

## Disclaimer

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

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

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

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

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## Overview

**Date Run:** October 25, 2017

**Request Description:** The purpose of this report was to compare the frequency of diagnoses for deep vein thrombosis using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) versus International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes. ICD-10-CM 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). Forward-backward mapping (FBM) was used to map ICD-9-CM to ICD-10-CM codes.<sup>1</sup>

**Sentinel Modular Program Tool Used:** Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.0.5

**Data Source:** This request was run against data from 12 Data Partners contributing to the Sentinel Distributed Database (SDD). Data from October 1, 2010 to September 30, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to September 30, 2016; 2) April 1, 2015 to September 30, 2015; and 3) April 1, 2016 to September 30, 2016. This request was distributed to Data Partners on October 25, 2017. See Appendix A for a list of dates of available data for each Data Partner.

**Study Design:** We examined the incidence and prevalence across the ICD-9-CM era (October 2010 - September 2015) and ICD-10-CM era (October 2015 - September 2016) in the United States. Incidence was additionally evaluated from April 2015 to September 2015 and April 2016 to September 2016. See Appendix B for specific codes used to define deep vein thrombosis in this request.

**Cohort Eligibility Criteria:** Members included in the cohort were required to be continuously enrolled in health plans with medical and drug coverage for at least six months (183 days) before their diagnosis date, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: 21-64, 65-74, 75-84, and 85-99 years.

**Incident Cohorts:** Members included in the incident cohorts were required to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to deep vein thrombosis diagnosis, during which gaps in coverage of up to 45 days were allowed. Incident deep vein thrombosis was defined as no previous deep vein thrombosis diagnoses in the 183 days preceding the index date with respect to ICD-9-CM and ICD-10-CM codes.

**Prevalent Cohorts:** There was no enrollment time requirement for members in the prevalent cohorts. All qualifying diagnosis codes that occurred between October 1, 2010 and September 30, 2016 were included.

**Please see Appendix C for detailed specifications of parameters used in the analyses for this request.**

**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.

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

<sup>1</sup>Fung, 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.

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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, 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 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.

**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.

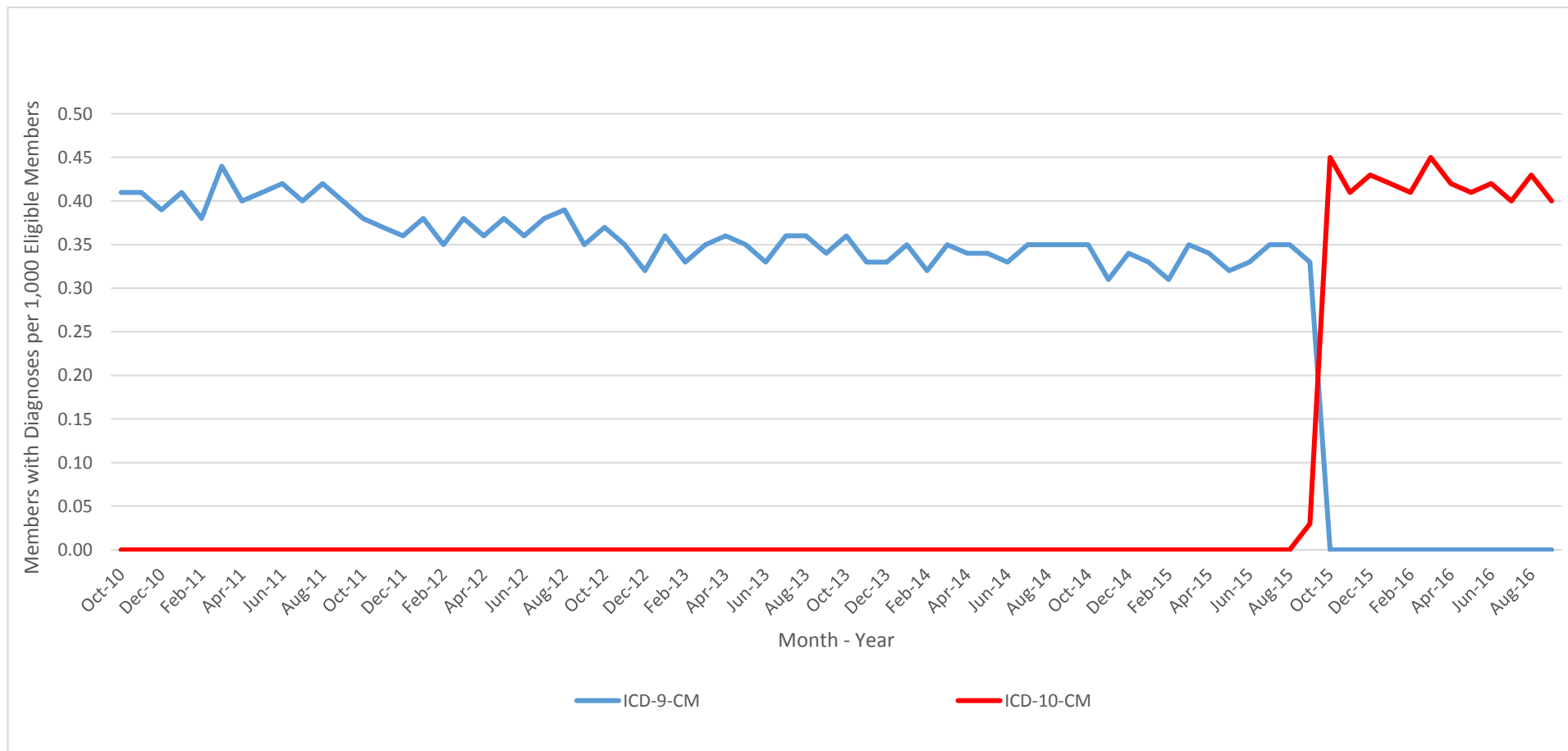
\*all terms may not be used in this report

