

Disclaimer

The FDA chose a specific outcome algorithm that met its need for a given medical product-outcome assessment. The use of a specific outcome algorithm in a Sentinel assessment should not be interpreted as an endorsement from FDA to use the algorithm for all safety assessments. Investigators should always consider the objective, study design, analytic approach, and data source of a given medical product safety assessment when choosing the outcome algorithm. The suitability of an outcome algorithm may change when applied to different scenarios. For additional information, please refer to the

[Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data](#) guidance document provided by the FDA.

Overview

Title	Thromboembolic Stroke Algorithm Defined in "Thromboembolic Stroke, Intracranial Hemorrhage, Gastrointestinal Bleeding, and Major Extracranial Bleeding Following Apixaban, Dabigatran, and Rivaroxaban Use in Patients Aged 64 Years and Younger with Atrial Fibrillation: An Inverse Probability of Treatment Weighting Analysis"
Request IDs	cder_mpl2p_wp039, cder_mpl2p_wp044, cder_mpl2p_wp047
Description	<p>This report lists International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis codes and algorithms used to define thromboembolic stroke in this request.</p> <p>For additional information about the algorithm and how it was defined relative to the cohort and exposures of interest in the inferential analysis, see the analysis page here: https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/thromboembolic-stroke-intracranial-hemorrhage-0</p>
Outcome	Thromboembolic stroke
Algorithm to Define Outcome	The thromboembolic stroke outcome is defined as evidence of an ICD-9-CM or ICD-10-CM diagnosis code from Code List 1 that is the primary diagnosis from an inpatient encounter.
Query Period	October 19, 2010 - February 28, 2022
Request Send Dates	November 15, 2022, March 20, 2023, and July 7, 2023

Glossary

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)

Outcome - outcome of interest (either primary or secondary)

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

Request Send Date - date the request was sent to Sentinel Data Partners

**List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM)
Diagnosis Codes Used to Define Thromboembolic Stroke in this Request**

Code	Description	Code Type	Code Category
433.01	Occlusion and stenosis of basilar artery with cerebral infarction	ICD-9-CM	Diagnosis
433.11	Occlusion and stenosis of carotid artery with cerebral infarction	ICD-9-CM	Diagnosis
433.21	Occlusion and stenosis of vertebral artery with cerebral infarction	ICD-9-CM	Diagnosis
433.31	Occlusion and stenosis of multiple and bilateral precerebral arteries with cerebral infarction	ICD-9-CM	Diagnosis
433.81	Occlusion and stenosis of other specified precerebral artery with cerebral infarction	ICD-9-CM	Diagnosis
433.91	Occlusion and stenosis of unspecified precerebral artery with cerebral infarction	ICD-9-CM	Diagnosis
434.01	Cerebral thrombosis with cerebral infarction	ICD-9-CM	Diagnosis
434.11	Cerebral embolism with cerebral infarction	ICD-9-CM	Diagnosis
434.91	Unspecified cerebral artery occlusion with cerebral infarction	ICD-9-CM	Diagnosis
436	Acute, but ill-defined, cerebrovascular disease	ICD-9-CM	Diagnosis
I63.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar arteries	ICD-10-CM	Diagnosis
I63.139	Cerebral infarction due to embolism of unspecified carotid artery	ICD-10-CM	Diagnosis
I63.239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries	ICD-10-CM	Diagnosis
I63.019	Cerebral infarction due to thrombosis of unspecified vertebral artery	ICD-10-CM	Diagnosis
I63.119	Cerebral infarction due to embolism of unspecified vertebral artery	ICD-10-CM	Diagnosis
I63.219	Cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral arteries	ICD-10-CM	Diagnosis
I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery	ICD-10-CM	Diagnosis
I63.20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries	ICD-10-CM	Diagnosis
I63.30	Cerebral infarction due to thrombosis of unspecified cerebral artery	ICD-10-CM	Diagnosis
I63.40	Cerebral infarction due to embolism of unspecified cerebral artery	ICD-10-CM	Diagnosis
I63.50	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery	ICD-10-CM	Diagnosis
I67.89	Other cerebrovascular disease	ICD-10-CM	Diagnosis
I63.00	Cerebral infarction due to thrombosis of unspecified precerebral artery	ICD-10-CM	Diagnosis
I63.011	Cerebral infarction due to thrombosis of right vertebral artery	ICD-10-CM	Diagnosis
I63.012	Cerebral infarction due to thrombosis of left vertebral artery	ICD-10-CM	Diagnosis
I63.013	Cerebral infarction due to thrombosis of bilateral vertebral arteries	ICD-10-CM	Diagnosis
I63.02	Cerebral infarction due to thrombosis of basilar artery	ICD-10-CM	Diagnosis
I63.031	Cerebral infarction due to thrombosis of right carotid artery	ICD-10-CM	Diagnosis
I63.032	Cerebral infarction due to thrombosis of left carotid artery	ICD-10-CM	Diagnosis
I63.033	Cerebral infarction due to thrombosis of bilateral carotid arteries	ICD-10-CM	Diagnosis
I63.039	Cerebral infarction due to thrombosis of unspecified carotid artery	ICD-10-CM	Diagnosis
I63.09	Cerebral infarction due to thrombosis of other precerebral artery	ICD-10-CM	Diagnosis
I63.10	Cerebral infarction due to embolism of unspecified precerebral artery	ICD-10-CM	Diagnosis
I63.111	Cerebral infarction due to embolism of right vertebral artery	ICD-10-CM	Diagnosis
I63.112	Cerebral infarction due to embolism of left vertebral artery	ICD-10-CM	Diagnosis
I63.113	Cerebral infarction due to embolism of bilateral vertebral arteries	ICD-10-CM	Diagnosis
I63.12	Cerebral infarction due to embolism of basilar artery	ICD-10-CM	Diagnosis

