 10.9 | 0.3 |
| 2021 | 4 | 118 | 0.7 | 0.2 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| ***Yes*** | | | | |
| 2008 | 0 | 2 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 2 | 0.0 | - |
| 2014 | 0 | 2 | 0.0 | - |
| 2015 | 0 | 3 | 0.0 | - |
| 2016 | 1 | 3 | 0.2 | 0.2 |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 2 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***No*** | | | | |
| 2008 | 1 | 16 | 0.2 | 0.2 |
| 2009 | 0 | 18 | 0.0 | - |
| 2010 | 0 | 19 | 0.0 | - |
| 2011 | 2 | 23 | 0.3 | 0.2 |
| 2012 | 0 | 22 | 0.0 | - |
| 2013 | 0 | 21 | 0.0 | - |
| 2014 | 0 | 19 | 0.0 | - |
| 2015 | 0 | 17 | 0.0 | - |
| 2016 | 2 | 21 | 1.0 | 0.5 |
| 2017 | 3 | 25 | 0.7 | 0.2 |
| 2018 | 1 | 21 | 0.5 | 0.5 |
| 2019 | 3 | 24 | 0.7 | 0.2 |
| 2020 | 0 | 4 | 0.0 | - |
| 2021 | 0 | 4 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 1 | 112 | 0.1 | 0.1 |
| 2009 | 0 | 103 | 0.0 | - |
| 2010 | 1 | 105 | 0.2 | 0.2 |
| 2011 | 2 | 106 | 1.4 | 0.7 |
| 2012 | 3 | 109 | 0.9 | 0.3 |
| 2013 | 2 | 111 | 0.7 | 0.4 |
| 2014 | 0 | 126 | 0.0 | - |
| 2015 | 6 | 120 | 2.1 | 0.4 |
| 2016 | 5 | 120 | 1.6 | 0.3 |
| 2017 | 8 | 160 | 2.7 | 0.3 |
| 2018 | 6 | 142 | 2.0 | 0.3 |
| 2019 | 7 | 161 | 1.9 | 0.3 |
| 2020 | 7 | 161 | 3.1 | 0.4 |
| 2021 | 1 | 42 | 0.2 | 0.2 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| ***Yes*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 0 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 2 | 0.0 | - |
| 2018 | 0 | 2 | 0.0 | - |
| 2019 | 0 | 2 | 0.0 | - |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***No*** | | | | |
| 2008 | 0 | 2 | 0.0 | - |
| 2009 | 0 | 2 | 0.0 | - |
| 2010 | 1 | 3 | 0.3 | 0.3 |
| 2011 | 0 | 3 | 0.0 | - |
| 2012 | 0 | 2 | 0.0 | - |
| 2013 | 1 | 3 | 0.6 | 0.6 |
| 2014 | 0 | 2 | 0.0 | - |
| 2015 | 0 | 5 | 0.0 | - |
| 2016 | 2 | 6 | 0.8 | 0.4 |
| 2017 | 1 | 7 | 0.4 | 0.4 |
| 2018 | 1 | 10 | 0.4 | 0.4 |
| 2019 | 1 | 10 | 0.3 | 0.3 |
| 2020 | 0 | 3 | 0.0 | - |
| 2021 | 0 | 2 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 0 | 24 | 0.0 | - |
| 2009 | 2 | 26 | 0.5 | 0.2 |
| 2010 | 1 | 24 | 0.2 | 0.2 |
| 2011 | 2 | 23 | 0.6 | 0.3 |
| 2012 | 0 | 23 | 0.0 | - |
| 2013 | 2 | 27 | 0.6 | 0.3 |
| 2014 | 1 | 28 | 0.3 | 0.3 |
| 2015 | 3 | 24 | 0.9 | 0.3 |
| 2016 | 1 | 28 | 0.3 | 0.3 |
| 2017 | 4 | 51 | 1.2 | 0.3 |
| 2018 | 3 | 60 | 1.6 | 0.5 |
| 2019 | 4 | 63 | 3.4 | 0.9 |
| 2020 | 6 | 74 | 2.2 | 0.4 |
| 2021 | 0 | 21 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| ***Yes*** | | | | |
| 2008 | 0 | 3 | 0.0 | - |
| 2009 | 0 | 2 | 0.0 | - |
| 2010 | 0 | 2 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 1 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 2 | 0.0 | - |
| 2020 | 0 | 2 | 0.0 | - |
| 2021 | 0 | 2 | 0.0 | - |
| ***No*** | | | | |
| 2008 | 3 | 27 | 0.4 | 0.1 |
| 2009 | 0 | 27 | 0.0 | - |
| 2010 | 0 | 32 | 0.0 | - |
| 2011 | 0 | 28 | 0.0 | - |
| 2012 | 0 | 28 | 0.0 | - |
| 2013 | 0 | 24 | 0.0 | - |
| 2014 | 2 | 24 | 0.8 | 0.4 |
| 2015 | 2 | 32 | 0.8 | 0.4 |
| 2016 | 6 | 36 | 2.9 | 0.5 |
| 2017 | 4 | 35 | 1.7 | 0.4 |
| 2018 | 1 | 26 | 0.4 | 0.4 |
| 2019 | 3 | 25 | 0.7 | 0.2 |
| 2020 | 2 | 7 | 0.9 | 0.4 |
