

## Disclaimer

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

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

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

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

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at [info@sentinelssystem.org](mailto:info@sentinelssystem.org).

## Overview for Request cder\_mpl1p\_wp028

**Request ID:** cder\_mpl1p\_wp028\_nsdv\_v01

**Request Description:** We designed this request to estimate rates of stillbirths and the proportion of those stillbirths that had a select 12 prenatal tests recommended during pregnancy. We previously identified the 12 tests in prior Sentinel analysis (cderr\_mpl1p\_wp019), with promising performance to be used in an algorithm to identify pregnancy start based on gestational age at the time of the test. This report contains estimates of utilization of the 12 selected prenatal tests among a population of women with stillbirths based on a prenatal test-based pregnancy duration algorithm that we developed in the Sentinel Distributed Database (SDD).

**Sentinel Modular Program Tool Used:** Cohort Identification and Descriptive Analysis (CIDA) tool, version 7.3.0 with additional custom programming

**Data Source:** In this report, we included data from January 1, 2006 through November 30, 2018 from 16 Data Partners (DPs) contributing to the SDD. We distributed this request on June 11, 2019. See Appendix A for a list of dates of available data for each DP.

**Study Design:** We designed this request to calculate background rates of prenatal tests of interest. We present data overall and within each of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) eras.

**Event of Interest:** The event of interest was stillbirth, which we defined using ICD-9-CM and ICD-10-CM diagnosis codes. We examined three separate cohorts of women with stillbirths: stillbirth identified via ICD-9-CM and ICD-10-CM codes, stillbirth identified via ICD-9-CM codes only, and stillbirth identified via ICD-10-CM codes only. Please see Appendix B for a list of diagnosis codes used to identify stillbirths. We assessed the incident stillbirth population for each of the three cohorts, which was defined as no stillbirth codes observed in the 140 days prior to first qualifying (index) stillbirth event. We required the index stillbirth event to have occurred in an inpatient care setting.

**Cohort Eligibility Criteria:** We included all valid index stillbirth events that occurred between January 1, 2006 and November 30, 2018. Patients were allowed to contribute multiple stillbirth events. Those included in the cohorts were required to be continuously enrolled in health plans with at least medical coverage for at least 301 days prior to their index date, during which gaps in coverage of up to 45 days were allowed. We included females 15-45 years of age in this analysis.

**Baseline Characteristics:** This report contains baseline tables for patients with stillbirths. The 12 prenatal tests assessed as baseline characteristics were:

1. In vitro fertilization/intrauterine insemination
2. Nuchal translucency measurement
3. Chorionic villus sampling, any method
4. PAPP-A serum test
5. Group B streptococcus screening (genital)
6. Assay of estriol
7. Inhibin A
8. Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA
9. Detailed fetal anatomic examination
10. Alpha-fetoprotein, amniotic
11. Glucose
12. Complete ultrasounds in second and third trimesters

These prenatal tests were defined by Current Procedural Terminology, Fourth Edition (CPT-4) and Healthcare Common Procedure Coding System (HCPCS) procedure codes. Please see Appendix C for a list of codes used to define prenatal tests of interest. We examined prenatal tests of interest during three separate time periods: 224 days, 280 days, and 301 days prior to index date (stillbirth event), and including the index date.

**Overview for Request cder\_mpl1p\_wp028**

Please see Appendices D1 and D2 for the specifications of parameters used in the analyses for this request.

**Limitations:** Algorithms used to define index events, inclusions, exclusions, and characteristics are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

**Notes:** Please contact the Sentinel Operations Center ([info@sentinelsystem.org](mailto:info@sentinelsystem.org)) for questions and to provide comments/suggestions for future enhancements to this document.

## Table of Contents

<b><u>Glossary</u></b>	List of Terms Found in this Report and their Definitions
<b><u>Table 1a</u></b>	Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018
<b><u>Table 1b</u></b>	Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Era in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018
<b><u>Table 1c</u></b>	Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Era in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018
<b><u>Table 2a</u></b>	Number of Presumed Stillbirths by Prenatal Test, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018, by Time Prior to Presumed Stillbirth
<b><u>Table 2b</u></b>	Number of Presumed Stillbirths by Prenatal Test, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018, by Time Prior to Presumed Stillbirth
<b><u>Table 2c</u></b>	Number of Presumed Stillbirths by Prenatal Test, Defined by the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018, by Time Prior to Presumed Stillbirth
<b><u>Table 3</u></b>	Summary of Stillbirth Population, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) in the Sentinel Distributed Database between January 1, 2006 and November 30, 2018, Overall
<b><u>Table 4</u></b>	Summary of Stillbirth Population, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) in the Sentinel Distributed Database between January 1, 2006 and November 30, 2018, by Year
<b><u>Table 5a</u></b>	Frequency Distribution of Stillbirths by Gestational Age, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018
<b><u>Table 5b</u></b>	Frequency Distribution of Stillbirths by Gestational Age, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018
<b><u>Table 5c</u></b>	Frequency Distribution of Stillbirths by Gestational Age, Defined by the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018
<b><u>Appendix A</u></b>	Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 11, 2019)
<b><u>Appendix B</u></b>	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) Diagnoses Codes Used to Define Stillbirth