**Table 1. Comparison of Incident\* Deep Vein Thrombosis Diagnoses in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras (April 1, 2015 - September 30, 2015 and April 1, 2016 - September 30, 2016)**

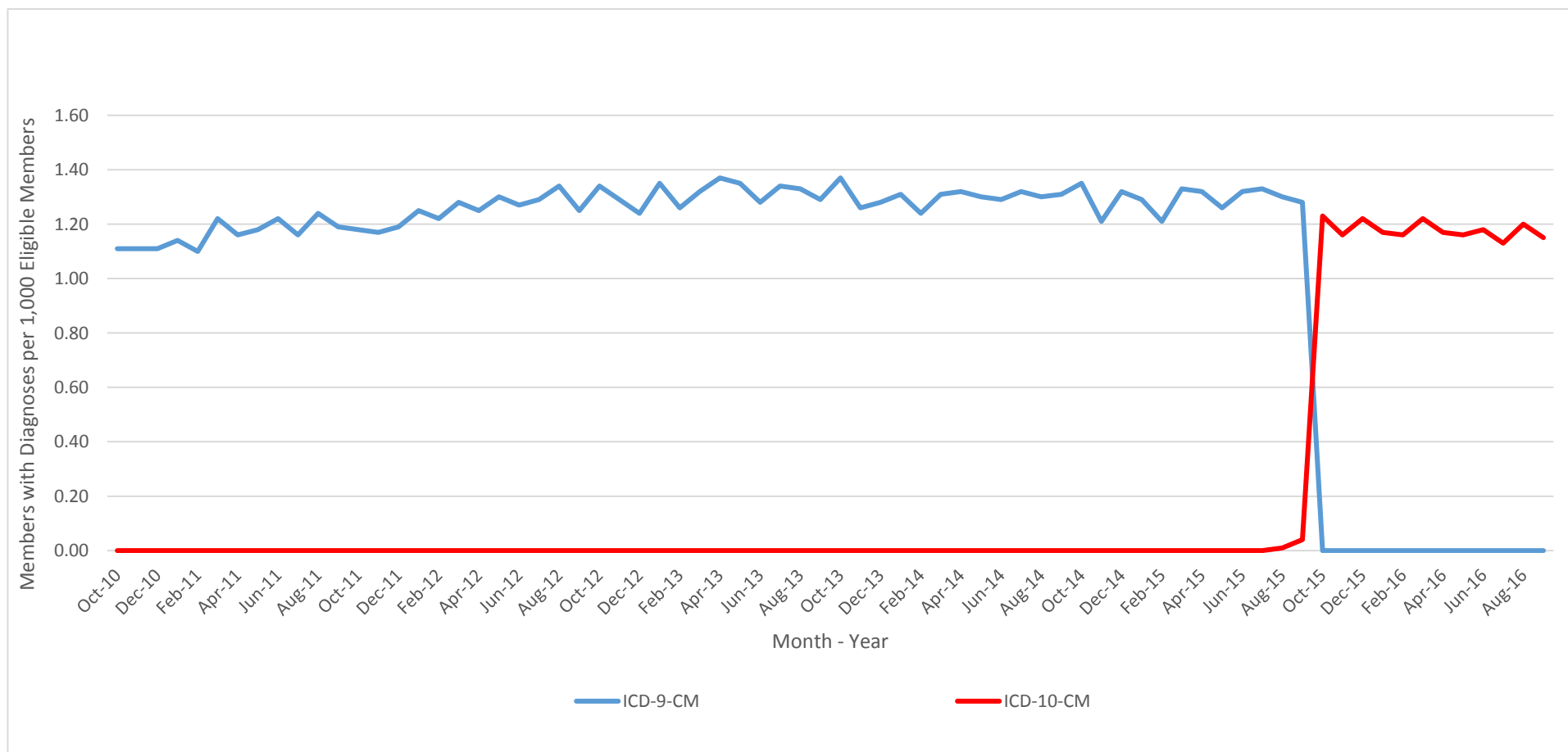
	Members with Diagnosis	Eligible Members	Members with Diagnosis per 1,000 Eligible Members
<b>Deep Vein Thrombosis</b>			
<b>ICD-9-CM: April 1, 2015 - September 30, 2015</b>	72,927	32,338,522	2.26
<b>ICD-10-CM: April 1, 2016 - September 30, 2016</b>	73,946	33,717,750	2.19

\*Incidence defined by a 183 day washout

**Figure 1. Incidence of Deep Vein Thrombosis Diagnoses per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 183-Day Washout**



**Figure 2. Prevalence of Deep Vein Thrombosis Diagnosis per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 0-Day Washout**





**Appendix A. Dates of Available Data for Each Data Partner as of Request Distribution Date (October 25, 2017)**

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<b>DP ID</b>	<b>Start Date<sup>1</sup></b>	<b>End Date<sup>1</sup></b>
DP0001	10/1/2010	6/30/2016
DP0002	10/1/2010	6/30/2016
DP0003	10/1/2010	9/30/2016
DP0004	10/1/2010	9/30/2016
DP0005	10/1/2010	9/30/2016
DP0006	10/1/2010	9/30/2016
DP0007	10/1/2010	9/30/2016
DP0008	10/1/2010	9/30/2016
DP0009	10/1/2010	9/30/2016
DP0010	10/1/2010	9/30/2016
DP0011	10/1/2010	9/30/2016
DP0012	10/1/2010	9/30/2016