| 2021 | 0 | 3 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 4 | 109 | 1.2 | 0.3 |
| 2009 | 2 | 113 | 0.3 | 0.2 |
| 2010 | 6 | 132 | 1.8 | 0.3 |
| 2011 | 4 | 113 | 0.8 | 0.2 |
| 2012 | 7 | 134 | 1.9 | 0.3 |
| 2013 | 8 | 151 | 3.0 | 0.4 |
| 2014 | 14 | 146 | 5.2 | 0.4 |
| 2015 | 27 | 169 | 11.0 | 0.4 |
| 2016 | 28 | 193 | 13.4 | 0.5 |
| 2017 | 19 | 204 | 7.9 | 0.4 |
| 2018 | 29 | 206 | 13.7 | 0.5 |
| 2019 | 21 | 209 | 7.8 | 0.4 |
| 2020 | 15 | 151 | 4.1 | 0.3 |
| 2021 | 3 | 45 | 0.5 | 0.2 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| ***Yes*** | | | | |
| 2008 | 0 | 1 | 0.0 | - |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 1 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 1 | 0.0 | - |
| 2014 | 0 | 1 | 0.0 | - |
| 2015 | 0 | 1 | 0.0 | - |
| 2016 | 0 | 1 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 0 | 0.0 | - |
| 2020 | 1 | 1 | 0.0 | 0.0 |
| 2021 | 0 | 0 | 0.0 | - |
| ***No*** | | | | |
| 2008 | 2 | 5 | 0.5 | 0.2 |
| 2009 | 0 | 5 | 0.0 | - |
| 2010 | 1 | 8 | 0.2 | 0.2 |
| 2011 | 0 | 8 | 0.0 | - |
| 2012 | 1 | 10 | 0.2 | 0.2 |
| 2013 | 0 | 12 | 0.0 | - |
| 2014 | 3 | 15 | 1.6 | 0.5 |
| 2015 | 3 | 17 | 1.4 | 0.5 |
| 2016 | 1 | 15 | 0.5 | 0.5 |
| 2017 | 0 | 18 | 0.0 | - |
| 2018 | 2 | 16 | 0.7 | 0.4 |
| 2019 | 0 | 12 | 0.0 | - |
| 2020 | 0 | 3 | 0.0 | - |
| 2021 | 0 | 3 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 0 | 41 | 0.0 | - |
| 2009 | 1 | 58 | 0.3 | 0.3 |
| 2010 | 1 | 75 | 0.2 | 0.2 |
| 2011 | 4 | 71 | 1.3 | 0.3 |
| 2012 | 1 | 67 | 0.1 | 0.1 |
| 2013 | 3 | 77 | 0.9 | 0.3 |
| 2014 | 6 | 74 | 2.3 | 0.4 |
| 2015 | 5 | 68 | 2.3 | 0.5 |
| 2016 | 7 | 74 | 3.4 | 0.5 |
| 2017 | 4 | 83 | 2.1 | 0.5 |
| 2018 | 3 | 81 | 1.1 | 0.4 |
| 2019 | 10 | 103 | 5.3 | 0.5 |
| 2020 | 5 | 70 | 1.5 | 0.3 |
| 2021 | 0 | 21 | 0.0 | - |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Absent** | | | | |
| ***Yes*** | | | | |
| 2008 | 0 | 6 | 0.0 | - |
| 2009 | 0 | 3 | 0.0 | - |
| 2010 | 0 | 3 | 0.0 | - |
| 2011 | 0 | 1 | 0.0 | - |
| 2012 | 0 | 3 | 0.0 | - |
| 2013 | 0 | 4 | 0.0 | - |
| 2014 | 0 | 4 | 0.0 | - |
| 2015 | 0 | 4 | 0.0 | - |
| 2016 | 1 | 5 | 0.2 | 0.2 |
| 2017 | 0 | 4 | 0.0 | - |
| 2018 | 0 | 4 | 0.0 | - |
| 2019 | 0 | 5 | 0.0 | - |
| 2020 | 0 | 4 | 0.0 | - |
| 2021 | 0 | 2 | 0.0 | - |
| ***No*** | | | | |
| 2008 | 4 | 45 | 0.8 | 0.2 |
| 2009 | 0 | 47 | 0.0 | - |
| 2010 | 1 | 57 | 0.2 | 0.2 |
| 2011 | 1 | 54 | 0.2 | 0.2 |
| 2012 | 1 | 54 | 0.2 | 0.2 |
| 2013 | 1 | 52 | 0.6 | 0.6 |
| 2014 | 2 | 51 | 0.9 | 0.5 |
| 2015 | 4 | 59 | 1.9 | 0.5 |
| 2016 | 11 | 69 | 5.3 | 0.5 |
| 2017 | 8 | 72 | 2.7 | 0.3 |
| 2018 | 5 | 66 | 2.0 | 0.4 |
| 2019 | 5 | 62 | 1.3 | 0.3 |
| 2020 | 2 | 16 | 0.9 | 0.4 |
| 2021 | 0 | 11 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 5 | 229 | 1.3 | 0.3 |
| 2009 | 4 | 250 | 0.8 | 0.2 |
| 2010 | 8 | 284 | 2.1 | 0.3 |
| 2011 | 11 | 276 | 3.9 | 0.4 |
| 2012 | 7 | 282 | 1.4 | 0.2 |
| 2013 | 9 | 300 | 2.8 | 0.3 |
| 2014 | 12 | 312 | 4.4 | 0.4 |
| 2015 | 32 | 322 | 13.2 | 0.4 |
| 2016 | 28 | 332 | 13.4 | 0.5 |
| 2017 | 22 | 392 | 8.6 | 0.4 |
| 2018 | 27 | 402 | 12.4 | 0.5 |
| 2019 | 28 | 439 | 10.9 | 0.4 |
| 2020 | 27 | 379 | 8.9 | 0.3 |
| 2021 | 4 | 118 | 0.7 | 0.2 |

