

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

<u>Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data</u> guidance document provided by the FDA.



Overview

Title	Thromboembolic Stroke Algorithm Defined in "Thromboembolic Stroke, Intracranial Hemorrhage, Gastrointestinal Bleeding, and Major Extracranial Bleeding following Dabigatran, Rivaroxaban, and Apixaban Use in Patients with Atrial Fibrillation: A Propensity Score Matched Analysis"
Request ID	cder_mpl2p_wp025
Description	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. 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/assessments/drugs/thromboembolic-stroke-intracranial-hemorrhage-gastrointestinal-bleeding-and-major
Outcome	Thromboembolic stroke
Algorithm to Define	The thromboembolic stroke outcome is defined as evidence of an ICD-9-CM or ICD-10-CM diagnosis code
Outcome	from Code List 1 that is the primary diagnosis from an inpatient encounter.
Query Period	October 19, 2010 - February 29, 2020
Request Send Date	September 1, 2020



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



Code List 1. 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	ICD-9-CM	Diagnosis
	infarction		
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
163.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar arteries	ICD-10-CM	Diagnosis
163.139	Cerebral infarction due to embolism of unspecified carotid artery	ICD-10-CM	Diagnosis
163.239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries	ICD-10-CM	Diagnosis
163.019	Cerebral infarction due to thrombosis of unspecified vertebral artery	ICD-10-CM	Diagnosis
163.119	Cerebral infarction due to embolism of unspecified vertebral artery	ICD-10-CM	Diagnosis
163.219	Cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral arteries	ICD-10-CM	Diagnosis
163.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery	ICD-10-CM	Diagnosis
163.20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral	ICD-10-CM	Diagnosis
	arteries		
163.30	Cerebral infarction due to thrombosis of unspecified cerebral artery	ICD-10-CM	Diagnosis
163.40	Cerebral infarction due to embolism of unspecified cerebral artery	ICD-10-CM	Diagnosis
163.50	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral	ICD-10-CM	Diagnosis
	artery		
167.89	Other cerebrovascular disease	ICD-10-CM	Diagnosis
163.00	Cerebral infarction due to thrombosis of unspecified precerebral artery	ICD-10-CM	Diagnosis
163.011	Cerebral infarction due to thrombosis of right vertebral artery	ICD-10-CM	Diagnosis
163.012	Cerebral infarction due to thrombosis of left vertebral artery	ICD-10-CM	Diagnosis
163.013	Cerebral infarction due to thrombosis of bilateral vertebral arteries	ICD-10-CM	Diagnosis
163.02	Cerebral infarction due to thrombosis of basilar artery	ICD-10-CM	Diagnosis
163.031	Cerebral infarction due to thrombosis of right carotid artery	ICD-10-CM	Diagnosis
163.032	Cerebral infarction due to thrombosis of left carotid artery	ICD-10-CM	Diagnosis
163.033	Cerebral infarction due to thrombosis of bilateral carotid arteries	ICD-10-CM	Diagnosis
163.039	Cerebral infarction due to thrombosis of unspecified carotid artery	ICD-10-CM	Diagnosis
163.09	Cerebral infarction due to thrombosis of other precerebral artery	ICD-10-CM	Diagnosis
163.10	Cerebral infarction due to embolism of unspecified precerebral artery	ICD-10-CM	Diagnosis
163.111	Cerebral infarction due to embolism of right vertebral artery	ICD-10-CM	Diagnosis
163.112	Cerebral infarction due to embolism of left vertebral artery	ICD-10-CM	Diagnosis
163.113	Cerebral infarction due to embolism of bilateral vertebral arteries	ICD-10-CM	· ·
163.12	Cerebral infarction due to embolism of basilar artery	ICD-10-CM	Diagnosis
163.131	Cerebral infarction due to embolism of right carotid artery	ICD-10-CM	Diagnosis
163.132	Cerebral infarction due to embolism of left carotid artery	ICD-10-CM	Diagnosis