<sup>1</sup>The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

**Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Deep Vein Thrombosis**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>
<b>ICD-9-CM</b>		
451.1	Phlebitis and thrombophlebitis of deep veins of lower extremities	ICD-9-CM
451.11	Phlebitis and thrombophlebitis of femoral vein (deep) (superficial)	ICD-9-CM
451.19	Phlebitis and thrombophlebitis of other deep vessels of lower extremities	ICD-9-CM
451.2	Phlebitis and thrombophlebitis of lower extremities, unspecified	ICD-9-CM
451.81	Phlebitis and thrombophlebitis of iliac vein	ICD-9-CM
451.83	Phlebitis and thrombophlebitis of deep veins of upper extremities	ICD-9-CM
453.4	Acute venous embolism and thrombosis of deep vessels of lower extremity	ICD-9-CM
453.40	Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity	ICD-9-CM
453.41	Acute venous embolism and thrombosis of deep vessels of proximal lower extremity	ICD-9-CM
453.42	Acute venous embolism and thrombosis of deep vessels of distal lower extremity	ICD-9-CM
453.84	Acute venous embolism and thrombosis of axillary veins	ICD-9-CM
<b>ICD-10-CM</b>		
I80.10	Phlebitis and thrombophlebitis of unspecified femoral vein	ICD-10-CM
I80.11	Phlebitis and thrombophlebitis of right femoral vein	ICD-10-CM
I80.12	Phlebitis and thrombophlebitis of left femoral vein	ICD-10-CM
I80.13	Phlebitis and thrombophlebitis of femoral vein, bilateral	ICD-10-CM
I80.201	Phlebitis and thrombophlebitis of unspecified deep vessels of right lower extremity	ICD-10-CM
I80.202	Phlebitis and thrombophlebitis of unspecified deep vessels of left lower extremity	ICD-10-CM
I80.203	Phlebitis and thrombophlebitis of unspecified deep vessels of lower extremities, bilateral	ICD-10-CM
I80.209	Phlebitis and thrombophlebitis of unspecified deep vessels of unspecified lower extremity	ICD-10-CM
I80.211	Phlebitis and thrombophlebitis of right iliac vein	ICD-10-CM
I80.212	Phlebitis and thrombophlebitis of left iliac vein	ICD-10-CM
I80.213	Phlebitis and thrombophlebitis of iliac vein, bilateral	ICD-10-CM
I80.219	Phlebitis and thrombophlebitis of unspecified iliac vein	ICD-10-CM
I80.221	Phlebitis and thrombophlebitis of right popliteal vein	ICD-10-CM
I80.222	Phlebitis and thrombophlebitis of left popliteal vein	ICD-10-CM
I80.223	Phlebitis and thrombophlebitis of popliteal vein, bilateral	ICD-10-CM
I80.229	Phlebitis and thrombophlebitis of unspecified popliteal vein	ICD-10-CM
I80.231	Phlebitis and thrombophlebitis of right tibial vein	ICD-10-CM
I80.232	Phlebitis and thrombophlebitis of left tibial vein	ICD-10-CM
I80.233	Phlebitis and thrombophlebitis of tibial vein, bilateral	ICD-10-CM
I80.239	Phlebitis and thrombophlebitis of unspecified tibial vein	ICD-10-CM
I80.291	Phlebitis and thrombophlebitis of other deep vessels of right lower extremity	ICD-10-CM
I80.292	Phlebitis and thrombophlebitis of other deep vessels of left lower extremity	ICD-10-CM
I80.293	Phlebitis and thrombophlebitis of other deep vessels of lower extremity, bilateral	ICD-10-CM
I80.299	Phlebitis and thrombophlebitis of other deep vessels of unspecified lower extremity	ICD-10-CM
I80.3	Phlebitis and thrombophlebitis of lower extremities, unspecified	ICD-10-CM
I80.8	Phlebitis and thrombophlebitis of other sites	ICD-10-CM
I82.401	Acute embolism and thrombosis of unspecified deep veins of right lower extremity	ICD-10-CM
I82.402	Acute embolism and thrombosis of unspecified deep veins of left lower extremity	ICD-10-CM