Table of Contents, Continued	
<b><u>Appendix C</u></b>	List of Current Procedural Terminology, Fourth Edition (CPT-4) and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Prenatal Tests of Interest, by Test Groups
<b><u>Appendix D1</u></b>	Specifications for Parameters for this Request
<b><u>Appendix D2</u></b>	Specifications for Prenatal Tests in this Request

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

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

**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).

**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.

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

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

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

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

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

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

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

**Member-Years** - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

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

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

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

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

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

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

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

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

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

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

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

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

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

\*all terms may not be used in this report

**Table 1a. Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018**

<b>Characteristic<sup>1</sup></b>	<b>Number</b>	
Number of presumed stillbirths	40,484	
Number of unique patients	40,029	
<b>Patient Characteristics</b>	<b>Mean</b>	<b>Standard Deviation</b>
Mean Age (Years)	31	5.8
	<b>Number</b>	<b>Percent</b>
Year		
2006	716	1.8%
2007	1,500	3.7%
2008	1,847	4.6%
2009	3,454	8.5%
2010	3,334	8.2%
2011	3,507	8.7%
2012	3,533	8.7%
2013	3,648	9.0%
2014	3,794	9.4%
2015	4,187	10.3%
2016	4,896	12.1%
2017	4,533	11.2%
2018	1,535	3.8%
<b>Recorded History of Procedure of Interest in the 224 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	1,280	3.2%
Nuchal Translucency Measurement	12,640	31.2%
Chorionic villus sampling, any method	609	1.5%
PAPP-A serum test	9,708	24.0%
Group B streptococcus screening (genital)	10,259	25.3%
Assay of estriol	10,835	26.8%
Inhibin A	10,458	25.8%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	3,101	7.7%
Detailed fetal anatomic examination	18,808	46.5%
Alpha-fetoprotein, amniotic	2,193	5.4%
Glucose	17,960	44.4%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	23,989	59.3%
<b>Recorded History of Procedure of Interest in the 280 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	1,928	4.8%
Nuchal Translucency Measurement	12,652	31.3%
Chorionic villus sampling, any method	612	1.5%
PAPP-A serum test	9,720	24.0%
Group B streptococcus screening (genital)	10,460	25.8%
Assay of estriol	10,858	26.8%
Inhibin A	10,477	25.9%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	3,105	7.7%
Detailed fetal anatomic examination	18,840	46.5%
Alpha-fetoprotein, amniotic	2,196	5.4%
Glucose	18,045	44.6%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	24,054	59.4%



**Table 1a. Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018**

<b>Recorded History of Procedure of Interest in the 301 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	1,960	4.8%
Nuchal Translucency Measurement	12,658	31.3%
Chorionic villus sampling, any method	614	1.5%
PAPP-A serum test	9,725	24.0%
Group B streptococcus screening (genital)	10,535	26.0%
Assay of estriol	10,876	26.9%
Inhibin A	10,492	25.9%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	3,106	7.7%
Detailed fetal anatomic examination	18,858	46.6%
Alpha-fetoprotein, amniotic	2,196	5.4%
Glucose	18,096	44.7%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	24,084	59.5%

<sup>1</sup>All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

**Table 1b. Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Era in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018**

<b>Characteristic<sup>1</sup></b>	<b>Number</b>	
Number of presumed stillbirths	28,028	
Number of unique patients	27,757	
<b>Demographics</b>	<b>Mean</b>	<b>Standard Deviation</b>
Mean Age (Years)	30.9	5.9
	<b>Number</b>	<b>Percent</b>
Year		
2006	716	2.6%
2007	1,500	5.4%
2008	1,847	6.6%
2009	3,454	12.3%
2010	3,334	11.9%
2011	3,507	12.5%
2012	3,533	12.6%
2013	3,648	13.0%
2014	3,794	13.5%
2015	2,695	9.6%
2016	0	0.0%
2017	0	0.0%
2018	0	0.0%
<b>Recorded History of Procedure of Interest in the 224 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	895	3.2%
Nuchal Translucency Measurement	8,404	30.0%
Chorionic villus sampling, any method	453	1.6%
PAPP-A serum test	7,324	26.1%
Group B streptococcus screening (genital)	7,253	25.9%
Assay of estriol	8,585	30.6%
Inhibin A	8,090	28.9%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	249	0.9%
Detailed fetal anatomic examination	13,474	48.1%
Alpha-fetoprotein, amniotic	1,795	6.4%
Glucose	12,341	44.0%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	17,040	60.8%
<b>Recorded History of Procedure of Interest in the 280 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	1,373	4.9%
Nuchal Translucency Measurement	8,411	30.0%
Chorionic villus sampling, any method	455	1.6%
PAPP-A serum test	7,334	26.2%
Group B streptococcus screening (genital)	7,405	26.4%
Assay of estriol	8,602	30.7%
Inhibin A	8,104	28.9%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	249	0.9%
Detailed fetal anatomic examination	13,498	48.2%
Alpha-fetoprotein, amniotic	1,797	6.4%
Glucose	12,398	44.2%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	17,085	61.0%

