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

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

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

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Overview

Date Run: April 28, 2017

Request Description: The purpose of this report was to compare the frequency of diagnoses and procedures for lower limb amputation using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) codes. ICD-10-PCS code definitions were determined by mapping from ICD-9-CM code definitions using the Centers for Medicare and Medicaid Services (CMS) General Equivalence Mappings (GEMs). Simple forward mapping (SFM) and forward-backward mapping (FBM) were used to map ICD-9-CM to ICD-10-PCS codes.¹

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.3.6

Data Source: This request was run against the IBM® MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 121 million members. Data from October 1, 2010 to March 31, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to March 31, 2016, 2) January 1, 2015 to March 31, 2015, and 3) January 1, 2016 to March 31, 2016. See Appendix A for the dates of available data used in this report.

Study Design: We examined the incidence of lower limb amputation across the ICD-9-CM era (October 2010 to September 2015) and ICD-10-PCS era (October 2015 to March 2016) in the US. Incidence was additionally evaluated from January 2015 to March 2015 and January 2016 to March 2016. See Appendix B for specific codes.

Cohort Eligibility Criteria: Members included in the cohort were required to be continuously enrolled in health plans with at least medical coverage for at least 183 days prior to lower limb amputation, during which gaps in coverage of up to 45 days were allowed. Incident lower limb amputation was defined as no previous lower limb amputation in the 183 days preceding the index date with respect to ICD-9-CM and ICD-10-PCS codes. The following age groups were included in the cohort: 2-17, 18-44, 45-64, 65+ years.

Limitations: Algorithms used to define outcomes are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind. The MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented.²

Please refer to Appendix C for detailed specifications of parameters used in the analyses for this request.

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

¹Fung, K. W., et al. (2016). "Preparing for the ICD-10-CM Transition: Automated Methods for Translating ICD Codes in Clinical Phenotype Definitions." EGEMS (Wash DC) 4(1): 1211.

²IBM Watson Health (2018). [online] ibm.com. Available at: <https://www.ibm.com/downloads/cas/OWZWJ0QO> [Accessed 01 Mar. 2019].

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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). 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: (1): Cohort includes only the first valid treatment episode during the query period; (2): Cohort includes all valid treatment episodes during the query period; (3): Cohort includes all valid treatment episodes during the query period until an event occurs.

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 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 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 days 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.

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

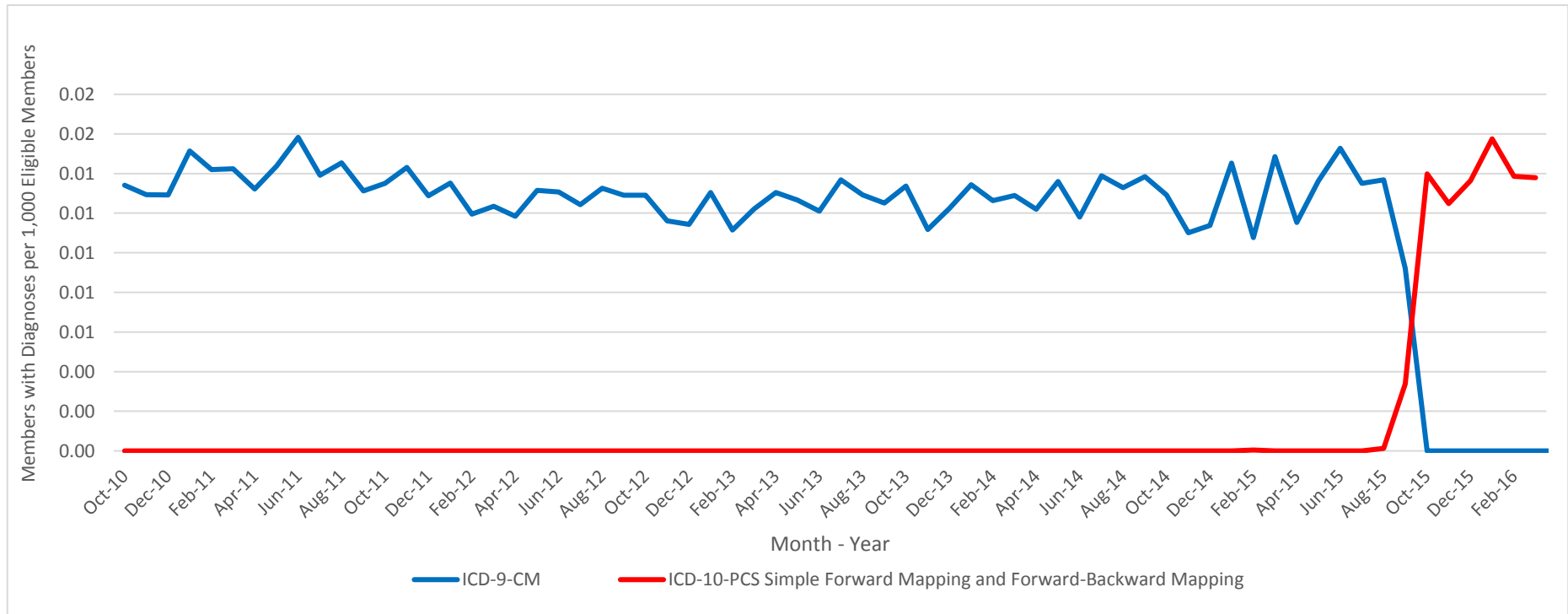
Table 1. Comparison of Incident* Lower Limb Amputation Diagnoses and Procedures in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Eras (January 1, 2015 - March 31, 2015 and January 1, 2016 - March 31, 2016)