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

| | New Users | Eligible Members[1] | Years at Risk | Average Person-Years at Risk |
|---|---|---|---|---|
| **Hematologic Outcomes: Present** | | | | |
| ***Yes*** | | | | |
| 2008 | 0 | 0 | 0.0 | - |
| 2009 | 0 | 0 | 0.0 | - |
| 2010 | 0 | 0 | 0.0 | - |
| 2011 | 0 | 0 | 0.0 | - |
| 2012 | 0 | 1 | 0.0 | - |
| 2013 | 0 | 0 | 0.0 | - |
| 2014 | 0 | 0 | 0.0 | - |
| 2015 | 0 | 0 | 0.0 | - |
| 2016 | 0 | 0 | 0.0 | - |
| 2017 | 0 | 0 | 0.0 | - |
| 2018 | 0 | 0 | 0.0 | - |
| 2019 | 0 | 1 | 0.0 | - |
| 2020 | 1 | 1 | 0.0 | 0.0 |
| 2021 | 0 | 0 | 0.0 | - |
| ***No*** | | | | |
| 2008 | 2 | 5 | 0.2 | 0.1 |
| 2009 | 0 | 1 | 0.0 | - |
| 2010 | 0 | 3 | 0.0 | - |
| 2011 | 0 | 5 | 0.0 | - |
| 2012 | 0 | 2 | 0.0 | - |
| 2013 | 0 | 3 | 0.0 | - |
| 2014 | 2 | 4 | 1.0 | 0.5 |
| 2015 | 1 | 6 | 0.2 | 0.2 |
| 2016 | 0 | 5 | 0.0 | - |
| 2017 | 0 | 1 | 0.0 | - |
| 2018 | 0 | 2 | 0.0 | - |
| 2019 | 1 | 3 | 0.2 | 0.2 |
| 2020 | 0 | 1 | 0.0 | - |
| 2021 | 0 | 0 | 0.0 | - |
| ***Unknown*** | | | | |
| 2008 | 0 | 20 | 0.0 | - |
| 2009 | 0 | 11 | 0.0 | - |
| 2010 | 1 | 23 | 0.2 | 0.2 |
| 2011 | 0 | 19 | 0.0 | - |
| 2012 | 2 | 17 | 0.8 | 0.4 |
| 2013 | 5 | 24 | 2.0 | 0.4 |
| 2014 | 8 | 28 | 2.8 | 0.3 |
| 2015 | 7 | 23 | 2.4 | 0.3 |
| 2016 | 9 | 25 | 3.4 | 0.4 |
| 2017 | 8 | 35 | 3.6 | 0.4 |
| 2018 | 11 | 29 | 5.4 | 0.5 |
| 2019 | 7 | 31 | 3.7 | 0.5 |
| 2020 | 3 | 21 | 1.2 | 0.4 |
| 2021 | 0 | 1 | 0.0 | - |

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

**Table 12. Summary of Time to the End of the At-Risk Period for the Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Number of Episodes by Episode Length | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
| | Total | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| | 372 | 11 | 3.0% | 7 | 1.9% | 121 | 32.5% | 110 | 29.6% | 114 | 30.6% | 9 | 2.4% |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| | 74 | 0 | 0.0% | 1 | 1.4% | 35 | 47.3% | 21 | 28.4% | 16 | 21.6% | 1 | 1.4% |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| | 24 | 0 | 0.0% | 1 | 4.2% | 4 | 16.7% | 8 | 33.3% | 9 | 37.5% | 2 | 8.3% |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| | 240 | 9 | 3.8% | 4 | 1.7% | 76 | 31.7% | 72 | 30.0% | 74 | 30.8% | 5 | 2.1% |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| | 34 | 2 | 5.9% | 1 | 2.9% | 6 | 17.6% | 9 | 26.5% | 15 | 44.1% | 1 | 2.9% |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| | 270 | 9 | 3.3% | 7 | 2.6% | 84 | 31.1% | 84 | 31.1% | 80 | 29.6% | 6 | 2.2% |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| | 68 | 2 | 2.9% | 0 | 0.0% | 24 | 35.3% | 14 | 20.6% | 27 | 39.7% | 1 | 1.5% |

| Distribution of At-Risk Time in Days, by Episode | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | |
| **Overall** | | | | | | | |
| | 1 | 60 | 136 | 199 | 447 | 139.8 | 85.2 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | |
| | 15 | 60 | 93 | 177 | 447 | 118.3 | 74.7 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | |
| | 25 | 95 | 151 | 214 | 447 | 170.7 | 105.9 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | |
| | 1 | 61 | 140 | 203 | 420 | 140.3 | 84.5 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | |
| | 12 | 80 | 175 | 219 | 402 | 160.7 | 87.4 |
| **Hematologic Outcomes: Absent** | | | | | | | |
| | 1 | 60 | 135 | 197 | 447 | 138.1 | 85.8 |
| **Hematologic Outcomes: Present** | | | | | | | |
| | 12 | 61 | 151 | 208 | 408 | 146.0 | 80.4 |

**Table 13. Summary of Reasons for End of At-Risk Period for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021[1]**

| | | Censoring Reason | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | End of Exposure Episode[2] | | Evidence of Death[3] | | Disenrollment[4] | | End of Data Partner Data[5] | | End of Query Period[6] | |
| | Total | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | |
| | 372 | 302 | 81.2% | 0 | 0.0% | 69 | 18.5% | 23 | 6.2% | 0 | 0.0% |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | |
| | 62 | 51 | 82.3% | 0 | 0.0% | 11 | 17.7% | 4 | 6.5% | 0 | 0.0% |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | |
| | 36 | 27 | 75.0% | 0 | 0.0% | 9 | 25.0% | 6 | 16.7% | 0 | 0.0% |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | |
| | 210 | 170 | 81.0% | 0 | 0.0% | 40 | 19.0% | 11 | 5.2% | 0 | 0.0% |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | |
| | 64 | 54 | 84.4% | 0 | 0.0% | 9 | 14.1% | 2 | 3.1% | 0 | 0.0% |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | |
| | 270 | 215 | 79.6% | 0 | 0.0% | 55 | 20.4% | 20 | 7.4% | 0 | 0.0% |
| **Hematologic Outcomes: Present** | | | | | | | | | | | |
| | 68 | 57 | 83.8% | 0 | 0.0% | 11 | 16.2% | 1 | 1.5% | 0 | 0.0% |

[1]An episode may be censored due to more than one reason if they occur on the same date. Therefore, the sum of the reasons for censoring may be greater than the total number of episodes.

[2]Represents episodes censored due to end of the exposure episode. In as-treated analyses, exposure episodes are defined using days supplied as recorded in outpatient pharmacy dispensing records, and episodes end after days supplied are exhausted or a pre-determined maximum episode duration is met. In point exposure analyses, exposure episodes end when a pre-determined maximum episode duration is met.

[3]Represents episodes censored due to evidence of death. Death data source and completeness varies by Data Partner.

[4]Represents episodes censored due to disenrollment from health plan. Data Partners often artificially assign a "disenrollment" date equal to data end date for members still enrolled on that date. Therefore, a patient may have dual reasons for censoring as "disenrollment" and "end of data" on the same day - this can be interpreted as right-censoring in most cases.

[5]Represents episodes censored due to Data Partner data end date. This end date represents the last day of the most recent year-month in which all of a Data Partner's data tables in the Sentinel Common Data Model have at least 80% of the record count relative to the prior month.