**Table 1b. Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Era in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018**

<b>Recorded History of Procedure of Interest in the 301 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	1,394	5.0%
Nuchal Translucency Measurement	8,415	30.0%
Chorionic villus sampling, any method	457	1.6%
PAPP-A serum test	7,338	26.2%
Group B streptococcus screening (genital)	7,459	26.6%
Assay of estriol	8,619	30.8%
Inhibin A	8,118	29.0%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	249	0.9%
Detailed fetal anatomic examination	13,512	48.2%
Alpha-fetoprotein, amniotic	1,797	6.4%
Glucose	12,434	44.4%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	17,108	61.0%

<sup>1</sup>All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

**Table 1c. Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) era in the Sentinel Distributed Database (SDD) from January 1, 2006 to November 30, 2018**

<b>Characteristic<sup>1</sup></b>	<b>Number</b>	
Number of presumed stillbirths	12,458	
Number of unique patients	12,374	
<b>Demographics</b>	<b>Mean</b>	<b>Standard Deviation</b>
Mean Age (Years)	31.3	5.7
	<b>Number</b>	<b>Percent</b>
Year		
2006	0	0.0%
2007	0	0.0%
2008	0	0.0%
2009	0	0.0%
2010	0	0.0%
2011	0	0.0%
2012	0	0.0%
2013	0	0.0%
2014	0	0.0%
2015	1,494	12.0%
2016	4,896	39.3%
2017	4,533	36.4%
2018	1,535	12.3%
<b>Recorded History of Procedure of Interest in the 224 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	385	3.1%
Nuchal Translucency Measurement	4,237	34.0%
Chorionic villus sampling, any method	156	1.3%
PAPP-A serum test	2,385	19.1%
Group B streptococcus screening (genital)	3,006	24.1%
Assay of estriol	2,251	18.1%
Inhibin A	2,369	19.0%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,852	22.9%
Detailed fetal anatomic examination	5,335	42.8%
Alpha-fetoprotein, amniotic	398	3.2%
Glucose	5,621	45.1%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	6,950	55.8%
<b>Recorded History of Procedure of Interest in the 280 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	555	4.5%
Nuchal Translucency Measurement	4,242	34.1%
Chorionic villus sampling, any method	157	1.3%
PAPP-A serum test	2,387	19.2%
Group B streptococcus screening (genital)	3,055	24.5%
Assay of estriol	2,257	18.1%
Inhibin A	2,374	19.1%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,856	22.9%
Detailed fetal anatomic examination	5,343	42.9%
Alpha-fetoprotein, amniotic	399	3.2%
Glucose	5,649	45.3%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	6,970	55.9%

**Table 1c. Baseline Characteristics for Incident Stillbirth in the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) era in the Sentinel Distributed Database (SDD) from January 1, 2006 to November 30, 2018**

<b>Recorded History of Procedure of Interest in the 301 Days Prior to Index</b>	<b>Number</b>	<b>Percent</b>
In vitro fertilization/intrauterine insemination	566	4.5%
Nuchal Translucency Measurement	4,244	34.1%
Chorionic villus sampling, any method	157	1.3%
PAPP-A serum test	2,388	19.2%
Group B streptococcus screening (genital)	3,076	24.7%
Assay of estriol	2,258	18.1%
Inhibin A	2,375	19.1%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,857	22.9%
Detailed fetal anatomic examination	5,347	42.9%
Alpha-fetoprotein, amniotic	399	3.2%
Glucose	5,664	45.5%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	6,977	56.0%

<sup>1</sup>All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

**Table 2a. Number of Presumed Stillbirths by Prenatal Test, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018, by Time Prior to Presumed Stillbirth**