**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 Deep Vein Thrombosis**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>
I82.403	Acute embolism and thrombosis of unspecified deep veins of lower extremity, bilateral	ICD-10-CM
I82.409	Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity	ICD-10-CM
I82.411	Acute embolism and thrombosis of right femoral vein	ICD-10-CM
I82.412	Acute embolism and thrombosis of left femoral vein	ICD-10-CM
I82.413	Acute embolism and thrombosis of femoral vein, bilateral	ICD-10-CM
I82.419	Acute embolism and thrombosis of unspecified femoral vein	ICD-10-CM
I82.421	Acute embolism and thrombosis of right iliac vein	ICD-10-CM
I82.422	Acute embolism and thrombosis of left iliac vein	ICD-10-CM
I82.423	Acute embolism and thrombosis of iliac vein, bilateral	ICD-10-CM
I82.429	Acute embolism and thrombosis of unspecified iliac vein	ICD-10-CM
I82.431	Acute embolism and thrombosis of right popliteal vein	ICD-10-CM
I82.432	Acute embolism and thrombosis of left popliteal vein	ICD-10-CM
I82.433	Acute embolism and thrombosis of popliteal vein, bilateral	ICD-10-CM
I82.439	Acute embolism and thrombosis of unspecified popliteal vein	ICD-10-CM
I82.441	Acute embolism and thrombosis of right tibial vein	ICD-10-CM
I82.442	Acute embolism and thrombosis of left tibial vein	ICD-10-CM
I82.443	Acute embolism and thrombosis of tibial vein, bilateral	ICD-10-CM
I82.449	Acute embolism and thrombosis of unspecified tibial vein	ICD-10-CM
I82.491	Acute embolism and thrombosis of other specified deep vein of right lower extremity	ICD-10-CM
I82.492	Acute embolism and thrombosis of other specified deep vein of left lower extremity	ICD-10-CM
I82.493	Acute embolism and thrombosis of other specified deep vein of lower extremity, bilateral	ICD-10-CM
I82.499	Acute embolism and thrombosis of other specified deep vein of unspecified lower extremity	ICD-10-CM
I82.4Y1	Acute embolism and thrombosis of unspecified deep veins of right proximal lower extremity	ICD-10-CM
I82.4Y2	Acute embolism and thrombosis of unspecified deep veins of left proximal lower extremity	ICD-10-CM
I82.4Y3	Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral	ICD-10-CM
I82.4Y9	Acute embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity	ICD-10-CM
I82.4Z1	Acute embolism and thrombosis of unspecified deep veins of right distal lower extremity	ICD-10-CM
I82.4Z2	Acute embolism and thrombosis of unspecified deep veins of left distal lower extremity	ICD-10-CM
I82.4Z3	Acute embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral	ICD-10-CM
I82.4Z9	Acute embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity	ICD-10-CM
I82.A11	Acute embolism and thrombosis of right axillary vein	ICD-10-CM
I82.A12	Acute embolism and thrombosis of left axillary vein	ICD-10-CM
I82.A13	Acute embolism and thrombosis of axillary vein, bilateral	ICD-10-CM
I82.A19	Acute embolism and thrombosis of unspecified axillary vein	ICD-10-CM

**Appendix C. Specifications for Parameters for this Request**

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool version 5.0.5 was used to compare the frequency of diagnoses for deep vein thrombosis using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes.

**Enrollment Gap:** 45 days

**Age Groups:** 21-64, 65-74, 75-84, 85-99 years

**Enrollment Requirement:** 183 days for incidence scenarios; 0 days for prevalence scenarios

**Coverage Requirement:** Medical and drug coverage

Scenario	Query Start Date	Query End Date	Event					
			Event	Event Code Type	Incident with Respect To:	Washout (days)	Cohort Definition	Care Setting
1	4/1/2015	9/30/2015	Deep Vein Thrombosis	ICD-9-CM	ICD-9-CM	183	First valid event only	Any
2	4/1/2016	9/30/2016	Deep Vein Thrombosis	ICD-10-CM	ICD-10-CM	183	First valid event only	Any
3	10/1/2010	9/30/2016	Deep Vein Thrombosis	ICD-9-CM	ICD-9-CM or ICD-10-CM	183	First valid event only	Any
4	10/1/2010	9/30/2016	Deep Vein Thrombosis	ICD-10-CM	ICD-9-CM or ICD-10-CM	183	First valid event only	Any
5	10/1/2010	9/30/2016	Deep Vein Thrombosis	ICD-9-CM	N/A	0	Any valid events	Any
6	10/1/2010	9/30/2016	Deep Vein Thrombosis	ICD-10-CM	N/A	0	Any valid events	Any

ICD-9-CM and ICD-10-CM are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings.