

## Disclaimer

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

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

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

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## Overview for Request cber\_mpl1r\_wp006\_nsdp\_v01

**Request ID:** cber\_mpl1r\_wp006\_nsdp\_v01

**Request Description:** This report contains estimates of the number of tetanus, diphtheria, and pertussis (Tdap) vaccinations that occurred during a pregnancy ending in a liveborn delivery, and during the delivery visit.

**Sentinel Modular Program Tool Used:** Cohort Identification and Descriptive Analysis (CIDA) tool, Version 3.0.3

**Data Source:** The query was run against the Sentinel Distributed Database (SDD) for the time period of January 1, 2010 to September 30, 2015. This request was distributed to 6 Data Partners on November 2, 2016. See Appendix A for a list of the latest dates of available data for each Data Partner.

**Cohort Eligibility Criteria:** Females in the following age groups were included in the cohort: 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, and 50-54 years. Eligible females were required to be enrolled in plans with medical coverage for at least 294 days before their delivery date, with gaps in coverage of up to 45 days.

**Pregnancy Episode Creation:** A previously-validated algorithm from Sentinel's Medication Exposure in Pregnancy Risk Evaluation Program was used to define pregnancy episodes. This algorithm uses pre/postterm delivery codes that occurred within 7 days of a delivery date in the inpatient care setting to determine a pregnancy duration. In absence of pre/postterm codes, pregnancy duration was set to 273 days. Please see Appendices B and C for a list of delivery codes defined using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes and Current Procedural Terminology (CPT-4) procedure codes and the algorithm used to define pregnancy episodes. Pregnancy episodes were excluded from the cohort if there was evidence of a delivery code in the 294 days prior to the delivery code of interest.

**Exposure Identification During Pregnancy:** Tdap vaccinations were defined using CPT-4 procedure code 90715 and ICD-9-CM procedure codes 99.37 and 99.39. The following three exposure groups were identified: 1) Tdap code occurred during pregnancy or delivery visit; 2) Tdap code occurred during pregnancy, excluding the delivery visit; and 3) Tdap code occurred during pregnancy, excluding the delivery visit and the 14 days before the start of the delivery visit.

**Results:** The total number of pregnancies and the number and percentage of pregnancies with Tdap in each of the three exposure groups were calculated. Furthermore, the number and percentage of pregnancies with Tdap use during the delivery visit were calculated. Results were stratified by trimester, maternal age at delivery, and year of delivery.

**Limitations:** Algorithms used to define deliveries, pregnancy start dates, and exposure use are imperfect; thus, it is possible that there may be misclassification. Please note that not all Data Partners have complete data through the end of 2015; therefore, 2015 data should be interpreted with caution (see Appendix A).

Please see Appendix D for the specifications of parameters used in the modular program.

**Notes:** Please contact the Sentinel Operations Center Query Fulfillment Team ([qf@sentinelssystem.org](mailto:qf@sentinelssystem.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. This is equivalent to the "RxAmt" value in the SCDM.

**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). Along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

**Ambulatory Visit (AV)** - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, 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.

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

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

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

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

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

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

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

**Event Deduplication** - specifies how events are counted by the MP algorithm: 0: Counts all occurrences of an HOI during an exposure episode; 1: 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 Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode.

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

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

**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.

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

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

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

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

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

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

\*all terms may not be used in this report

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

**Table 1: Summary of Tdap Vaccinations during Pregnancies Ending in a Liveborn Delivery in the Sentinel Distributed Database between January 1, 2010 and September 30, 2015, by Trimester**

	<b>At Least One Trimester</b>	<b>Trimester 1*</b>	<b>Trimester 2**</b>	<b>Trimester 3***</b>
Total Number of Pregnancies	2,633,462 (100%)	2,633,462 (100%)	2,633,462 (100%)	2,633,123 (100%)
Tdap Use during Pregnancy and Delivery Visit	490,217 (18.61%)	10,719 (0.41%)	23,606 (0.90%)	457,726 (17.38%)
Tdap Use during Pregnancy, Excluding Delivery Visit	406,321 (15.43%)	10,719 (0.41%)	23,603 (0.90%)	373,557 (14.19%)
Tdap Use during Pregnancy, Excluding Delivery Visit and 14 Days Before Delivery Visit	383,414 (14.56%)	10,719 (0.41%)	23,601 (0.90%)	350,547 (13.31%)