Prenatal Test(s) <sup>1,2</sup>	Number of Presumed Stillbirths					
	224 Days Prior to Presumed Stillbirth		280 Days Prior to Presumed Stillbirth		301 Days Prior to Presumed Stillbirth	
	Number	Percent	Number	Percent	Number	Percent
Number of episodes	40,484		40,484		40,484	
Procedure 1	1,280	3.2%	1,928	4.8%	1,960	4.8%
Procedure 1   Test 6	13,197	32.6%	13,491	33.3%	13,510	33.4%
Procedure 1   Test 6   Test 2	13,464	33.3%	13,736	33.9%	13,757	34.0%
Procedure 1   Test 6   Test 2   Test 11	14,418	35.6%	14,672	36.2%	14,693	36.3%
Procedure 1   Test 6   Test 2   Test 11   Test 14	20,870	51.6%	21,142	52.2%	21,213	52.4%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10	25,448	62.9%	25,666	63.4%	25,729	63.6%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13	25,464	62.9%	25,682	63.4%	25,744	63.6%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8	26,636	65.8%	26,842	66.3%	26,901	66.4%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5	31,562	78.0%	31,691	78.3%	31,734	78.4%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9	31,672	78.2%	31,799	78.5%	31,842	78.7%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9   Test 15	34,001	84.0%	34,100	84.2%	34,143	84.3%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9   Test 15   Test 4	37,433	92.5%	37,498	92.6%	37,525	92.7%
No recorded prenatal tests	3,051	7.5%	2,986	7.4%	2,959	7.3%

<sup>1</sup> Refer to Appendix D2 for a list of prenatal procedures and tests

<sup>2</sup> The " | " sign signifies "OR" operator

**Table 2b. Number of Presumed Stillbirths by Prenatal Test, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018, by Time Prior to Presumed Stillbirth**

Prenatal Test(s) <sup>1,2</sup>	Number of Presumed Stillbirths					
	224 Days Prior to Presumed Stillbirth		280 Days Prior to Presumed Stillbirth		301 Days Prior to Presumed Stillbirth	
	Number	Percent	Number	Percent	Number	Percent
Number of episodes	28,028		28,028		28,028	
Procedure 1	895	3.2%	1,373	4.9%	1,394	5.0%
Procedure 1   Test 6	8,800	31.4%	9,016	32.2%	9,027	32.2%
Procedure 1   Test 6   Test 2	9,006	32.1%	9,204	32.8%	9,217	32.9%
Procedure 1   Test 6   Test 2   Test 11	9,769	34.9%	9,952	35.5%	9,965	35.6%
Procedure 1   Test 6   Test 2   Test 11   Test 14	14,408	51.4%	14,615	52.1%	14,668	52.3%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10	18,130	64.7%	18,294	65.3%	18,340	65.4%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13	18,137	64.7%	18,301	65.3%	18,347	65.5%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8	18,237	65.1%	18,397	65.6%	18,442	65.8%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5	21,945	78.3%	22,046	78.7%	22,078	78.8%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9	22,036	78.6%	22,135	79.0%	22,167	79.1%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9   Test 15	23,576	84.1%	23,654	84.4%	23,686	84.5%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9   Test 15   Test 4	26,046	92.9%	26,094	93.1%	26,115	93.2%
No recorded prenatal tests	1,982	7.1%	1,934	6.9%	1,913	6.8%

<sup>1</sup> Refer to Appendix D2 for a list of prenatal procedures and tests

<sup>2</sup> The " | " sign signifies "OR" operator

**Table 2c. Number of Presumed Stillbirths by Prenatal Test, Defined by the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018, by Time Prior to Presumed Stillbirth**

Prenatal Test(s) <sup>1,2</sup>	Number of Presumed Stillbirths					
	224 Days Prior to Presumed Stillbirth		280 Days Prior to Presumed Stillbirth		301 Days Prior to Presumed Stillbirth	
	Number	Percent	Number	Percent	Number	Percent
Number of episodes	12,458		12,458		12,458	
Procedure 1	385	3.1%	555	4.5%	566	4.5%
Procedure 1   Test 6	4,398	35.3%	4,476	35.9%	4,484	36.0%
Procedure 1   Test 6   Test 2	4,459	35.8%	4,533	36.4%	4,541	36.5%
Procedure 1   Test 6   Test 2   Test 11	4,650	37.3%	4,721	37.9%	4,729	38.0%
Procedure 1   Test 6   Test 2   Test 11   Test 14	6,463	51.9%	6,528	52.4%	6,546	52.5%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10	7,319	58.7%	7,373	59.2%	7,390	59.3%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13	7,328	58.8%	7,382	59.3%	7,398	59.4%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8	8,400	67.4%	8,446	67.8%	8,460	67.9%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5	9,619	77.2%	9,647	77.4%	9,658	77.5%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9	9,638	77.4%	9,666	77.6%	9,677	77.7%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9   Test 15	10,427	83.7%	10,448	83.9%	10,459	84.0%
Procedure 1   Test 6   Test 2   Test 11   Test 14   Test 10   Test 13   Test 8   Test 5   Test 9   Test 15   Test 4	11,389	91.4%	11,406	91.6%	11,412	91.6%
No recorded prenatal tests	1,069	8.6%	1,052	8.4%	1,046	8.4%

