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, post market 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_wp120

Request ID: cder_mpl1r_wp120_nsdp_v01

Request Description: We conducted this exploratory analysis to examine stillbirths and the proportion of those stillbirths that had a select 12 prenatal tests recommended during pregnancy. In a prior Sentinel analysis (cder_mpl1p_wp019), these 12 tests had been identified 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 in the Sentinel Distributed Database (SDD).

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 6.0.0.

Data Source: We included data from 16 Data Partners contributing to the SDD in this report. We distributed this request to the Data Partners on January 7, 2019 and included data from January 1, 2006 to June 30, 2018. See Appendix A for a list of dates of available data for each Data Partner.

Study Design: We designed this request to calculate background rates of prenatal tests of interest among pregnancies resulting in stillbirths. 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. Data were further stratified by year.

Event of Interest: The event of interest was stillbirth, which we defined using ICD-9-CM and ICD-10-CM diagnosis codes. We assessed incident and prevalent stillbirth populations separately. Incidence was defined as no stillbirth observed in the 140 days prior to the first qualifying (index) stillbirth event. Please see Appendix B for specific codes used to define stillbirth in this request.

Cohort Eligibility Criteria: We included females 15-45 years of age in the analysis. Eligible members were required to be enrolled in health plans with medical coverage for the duration of the baseline characteristics evaluation windows (224 and 280 days prior to and including the index date), with allowable gaps in coverage of up to 45 days.

Baseline Characteristics: This report contains baseline descriptive statistics for patients with stillbirths. We assessed members' medical history for 12 prenatal tests prior to baseline. These 12 prenatal tests 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 and were examined during two separate time periods: 224 days prior and 280 days prior to index date (stillbirth event), and including the index date. The prenatal tests were assessed separately and in combination. Please refer to Appendix C for specific codes used to define the baseline characteristics.

Please refer to Appendix D1 and Appendix D2 for detailed 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.

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

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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 Stillbirths, Defined by 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 (SDD) from January 1, 2006 to June 30, 2018

Characteristic[1]	Number	
Number of presumed stillbirths	40,342	
Number of unique patients	39,897	
Patient Characteristics	**Mean**	**Standard Deviation**
Mean Age (Years)	31.0	5.8
	Number	**Percent**
Age (Years)		
15-45	40,342	100.0%
Sex		
Female	39,897	100.0%
Year		
2006	771	1.9%
2007	1,532	3.8%
2008	2,004	5.0%
2009	3,534	8.8%
2010	3,406	8.4%
2011	3,601	8.9%
2012	3,626	9.0%
2013	3,731	9.2%
2014	3,875	9.6%
2015	4,293	10.6%
2016	4,980	12.3%
2017	4,100	10.2%
2018	889	2.2%
Recorded History of Procedure of Interest in the 224 Days Prior to Index	**Number**	**Percent**
In vitro fertilization/intrauterine insemination	1,268	3.1%
Nuchal Translucency Measurement	12,542	31.1%
Chorionic villus sampling, any method	599	1.5%
PAPP-A serum test	9,751	24.2%
Group B streptococcus screening (genital)	10,293	25.5%
Assay of estriol	10,942	27.1%
Inhibin A	10,550	26.2%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,772	6.9%
Detailed fetal anatomic examination	18,776	46.5%
Alpha-fetoprotein, amniotic	2,204	5.5%
Glucose	17,965	44.5%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	23,925	59.3%

Table 1a. Baseline Characteristics for Incident Stillbirths, Defined by 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 (SDD) from January 1, 2006 to June 30, 2018

Recorded History of Procedure of Interest in the 280 Days Prior to Index	Number	Percent
In vitro fertilization/intrauterine insemination	1,918	4.8%
Nuchal Translucency Measurement	12,555	31.1%
Chorionic villus sampling, any method	602	1.5%
PAPP-A serum test	9,764	24.2%
Group B streptococcus screening (genital)	10,490	26.0%
Assay of estriol	10,966	27.2%
Inhibin A	10,569	26.2%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,774	6.9%
Detailed fetal anatomic examination	18,807	46.6%
Alpha-fetoprotein, amniotic	2,207	5.5%
Glucose	18,048	44.7%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	23,991	59.5%

[1]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 Stillbirths, Defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes in the Sentinel Distributed Database (SDD) from January 1, 2006 to June 30, 2018

Characteristic[1]	Number	
Number of presumed stillbirths	28,827	
Number of unique patients	28,551	
Patient Characteristics	**Mean**	**Standard Deviation**
Mean Age (Years)	30.9	5.9
	Number	**Percent**
Age (Years)		
15-45	28,827	100.0%
Sex		
Female	28,551	100.0%
Year		
2006	771	2.7%
2007	1,532	5.3%
2008	2,004	7.0%
2009	3,534	12.3%
2010	3,406	11.8%
2011	3,601	12.5%
2012	3,626	12.6%
2013	3,731	12.9%
2014	3,875	13.4%
2015	2,747	9.5%
2016	0	0.0%
2017	0	0.0%
2018	0	0.0%
Recorded History of Procedure of Interest in the 224 Days Prior to Index	**Number**	**Percent**
In vitro fertilization/intrauterine insemination	921	3.2%
Nuchal Translucency Measurement	8,646	30.0%
Chorionic villus sampling, any method	464	1.6%
PAPP-A serum test	7,524	26.1%
Group B streptococcus screening (genital)	7,475	25.9%
Assay of estriol	8,836	30.7%
Inhibin A	8,330	28.9%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	256	0.9%
Detailed fetal anatomic examination	13,855	48.1%
Alpha-fetoprotein, amniotic	1,835	6.4%
Glucose	12,704	44.1%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	17,493	60.7%

Table 1b. Baseline Characteristics for Incident Stillbirths, Defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes in the Sentinel Distributed Database (SDD) from January 1, 2006 to June 30, 2018

Recorded History of Procedure of Interest in the 280 Days Prior to Index	Number	Percent
In vitro fertilization/intrauterine insemination	1,415	4.9%
Nuchal Translucency Measurement	8,653	30.0%
Chorionic villus sampling, any method	466	1.6%
PAPP-A serum test	7,534	26.1%
Group B streptococcus screening (genital)	7,631	26.5%
Assay of estriol	8,854	30.7%
Inhibin A	8,344	28.9%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	256	0.9%
Detailed fetal anatomic examination	13,880	48.1%
Alpha-fetoprotein, amniotic	1,837	6.4%
Glucose	12,763	44.3%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	17,543	60.9%

[1]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 Stillbirths, Defined by International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database (SDD) from January 1, 2006 to June 30, 2018

Characteristic[1]	Number	
Number of presumed stillbirths	11,517	
Number of unique patients	11,444	
Patient Characteristics	**Mean**	**Standard Deviation**
Mean Age (Years)	31.3	5.7
	Number	**Percent**
Age (Years)		
15-45	11,517	100.0%
Sex		
Female	11,444	100.0%
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	1,548	13.4%
2016	4,980	43.2%
2017	4,100	35.6%
2018	889	7.7%
Recorded History of Procedure of Interest in the 224 Days Prior to Index	**Number**	**Percent**
In vitro fertilization/intrauterine insemination	347	3.0%
Nuchal Translucency Measurement	3,897	33.8%
Chorionic villus sampling, any method	135	1.2%
PAPP-A serum test	2,228	19.3%
Group B streptococcus screening (genital)	2,818	24.5%
Assay of estriol	2,107	18.3%
Inhibin A	2,221	19.3%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,516	21.8%
Detailed fetal anatomic examination	4,922	42.7%
Alpha-fetoprotein, amniotic	369	3.2%
Glucose	5,263	45.7%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	6,433	55.9%

Table 1c. Baseline Characteristics for Incident Stillbirths, Defined by International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database (SDD) from January 1, 2006 to June 30, 2018

Recorded History of Procedure of Interest in the 280 Days Prior to Index	Number	Percent
In vitro fertilization/intrauterine insemination	503	4.4%
Nuchal Translucency Measurement	3,903	33.9%
Chorionic villus sampling, any method	136	1.2%
PAPP-A serum test	2,231	19.4%
Group B streptococcus screening (genital)	2,859	24.8%
Assay of estriol	2,113	18.3%
Inhibin A	2,226	19.3%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,518	21.9%
Detailed fetal anatomic examination	4,928	42.8%
Alpha-fetoprotein, amniotic	370	3.2%
Glucose	5,287	45.9%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	6,449	56.0%

[1]All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

Table 1d. Baseline Characteristics for Prevalent Stillbirths, Defined by 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 (SDD) from January 1, 2006 to June 30, 2018

Characteristic[1]	Number	
Number of presumed stillbirths	41,467	
Number of unique patients	40,562	
Patient Characteristics	**Mean**	**Standard Deviation**
Mean Age (Years)	31.0	5.8
	Number	**Percent**
Age (Years)		
15-45	41,467	100.0%
Sex		
Female	40,562	100.0%
Year		
2006	788	1.9%
2007	1,550	3.7%
2008	2,055	5.0%
2009	3,637	8.8%
2010	3,477	8.4%
2011	3,685	8.9%
2012	3,712	9.0%
2013	3,804	9.2%
2014	4,000	9.6%
2015	4,396	10.6%
2016	5,170	12.5%
2017	4,277	10.3%
2018	916	2.2%
Recorded History of Procedure of Interest in the 224 Days Prior to Index	**Number**	**Percent**
In vitro fertilization/intrauterine insemination	1,319	3.2%
Nuchal Translucency Measurement	12,909	31.1%
Chorionic villus sampling, any method	609	1.5%
PAPP-A serum test	10,034	24.2%
Group B streptococcus screening (genital)	10,492	25.3%
Assay of estriol	11,228	27.1%
Inhibin A	10,830	26.1%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,871	6.9%
Detailed fetal anatomic examination	19,293	46.5%
Alpha-fetoprotein, amniotic	2,250	5.4%
Glucose	18,390	44.3%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	24,588	59.3%

Table 1d. Baseline Characteristics for Prevalent Stillbirths, Defined by 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 (SDD) from January 1, 2006 to June 30, 2018

Recorded History of Procedure of Interest in the 280 Days Prior to Index	Number	Percent
In vitro fertilization/intrauterine insemination	1,984	4.8%
Nuchal Translucency Measurement	12,922	31.2%
Chorionic villus sampling, any method	612	1.5%
PAPP-A serum test	10,047	24.2%
Group B streptococcus screening (genital)	10,692	25.8%
Assay of estriol	11,252	27.1%
Inhibin A	10,849	26.2%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,873	6.9%
Detailed fetal anatomic examination	19,325	46.6%
Alpha-fetoprotein, amniotic	2,253	5.4%
Glucose	18,477	44.6%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	24,657	59.5%

[1]All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

Table 1e. Baseline Characteristics for Prevalent Stillbirths, Defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes in the Sentinel Distributed Database (SDD) from January 1, 2006 to June 30, 2018

Characteristic[1]	Number	
Number of presumed stillbirths	29,523	
Number of unique patients	28,928	
Patient Characteristics	**Mean**	**Standard Deviation**
Mean Age (Years)	30.9	5.9
	Number	**Percent**
Age (Years)		
15-45	29,523	100.0%
Sex		
Female	28,928	100.0%
Year		
2006	788	2.7%
2007	1,550	5.3%
2008	2,055	7.0%
2009	3,637	12.3%
2010	3,477	11.8%
2011	3,685	12.5%
2012	3,712	12.6%
2013	3,804	12.9%
2014	4,000	13.5%
2015	2,815	9.5%
2016	0	0.0%
2017	0	0.0%
2018	0	0.0%
Recorded History of Procedure of Interest in the 224 Days Prior to Index	**Number**	**Percent**
In vitro fertilization/intrauterine insemination	956	3.2%
Nuchal Translucency Measurement	8,862	30.0%
Chorionic villus sampling, any method	472	1.6%
PAPP-A serum test	7,713	26.1%
Group B streptococcus screening (genital)	7,595	25.7%
Assay of estriol	9,040	30.6%
Inhibin A	8,526	28.9%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	257	0.9%
Detailed fetal anatomic examination	14,177	48.0%
Alpha-fetoprotein, amniotic	1,870	6.3%
Glucose	12,959	43.9%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	17,918	60.7%

Table 1e. Baseline Characteristics for Prevalent Stillbirths, Defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes in the Sentinel Distributed Database (SDD) from January 1, 2006 to June 30, 2018

Recorded History of Procedure of Interest in the 280 Days Prior to Index	Number	Percent
In vitro fertilization/intrauterine insemination	1,461	4.9%
Nuchal Translucency Measurement	8,869	30.0%
Chorionic villus sampling, any method	474	1.6%
PAPP-A serum test	7,723	26.2%
Group B streptococcus screening (genital)	7,752	26.3%
Assay of estriol	9,058	30.7%
Inhibin A	8,540	28.9%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	257	0.9%
Detailed fetal anatomic examination	14,203	48.1%
Alpha-fetoprotein, amniotic	1,872	6.3%
Glucose	13,021	44.1%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	17,970	60.9%

[1]All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

Table 1f. Baseline Characteristics for Prevalent Stillbirths, Defined by International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database (SDD) from January 1, 2006 to June 30, 2018

Characteristic[1]	Number	
Number of presumed stillbirths	11,946	
Number of unique patients	11,737	
Patient Characteristics	**Mean**	**Standard Deviation**
Mean Age (Years)	31.3	5.7
	Number	**Percent**
Age (Years)		
15-45	11,946	100.0%
Sex		
Female	11,737	100.0%
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	1,583	13.3%
2016	5,170	43.3%
2017	4,277	35.8%
2018	916	7.7%
Recorded History of Procedure of Interest in the 224 Days Prior to Index	**Number**	**Percent**
In vitro fertilization/intrauterine insemination	363	3.0%
Nuchal Translucency Measurement	4,048	33.9%
Chorionic villus sampling, any method	137	1.1%
PAPP-A serum test	2,322	19.4%
Group B streptococcus screening (genital)	2,897	24.3%
Assay of estriol	2,189	18.3%
Inhibin A	2,305	19.3%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,614	21.9%
Detailed fetal anatomic examination	5,117	42.8%
Alpha-fetoprotein, amniotic	380	3.2%
Glucose	5,433	45.5%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	6,671	55.8%

Table 1f. Baseline Characteristics for Prevalent Stillbirths, Defined by International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes in the Sentinel Distributed Database (SDD) from January 1, 2006 to June 30, 2018

Recorded History of Procedure of Interest in the 280 Days Prior to Index	Number	Percent
In vitro fertilization/intrauterine insemination	523	4.4%
Nuchal Translucency Measurement	4,054	33.9%
Chorionic villus sampling, any method	138	1.2%
PAPP-A serum test	2,325	19.5%
Group B streptococcus screening (genital)	2,940	24.6%
Assay of estriol	2,195	18.4%
Inhibin A	2,310	19.3%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	2,616	21.9%
Detailed fetal anatomic examination	5,123	42.9%
Alpha-fetoprotein, amniotic	381	3.2%
Glucose	5,458	45.7%
Complete ultrasounds (maternal and fetal evaluation); second and third trimesters	6,688	56.0%

[1]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. Evaluation for Prenatal Test(s) for Incident Stillbirth, Defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), with Prenatal Tests in the 224 Days Prior to Index, in the Sentinel Distributed Database from January 1, 2006 to June 30, 2018