\* Trimester 1 = 0-90 days following pregnancy start

\*\* Trimester 2 = 91-180 days following pregnancy start

\*\*\* Trimester 3 = 180+ days following pregnancy start and until delivery

**Table 2: Summary of Tdap Vaccinations during Pregnancies Ending in a Liveborn Delivery in the Sentinel Distributed Database between January 1, 2010 and September 30, 2015, by Maternal Age at Delivery**

	<b>10-14 Years</b>	<b>15-19 Years</b>	<b>20-24 Years</b>	<b>25-29 Years</b>	<b>30-34 Years</b>	<b>35-39 Years</b>	<b>40-44 Years</b>	<b>45-49 Years</b>	<b>50-54 Years</b>
Total Number of Pregnancies	1,110 (100%)	92,895 (100%)	314,881 (100%)	700,385 (100%)	925,187 (100%)	474,535 (100%)	109,103 (100%)	11,464 (100%)	3,902 (100%)
Tdap Use during Pregnancy and Delivery Visit	108 (9.73%)	10,344 (11.14%)	49,163 (15.61%)	128,098 (18.29%)	188,451 (20.37%)	92,977 (19.59%)	19,332 (17.72%)	1,487 (12.97%)	257 (6.59%)
Tdap Use during Pregnancy, Excluding Delivery Visit	94 (8.47%)	8,029 (8.64%)	38,916 (12.36%)	105,005 (14.99%)	159,011 (17.19%)	77,902 (16.42%)	15,863 (14.54%)	1,267 (11.05%)	234 (6.00%)
Tdap Use during Pregnancy, Excluding Delivery Visit and 14 Days Before Delivery Visit	89 (8.02%)	7,540 (8.12%)	36,757 (11.67%)	99,346 (14.18%)	150,420 (16.26%)	73,152 (15.42%)	14,748 (13.52%)	1,164 (10.15%)	198 (5.07%)

**Table 3: Summary of Tdap Vaccinations during Pregnancies Ending in a Liveborn Delivery in the Sentinel Distributed Database between January 1, 2010 and September 30, 2015, by Year of Delivery**

	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
Total Number of Pregnancies	450,830 (100%)	464,332 (100%)	466,295 (100%)	470,585 (100%)	457,745 (100%)	323,675 (100%)
Tdap Use during Pregnancy and Delivery Visit	12,512 (2.78%)	24,358 (5.25%)	45,869 (9.84%)	108,982 (23.16%)	164,231 (35.88%)	134,265 (41.48%)
Tdap Use during Pregnancy, Excluding Delivery Visit	3,592 (0.80%)	7,682 (1.65%)	27,442 (5.89%)	91,701 (19.49%)	150,302 (32.84%)	125,602 (38.80%)
Tdap Use during Pregnancy, Excluding Delivery Visit and 14 Days Before Delivery Visit	3,274 (0.73%)	7,040 (1.52%)	24,642 (5.28%)	85,296 (18.13%)	142,695 (31.17%)	120,467 (37.22%)

**Appendix A: Latest Date of Available Data for Each Data Partner up to Request End Date (9/30/2015)**

<b>Masked ID</b>	<b>End Date</b>
DP0001	9/30/2015
DP0002	9/30/2015
DP0003	6/30/2015
DP0004	9/30/2015
DP0005	9/30/2015
DP0006	12/31/2014



**Appendix B: List of Diagnosis and Procedure Codes used to Define Full Term, Liveborn Deliveries in this Request**

Full Term Delivery Codes		
Code Category	Code Type	Code
Procedure	CPT4	59409
Procedure	CPT4	59410
Procedure	CPT4	59510
Procedure	CPT4	59514
Procedure	CPT4	59515
Procedure	CPT4	59610
Procedure	CPT4	59612
Procedure	CPT4	59614
Procedure	CPT4	59618
Procedure	CPT4	59620
Procedure	CPT4	59622
Diagnosis	ICD-9-CM	64101
Diagnosis	ICD-9-CM	64111
Diagnosis	ICD-9-CM	64121
Diagnosis	ICD-9-CM	64131
Diagnosis	ICD-9-CM	64181
Diagnosis	ICD-9-CM	64191
Diagnosis	ICD-9-CM	64201
Diagnosis	ICD-9-CM	64202
Diagnosis	ICD-9-CM	64211
Diagnosis	ICD-9-CM	64212
Diagnosis	ICD-9-CM	64221
Diagnosis	ICD-9-CM	64222
Diagnosis	ICD-9-CM	64231
Diagnosis	ICD-9-CM	64232
Diagnosis	ICD-9-CM	64241
Diagnosis	ICD-9-CM	64242
Diagnosis	ICD-9-CM	64251
Diagnosis	ICD-9-CM	64252
Diagnosis	ICD-9-CM	64261
Diagnosis	ICD-9-CM	64262
Diagnosis	ICD-9-CM	64271
Diagnosis	ICD-9-CM	64272
Diagnosis	ICD-9-CM	64291
Diagnosis	ICD-9-CM	64292
Diagnosis	ICD-9-CM	64301
Diagnosis	ICD-9-CM	64311
Diagnosis	ICD-9-CM	64321
Diagnosis	ICD-9-CM	64381
Diagnosis	ICD-9-CM	64391
Diagnosis	ICD-9-CM	64421