<sup>1</sup> Refer to Appendix D2 for a list of prenatal procedures and tests

<sup>2</sup> The " | " sign signifies "OR" operator



**Table 3. Summary of Stillbirth Population, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) in the Sentinel Distributed Database between January 1, 2006 and November 30, 2018, Overall**

<b>Code Type</b>	<b>Number of Patients</b>	<b>Number of Presumed Stillbirths</b>	<b>Number of Presumed Stillbirths per Patient</b>
<b>Incident Stillbirth</b>			
ICD-9-CM and ICD-10-CM	40,029	40,484	1.01
ICD-9-CM	27,757	28,028	1.01
ICD-10-CM	12,374	12,458	1.01

<sup>1</sup>For pregnancy episodes that span both the ICD-9-CM and ICD-10-CM eras, the episode as well as the patient are counted in both eras

**Table 4. Summary of Stillbirth Population, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) in the Sentinel Distributed Database between January 1, 2006 and November 30, 2018, by Year**

Year <sup>1</sup>	Number of Patients	Number of Presumed Stillbirths	Number of Presumed Stillbirths per Patient
<b>Incident Stillbirth (ICD-9-CM and ICD-10-CM)</b>			
2006	716	716	1.00
2007	1,498	1,500	1.00
2008	1,844	1,847	1.00
2009	3,451	3,454	1.00
2010	3,330	3,334	1.00
2011	3,506	3,507	1.00
2012	3,531	3,533	1.00
2013	3,645	3,648	1.00
2014	3,789	3,794	1.00
2015	4,182	4,187	1.00
2016	4,890	4,896	1.00
2017	4,524	4,533	1.00
2018	1,535	1,535	1.00
<b>Incident Stillbirth (ICD-9-CM)</b>			
2006	716	716	1.00
2007	1,498	1,500	1.00
2008	1,844	1,847	1.00
2009	3,451	3,454	1.00
2010	3,330	3,334	1.00
2011	3,506	3,507	1.00
2012	3,531	3,533	1.00
2013	3,645	3,648	1.00
2014	3,789	3,794	1.00
2015	2,695	2,695	1.00
2016	0	0	-
2017	0	0	-
2018	0	0	-
<b>Incident Stillbirth (ICD-10-CM)</b>			
2006	0	0	-
2007	0	0	-
2008	0	0	-
2009	0	0	-
2010	0	0	-
2011	0	0	-
2012	0	0	-
2013	0	0	-
2014	0	0	-
2015	1,494	1,494	1.00
2016	4,890	4,896	1.00
2017	4,524	4,533	1.00
2018	1,535	1,535	1.00

<sup>1</sup>For pregnancy episodes that span more than one calendar year, the episode as well as the patient are counted in both years

**Table 5a. Frequency Distribution of Stillbirths by Gestational Age, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018**

Completed Gestational Week <sup>1</sup>	Presumed Stillbirths with Codes Identified in the Previous 224 Days		Presumed Stillbirths with Codes Identified in the Previous 280 Days		Presumed Stillbirths with Codes Identified in the Previous 301 Days	
	Number	Percent <sup>2</sup>	Number	Percent <sup>2</sup>	Number	Percent <sup>2</sup>
<20	5,671	14%	5,586	14%	5,562	14%
20	2,206	5%	2,172	5%	2,164	5%
21	2,060	5%	2,040	5%	2,034	5%
22	1,887	5%	1,862	5%	1,856	5%
23	1,548	4%	1,533	4%	1,521	4%
24	1,111	3%	1,098	3%	1,095	3%
25	903	2%	899	2%	896	2%
26	811	2%	804	2%	799	2%
27	821	2%	816	2%	811	2%
28	799	2%	794	2%	792	2%
29	726	2%	721	2%	718	2%
30	750	2%	747	2%	745	2%
31	839	2%	831	2%	830	2%
32	825	2%	818	2%	816	2%
33	837	2%	826	2%	822	2%
34	893	2%	929	2%	927	2%
35	923	2%	949	2%	946	2%
36	1,960	5%	1,982	5%	1,977	5%
37	2,127	5%	2,133	5%	2,130	5%
38	2,648	7%	2,662	7%	2,656	7%
39	3,029	7%	2,990	7%	2,985	7%
40	1,993	5%	1,967	5%	1,964	5%
41	809	2%	794	2%	793	2%
≥42	1,257	3%	1,545	4%	1,686	4%