Prenatal Test(s)[1,2]	Incident Stillbirth (ICD-9-CM + ICD-10-CM)		Stillbirth (ICD-9-CM only)		Stillbirth (ICD-10-CM only)	
	Number	Percent	Number	Percent	Number	Percent
Number of episodes	40,342	100.0%	28,827	100.0%	11,517	100.0%
Procedure 1	1,268	3.1%	921	3.2%	347	3.0%
Procedure 1 | Test 6	13,091	32.5%	9,055	31.4%	4,037	35.1%
Procedure 1 | Test 6 | Test 2	13,355	33.1%	9,265	32.1%	4,091	35.5%
Procedure 1 | Test 6 | Test 2 | Test 11	14,330	35.5%	10,050	34.9%	4,281	37.2%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14	20,823	51.6%	14,835	51.5%	5,989	52.0%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10	25,433	63.0%	18,654	64.7%	6,780	58.9%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13	25,450	63.1%	18,662	64.7%	6,789	58.9%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8	26,497	65.7%	18,766	65.1%	7,732	67.1%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5	31,424	77.9%	22,559	78.3%	8,867	77.0%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9	31,535	78.2%	22,653	78.6%	8,884	77.1%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9 | Test 15	33,859	83.9%	24,232	84.1%	9,629	83.6%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9 | Test 15 | Test 4	37,300	92.5%	26,771	92.9%	10,531	91.4%
No recorded prenatal tests	3,042	7.5%	2,056	7.1%	986	8.6%

[1] Refer to Appendix D2 for a list of prenatal procedures and tests

[2] The " | " sign signifies "OR" operator

Table 2b. Evaluation for Prenatal Test(s) for Incident Stillbirth, Defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), with Prenatal Tests in the 280 Days Prior to Index, in the Sentinel Distributed Database from January 1, 2006 to June 30, 2018

Prenatal Test(s)[1,2]	Incident Stillbirth (ICD-9-CM + ICD-10-CM)		Stillbirth (ICD-9-CM only)		Stillbirth (ICD-10-CM only)	
	Number	Percent	Number	Percent	Number	Percent
Number of episodes	40,342	100.0%	28,827	100.0%	11,517	100.0%
Procedure 1	1,918	4.8%	1,415	4.9%	503	4.4%
Procedure 1 | Test 6	13,390	33.2%	9,278	32.2%	4,113	35.7%
Procedure 1 | Test 6 | Test 2	13,631	33.8%	9,469	32.8%	4,163	36.1%
Procedure 1 | Test 6 | Test 2 | Test 11	14,586	36.2%	10,237	35.5%	4,350	37.8%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14	21,093	52.3%	15,047	52.2%	6,047	52.5%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10	25,649	63.6%	18,821	65.3%	6,829	59.3%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13	25,666	63.6%	18,829	65.3%	6,838	59.4%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8	26,701	66.2%	18,929	65.7%	7,773	67.5%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5	31,553	78.2%	22,662	78.6%	8,893	77.2%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9	31,662	78.5%	22,754	78.9%	8,910	77.4%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9 | Test 15	33,957	84.2%	24,312	84.3%	9,647	83.8%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9 | Test 15 | Test 4	37,362	92.6%	26,820	93.0%	10,544	91.6%
No recorded prenatal tests	2,980	7.4%	2,007	7.0%	973	8.4%

[1] Refer to Appendix D2 for a list of prenatal procedures and tests

[2] The " | " sign signifies "OR" operator

Table 2c. Evaluation for Prenatal Test(s) for Prevalent Stillbirth, Defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), with Prenatal Tests in the 224 days prior to index, in the Sentinel Distributed Database from January 1, 2006 to June 30, 2018

Prenatal Test(s)[1,2]	Prevalent Stillbirth (ICD-9-CM + ICD-10-CM)		Stillbirth (ICD-9-CM only)		Stillbirth (ICD-10-CM only)	
	Number	Percent	Number	Percent	Number	Percent
Number of episodes	41,467	100.0%	29,523	100.0%	11,946	100.0%
Procedure 1	1,319	3.2%	956	3.2%	363	3.0%
Procedure 1 | Test 6	13,482	32.5%	9,287	31.5%	4,196	35.1%
Procedure 1 | Test 6 | Test 2	13,751	33.2%	9,502	32.2%	4,250	35.6%
Procedure 1 | Test 6 | Test 2 | Test 11	14,752	35.6%	10,306	34.9%	4,447	37.2%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14	21,349	51.5%	15,160	51.3%	6,190	51.8%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10	26,077	62.9%	19,066	64.6%	7,012	58.7%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13	26,095	62.9%	19,074	64.6%	7,022	58.8%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8	27,192	65.6%	19,179	65.0%	8,014	67.1%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5	32,270	77.8%	23,081	78.2%	9,191	76.9%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9	32,384	78.1%	23,178	78.5%	9,208	77.1%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9 | Test 15	34,765	83.8%	24,794	84.0%	9,973	83.5%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9 | Test 15 | Test 4	38,324	92.4%	27,411	92.8%	10,915	91.4%
No recorded prenatal tests	3,143	7.6%	2,112	7.2%	1,031	8.6%

[1] Refer to Appendix D2 for a list of prenatal procedures and tests

[2] The " | " sign signifies "OR" operator

Table 2d. Evaluation for Prenatal Test(s) for Prevalent Stillbirth, Defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), with Prenatal Tests in the 280 Days Prior to Index, in the Sentinel Distributed Database from January 1, 2006 to June 30, 2018

Prenatal Test(s)[1,2]	Prevalent Stillbirth (ICD-9-CM + ICD-10-CM)		Stillbirth (ICD-9-CM only)		Stillbirth (ICD-10-CM only)	
	Number	Percent	Number	Percent	Number	Percent
Number of episodes	41,467	100.0%	29,523	100.0%	11,946	100.0%
Procedure 1	1,984	4.8%	1,461	4.9%	523	4.4%
Procedure 1 | Test 6	13,788	33.3%	9,515	32.2%	4,274	35.8%
Procedure 1 | Test 6 | Test 2	14,034	33.8%	9,711	32.9%	4,324	36.2%
Procedure 1 | Test 6 | Test 2 | Test 11	15,015	36.2%	10,498	35.6%	4,518	37.8%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14	21,625	52.1%	15,376	52.1%	6,250	52.3%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10	26,298	63.4%	19,236	65.2%	7,063	59.1%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13	26,316	63.5%	19,244	65.2%	7,073	59.2%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8	27,399	66.1%	19,345	65.5%	8,055	67.4%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5	32,401	78.1%	23,186	78.5%	9,217	77.2%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9	32,513	78.4%	23,281	78.9%	9,234	77.3%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9 | Test 15	34,864	84.1%	24,875	84.3%	9,991	83.6%
Procedure 1 | Test 6 | Test 2 | Test 11 | Test 14 | Test 10 | Test 13 | Test 8 | Test 5 | Test 9 | Test 15 | Test 4	38,386	92.6%	27,460	93.0%	10,928	91.5%
No recorded prenatal tests	3,081	7.4%	2,063	7.0%	1,018	8.5%

[1] Refer to Appendix D2 for a list of prenatal procedures and tests

[2] The " | " sign signifies "OR" operator

Table 3. Summary of Stillbirth Population, Defined by 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 from January 1, 2006 to June 30, 2018, Overall

Code Type	Number of Patients	Number of Presumed Stillbirths	Number of Presumed Stillbirths per Patient
Incident Stillbirth			
ICD-9-CM and ICD-10-CM	39,897	40,342	1.01
ICD-9-CM	28,551	28,827	1.01
ICD-10-CM	11,444	11,517	1.01
Prevalent Stillbirth			
ICD-9-CM and ICD-10-CM	40,562	41,467	1.02
ICD-9-CM	28,928	29,523	1.02
ICD-10-CM	11,737	11,946	1.02

[1]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 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 from January 1, 2006 to June 30, 2018, by Year

Year	Number of Patients	Number of Presumed Stillbirths	Number of Presumed Stillbirths per Patient
Incident Stillbirth (ICD-9-CM and ICD-10-CM)			
2006	771	771	1.00
2007	1,530	1,532	1.00
2008	2,001	2,004	1.00
2009	3,531	3,534	1.00
2010	3,402	3,406	1.00
2011	3,600	3,601	1.00
2012	3,624	3,626	1.00
2013	3,728	3,731	1.00
2014	3,870	3,875	1.00
2015	4,288	4,293	1.00
2016	4,974	4,980	1.00
2017	4,096	4,100	1.00
2018	889	889	1.00
Incident Stillbirth (ICD-9-CM only)			
2006	771	771	1.00
2007	1,530	1,532	1.00
2008	2,001	2,004	1.00
2009	3,531	3,534	1.00
2010	3,402	3,406	1.00
2011	3,600	3,601	1.00
2012	3,624	3,626	1.00
2013	3,728	3,731	1.00
2014	3,870	3,875	1.00
2015	2,747	2,747	1.00
2016	0	0	-
2017	0	0	-
2018	0	0	-
Incident Stillbirth (ICD-10-CM only)			
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	1,548	1,548	1.00
2016	4,974	4,980	1.00
2017	4,096	4,100	1.00
2018	889	889	1.00

Table 4. Summary of Stillbirth Population, Defined by 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 from January 1, 2006 to June 30, 2018, by Year

Year	Number of Patients	Number of Presumed Stillbirths	Number of Presumed Stillbirths per Patient
Prevalent Stillbirth (ICD-9-CM + ICD-10-CM)			
2006	781	788	1.01
2007	1,543	1,550	1.00
2008	2,032	2,055	1.01
2009	3,577	3,637	1.02
2010	3,442	3,477	1.01
2011	3,646	3,685	1.01
2012	3,673	3,712	1.01
2013	3,774	3,804	1.01
2014	3,936	4,000	1.02
2015	4,358	4,396	1.01
2016	5,113	5,170	1.01
2017	4,221	4,277	1.01
2018	900	916	1.02
Prevalent Stillbirth (ICD-9-CM only)			
2006	781	788	1.01
2007	1,543	1,550	1.00
2008	2,032	2,055	1.01
2009	3,577	3,637	1.02
2010	3,442	3,477	1.01
2011	3,646	3,685	1.01
2012	3,673	3,712	1.01
2013	3,774	3,804	1.01
2014	3,936	4,000	1.02
2015	2,794	2,815	1.01
2016	0	0	-
2017	0	0	-
2018	0	0	-
Prevalent Stillbirth (ICD-10-CM only)			
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	1,572	1,583	1.01
2016	5,113	5,170	1.01
2017	4,221	4,277	1.01
2018	900	916	1.02

[1]For pregnancy episodes that span more than one calendar year, the episode as well as the patient are counted in both years

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (January 7, 2019)

DP ID	Start Date[1]	End Date[1]
DP01	06/01/2007	04/30/2018
DP02	01/01/2000	10/31/2017
DP03	01/01/2000	06/30/2018
DP04	01/01/2008	03/31/2018
DP05	01/01/2004	05/31/2018
DP06	01/01/2000	12/31/2016
DP07	01/01/2006	05/31/2018
DP08	01/01/2005	12/17/2017
DP09	01/01/2000	03/31/2016
DP10	01/01/2000	05/31/2015
DP11	01/01/2000	03/31/2018
DP12	01/01/2000	12/31/2017
DP13	01/01/2000	06/30/2018
DP14	01/01/2008	09/30/2017
DP15	01/01/2000	03/31/2018
DP16	01/01/2012	06/30/2017