	Members with Diagnosis	Eligible Members	Members with Diagnosis per 1,000 Eligible Members
Lower Limb Amputation			
ICD-9-CM: January 1, 2015 - March 31, 2015	1,038	22,224,047	0.05
ICD-10-PCS**: January 1, 2016 - March 31, 2016	1,003	22,698,573	0.04

* Incidence defined by 90 day washout

** Codes determined from simple forward mapping (SFM) and forward-backward mapping (FBM)

Figure 1. Incidence of Lower Limb Amputation Diagnoses and Procedures per 1,000 Eligible Members from October 2010 - March 2016 by Code Type, 183-Day Washout



Appendix A. Dates Available for IBM® MarketScan® Commercial and Medicare Supplemental Databases

Databases	Start Date	End Date
IBM MarketScan Commercial and Medicare Supplemental Databases ¹	1/1/2010	3/31/2016

¹ The IBM MarketScan Databases includes a sample of 121 million employees, dependents, and retirees in the United States with primary or Medicare supplemental coverage through privately insured fee-for-service, point-of-service, or capitated health plans. The IBM MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented. For more information on the IBM MarketScan Databases, please review the White Paper here: <https://www.ibm.com/downloads/cas/OWZWJ0QO>

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Codes Used to Define Lower Limb Amputation