<sup>1</sup> Rounded down to completed week

<sup>2</sup> Percentage is calculated of the total number of presumed stillbirths with a prenatal test of interest (denominator)

**Table 5b. Frequency Distribution of Stillbirths by Gestational Age, Defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018**

Completed Gestational Week <sup>1</sup>	Presumed Stillbirths with Codes Identified in the Previous 224 Days		Presumed Stillbirths with Codes Identified in the Previous 280 Days		Presumed Stillbirths with Codes Identified in the Previous 301 Days	
	Number	Percent <sup>2</sup>	Number	Percent <sup>2</sup>	Number	Percent <sup>2</sup>
<20	3,535	13%	3,484	12%	3,467	12%
20	1,500	5%	1,474	5%	1,467	5%
21	1,387	5%	1,374	5%	1,370	5%
22	1,313	5%	1,292	5%	1,288	5%
23	1,146	4%	1,133	4%	1,121	4%
24	810	3%	798	3%	796	3%
25	685	2%	683	2%	682	2%
26	603	2%	596	2%	592	2%
27	606	2%	603	2%	599	2%
28	609	2%	605	2%	603	2%
29	538	2%	534	2%	531	2%
30	539	2%	537	2%	535	2%
31	605	2%	599	2%	599	2%
32	609	2%	605	2%	603	2%
33	617	2%	608	2%	605	2%
34	658	2%	687	2%	685	2%
35	663	2%	677	2%	674	2%
36	1,416	5%	1,434	5%	1,430	5%
37	1,498	5%	1,501	5%	1,499	5%
38	1,823	7%	1,836	7%	1,834	7%
39	2,044	7%	2,014	7%	2,010	7%
40	1,327	5%	1,310	5%	1,308	5%
41	562	2%	555	2%	555	2%
≥42	953	3%	1,155	4%	1,262	5%

<sup>1</sup> Rounded down to completed week

<sup>2</sup> Percentage is calculated of the total number of presumed stillbirths with a prenatal test of interest (denominator)

**Table 5c. Frequency Distribution of Stillbirths by Gestational Age, Defined by the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database from January 1, 2006 to November 30, 2018**

Completed Gestational Week <sup>1</sup>	Presumed Stillbirths with Codes Identified in the Previous 224 Days		Presumed Stillbirths with Codes Identified in the Previous 280 Days		Presumed Stillbirths with Codes Identified in the Previous 301 Days	
	Number	Percent <sup>2</sup>	Number	Percent <sup>2</sup>	Number	Percent <sup>2</sup>
<20	2,136	17%	2,102	17%	2,095	17%
20	706	6%	698	6%	697	6%
21	673	5%	666	5%	664	5%
22	574	5%	570	5%	568	5%
23	402	3%	400	3%	400	3%
24	301	2%	300	2%	299	2%
25	218	2%	216	2%	214	2%
26	208	2%	208	2%	207	2%
27	215	2%	213	2%	212	2%
28	190	2%	189	2%	189	2%
29	188	2%	187	2%	187	2%
30	211	2%	210	2%	210	2%
31	234	2%	232	2%	231	2%
32	217	2%	214	2%	214	2%
33	220	2%	218	2%	217	2%
34	235	2%	242	2%	242	2%
35	260	2%	272	2%	272	2%
36	544	4%	548	4%	547	4%
37	629	5%	632	5%	631	5%
38	826	7%	827	7%	823	7%
39	985	8%	976	8%	975	8%
40	666	5%	657	5%	656	5%
41	247	2%	239	2%	238	2%
≥42	304	2%	390	3%	424	3%

<sup>1</sup> Rounded down to completed week

<sup>2</sup> Percentage is calculated of the total number of presumed stillbirths with a prenatal test of interest (denominator)

**Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 11, 2019)**

---

DP ID	Start Date <sup>1</sup>	End Date <sup>1</sup>
DP01	01/01/2000	07/31/2017
DP02	01/01/2000	03/31/2018
DP03	01/01/2004	08/31/2018
DP04	01/01/2008	11/30/2018
DP05	01/01/2000	06/30/2018
DP06	01/01/2000	12/31/2017
DP07	01/01/2006	05/31/2018
DP08	01/01/2000	12/31/2017
DP09	06/01/2007	07/31/2018
DP10	01/01/2000	03/31/2016
DP11	01/01/2005	09/30/2017
DP12	01/01/2000	06/30/2018
DP13	01/01/2000	03/31/2018
DP14	01/01/2008	12/31/2017
DP15	01/01/2000	04/30/2018
DP16	01/01/2012	06/30/2017