[1] 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) Diagnosis Codes Used to Define Stillbirth

Code	Description	Code Type
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

Code	Description	Code Type
58321	Artificial insemination; intra-cervical	CPT-4
58322	Artificial insemination	CPT-4
58974	Transfer of embryo	CPT-4
58976	Gamete, zygote, or embryo intrafallopian transfer	CPT-4
S4011	In vitro fertilization	HCPCS
S4013	Complete cycle gift case rate	HCPCS
S4014	Complete cycle zift case rate	HCPCS
S4015	Complete in vitro fertilization cycle case rate not otherwise specified	HCPCS
S4016	Frozen in vitro fertilization cycle case rate	HCPCS
S4035	Stimulated intrauterine insemination (IUI), case rate	HCPCS
S4037	Cryopreserved embryo transfer, case rate	HCPCS
76813	Nuchal translucency measurement (single or first gestation)	CPT-4
76814	Nuchal translucency measurement (each additional gestation)	CPT-4
59015	Chorionic villus sampling, any method	CPT-4
84163	Papp-a serum test	CPT-4
87081	Group B streptococcus screening (genital)	CPT-4
82677	Assay of estriol	CPT-4
86336	Inhibin A	CPT-4
81420	Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	CPT-4
76811	Detailed fetal anatomic examination (single or first gestation)	CPT-4
76812	Detailed fetal anatomic examination (each additional gestation)	CPT-4
82106	Alpha-fetoprotein, amniotic	CPT-4
82950	Glucose; post glucose dose (includes glucose)	CPT-4
82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)	CPT-4
76805	Complete ultrasounds (maternal and fetal evaluation); second and third trimesters (single or first gestation)	CPT-4
76810	Complete ultrasounds (maternal and fetal evaluation); second and third trimesters (each additional gestation)	CPT-4

Appendix D1. Specifications for Parameters Used in this Request

We conducted this exploratory analysis to examine stillbirths and the proportion of those stillbirths that had a select 12 prenatal tests recommended during pregnancy. In a prior Sentinel analysis (cder_mpl1p_wp019), these 12 tests had been identified 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, version 6.0.0, was used for this Type 1 analysis to examine the prevalence of the prenatal test codes in the population of potential stillbirths in Sentinel Distributed Database.

Query Period: January 1, 2006 - June 30, 2018
Coverage Requirement: At least medical
Pre-index enrollment requirement: 224 days; 280 days
Enrollment Gap: 45 days
Age Stratification: 15-45 years
Sex: Female
Envelope macro: Reclassify encounters during inpatient stay as inpatient

		Exposure					Baseline Characteristics		
Scenario	Exposure	Care Setting	Exposure Washout (Days)	Incidence Criteria	Incidence Criteria Care Setting	Cohort Definition	Characteristics	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	0	None	Any	Include all valid index dates per individual	Prenatal Tests (See Appendix D2)	Any	See Appendix D2
2	Stillbirth (ICD-9-CM)	Inpatient	0	None	Any	Include all valid index dates per individual	Prenatal Tests (See Appendix D2)	Any	See Appendix D2
3	Stillbirth (ICD-10-CM)	Inpatient	0	None	Any	Include all valid index dates per individual	Prenatal Tests (See Appendix D2)	Any	See Appendix D2
4	Stillbirth (ICD-9-CM and ICD-10-CM)	Inpatient	140	ICD-9-CM or ICD-10-CM	Any	Include all valid index dates per individual	Prenatal Tests (See Appendix D2)	Any	See Appendix D2
5	Stillbirth (ICD-9-CM)	Inpatient	140	ICD-9-CM	Any	Include all valid index dates per individual	Prenatal Tests (See Appendix D2)	Any	See Appendix D2
6	Stillbirth (ICD-10-CM)	Inpatient	140	ICD-10-CM	Any	Include all valid index dates per individual	Prenatal Tests (See Appendix D2)	Any	See Appendix D2

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