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Diagnosis	ICD-9-CM	64501
Diagnosis	ICD-9-CM	64511
Diagnosis	ICD-9-CM	64521
Diagnosis	ICD-9-CM	64522
Diagnosis	ICD-9-CM	64601
Diagnosis	ICD-9-CM	64611
Diagnosis	ICD-9-CM	64612
Diagnosis	ICD-9-CM	64621
Diagnosis	ICD-9-CM	64622
Diagnosis	ICD-9-CM	64631
Diagnosis	ICD-9-CM	64641
Diagnosis	ICD-9-CM	64642
Diagnosis	ICD-9-CM	64651
Diagnosis	ICD-9-CM	64652
Diagnosis	ICD-9-CM	64661
Diagnosis	ICD-9-CM	64662
Diagnosis	ICD-9-CM	64671
Diagnosis	ICD-9-CM	64681
Diagnosis	ICD-9-CM	64682
Diagnosis	ICD-9-CM	64691
Diagnosis	ICD-9-CM	64701
Diagnosis	ICD-9-CM	64702
Diagnosis	ICD-9-CM	64711
Diagnosis	ICD-9-CM	64712
Diagnosis	ICD-9-CM	64721
Diagnosis	ICD-9-CM	64722
Diagnosis	ICD-9-CM	64731
Diagnosis	ICD-9-CM	64732
Diagnosis	ICD-9-CM	64741
Diagnosis	ICD-9-CM	64742
Diagnosis	ICD-9-CM	64751
Diagnosis	ICD-9-CM	64752
Diagnosis	ICD-9-CM	64761
Diagnosis	ICD-9-CM	64762
Diagnosis	ICD-9-CM	64781
Diagnosis	ICD-9-CM	64782
Diagnosis	ICD-9-CM	64791
Diagnosis	ICD-9-CM	64792
Diagnosis	ICD-9-CM	64801
Diagnosis	ICD-9-CM	64802
Diagnosis	ICD-9-CM	64811
Diagnosis	ICD-9-CM	64812
Diagnosis	ICD-9-CM	64821
Diagnosis	ICD-9-CM	64822

**Appendix B: List of Diagnosis and Procedure Codes used to Define Full Term, Liveborn Deliveries in this Request**

Diagnosis	ICD-9-CM	64831
Diagnosis	ICD-9-CM	64832
Diagnosis	ICD-9-CM	64841
Diagnosis	ICD-9-CM	64842
Diagnosis	ICD-9-CM	64851
Diagnosis	ICD-9-CM	64852
Diagnosis	ICD-9-CM	64861
Diagnosis	ICD-9-CM	64862
Diagnosis	ICD-9-CM	64871
Diagnosis	ICD-9-CM	64872
Diagnosis	ICD-9-CM	64881
Diagnosis	ICD-9-CM	64882
Diagnosis	ICD-9-CM	64891
Diagnosis	ICD-9-CM	64892
Diagnosis	ICD-9-CM	64901
Diagnosis	ICD-9-CM	64902
Diagnosis	ICD-9-CM	64911
Diagnosis	ICD-9-CM	64912
Diagnosis	ICD-9-CM	64921
Diagnosis	ICD-9-CM	64922
Diagnosis	ICD-9-CM	64931
Diagnosis	ICD-9-CM	64932
Diagnosis	ICD-9-CM	64941
Diagnosis	ICD-9-CM	64942
Diagnosis	ICD-9-CM	64951
Diagnosis	ICD-9-CM	64961
Diagnosis	ICD-9-CM	64962
Diagnosis	ICD-9-CM	64971
Diagnosis	ICD-9-CM	64981
Diagnosis	ICD-9-CM	64982
Diagnosis	ICD-9-CM	650
Diagnosis	ICD-9-CM	65101
Diagnosis	ICD-9-CM	65111
Diagnosis	ICD-9-CM	65121
Diagnosis	ICD-9-CM	65131
Diagnosis	ICD-9-CM	65141
Diagnosis	ICD-9-CM	65151
Diagnosis	ICD-9-CM	65161
Diagnosis	ICD-9-CM	65171
Diagnosis	ICD-9-CM	65181
Diagnosis	ICD-9-CM	65191
Diagnosis	ICD-9-CM	65201
Diagnosis	ICD-9-CM	65211
Diagnosis	ICD-9-CM	65221