<sup>1</sup> 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 International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnoses Codes Used to Define Stillbirth**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>
646.01	Papyraceous fetus, delivered, with or without mention antepartum condition	ICD-9-CM
656.4	Intrauterine death affecting management of mother	ICD-9-CM
768	Fetal death from asphyxia or anoxia before onset of labor/at unspecified time	ICD-9-CM
768.1	Fetal death from asphyxia or anoxia during labor	ICD-9-CM
V27.1	Single stillborn	ICD-9-CM
V27.3	Twins, one liveborn and one stillborn	ICD-9-CM
V27.4	Twins, both stillborn	ICD-9-CM
V27.6	Other multiple birth, some liveborn	ICD-9-CM
V27.7	Other multiple birth, all stillborn	ICD-9-CM
V32.x	Twin birth mate stillborn	ICD-9-CM
V35.x	Other multiple birth mates all stillborn	ICD-9-CM
V36.x	Other multiple birth mates liveborn and stillborn	ICD-9-CM
O36.4	Maternal care for intrauterine death	ICD-10-CM
Z37.1	Single stillbirth	ICD-10-CM
Z37.3	Twins, one liveborn and one stillborn, pregnancy resulting from both spontaneous ovulation and conception	ICD-10-CM
Z37.4	Twins, both stillborn	ICD-10-CM
Z37.6	Other multiple births, some liveborn	ICD-10-CM
Z37.7	Other multiple births, all stillborn	ICD-10-CM
P95	Stillbirth (may be on newborn record, not mother's)	ICD-10-CM
O31.00X0	Papyraceous fetus, unspecified trimester, not applicable or unspecified	ICD-10-CM
O31.00X1	Papyraceous fetus, unspecified trimester, fetus 1	ICD-10-CM
O31.00X2	Papyraceous fetus, unspecified trimester, fetus 2	ICD-10-CM
O31.00X3	Papyraceous fetus, unspecified trimester, fetus 3	ICD-10-CM
O31.00X4	Papyraceous fetus, unspecified trimester, fetus 4	ICD-10-CM
O31.00X5	Papyraceous fetus, unspecified trimester, fetus 5	ICD-10-CM
O31.00X9	Papyraceous fetus, unspecified trimester, other fetus	ICD-10-CM
O31.02X0	Papyraceous fetus, second trimester, not applicable or unspecified	ICD-10-CM
O31.02X1	Papyraceous fetus, second trimester, fetus 1	ICD-10-CM
O31.02X2	Papyraceous fetus, second trimester, fetus 2	ICD-10-CM
O31.02X3	Papyraceous fetus, second trimester, fetus 3	ICD-10-CM
O31.02X4	Papyraceous fetus, second trimester, fetus 4	ICD-10-CM
O31.02X5	Papyraceous fetus, second trimester, fetus 5	ICD-10-CM
O31.02X9	Papyraceous fetus, second trimester, other fetus	ICD-10-CM
O31.03X0	Papyraceous fetus, third trimester, not applicable or unspecified	ICD-10-CM
O31.03X1	Papyraceous fetus, third trimester, fetus 1	ICD-10-CM
O31.03X2	Papyraceous fetus, third trimester, fetus 2	ICD-10-CM
O31.03X3	Papyraceous fetus, third trimester, fetus 3	ICD-10-CM
O31.03X4	Papyraceous fetus, third trimester, fetus 4	ICD-10-CM
O31.03X5	Papyraceous fetus, third trimester, fetus 5	ICD-10-CM
O31.03X9	Papyraceous fetus, third trimester, other fetus	ICD-10-CM

**Appendix C. List of Current Procedural Terminology, Fourth Edition (CPT-4) and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Prenatal Tests of Interest, by Test Groups**