[6]Represents episodes censored due to user-specified study end date.

**Table 14. Summary of Time to the End of the At-Risk Period Due to End Of Exposure Episode for Exposure of Interest in the Sentinel Distributed Database between January 1, 2008 and May 31, 2021**

**End Of Exposure Episode by Episode Length[1]**

| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| | 372 | 302 | 0 | 0.0% | 0 | 0.0% | 104 | 34.4% | 84 | 27.8% | 107 | 35.4% | 7 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| | 62 | 51 | 0 | 0.0% | 0 | 0.0% | 22 | 43.1% | 15 | 29.4% | 14 | 27.5% | 0 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| | 36 | 27 | 0 | 0.0% | 0 | 0.0% | 10 | 37.0% | 7 | 25.9% | 8 | 29.6% | 2 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| | 210 | 170 | 0 | 0.0% | 0 | 26.70% | 56 | 32.9% | 49 | 28.8% | 60 | 35.3% | 5 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| | 64 | 54 | 0 | 0.0% | 0 | 0.0% | 16 | 29.6% | 13 | 24.1% | 25 | 46.3% | 0 |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| | 270 | 215 | 0 | 0.0% | 0 | 0.0% | 71 | 33.0% | 64 | 29.8% | 76 | 35.3% | 4 |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| | 68 | 57 | 0 | 0.0% | 0 | 0.0% | 23 | 40.4% | 9 | 15.8% | 24 | 42.1% | 1 |

**Distribution of At-Risk Time in Days, by Episode**

| Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
|---|---|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | |
| **Overall** | | | | | | |
| 36 | 61 | 145 | 205 | 447 | 148.3 | 82.6 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | |
| 36 | 60 | 96 | 186 | 249 | 120.3 | 66.6 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | |
| 51 | 60 | 115 | 213 | 447 | 153.7 | 104.3 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | |
| 37 | 74 | 152 | 206 | 420 | 152.3 | 84.4 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | |
| 44 | 79 | 176 | 213 | 344 | 159.4 | 74.4 |
| **Hematologic Outcomes: Absent** | | | | | | |
| 36 | 61 | 145 | 203 | 420 | 148.6 | 81.3 |
| **Hematologic Outcomes: Present** | | | | | | |
| 41 | 61 | 154 | 210 | 408 | 148.3 | 81.6 |

[1]Represents episodes censored due to end of the exposure episode. In as-treated analyses, exposure episodes are defined using days supplied as recorded in outpatient pharmacy dispensing records, and episodes end after days supplied are exhausted or a pre-determined maximum episode duration is met. In point exposure analyses, exposure episodes end when a pre-determined maximum episode duration is met.

**Table 15. Summary of Time to End of At-Risk Period Due to Evidence Of Death for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

**Number of Episodes Censored Due to Evidence Of Death by Episode Length[1]**

| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| | 372 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| | 62 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| | 36 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| | 210 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| | 64 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| | 270 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| | 68 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |

**Distribution of At-Risk Time in Days, by Episode**

| | Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
|---|---|---|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | |
| **Overall** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hematologic Outcomes: Absent** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hematologic Outcomes: Present** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

[1]Represents episodes censored due to evidence of death. Death data source and completeness varies by Data Partner.

**Table 16. Summary of Time to End of At-Risk Period Due to Disenrollment for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

**Number of Episodes Censored Due to Disenrollment by Episode Length**

| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Episodes | Total Episodes Censored Due to Disenrollment[1] | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| 372 | 69 | 11 | 15.9% | 7 | 10.1% | 16 | 23.2% | 26 | 37.7% | 7 | 10.1% | 2 | 2.9% |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 62 | 11 | 0 | 0.0% | 0 | 0.0% | 7 | 63.6% | 3 | 27.3% | 0 | 0.0% | 1 | 9.1% |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 36 | 9 | 0 | 0.0% | 2 | 22.2% | 0 | 0.0% | 4 | 44.4% | 3 | 33.3% | 0 | 0.0% |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 210 | 40 | 8 | 20.0% | 4 | 10.00% | 7 | 17.5% | 17 | 42.5% | 4 | 10.0% | 0 | 0.0% |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 64 | 9 | 3 | 33.3% | 1 | 11.1% | 2 | 22.2% | 2 | 22.2% | 0 | 0.0% | 1 | 11.1% |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| 270 | 55 | 9 | 16.4% | 7 | 12.7% | 13 | 23.6% | 20 | 36.4% | 4 | 7.3% | 2 | 3.6% |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| 68 | 11 | 2 | 18.2% | 0 | 0.0% | 1 | 9.1% | 5 | 45.5% | 3 | 27.3% | 0 | 0.0% |

**Distribution of At-Risk Time in Days, by Episode**

| Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
|---|---|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | |
| **Overall** | | | | | | |
| 1 | 30 | 91 | 148 | 447 | 103.2 | 87.8 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | |
| 34 | 59 | 76 | 172 | 447 | 126.9 | 117.9 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | |
| 15 | 95 | 118 | 199 | 248 | 129.4 | 80.5 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | |
| 1 | 24 | 95 | 146 | 240 | 93.4 | 70.4 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | |
| 1 | 14 | 64 | 103 | 402 | 91.9 | 123.8 |
| **Hematologic Outcomes: Absent** | | | | | | |
| 1 | 27 | 78 | 142 | 447 | 97.1 | 91.2 |
| **Hematologic Outcomes: Present** | | | | | | |
| 12 | 89 | 143 | 206 | 240 | 133.9 | 76.2 |

[1]Represents episodes censored due to disenrollment from health plan. Data Partners often artificially assign a "disenrollment" date equal to data end date for members still enrolled on that date. Therefore, a patient may have dual reasons for censoring as "disenrollment" and "end of data" on the same day - this can be interpreted as right-censoring in most cases.