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Code	Description	Code Type	Code Category
I63.131	Cerebral infarction due to embolism of right carotid artery	ICD-10-CM	Diagnosis
I63.132	Cerebral infarction due to embolism of left carotid artery	ICD-10-CM	Diagnosis
I63.133	Cerebral infarction due to embolism of bilateral carotid arteries	ICD-10-CM	Diagnosis
I63.19	Cerebral infarction due to embolism of other precerebral artery	ICD-10-CM	Diagnosis
I63.211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral arteries	ICD-10-CM	Diagnosis
I63.212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral arteries	ICD-10-CM	Diagnosis
I63.213	Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries	ICD-10-CM	Diagnosis
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries	ICD-10-CM	Diagnosis
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries	ICD-10-CM	Diagnosis
I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries	ICD-10-CM	Diagnosis
I63.29	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries	ICD-10-CM	Diagnosis
I63.311	Cerebral infarction due to thrombosis of right middle cerebral artery	ICD-10-CM	Diagnosis
I63.312	Cerebral infarction due to thrombosis of left middle cerebral artery	ICD-10-CM	Diagnosis
I63.313	Cerebral infarction due to thrombosis of bilateral middle cerebral arteries	ICD-10-CM	Diagnosis
I63.319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery	ICD-10-CM	Diagnosis
I63.321	Cerebral infarction due to thrombosis of right anterior cerebral artery	ICD-10-CM	Diagnosis
I63.322	Cerebral infarction due to thrombosis of left anterior cerebral artery	ICD-10-CM	Diagnosis
I63.323	Cerebral infarction due to thrombosis of bilateral anterior arteries	ICD-10-CM	Diagnosis
I63.329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery	ICD-10-CM	Diagnosis
I63.331	Cerebral infarction due to thrombosis of right posterior cerebral artery	ICD-10-CM	Diagnosis
I63.332	Cerebral infarction due to thrombosis of left posterior cerebral artery	ICD-10-CM	Diagnosis
I63.333	Cerebral infarction to thrombosis of bilateral posterior arteries	ICD-10-CM	Diagnosis
I63.339	Cerebral infarction due to thrombosis of unspecified posterior cerebral artery	ICD-10-CM	Diagnosis
I63.341	Cerebral infarction due to thrombosis of right cerebellar artery	ICD-10-CM	Diagnosis
I63.342	Cerebral infarction due to thrombosis of left cerebellar artery	ICD-10-CM	Diagnosis
I63.343	Cerebral infarction to thrombosis of bilateral cerebellar arteries	ICD-10-CM	Diagnosis
I63.349	Cerebral infarction due to thrombosis of unspecified cerebellar artery	ICD-10-CM	Diagnosis
I63.39	Cerebral infarction due to thrombosis of other cerebral artery	ICD-10-CM	Diagnosis
I63.411	Cerebral infarction due to embolism of right middle cerebral artery	ICD-10-CM	Diagnosis
I63.412	Cerebral infarction due to embolism of left middle cerebral artery	ICD-10-CM	Diagnosis
I63.413	Cerebral infarction due to embolism of bilateral middle cerebral arteries	ICD-10-CM	Diagnosis
I63.419	Cerebral infarction due to embolism of unspecified middle cerebral artery	ICD-10-CM	Diagnosis
I63.421	Cerebral infarction due to embolism of right anterior cerebral artery	ICD-10-CM	Diagnosis
I63.422	Cerebral infarction due to embolism of left anterior cerebral artery	ICD-10-CM	Diagnosis
I63.423	Cerebral infarction due to embolism of bilateral anterior cerebral arteries	ICD-10-CM	Diagnosis
I63.429	Cerebral infarction due to embolism of unspecified anterior cerebral artery	ICD-10-CM	Diagnosis
I63.431	Cerebral infarction due to embolism of right posterior cerebral artery	ICD-10-CM	Diagnosis
I63.432	Cerebral infarction due to embolism of left posterior cerebral artery	ICD-10-CM	Diagnosis
I63.433	Cerebral infarction due to embolism of bilateral posterior cerebral arteries	ICD-10-CM	Diagnosis
I63.439	Cerebral infarction due to embolism of unspecified posterior cerebral artery	ICD-10-CM	Diagnosis
I63.441	Cerebral infarction due to embolism of right cerebellar artery	ICD-10-CM	Diagnosis
I63.442	Cerebral infarction due to embolism of left cerebellar artery	ICD-10-CM	Diagnosis