**Appendix B: List of Diagnosis and Procedure Codes used to Define Full Term, Liveborn Deliveries in this Request**

Diagnosis	ICD-9-CM	65231
Diagnosis	ICD-9-CM	65241
Diagnosis	ICD-9-CM	65251
Diagnosis	ICD-9-CM	65261
Diagnosis	ICD-9-CM	65271
Diagnosis	ICD-9-CM	65281
Diagnosis	ICD-9-CM	65291
Diagnosis	ICD-9-CM	65301
Diagnosis	ICD-9-CM	65311
Diagnosis	ICD-9-CM	65321
Diagnosis	ICD-9-CM	65331
Diagnosis	ICD-9-CM	65341
Diagnosis	ICD-9-CM	65351
Diagnosis	ICD-9-CM	65361
Diagnosis	ICD-9-CM	65371
Diagnosis	ICD-9-CM	65381
Diagnosis	ICD-9-CM	65391
Diagnosis	ICD-9-CM	65401
Diagnosis	ICD-9-CM	65402
Diagnosis	ICD-9-CM	65411
Diagnosis	ICD-9-CM	65412
Diagnosis	ICD-9-CM	65421
Diagnosis	ICD-9-CM	65431
Diagnosis	ICD-9-CM	65432
Diagnosis	ICD-9-CM	65441
Diagnosis	ICD-9-CM	65442
Diagnosis	ICD-9-CM	65451
Diagnosis	ICD-9-CM	65452
Diagnosis	ICD-9-CM	65461
Diagnosis	ICD-9-CM	65462
Diagnosis	ICD-9-CM	65471
Diagnosis	ICD-9-CM	65472
Diagnosis	ICD-9-CM	65481
Diagnosis	ICD-9-CM	65482
Diagnosis	ICD-9-CM	65491
Diagnosis	ICD-9-CM	65492
Diagnosis	ICD-9-CM	65501
Diagnosis	ICD-9-CM	65511
Diagnosis	ICD-9-CM	65521
Diagnosis	ICD-9-CM	65531
Diagnosis	ICD-9-CM	65541
Diagnosis	ICD-9-CM	65551
Diagnosis	ICD-9-CM	65561
Diagnosis	ICD-9-CM	65571

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Diagnosis	ICD-9-CM	65581
Diagnosis	ICD-9-CM	65591
Diagnosis	ICD-9-CM	65601
Diagnosis	ICD-9-CM	65611
Diagnosis	ICD-9-CM	65621
Diagnosis	ICD-9-CM	65631
Diagnosis	ICD-9-CM	65641
Diagnosis	ICD-9-CM	65651
Diagnosis	ICD-9-CM	65661
Diagnosis	ICD-9-CM	65671
Diagnosis	ICD-9-CM	65681
Diagnosis	ICD-9-CM	65691
Diagnosis	ICD-9-CM	65701
Diagnosis	ICD-9-CM	65801
Diagnosis	ICD-9-CM	65811
Diagnosis	ICD-9-CM	65821
Diagnosis	ICD-9-CM	65831
Diagnosis	ICD-9-CM	65841
Diagnosis	ICD-9-CM	65881
Diagnosis	ICD-9-CM	65891
Diagnosis	ICD-9-CM	65901
Diagnosis	ICD-9-CM	65911
Diagnosis	ICD-9-CM	65921
Diagnosis	ICD-9-CM	65931
Diagnosis	ICD-9-CM	65941
Diagnosis	ICD-9-CM	65951
Diagnosis	ICD-9-CM	65961
Diagnosis	ICD-9-CM	65971
Diagnosis	ICD-9-CM	65981
Diagnosis	ICD-9-CM	65991
Diagnosis	ICD-9-CM	66001
Diagnosis	ICD-9-CM	66011
Diagnosis	ICD-9-CM	66021
Diagnosis	ICD-9-CM	66031
Diagnosis	ICD-9-CM	66041
Diagnosis	ICD-9-CM	66051
Diagnosis	ICD-9-CM	66061
Diagnosis	ICD-9-CM	66071
Diagnosis	ICD-9-CM	66081
Diagnosis	ICD-9-CM	66091
Diagnosis	ICD-9-CM	66101
Diagnosis	ICD-9-CM	66111
Diagnosis	ICD-9-CM	66121
Diagnosis	ICD-9-CM	66131

**Appendix B: List of Diagnosis and Procedure Codes used to Define Full Term, Liveborn Deliveries in this Request**

Diagnosis	ICD-9-CM	66141
Diagnosis	ICD-9-CM	66191
Diagnosis	ICD-9-CM	66201
Diagnosis	ICD-9-CM	66211
Diagnosis	ICD-9-CM	66221
Diagnosis	ICD-9-CM	66231
Diagnosis	ICD-9-CM	66301
Diagnosis	ICD-9-CM	66311
Diagnosis	ICD-9-CM	66321
Diagnosis	ICD-9-CM	66331
Diagnosis	ICD-9-CM	66341
Diagnosis	ICD-9-CM	66351
Diagnosis	ICD-9-CM	66361
Diagnosis	ICD-9-CM	66381
Diagnosis	ICD-9-CM	66391
Diagnosis	ICD-9-CM	66401
Diagnosis	ICD-9-CM	66411
Diagnosis	ICD-9-CM	66421
Diagnosis	ICD-9-CM	66431
Diagnosis	ICD-9-CM	66441
Diagnosis	ICD-9-CM	66451
Diagnosis	ICD-9-CM	66461
Diagnosis	ICD-9-CM	66481
Diagnosis	ICD-9-CM	66491
Diagnosis	ICD-9-CM	66501
Diagnosis	ICD-9-CM	66511
Diagnosis	ICD-9-CM	66522
Diagnosis	ICD-9-CM	66531
Diagnosis	ICD-9-CM	66541
Diagnosis	ICD-9-CM	66551
Diagnosis	ICD-9-CM	66561
Diagnosis	ICD-9-CM	66571
Diagnosis	ICD-9-CM	66572
Diagnosis	ICD-9-CM	66581
Diagnosis	ICD-9-CM	66582
Diagnosis	ICD-9-CM	66591
Diagnosis	ICD-9-CM	66592
Diagnosis	ICD-9-CM	66602
Diagnosis	ICD-9-CM	66612
Diagnosis	ICD-9-CM	66622
Diagnosis	ICD-9-CM	66632
Diagnosis	ICD-9-CM	66702
Diagnosis	ICD-9-CM	66712
Diagnosis	ICD-9-CM	66801

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Diagnosis	ICD-9-CM	66802
Diagnosis	ICD-9-CM	66811
Diagnosis	ICD-9-CM	66812
Diagnosis	ICD-9-CM	66821
Diagnosis	ICD-9-CM	66822
Diagnosis	ICD-9-CM	66881
Diagnosis	ICD-9-CM	66882
Diagnosis	ICD-9-CM	66891
Diagnosis	ICD-9-CM	66892
Diagnosis	ICD-9-CM	66901
Diagnosis	ICD-9-CM	66902
Diagnosis	ICD-9-CM	66911
Diagnosis	ICD-9-CM	66912
Diagnosis	ICD-9-CM	66921
Diagnosis	ICD-9-CM	66922
Diagnosis	ICD-9-CM	66932
Diagnosis	ICD-9-CM	66941
Diagnosis	ICD-9-CM	66942
Diagnosis	ICD-9-CM	66951
Diagnosis	ICD-9-CM	66961
Diagnosis	ICD-9-CM	66971
Diagnosis	ICD-9-CM	66981
Diagnosis	ICD-9-CM	66982
Diagnosis	ICD-9-CM	66991
Diagnosis	ICD-9-CM	66992
Diagnosis	ICD-9-CM	67002
Diagnosis	ICD-9-CM	67012
Diagnosis	ICD-9-CM	67022
Diagnosis	ICD-9-CM	67032
Diagnosis	ICD-9-CM	67082
Diagnosis	ICD-9-CM	67101
Diagnosis	ICD-9-CM	67102
Diagnosis	ICD-9-CM	67111
Diagnosis	ICD-9-CM	67112
Diagnosis	ICD-9-CM	67121
Diagnosis	ICD-9-CM	67122
Diagnosis	ICD-9-CM	67131
Diagnosis	ICD-9-CM	67142
Diagnosis	ICD-9-CM	67151
Diagnosis	ICD-9-CM	67152
Diagnosis	ICD-9-CM	67181
Diagnosis	ICD-9-CM	67182
Diagnosis	ICD-9-CM	67191
Diagnosis	ICD-9-CM	67192

**Appendix B: List of Diagnosis and Procedure Codes used to Define Full Term, Liveborn Deliveries in this Request**

Diagnosis	ICD-9-CM	67202
Diagnosis	ICD-9-CM	67301
Diagnosis	ICD-9-CM	67302
Diagnosis	ICD-9-CM	67311
Diagnosis	ICD-9-CM	67312
Diagnosis	ICD-9-CM	67321
Diagnosis	ICD-9-CM	67322
Diagnosis	ICD-9-CM	67331
Diagnosis	ICD-9-CM	67332
Diagnosis	ICD-9-CM	67381
Diagnosis	ICD-9-CM	67382
Diagnosis	ICD-9-CM	67401
Diagnosis	ICD-9-CM	67402
Diagnosis	ICD-9-CM	67412
Diagnosis	ICD-9-CM	67422
Diagnosis	ICD-9-CM	67432
Diagnosis	ICD-9-CM	67442
Diagnosis	ICD-9-CM	67451
Diagnosis	ICD-9-CM	67452
Diagnosis	ICD-9-CM	67482
Diagnosis	ICD-9-CM	67492
Diagnosis	ICD-9-CM	67501
Diagnosis	ICD-9-CM	67502
Diagnosis	ICD-9-CM	67511
Diagnosis	ICD-9-CM	67512
Diagnosis	ICD-9-CM	67521
Diagnosis	ICD-9-CM	67522
Diagnosis	ICD-9-CM	67581
Diagnosis	ICD-9-CM	67582
Diagnosis	ICD-9-CM	67591
Diagnosis	ICD-9-CM	67592
Diagnosis	ICD-9-CM	67601
Diagnosis	ICD-9-CM	67602
Diagnosis	ICD-9-CM	67611
Diagnosis	ICD-9-CM	67612
Diagnosis	ICD-9-CM	67621
Diagnosis	ICD-9-CM	67622
Diagnosis	ICD-9-CM	67631
Diagnosis	ICD-9-CM	67632
Diagnosis	ICD-9-CM	67641
Diagnosis	ICD-9-CM	67642
Diagnosis	ICD-9-CM	67651
Diagnosis	ICD-9-CM	67652
Diagnosis	ICD-9-CM	67661



**Appendix B: List of Diagnosis and Procedure Codes used to Define Full Term, Liveborn Deliveries in this Request**

Diagnosis	ICD-9-CM	67662
Diagnosis	ICD-9-CM	67681
Diagnosis	ICD-9-CM	67682
Diagnosis	ICD-9-CM	67691
Diagnosis	ICD-9-CM	67692
Diagnosis	ICD-9-CM	67801
Diagnosis	ICD-9-CM	67811
Diagnosis	ICD-9-CM	67901
Diagnosis	ICD-9-CM	67902
Diagnosis	ICD-9-CM	67911
Diagnosis	ICD-9-CM	67912
Procedure	ICD-9-CM	72
Procedure	ICD-9-CM	720
Procedure	ICD-9-CM	721
Procedure	ICD-9-CM	722
Procedure	ICD-9-CM	7221
Procedure	ICD-9-CM	7229
Procedure	ICD-9-CM	723
Procedure	ICD-9-CM	7231
Procedure	ICD-9-CM	7239
Procedure	ICD-9-CM	724
Procedure	ICD-9-CM	725
Procedure	ICD-9-CM	7251
Procedure	ICD-9-CM	7252
Procedure	ICD-9-CM	7253
Procedure	ICD-9-CM	7254
Procedure	ICD-9-CM	726
Procedure	ICD-9-CM	727
Procedure	ICD-9-CM	7271
Procedure	ICD-9-CM	7279
Procedure	ICD-9-CM	728
Procedure	ICD-9-CM	729
Procedure	ICD-9-CM	73
Procedure	ICD-9-CM	730
Procedure	ICD-9-CM	7301
Procedure	ICD-9-CM	7309
Procedure	ICD-9-CM	731
Procedure	ICD-9-CM	732
Procedure	ICD-9-CM	7321
Procedure	ICD-9-CM	7322
Procedure	ICD-9-CM	733
Procedure	ICD-9-CM	734
Procedure	ICD-9-CM	735
Procedure	ICD-9-CM	7351

**Appendix B: List of Diagnosis and Procedure Codes used to Define Full Term, Liveborn Deliveries in this Request**

Procedure	ICD-9-CM	7359
Procedure	ICD-9-CM	736
Procedure	ICD-9-CM	738
Procedure	ICD-9-CM	739
Procedure	ICD-9-CM	7391
Procedure	ICD-9-CM	7392
Procedure	ICD-9-CM	7393
Procedure	ICD-9-CM	7394
Procedure	ICD-9-CM	7399
Procedure	ICD-9-CM	740
Procedure	ICD-9-CM	741
Procedure	ICD-9-CM	742
Procedure	ICD-9-CM	744
Procedure	ICD-9-CM	749
Procedure	ICD-9-CM	7499
Diagnosis	ICD-9-CM	7630
Diagnosis	ICD-9-CM	7632
Diagnosis	ICD-9-CM	7633
Diagnosis	ICD-9-CM	7634
Diagnosis	ICD-9-CM	7636
Diagnosis	ICD-9-CM	7680
Diagnosis	ICD-9-CM	7681
Diagnosis	ICD-9-CM	V27
Diagnosis	ICD-9-CM	V270
Diagnosis	ICD-9-CM	V271
Diagnosis	ICD-9-CM	V272
Diagnosis	ICD-9-CM	V273
Diagnosis	ICD-9-CM	V274
Diagnosis	ICD-9-CM	V275
Diagnosis	ICD-9-CM	V276
Diagnosis	ICD-9-CM	V277
Diagnosis	ICD-9-CM	V279
Diagnosis	ICD-9-CM	V30
Diagnosis	ICD-9-CM	V300
Diagnosis	ICD-9-CM	V3000
Diagnosis	ICD-9-CM	V3001
Diagnosis	ICD-9-CM	V301
Diagnosis	ICD-9-CM	V302
Diagnosis	ICD-9-CM	V31
Diagnosis	ICD-9-CM	V310
Diagnosis	ICD-9-CM	V3100
Diagnosis	ICD-9-CM	V3101
Diagnosis	ICD-9-CM	V311
Diagnosis	ICD-9-CM	V312

**Appendix B: List of Diagnosis and Procedure Codes used to Define Full Term, Liveborn Deliveries in this Request**

Diagnosis	ICD-9-CM	V32
Diagnosis	ICD-9-CM	V320
Diagnosis	ICD-9-CM	V3200
Diagnosis	ICD-9-CM	V3201
Diagnosis	ICD-9-CM	V321
Diagnosis	ICD-9-CM	V322
Diagnosis	ICD-9-CM	V33
Diagnosis	ICD-9-CM	V330
Diagnosis	ICD-9-CM	V3300
Diagnosis	ICD-9-CM	V3301
Diagnosis	ICD-9-CM	V331
Diagnosis	ICD-9-CM	V332
Diagnosis	ICD-9-CM	V34
Diagnosis	ICD-9-CM	V340
Diagnosis	ICD-9-CM	V3400
Diagnosis	ICD-9-CM	V3401
Diagnosis	ICD-9-CM	V341
Diagnosis	ICD-9-CM	V342
Diagnosis	ICD-9-CM	V35
Diagnosis	ICD-9-CM	V350
Diagnosis	ICD-9-CM	V3500
Diagnosis	ICD-9-CM	V3501
Diagnosis	ICD-9-CM	V351
Diagnosis	ICD-9-CM	V352
Diagnosis	ICD-9-CM	V36
Diagnosis	ICD-9-CM	V360
Diagnosis	ICD-9-CM	V3600
Diagnosis	ICD-9-CM	V3601
Diagnosis	ICD-9-CM	V361
Diagnosis	ICD-9-CM	V362
Diagnosis	ICD-9-CM	V37
Diagnosis	ICD-9-CM	V370
Diagnosis	ICD-9-CM	V3700
Diagnosis	ICD-9-CM	V3701
Diagnosis	ICD-9-CM	V371
Diagnosis	ICD-9-CM	V372
Diagnosis	ICD-9-CM	V39
Diagnosis	ICD-9-CM	V390
Diagnosis	ICD-9-CM	V3900
Diagnosis	ICD-9-CM	V3901
Diagnosis	ICD-9-CM	V391
Diagnosis	ICD-9-CM	V392

**Appendix C: List of Diagnosis Codes used to Define Pre/Postterm, Liveborn Deliveries and Algorithm used to Define Pregnancy Episodes in this Request**

Preterm and Postterm Delivery Codes*						
Code Category	Code Type	Code	Preterm Code	Postterm Code	Priority	Duration of Pregnancy (Days)
Diagnosis	ICD-9-CM	64421	Yes	No	8	245
Diagnosis	ICD-9-CM	6451*	No	Yes	2	287
Diagnosis	ICD-9-CM	6452*	No	Yes	1	294
Diagnosis	ICD-9-CM	7650*	Yes	No	5	196
Diagnosis	ICD-9-CM	7651*	Yes	No	8	245
Diagnosis	ICD-9-CM	76520	Yes	No	8	245
Diagnosis	ICD-9-CM	76521	Yes	No	7	168
Diagnosis	ICD-9-CM	76522	Yes	No	7	168
Diagnosis	ICD-9-CM	76523	Yes	No	6	182
Diagnosis	ICD-9-CM	76524	Yes	No	5	196
Diagnosis	ICD-9-CM	76525	Yes	No	4	210
Diagnosis	ICD-9-CM	76526	Yes	No	3	224
Diagnosis	ICD-9-CM	76527	Yes	No	2	238
Diagnosis	ICD-9-CM	76528	Yes	No	1	252
Diagnosis	ICD-9-CM	76621	No	Yes	2	287
Diagnosis	ICD-9-CM	76622	No	Yes	1	294
Diagnosis	ICD-9-CM	6451	No	Yes	2	287
Diagnosis	ICD-9-CM	6452	No	Yes	1	294
Diagnosis	ICD-9-CM	7650	Yes	No	5	196
Diagnosis	ICD-9-CM	7651	Yes	No	8	245

\*Each pre/postterm code is assigned an associated pregnancy duration and priority. If a preterm or postterm code is observed within a requester defined window before and after delivery, the duration associated with the code is used to calculate pregnancy duration. If multiple codes are observed, priority is used to determine appropriate duration. If no codes are observed, the requester defines the number of days used to define pregnancy duration.

Note that the default algorithm always assigns priority to observed preterm codes; that is, if both a preterm and postterm code is observed, pregnancy duration is calculated based on the duration assigned to the preterm code.

**Appendix D: Modular Program Specifications for cber\_mpl1r\_wp006\_nsdp\_v01**

Sentinel's Pregnancy Tool within the Cohort Identification and Descriptive Analysis Tool, Version 3.0.3, will be used to investigate Tdap vaccination use during pregnancies ending in a liveborn birth. Three runs of the program will be required. The first run will include Tdap vaccinations that occurred during pregnancy and the delivery visit and the second run will exclude Tdap vaccinations that occurred during the delivery visit. The second run can be subtracted from the first run to determine the number of Tdap vaccinations that only occurred during the delivery visit. The third run will exclude Tdap vaccinations that occurred during the delivery visit and in the 14 days before delivery. In total, 3 scenarios were examined in this request.

**Query Period (binds delivery date)** January 1, 2010 - September 30, 2015  
**Coverage Requirement** Medical  
**Enrollment Requirement** 294 Days  
**Enrollment Gap** 45 Days  
**Age Groups (calculated as age at delivery date)** 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54  
**Stratifications** Year, trimester, and age group (not Data Partner)  
**Data Partners** Six PRISM Data Partners only

Run #	Pregnancy Episode Creation					Exposure				
	Delivery Definition	Delivery Washout Period (days)	Pregnancy Duration Definition (Pre/Postterm Codes)	Pregnancy Duration in Absence of Pre/Postterm Codes (days)	Pre/Postterm Evaluation Window (days)	Incident exposure	Care Setting/ Diagnosis Position	Incident w/ respect to:	Washout (days)	Captures Exposure during Delivery Visit
1	Use Algorithm Codes*	294	Use Algorithm Codes*	273	7	Tdap Vaccination	Any	N/A	0	Yes
2	Use Algorithm Codes*	294	Use Algorithm Codes*	273	7	Tdap Vaccination	Any	N/A	0	No - does not capture exposure during delivery visit
3	Use Algorithm Codes*	294	Use Algorithm Codes*	273	7	Tdap Vaccination	Any	N/A	0	No - does not capture exposure during delivery visit or in the 14 days before the delivery visit

ICD-9-CM, ICD-10-CM, HCPCS, and CPT codes are provided by Optum360.

\*Use codes from a previously validated algorithm from Sentinel's Medication Exposure in Pregnancy Risk Evaluation Program (default). This algorithm uses pre/postterm delivery codes present around the delivery date to determine a pregnancy duration. Requesters must set a default pregnancy duration value should no pre/postterm codes be observed around the delivery date (e.g., 273 days [39 weeks]).