**Table 17. Summary of Time to End of At-Risk Period Due to End Of Data Partner (DP) Data for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Number of Episodes Censored Due to End Of Data Partner (DP) Data by Episode Length | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
| Total Episodes | Total Episodes Censored Due to End of DP Data[1] | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| 372 | 23 | 1 | 4.3% | 4 | 17.4% | 7 | 30.4% | 9 | 39.1% | 2 | 8.7% | 0 | 0.0% |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 62 | 4 | 0 | 0.0% | 0 | 0.0% | 3 | 75.0% | 1 | 25.0% | 0 | 0.0% | 0 | 0.0% |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 36 | 6 | 0 | 0.0% | 1 | 16.7% | 0 | 0.0% | 3 | 50.0% | 2 | 33.3% | 0 | 0.0% |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 210 | 11 | 1 | 9.1% | 3 | 27.3% | 3 | 27.3% | 4 | 36.4% | 0 | 0.0% | 0 | 0.0% |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 64 | 2 | 0 | 0.0% | 0 | 0.0% | 1 | 50.0% | 1 | 50.0% | 0 | 0.0% | 0 | 0.0% |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| 270 | 20 | 1 | 5.0% | 4 | 20.0% | 6 | 30.0% | 7 | 35.0% | 2 | 10.0% | 0 | 0.0% |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| 68 | 1 | 0 | 0.0% | 0 | 0.0% | 0 | 0.0% | 1 | 100.0% | 0 | 0.0% | 0 | 0.0% |

| Distribution of At-Risk Time in Days, by Episode | | | | | | |
|---|---|---|---|---|---|---|
| Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | |
| **Overall** | | | | | | |
| 9 | 33 | 89 | 138 | 248 | 92.9 | 63.2 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | |
| 40 | 58 | 83 | 131 | 173 | 94.5 | 56.3 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | |
| 25 | 95 | 138 | 199 | 248 | 140.3 | 79.0 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | |
| 9 | 29 | 44 | 99 | 155 | 65.6 | 49.9 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | |
| 80 | 80 | 98 | 115 | 115 | 97.5 | 24.7 |
| **Hematologic Outcomes: Absent** | | | | | | |
| 9 | 32 | 84 | 127 | 248 | 89.1 | 66.0 |
| **Hematologic Outcomes: Present** | | | | | | |
| 118 | 118 | 118 | 118 | 118 | 118.0 | N/A |

[1]Represents episodes censored due to Data Partner data end date. This end date represents the last day of the most recent year-month in which all of a Data Partner's data tables in the Sentinel Common Data Model have at least 80% of the record count relative to the prior month.

**Table 18. Summary of Time to End of At-Risk Period Due to End Of Query Period for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Number of Episodes Censored Due to End Of Query Period by Episode Length | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
| Total Episodes | Total Episodes Censored Due to End of Query Period[1] | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| 372 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 62 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 36 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 210 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 64 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| 270 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| 68 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |

| Distribution of At-Risk Time in Days, by Episode | | | | | | |
|---|---|---|---|---|---|---|
| Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | |
| **Overall** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hematologic Outcomes: Absent** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hematologic Outcomes: Present** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |

[1]Represents episodes censored due to user-specified study end date.

Table 19. Summary of Time to End of Observable Data for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021

**Number of Episodes by Observable Time**

| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| | 372 | 11 | 3.0% | 7 | 1.9% | 22 | 5.9% | 35 | 9.4% | 60 | 16.1% | 237 | 63.7% |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| | 62 | 0 | 0.0% | 0 | 0.0% | 8 | 12.9% | 5 | 8.1% | 8 | 12.9% | 41 | 66.1% |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| | 36 | 0 | 0.0% | 2 | 5.6% | 0 | 0.0% | 5 | 13.9% | 6 | 16.7% | 23 | 63.9% |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| | 210 | 8 | 3.8% | 4 | 1.9% | 10 | 4.8% | 22 | 10.5% | 41 | 19.5% | 125 | 59.5% |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| | 64 | 3 | 4.7% | 1 | 1.6% | 4 | 6.3% | 3 | 4.7% | 5 | 7.8% | 48 | 75.0% |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| | 270 | 9 | 3.3% | 7 | 2.6% | 16 | 5.9% | 29 | 10.7% | 40 | 14.8% | 169 | 62.6% |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| | 68 | 2 | 2.9% | 0 | 0.0% | 2 | 2.9% | 5 | 7.4% | 17 | 25.0% | 42 | 61.8% |

**Distribution of Observable Time in Days, by Episode**

| | Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
|---|---|---|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | |
| **Overall** | | | | | | | |
| | 1 | 235 | 528 | 1,163 | 4,111 | 825.8 | 823.6 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | |
| | 34 | 245 | 514 | 1,078 | 3,501 | 777.5 | 746.9 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | |
| | 15 | 218 | 463 | 1,038 | 3,925 | 820.5 | 897.6 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | |
| | 1 | 221 | 554 | 1,107 | 4,111 | 773.4 | 755.0 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | |
| | 1 | 346 | 673 | 1,598 | 4,110 | 1,047.5 | 1,026.6 |
| **Hematologic Outcomes: Absent** | | | | | | | |
| | 1 | 221 | 517 | 1,126 | 4,111 | 811.7 | 850.6 |
| **Hematologic Outcomes: Present** | | | | | | | |
| | 12 | 234 | 680 | 1,418 | 2,434 | 837.8 | 684.1 |

**Table 20. Summary of Reasons for End of Observable Data for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021[1,2]**

| | Censoring Reason | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Evidence of Death[3] | | Disenrollment[4] | | End of Data Partner Data[5] | | End of Query Period[6] | |
| | Total | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | |
| **Overall** | | | | | | | | | |
| | 372 | 0 | 0.0% | 354 | 95.2% | 170 | 45.7% | 0 | 0.0% |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | |
| | 62 | 0 | 0.0% | 59 | 95.2% | 26 | 41.9% | 0 | 0.0% |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | |
| | 36 | 0 | 0.0% | 35 | 97.2% | 14 | 38.9% | 0 | 0.0% |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | |
| | 210 | 0 | 0.0% | 201 | 95.7% | 97 | 46.2% | 0 | 0.0% |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | |
| | 64 | 0 | 0.0% | 59 | 92.2% | 33 | 51.6% | 0 | 0.0% |
| **Hematologic Outcomes: Absent** | | | | | | | | | |
| | 270 | 0 | 0.0% | 259 | 95.9% | 125 | 46.3% | 0 | 0.0% |
| **Hematologic Outcomes: Present** | | | | | | | | | |
| | 68 | 0 | 0.0% | 65 | 95.6% | 29 | 42.6% | 0 | 0.0% |

[1]An episode may be censored due to more than one reason if they occur on the same date. Therefore, the sum of the reasons for censoring may be greater than the total number of episodes.

[2]Time to end of observable data is for characterization purposes only. It does not necessarily represent at-risk time, and does not consider episode end, outcome occurrence, blackout period, or delay risk period start.

[3]Represents episodes censored due to evidence of death. Death data source and completeness varies by Data Partner.

[4]Represents episodes censored due to disenrollment from health plan. Data Partners often artificially assign a "disenrollment" date equal to data end date for members still enrolled on that date. Therefore, a patient may have dual reasons for censoring as "disenrollment" and "end of data" on the same day - this can be interpreted as right-censoring in most cases.

[5]Represents episodes censored due to Data Partner data end date. This end date represents the last day of the most recent year-month in which all of a Data Partner's data tables in the Sentinel Common Data Model have at least 80% of the record count relative to the prior month.

[6]Represents episodes censored due to user-specified study end date.

**Table 21. Summary of Time to End of Observable Data Due to Evidence Of Death for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Number of Episodes Censored Due to Evidence Of Death by Observable Time | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
| Total Episodes | Total Episodes Censored Due to Evidence of Death | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| 372 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 62 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 36 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 210 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 64 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| 270 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| 68 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |

| Distribution of At-Risk Time in Days, by Episode | | | | | | |
|---|---|---|---|---|---|---|
| Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | |
| **Overall** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hematologic Outcomes: Absent** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hematologic Outcomes: Present** | | | | | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |

**Table 22. Summary of Time to End of Observable Data Due to Disenrollment for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| | | Number of Episodes Censored Due to Disenrollment by Observable Time | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
| Total Episodes | Total Episodes Censored Due to Disenrollment[1] | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| 372 | 354 | 11 | 3.1% | 7 | 2.0% | 21 | 5.9% | 35 | 9.9% | 59 | 16.7% | 221 | 62.4% |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 62 | 59 | 0 | 0.0% | 0 | 0.0% | 8 | 13.6% | 5 | 8.5% | 7 | 11.9% | 39 | 66.1% |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 36 | 35 | 0 | 0.0% | 2 | 5.7% | 0 | 0.0% | 5 | 14.3% | 6 | 17.1% | 22 | 62.9% |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 210 | 201 | 8 | 4.0% | 4 | 2.0% | 10 | 5.0% | 22 | 10.9% | 41 | 20.4% | 116 | 57.7% |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 64 | 59 | 3 | 5.1% | 1 | 1.7% | 3 | 5.1% | 3 | 5.1% | 5 | 8.5% | 44 | 74.6% |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| 270 | 259 | 9 | 3.5% | 7 | 2.7% | 16 | 6.2% | 29 | 11.2% | 40 | 15.4% | 158 | 61.0% |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| 68 | 65 | 2 | 3.1% | 0 | 0.0% | 2 | 3.1% | 5 | 7.7% | 17 | 26.2% | 39 | 60.0% |

| | Distribution of Observable Time in Days, by Episode | | | | | | |
|---|---|---|---|---|---|---|---|
| | Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | |
| **Overall** | | | | | | | |
| | 1 | 225 | 518 | 1,107 | 4,111 | 793.6 | 794.3 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | |
| | 34 | 225 | 512 | 1,078 | 3,501 | 772.7 | 752.2 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | |
| | 15 | 207 | 443 | 1,035 | 3,251 | 731.8 | 733.4 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | |
| | 1 | 218 | 529 | 1,012 | 4,111 | 741.9 | 726.4 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | |
| | 1 | 301 | 666 | 1,576 | 4,110 | 1,027.2 | 1,035.4 |
| **Hematologic Outcomes: Absent** | | | | | | | |
| | 1 | 212 | 513 | 1,041 | 4,111 | 787.1 | 837.3 |
| **Hematologic Outcomes: Present** | | | | | | | |
| | 12 | 227 | 610 | 1,164 | 2,325 | 782.4 | 644.7 |

[1]Represents episodes censored due to disenrollment from health plan. Data Partners often artificially assign a "disenrollment" date equal to data end date for members still enrolled on that date. Therefore, a patient may have dual reasons for censoring as "disenrollment" and "end of data" on the same day - this can be interpreted as right-censoring in most cases.

**Table 23. Summary of Time to End of Observable Data Due to End Of Data Partner (DP) Data for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Number of Episodes Censored Due to End Of Data Partner (DP) Data by Observable Time | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
| Total Episodes | Total Episodes Censored Due to End of DP Data[1] | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| 372 | 170 | 1 | 0.6% | 4 | 2.4% | 8 | 4.7% | 12 | 7.1% | 18 | 10.6% | 127 | 74.7% |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 62 | 26 | 0 | 0.0% | 0 | 0.0% | 3 | 11.5% | 2 | 7.7% | 5 | 19.2% | 16 | 61.5% |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 36 | 14 | 0 | 0.0% | 1 | 7.1% | 0 | 0.0% | 3 | 21.4% | 3 | 21.4% | 7 | 50.0% |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 210 | 97 | 1 | 1.0% | 3 | 3.1% | 4 | 4.1% | 6 | 6.2% | 8 | 8.2% | 75 | 77.3% |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 64 | 33 | 0 | 0.0% | 0 | 0.0% | 1 | 3.0% | 1 | 3.0% | 2 | 6.1% | 29 | 87.9% |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| 270 | 125 | 1 | 0.8% | 4 | 3.2% | 7 | 5.6% | 10 | 8.0% | 14 | 11.2% | 89 | 71.2% |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| 68 | 29 | 0 | 0.0% | 0 | 0.0% | 0 | 0.0% | 1 | 3.4% | 2 | 6.9% | 26 | 89.7% |

| Distribution of Observable Time in Days, by Episode | | | | | | |
|---|---|---|---|---|---|---|
| Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | |
| **Overall** | | | | | | |
| 9 | 365 | 829 | 1,582 | 4,111 | 1,081.2 | 919.8 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | |
| 40 | 245 | 463 | 1,105 | 2,989 | 762.3 | 713.9 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | |
| 25 | 157 | 505 | 1,388 | 3,925 | 970.3 | 1,105.9 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | |
| 9 | 423 | 834 | 1,502 | 4,111 | 1,047.3 | 832.7 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | |
| 80 | 592 | 1,434 | 2,051 | 4,110 | 1,479.2 | 1,112.8 |
| **Hematologic Outcomes: Absent** | | | | | | |
| 9 | 309 | 760 | 1,464 | 4,111 | 1,030.9 | 947.1 |
| **Hematologic Outcomes: Present** | | | | | | |
| 118 | 680 | 1,164 | 1,825 | 2,434 | 1,240.6 | 683.6 |

[1]Represents episodes censored due to Data Partner data end date. This end date represents the last day of the most recent year-month in which all of a Data Partner's data tables in the Sentinel Common Data Model have at least 80% of the record count relative to the prior month.

**Table 24. Summary of Time to End of Observable Data Due to End Of Query Period for Exposure of Interest in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

**Number of Episodes Censored Due to End Of Query Period by Observable Time**

| | | 1-14 Days | | 15-30 Days | | 31-90 Days | | 91-180 Days | | 181-365 Days | | 366+ Days | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Episodes | Total Episodes Censored Due to End of Query Period[1] | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | | | | | | | |
| **Overall** | | | | | | | | | | | | | |
| 372 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 62 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | | | | | | | |
| 36 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 210 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | | | | | | | |
| 64 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hematologic Outcomes: Absent** | | | | | | | | | | | | | |
| 270 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |
| **Hematologic Outcomes: Present** | | | | | | | | | | | | | |
| 68 | 0 | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A | 0 | N/A |

**Distribution of At-Risk Time in Days, by Episode**

| | Minimum | Q1 | Median | Q3 | Maximum | Mean | Standard Deviation |
|---|---|---|---|---|---|---|---|
| **Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV)** | | | | | | | |
| **Overall** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hematologic Outcomes: Absent** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| **Hematologic Outcomes: Present** | | | | | | | |
| | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

[1]Represents episodes censored due to user-specified study end date.

**Table 25. Total Code Counts of Valganciclovir (VGCV) Use Among Infants with Congenital CMV (cCMV) in the Sentinel Distributed Database (SDD) between January 1, 2008 and May 31, 2021**

| Code | Code Description | Code Category | Code Type | Overall Counts |
|---|---|---|---|---|
| **Overall** | | | | |
| Valganciclovirhcl | Valganciclovirhcl | Prescription | N/A | 370 |
| Ganciclovir | Ganciclovir | Prescription | N/A | 2 |
| **Hearing Loss: Absent, Clinical Characteristics: Absent** | | | | |
| Valganciclovirhcl | Valganciclovirhcl | Prescription | N/A | 62 |
| **Hearing Loss: Present, Clinical Characteristics: Absent** | | | | |
| Valganciclovirhcl | Valganciclovirhcl | Prescription | N/A | 36 |
| **Hearing Loss: Absent, Clinical Characteristics: Present** | | | | |
| Valganciclovirhcl | Valganciclovirhcl | Prescription | N/A | 208 |
| Ganciclovir | Ganciclovir | Prescription | N/A | 2 |
| **Hearing Loss: Present, Clinical Characteristics: Present** | | | | |
| Valganciclovirhcl | Valganciclovirhcl | Prescription | N/A | 64 |
| **Hematologic Outcomes: Absent** | | | | |
| Valganciclovirhcl | Valganciclovirhcl | Prescription | N/A | 270 |
| **Hematologic Outcomes: Present** | | | | |
| Valganciclovirhcl | Valganciclovirhcl | Prescription | N/A | 66 |
| Ganciclovir | Ganciclovir | Prescription | N/A | 2 |

**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 Exposures 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 Inclusion 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 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 | Presbyacusis | 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 Equip | 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 | 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 E | 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 |
| F0DZ52Z | Assistive Listening Device Device Fitting using Sound Field / Booth | 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 |
|---|---|---|---|
| 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 contrala | 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 |

**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 |
|---|---|---|---|
| **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), unspecifie | Diagnosis | ICD-10-CM |
| H31.021 | Solar retinopathy, right eye | Diagnosis | ICD-10-CM |

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| 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 class | 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 |

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| Code | Description | Code Category | Code Type |
|---|---|---|---|
| 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 |
| **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 |
| 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 Appr | Procedure | ICD-10-PCS |
| 30230P1 | Transfusion of Nonautologous Frozen Red Cells into Peripheral Vein, Open App | 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 Approac | Procedure | ICD-10-PCS |
| 30240P1 | Transfusion of Nonautologous Frozen Red Cells into Central Vein, Open Approa | 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 Ap | Procedure | ICD-10-PCS |
| 30250P1 | Transfusion of Nonautologous Frozen Red Cells into Peripheral Artery, Open Ap | 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 |

**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 |
|---|---|---|---|
| 30260N1 | Transfusion of Nonautologous Red Blood Cells into Central Artery, Open Appro | Procedure | ICD-10-PCS |
| 30260P1 | Transfusion of Nonautologous Frozen Red Cells into Central Artery, Open Appr | 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, eac | Procedure | HCPCS |
| C1020 | Each unit red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, ir | Procedure | HCPCS |
| 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, | 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 @ Plat | 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 @ Platelets | 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 |
|---|---|---|---|
| 30233R1 | Transfusion of Nonautologous Platelets into Peripheral Vein, Percutaneous Apı | Procedure | ICD-10-PCS |
| 30240R | Administration @ Circulatory @ Transfusion @ Central Vein @ Open @ Platele | 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 Appro | Procedure | ICD-10-PCS |
| 30250R | Administration @ Circulatory @ Transfusion @ Peripheral Artery @ Open @ Pl | 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 @ Platelets | Procedure | ICD-10-PCS |
| 30253R1 | Transfusion of Nonautologous Platelets into Peripheral Artery, Percutaneous A | Procedure | ICD-10-PCS |
| 30260R | Administration @ Circulatory @ Transfusion @ Central Artery @ Open @ Plate | 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 Appı | 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 reducec | Procedure | HCPCS |
| C1014 | Platelet, leukoreduced, apheresis/pheresis, each unit | Procedure | HCPCS |
| C1015 | Platelets, pheresis, leukocyte-reduced, CMV negative, irradiated, each unit | Procedure | HCPCS |
| 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 |