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Code	Description	Code Type	Code Category
I63.443	Cerebral infarction due to embolism of bilateral cerebellar arteries	ICD-10-CM	Diagnosis
I63.449	Cerebral infarction due to embolism of unspecified cerebellar artery	ICD-10-CM	Diagnosis
I63.49	Cerebral infarction due to embolism of other cerebral artery	ICD-10-CM	Diagnosis
I63.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery	ICD-10-CM	Diagnosis
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery	ICD-10-CM	Diagnosis
I63.513	Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle arteries	ICD-10-CM	Diagnosis
I63.519	Cerebral infarction due to unspecified occlusion or stenosis of unspecified middle cerebral artery	ICD-10-CM	Diagnosis
I63.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery	ICD-10-CM	Diagnosis
I63.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery	ICD-10-CM	Diagnosis
I63.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior arteries	ICD-10-CM	Diagnosis
I63.529	Cerebral infarction due to unspecified occlusion or stenosis of unspecified anterior cerebral artery	ICD-10-CM	Diagnosis
I63.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery	ICD-10-CM	Diagnosis
I63.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery	ICD-10-CM	Diagnosis
I63.533	Cerebral infarction due to unspecified occlusion or stenosis of bilateral posterior arteries	ICD-10-CM	Diagnosis
I63.539	Cerebral infarction due to unspecified occlusion or stenosis of unspecified posterior cerebral artery	ICD-10-CM	Diagnosis
I63.541	Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery	ICD-10-CM	Diagnosis
I63.542	Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery	ICD-10-CM	Diagnosis
I63.543	Cerebral infarction due to unspecified occlusion or stenosis of bilateral cerebellar arteries	ICD-10-CM	Diagnosis
I63.549	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebellar artery	ICD-10-CM	Diagnosis
I63.6	Cerebral infarction due to cerebral venous thrombosis, nonpyogenic	ICD-10-CM	Diagnosis
I63.8	Other cerebral infarction	ICD-10-CM	Diagnosis
I63.9	Cerebral infarction, unspecified	ICD-10-CM	Diagnosis