Code	Description	Code Type	Gestational Days (Test-based Pregnancy Start)
<b>Procedure 1: In vitro fertilization/intrauterine insemination</b>			
58321	Artificial insemination; intra-cervical	CPT-4	14
58322	Artificial insemination	CPT-4	14
58974	Transfer of embryo	CPT-4	14
58976	Gamete, zygote, or embryo intrafallopian transfer	CPT-4	14
S4011	In vitro fertilization	HCPCS	14
S4013	Complete cycle gift case rate	HCPCS	14
S4014	Complete cycle zift case rate	HCPCS	14
S4015	Complete in vitro fertilization cycle case rate not otherwise specified	HCPCS	14
S4016	Frozen in vitro fertilization cycle case rate	HCPCS	14
S4035	Stimulated intrauterine insemination (IUI), case rate	HCPCS	14
S4037	Cryopreserved embryo transfer, case rate	HCPCS	14
<b>Test 2: Chorionic villus sampling, any method</b>			
59015	Chorionic villus sampling, any method	CPT-4	84
<b>Test 4: Complete Ultrasounds (Maternal and Fetal Evaluation); Second and Third Trimesters</b>			
76805	Complete ultrasounds (maternal and fetal evaluation); second and third trimesters (single or first gestation)	CPT-4	128
76810	Complete ultrasounds (maternal and fetal evaluation); second and third trimesters (each additional gestation)	CPT-4	128
<b>Test 5: Detailed fetal anatomic examination</b>			
76811	Detailed fetal anatomic examination (single or first gestation)	CPT-4	138
76812	Detailed fetal anatomic examination (Each additional Gestation)	CPT-4	138
<b>Test 6: Nuchal Translucency Measurement</b>			
76813	Nuchal translucency measurement (single or first gestation)	CPT-4	88
76814	Nuchal translucency measurement (each additional gestation)	CPT-4	88
<b>Test 8: Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA</b>			
81420	Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	CPT-4	85
<b>Test 9: Alpha-fetoprotein, amniotic</b>			
82106	Alpha-fetoprotein, amniotic	CPT-4	120
<b>Test 10: Assay of estriol</b>			
82677	Assay of estriol	CPT-4	119
<b>Test 11: PAPP-A serum test</b>			
84163	PAPP-A serum test	CPT-4	85
<b>Test 13: Inhibin A</b>			
86336	Inhibin A	CPT-4	119
<b>Test 14: Group B streptococcus screening (genital)</b>			
87081	Group B streptococcus screening (genital)	CPT-4	252
<b>Test 15: Glucose</b>			
82950	Glucose; post glucose dose (includes glucose)	CPT-4	190
82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)	CPT-4	190



### Appendix D1. Specifications for Parameters for this Request

We designed this request to estimate rates of stillbirths and the proportion of those stillbirths that had a select 12 prenatal tests recommended during pregnancy. We previously identified the 12 tests in prior Sentinel analysis (cder\_mpl1p\_wp019), with promising performance to be used in an algorithm to identify pregnancy start based on gestational age at the time of the test. Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool will be used for this Level 1+ Type 1 analysis to examine the prevalence of the prenatal test codes in the population of potential stillbirths in Sentinel Distributed Database (SDD).

**Query Period:** January 1, 2006 - November 30, 2018

**Coverage Requirement:** Medical coverage

**Pre-index enrollment requirement:** 301 days

**Post-index enrollment requirement:** None

**Enrollment Gap:** 45 days

**Age groups:** 15-45 years

**Stratifications:** Calendar year

**Sex:** Female

**Envelope macro:** Reclassify encounters during inpatient stay as inpatient

**Plus Components:** 1) Prenatal tests hierarchy; 2) Calculation of gestational age and estimated pregnancy starts

Scenario	Exposure/Event				Baseline Characteristics				
	Index Event	Care Setting	Cohort Definition	Washout Period (Days)	Incidence Criteria	Incidence Care Setting	Characteristics (Prenatal Tests)	Care Setting	Evaluation Window
1	Stillbirth (International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM))	Inpatient	Include all valid index dates per individual	140	ICD-9-CM or ICD-10-CM	Any	See Appendix D2	Any	See Appendix D2
2	Stillbirth (ICD-9-CM)	Inpatient	Include all valid index dates per individual	140	ICD-9-CM	Any	See Appendix D2	Any	See Appendix D2
3	Stillbirth (ICD-10-CM)	Inpatient	Include all valid index dates per individual	140	ICD-10-CM	Any	See Appendix D2	Any	See Appendix D2

**Appendix D2. Specifications for Prenatal Tests in this Request**

<b>Group</b>	<b>Care Setting</b>	<b>Evaluation Period 1</b>	<b>Evaluation Period 2</b>	<b>Evaluation Period 3</b>
Procedure 1: In vitro fertilization/intrauterine insemination	Any	-224, 0	-280, 0	-301, 0
Test 6: Nuchal Translucency Measurement	Any	-224, 0	-280, 0	-301, 0
Test 2: Chorionic villus sampling, any method	Any	-224, 0	-280, 0	-301, 0
Test 11: PAPP-A serum test	Any	-224, 0	-280, 0	-301, 0
Test 14: Group B streptococcus screening (genital)	Any	-224, 0	-280, 0	-301, 0
Test 10: Assay of estriol	Any	-224, 0	-280, 0	-301, 0
Test 13: Inhibin A	Any	-224, 0	-280, 0	-301, 0
Test 8: Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	Any	-224, 0	-280, 0	-301, 0
Test 5: Detailed fetal anatomic examination	Any	-224, 0	-280, 0	-301, 0
Test 9: Alpha-fetoprotein, amniotic	Any	-224, 0	-280, 0	-301, 0
Test 15: Glucose	Any	-224, 0	-280, 0	-301, 0
Test 4: Complete Ultrasounds (Maternal and Fetal Evaluation); Second and Third Trimesters	Any	-224, 0	-280, 0	-301, 0