**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 |
|---|---|---|---|
| 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 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 | Presbyacusis | 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 |

**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 |
|---|---|---|---|
| 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 |
| 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 |

**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 |
|---|---|---|---|
| H91.20 | 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 |
| 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 | 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 |

**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 |
|---|---|---|---|
| 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** | | | |
| 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 |

**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 |
|---|---|---|---|
| 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 |
| 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 |

**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 |
|---|---|---|---|
| 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 |
| 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 |

**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 |
|---|---|---|---|
| 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 |
| 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 |

**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 |
|---|---|---|---|
| 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 |
| **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 |

**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 |
|---|---|---|---|
| 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 method; cytomegalovirus | 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 |
| 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 | RE |
| **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 | RE |
| 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 Contra | Procedure | ICD-10-PCS |
| B33RZZZ | Magnetic Resonance Imaging (MRI) of Intracranial Arteries | Procedure | ICD-10-PCS |
| **Head Ultrasound** | | | |

**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 |
|---|---|---|---|
| 76536 | Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation | Procedure | CPT-4 |
| 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 |

**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 Categoriza** 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 | 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 |
| 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 | 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 | |
| 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 | |
| 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 | |
| 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 | |

**Appendix G. Specifications Defining Parameters for this Request**

| | Exposure | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Index | Cohort Definition | 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; | 180 days | N/A | N/A | N/A | N/A | N/A | N/A | Yes |
| 7 | cCMV or CMV | First valid exposure episodes during query period; | 180 days | N/A | N/A | N/A | N/A | N/A | N/A | |
| 8 | cCMV or CMV | First valid exposure episodes during query period; | 180 days | N/A | N/A | N/A | N/A | N/A | N/A | |
| 9 | cCMV or CMV | First valid exposure episodes during query period; | 180 days | N/A | N/A | N/A | N/A | N/A | N/A | |
| 10 | cCMV or CMV | First valid exposure episodes during query period; | 180 days | Any care setting | 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 | 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 | 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;<br>*DP end date;<br>*Query end date;<br>*Episode End Date<br>*Disenrollment | Yes |

**Appendix G. Specifications Defining Parameters for this Request**

| | Exposure | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Index | Cohort Definition | 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 |
| 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;<br>*DP end date;<br>*Query end date;<br>*Episode End Date<br>*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;<br>*DP end date;<br>*Query end date;<br>*Episode End Date<br>*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;<br>*DP end date;<br>*Query end date;<br>*Episode End Date<br>*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;<br>*DP end date;<br>*Query end date;<br>*Episode End Date<br>*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;<br>*DP end date;<br>*Query end date;<br>*Episode End Date<br>*Disenrollment | |
| 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;<br>*DP end date;<br>*Query end date;<br>*Episode End Date<br>*Disenrollment | Yes |

**Appendix G. Specifications Defining Parameters for this Request**

| | Exposure | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Scenario | Index | Cohort Definition | 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 |
| 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 | Ever (Prior to Index) | N/A |
| 2 | Hearing Loss | Exclusion | Ever (Prior to Index) | 15 days |
| | Clinical Characteristics | Exclusion | | |
| 3 | Hearing Loss | Inclusion | Ever (Prior to Index) | 15 days |
| | Clinical Characteristics | Exclusion | | |
| 4 | Hearing Loss | Exclusion | Ever (Prior to Index) | 16 days |
| | Clinical Characteristics | Inclusion | | |
| 5 | Hearing Loss | Inclusion | Ever (Prior to Index) | 15 days |
| | Clinical Characteristics | Inclusion | | |
| 6 | N/A | N/A | Ever (Prior to Index) | 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 | 45 days |
| 12 | VGVC or GGVC | Inclusion | 0 | 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 | 180 days |
| 19 | cCMV | Inclusion | Ever (Prior to Index) | 0 days |
| | Any Hematologic Outcomes | Inclusion | 0 | 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**

| 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 |
|---|---|---|---|---|---|---|
| | | | Covariates | | | |
| 4 | N/A | Only applicable for Inpatient and Institutional stays:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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 | N/A | Only applicable for Inpatient and Institutional stays:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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**

| 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 |
|---|---|---|---|---|---|---|
| | | | Covariates | | | |
| 8 | N/A | Only applicable for Inpatient and Institutional stays:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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, Neurologic abnormality | Only applicable for Inpatient and Institutional stays:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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**

| 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 |
|---|---|---|---|---|---|---|
| | | | Covariates | | | |
| 16 | N/A | Only applicable for Inpatient and Institutional stays:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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**

| 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 |
|---|---|---|---|---|---|---|
| | | | Covariates | | | |
| 18 | N/A | Only applicable for Inpatient and Institutional stays:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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 hematologic outcomes include, Neutropenia, Receipt of Rbc transfusion, Receipt of platelet transfusion, Receipt of GCSF transfusion | Only applicable for Inpatient and Institutional stays:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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 hematologic outcomes include, Neutropenia, Receipt of Rbc transfusion, Receipt of platelet transfusion, Receipt of GCSF transfusion | Only applicable for Inpatient and Institutional stays:<br>*Principal;<br>*Secondary;<br>*Unknown | *Washout lookback period should search for evidence of days supply;<br>*Washout lookback period should search for only evidence of a dispensing date | *Count all occurrences of an HOI during exposure period<br>*De-duplicates occurrences of the same event code and code type on the same day<br>*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. Diagram Detailing the Design for this Request

**Cohort D**

- Index on Valganciclovir/Ganciclovir
- Cohort requires no pre-index enrollment, and
  - requires CMV diagnosis prior to and within 45 days after index date for cohorts with disease severity assessments defined by clinical characteristics
  - requires CMV diagnosis prior to and up to index date for cohorts with disease severity defined by hematologic outcomes
- Assessment of Valganciclovir treatement duration

**Disease Severity Assessments**
***Hearing Loss:*** Evaluate hearing loss prior to and including index date
***Clinical Characteristics:*** Evaluate Clinical characteristics prior to and including index date
***Hematologic Outcomes:*** Evaluate Hematologic outcomes from index date up to 180 days after index date.