Code	Description	Code Type
ICD-9-CM		
84.1	Amputation Of Lower Limb	ICD-9-CM
84.10	Lower Limb Amputation, Not Otherwise Specified	ICD-9-CM
84.11	Amputation Of Toe	ICD-9-CM
84.12	Amputation Through Foot	ICD-9-CM
84.13	Disarticulation Of Ankle	ICD-9-CM
84.14	Amputation Of Ankle Through Malleoli Of Tibia And Fibula	ICD-9-CM
84.15	Other Amputation Below Knee	ICD-9-CM
84.16	Disarticulation Of Knee	ICD-9-CM
84.17	Amputation Above Knee	ICD-9-CM
ICD-10-PCS		
0Y6C0Z1	Detachment at Right Upper Leg, High, Open Approach	ICD-10-PCS
0Y6J0Z3	Detachment at Left Lower Leg, Low, Open Approach	ICD-10-PCS
0Y6J0Z2	Detachment at Left Lower Leg, Mid, Open Approach	ICD-10-PCS
0Y6J0Z1	Detachment at Left Lower Leg, High, Open Approach	ICD-10-PCS
0Y6H0Z3	Detachment at Right Lower Leg, Low, Open Approach	ICD-10-PCS
0Y6H0Z2	Detachment at Right Lower Leg, Mid, Open Approach	ICD-10-PCS
0Y6H0Z1	Detachment at Right Lower Leg, High, Open Approach	ICD-10-PCS
0Y6D0Z3	Detachment at Left Upper Leg, Low, Open Approach	ICD-10-PCS
0Y6D0Z2	Detachment at Left Upper Leg, Mid, Open Approach	ICD-10-PCS
0Y6D0Z1	Detachment at Left Upper Leg, High, Open Approach	ICD-10-PCS
0Y6C0Z3	Detachment at Right Upper Leg, Low, Open Approach	ICD-10-PCS
0Y6C0Z2	Detachment at Right Upper Leg, Mid, Open Approach	ICD-10-PCS
0Y6P0Z0	Detachment at Right 1st Toe, Complete, Open Approach	ICD-10-PCS
0Y6Y0Z3	Detachment at Left 5th Toe, Low, Open Approach	ICD-10-PCS
0Y6Y0Z2	Detachment at Left 5th Toe, Mid, Open Approach	ICD-10-PCS
0Y6Y0Z1	Detachment at Left 5th Toe, High, Open Approach	ICD-10-PCS
0Y6Y0Z0	Detachment at Left 5th Toe, Complete, Open Approach	ICD-10-PCS
0Y6X0Z3	Detachment at Right 5th Toe, Low, Open Approach	ICD-10-PCS
0Y6X0Z2	Detachment at Right 5th Toe, Mid, Open Approach	ICD-10-PCS
0Y6X0Z1	Detachment at Right 5th Toe, High, Open Approach	ICD-10-PCS
0Y6X0Z0	Detachment at Right 5th Toe, Complete, Open Approach	ICD-10-PCS
0Y6W0Z3	Detachment at Left 4th Toe, Low, Open Approach	ICD-10-PCS
0Y6W0Z2	Detachment at Left 4th Toe, Mid, Open Approach	ICD-10-PCS
0Y6W0Z1	Detachment at Left 4th Toe, High, Open Approach	ICD-10-PCS
0Y6W0Z0	Detachment at Left 4th Toe, Complete, Open Approach	ICD-10-PCS
0Y6V0Z3	Detachment at Right 4th Toe, Low, Open Approach	ICD-10-PCS
0Y6V0Z2	Detachment at Right 4th Toe, Mid, Open Approach	ICD-10-PCS
0Y6V0Z1	Detachment at Right 4th Toe, High, Open Approach	ICD-10-PCS
0Y6V0Z0	Detachment at Right 4th Toe, Complete, Open Approach	ICD-10-PCS
0Y6U0Z3	Detachment at Left 3rd Toe, Low, Open Approach	ICD-10-PCS
0Y6U0Z2	Detachment at Left 3rd Toe, Mid, Open Approach	ICD-10-PCS
0Y6U0Z1	Detachment at Left 3rd Toe, High, Open Approach	ICD-10-PCS

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Codes Used to Define Lower Limb Amputation