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Code	Description	Code Type	Code Category
163.133	Cerebral infarction due to embolism of bilateral carotid arteries	ICD-10-CM	Diagnosis
163.19	Cerebral infarction due to embolism of other precerebral artery	ICD-10-CM	Diagnosis
163.211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral arteries	ICD-10-CM	Diagnosis
163.212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral arteries	ICD-10-CM	Diagnosis
163.213	Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries	ICD-10-CM	Diagnosis
163.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries	ICD-10-CM	Diagnosis
163.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries	ICD-10-CM	Diagnosis
163.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries	ICD-10-CM	Diagnosis
163.29	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries	ICD-10-CM	Diagnosis
163.311	Cerebral infarction due to thrombosis of right middle cerebral artery	ICD-10-CM	Diagnosis
163.312	Cerebral infarction due to thrombosis of left middle cerebral artery	ICD-10-CM	Diagnosis
163.313	Cerebral infarction due to thrombosis of bilateral middle cerebral arteries	ICD-10-CM	Diagnosis
163.319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery	ICD-10-CM	Diagnosis
163.321	Cerebral infarction due to thrombosis of right anterior cerebral artery	ICD-10-CM	Diagnosis
163.322	Cerebral infarction due to thrombosis of left anterior cerebral artery	ICD-10-CM	Diagnosis
163.323	Cerebral infarction due to thrombosis of bilateral anterior arteries	ICD-10-CM	Diagnosis
163.329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery	ICD-10-CM	Diagnosis
163.331	Cerebral infarction due to thrombosis of right posterior cerebral artery	ICD-10-CM	Diagnosis
163.332	Cerebral infarction due to thrombosis of left posterior cerebral artery	ICD-10-CM	Diagnosis
163.333	Cerebral infarction to thrombosis of bilateral posterior arteries	ICD-10-CM	Diagnosis
163.339	Cerebral infarction due to thrombosis of unspecified posterior cerebral artery	ICD-10-CM	Diagnosis
163.341	Cerebral infarction due to thrombosis of right cerebellar artery	ICD-10-CM	Diagnosis
163.342	Cerebral infarction due to thrombosis of left cerebellar artery	ICD-10-CM	Diagnosis
163.343	Cerebral infarction to thrombosis of bilateral cerebellar arteries	ICD-10-CM	Diagnosis
163.349	Cerebral infarction due to thrombosis of unspecified cerebellar artery	ICD-10-CM	Diagnosis
163.39	Cerebral infarction due to thrombosis of other cerebral artery	ICD-10-CM	Diagnosis
163.411	Cerebral infarction due to embolism of right middle cerebral artery	ICD-10-CM	Diagnosis
163.412	Cerebral infarction due to embolism of left middle cerebral artery	ICD-10-CM	Diagnosis
163.413	Cerebral infarction due to embolism of bilateral middle cerebral arteries	ICD-10-CM	Diagnosis
163.419	Cerebral infarction due to embolism of unspecified middle cerebral artery	ICD-10-CM	Diagnosis
163.421	Cerebral infarction due to embolism of right anterior cerebral artery	ICD-10-CM	Diagnosis
163.422	Cerebral infarction due to embolism of left anterior cerebral artery	ICD-10-CM	Diagnosis
163.423	Cerebral infarction due to embolism of bilateral anterior cerebral arteries	ICD-10-CM	Diagnosis
163.429	Cerebral infarction due to embolism of unspecified anterior cerebral artery	ICD-10-CM	Diagnosis
163.431	Cerebral infarction due to embolism of right posterior cerebral artery	ICD-10-CM	Diagnosis
163.432	Cerebral infarction due to embolism of left posterior cerebral artery	ICD-10-CM	Diagnosis
163.433	Cerebral infarction due to embolism of bilateral posterior cerebral arteries	ICD-10-CM	Diagnosis
163.439	Cerebral infarction due to embolism of unspecified posterior cerebral artery	ICD-10-CM	Diagnosis
163.441	Cerebral infarction due to embolism of right cerebellar artery	ICD-10-CM	Diagnosis
163.442	Cerebral infarction due to embolism of left cerebellar artery	ICD-10-CM	Diagnosis
163.443	Cerebral infarction due to embolism of bilateral cerebellar arteries	ICD-10-CM	Diagnosis
163.449	Cerebral infarction due to embolism of unspecified cerebellar artery	ICD-10-CM	Diagnosis
163.49	Cerebral infarction due to embolism of other cerebral artery	ICD-10-CM	Diagnosis



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Code	Description	Code Type	Code Category
163.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral	ICD-10-CM	Diagnosis
	artery		
163.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery	ICD-10-CM	Diagnosis
163.513	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
163.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery	ICD-10-CM	Diagnosis
163.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery	ICD-10-CM	Diagnosis
163.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior arteries	ICD-10-CM	Diagnosis
163.529	Cerebral infarction due to unspecified occlusion or stenosis of unspecified anterior cerebral artery	ICD-10-CM	Diagnosis
163.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery	ICD-10-CM	Diagnosis
163.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery	ICD-10-CM	Diagnosis
163.533	Cerebral infarction due to unspecified occlusion or stenosis of bilateral posterior arteries	ICD-10-CM	Diagnosis
163.539	Cerebral infarction due to unspecified occlusion or stenosis of unspecified posterior cerebral artery	ICD-10-CM	Diagnosis
163.541	Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery	ICD-10-CM	Diagnosis
163.542	Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery	ICD-10-CM	Diagnosis
163.543	Cerebral infarction due to unspecified occlusion or stenosis of bilateral cerebellar arteries	ICD-10-CM	Diagnosis
163.549	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebellar artery	ICD-10-CM	Diagnosis
163.6	Cerebral infarction due to cerebral venous thrombosis, nonpyogenic	ICD-10-CM	Diagnosis
163.8	Other cerebral infarction	ICD-10-CM	Diagnosis
163.9	Cerebral infarction, unspecified	ICD-10-CM	Diagnosis