Code	Description	Code Type
0Y6U0Z0	Detachment at Left 3rd Toe, Complete, Open Approach	ICD-10-PCS
0Y6T0Z3	Detachment at Right 3rd Toe, Low, Open Approach	ICD-10-PCS
0Y6T0Z2	Detachment at Right 3rd Toe, Mid, Open Approach	ICD-10-PCS
0Y6T0Z1	Detachment at Right 3rd Toe, High, Open Approach	ICD-10-PCS
0Y6T0Z0	Detachment at Right 3rd Toe, Complete, Open Approach	ICD-10-PCS
0Y6S0Z3	Detachment at Left 2nd Toe, Low, Open Approach	ICD-10-PCS
0Y6S0Z2	Detachment at Left 2nd Toe, Mid, Open Approach	ICD-10-PCS
0Y6S0Z1	Detachment at Left 2nd Toe, High, Open Approach	ICD-10-PCS
0Y6S0Z0	Detachment at Left 2nd Toe, Complete, Open Approach	ICD-10-PCS
0Y6R0Z3	Detachment at Right 2nd Toe, Low, Open Approach	ICD-10-PCS
0Y6R0Z2	Detachment at Right 2nd Toe, Mid, Open Approach	ICD-10-PCS
0Y6R0Z1	Detachment at Right 2nd Toe, High, Open Approach	ICD-10-PCS
0Y6R0Z0	Detachment at Right 2nd Toe, Complete, Open Approach	ICD-10-PCS
0Y6Q0Z3	Detachment at Left 1st Toe, Low, Open Approach	ICD-10-PCS
0Y6Q0Z2	Detachment at Left 1st Toe, Mid, Open Approach	ICD-10-PCS
0Y6Q0Z1	Detachment at Left 1st Toe, High, Open Approach	ICD-10-PCS
0Y6Q0Z0	Detachment at Left 1st Toe, Complete, Open Approach	ICD-10-PCS
0Y6P0Z3	Detachment at Right 1st Toe, Low, Open Approach	ICD-10-PCS
0Y6P0Z2	Detachment at Right 1st Toe, Mid, Open Approach	ICD-10-PCS
0Y6P0Z1	Detachment at Right 1st Toe, High, Open Approach	ICD-10-PCS
0Y6M0Z4	Detachment at Right Foot, Complete 1st Ray, Open Approach	ICD-10-PCS
0Y6N0ZF	Detachment at Left Foot, Partial 5th Ray, Open Approach	ICD-10-PCS
0Y6N0ZD	Detachment at Left Foot, Partial 4th Ray, Open Approach	ICD-10-PCS
0Y6N0ZC	Detachment at Left Foot, Partial 3rd Ray, Open Approach	ICD-10-PCS
0Y6N0ZB	Detachment at Left Foot, Partial 2nd Ray, Open Approach	ICD-10-PCS
0Y6N0Z9	Detachment at Left Foot, Partial 1st Ray, Open Approach	ICD-10-PCS
0Y6N0Z8	Detachment at Left Foot, Complete 5th Ray, Open Approach	ICD-10-PCS
0Y6N0Z7	Detachment at Left Foot, Complete 4th Ray, Open Approach	ICD-10-PCS
0Y6N0Z6	Detachment at Left Foot, Complete 3rd Ray, Open Approach	ICD-10-PCS
0Y6N0Z5	Detachment at Left Foot, Complete 2nd Ray, Open Approach	ICD-10-PCS
0Y6N0Z4	Detachment at Left Foot, Complete 1st Ray, Open Approach	ICD-10-PCS
0Y6M0ZF	Detachment at Right Foot, Partial 5th Ray, Open Approach	ICD-10-PCS
0Y6M0ZD	Detachment at Right Foot, Partial 4th Ray, Open Approach	ICD-10-PCS
0Y6M0ZC	Detachment at Right Foot, Partial 3rd Ray, Open Approach	ICD-10-PCS
0Y6M0ZB	Detachment at Right Foot, Partial 2nd Ray, Open Approach	ICD-10-PCS
0Y6M0Z9	Detachment at Right Foot, Partial 1st Ray, Open Approach	ICD-10-PCS
0Y6M0Z8	Detachment at Right Foot, Complete 5th Ray, Open Approach	ICD-10-PCS
0Y6M0Z7	Detachment at Right Foot, Complete 4th Ray, Open Approach	ICD-10-PCS
0Y6M0Z6	Detachment at Right Foot, Complete 3rd Ray, Open Approach	ICD-10-PCS
0Y6M0Z5	Detachment at Right Foot, Complete 2nd Ray, Open Approach	ICD-10-PCS
0Y6M0Z0	Detachment at Right Foot, Complete, Open Approach	ICD-10-PCS
0Y6N0Z0	Detachment at Left Foot, Complete, Open Approach	ICD-10-PCS
0Y6F0ZZ	Detachment at Right Knee Region, Open Approach	ICD-10-PCS

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Codes Used to Define Lower Limb Amputation

Code	Description	Code Type
0Y6G0ZZ	Detachment at Left Knee Region, Open Approach	ICD-10-PCS

Appendix C. Specifications for Parameters for this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.3.6, was used to compare the frequency of diagnoses and procedures for lower limb amputation using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) versus International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) codes.

Enrollment Gap: 45 days

Age Groups: 2-17, 18-44, 45-64, 65+ years

Enrollment Requirement: 183 days

Coverage Requirement: At least medical coverage

Scenario	Query Start Date	Query End Date	Code Source	Event				
				Event	Incident with respect to:	Washout (days)	Cohort Definition	Caresetting
1	1/1/2015	3/31/2015	ICD-9-CM Code Search	Lower Limb Amputation	ICD-9-CM	90	First valid event only	Any
2	1/1/2016	3/31/2016	ICD-10-PCS SFM and FBM	Lower Limb Amputation	ICD-10-PCS SFM and FBM	90	First valid event only	Any
3	10/1/2010	3/31/2016	ICD-9-CM Code Search	Lower Limb Amputation	ICD-9-CM or ICD-10-PCS SFM and FBM	183	First valid event only	Any
4	10/1/2010	3/31/2016	ICD-10-PCS SFM and FBM	Lower Limb Amputation	ICD-9-CM or ICD-10-PCS SFM and FBM	183	First valid event only	Any

ICD-9-CM and ICD-10-PCS are provided by Optum360. ICD-10-PCS codes were mapped from ICD-9-CM codes with the Centers for Medicare and Medicaid Services General Equivalence Mappings, using simple forward mapping (SFM) and forward-backward mapping (FBM).