

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	Intracranial Hemorrhage 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 intracranial hemorrhage 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	Intracranial hemorrhage
Algorithm to Define Outcome	The intracranial hemorrhage outcome is defined as evidence of an ICD-9-CM or ICD-10-CM diagnosis code from the specified code list 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 Intracranial Hemorrhage in this Request**

Code	Description	Code Type	Code Category
430	Subarachnoid hemorrhage	ICD-9-CM	Diagnosis
431	Intracerebral hemorrhage	ICD-9-CM	Diagnosis
432	Other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
432	Nontraumatic extradural hemorrhage	ICD-9-CM	Diagnosis
432.1	Subdural hemorrhage	ICD-9-CM	Diagnosis
432.9	Unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
852	Subarachnoid hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis
852	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.01	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.02	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM	Diagnosis
852.03	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.04	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.05	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.06	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
852.09	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
852.2	Subdural hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis
852.2	Subdural hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.21	Subdural hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.22	Subdural hemorrhage following injury, without mention of open intracranial wound, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
852.23	Subdural hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.24	Subdural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.25	Subdural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.26	Subdural hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis

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Diagnosis Codes Used to Define Intracranial Hemorrhage in this Request**

Code	Description	Code Type	Code Category
852.29	Subdural hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
852.4	Extradural hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis
852.4	Extradural hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.41	Extradural hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.42	Extradural hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM	Diagnosis
852.43	Extradural hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.44	Extradural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.45	Extradural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.46	Extradural hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
852.49	Extradural hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
853	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound	ICD-9-CM	Diagnosis
853	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
853.01	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
853.02	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM	Diagnosis
853.03	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
853.04	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to preexisting conscious level	ICD-9-CM	Diagnosis
853.05	Other and unspecified intracranial hemorrhage following injury. Without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
853.06	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
853.09	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
I60.00	Nontraumatic subarachnoid hemorrhage from unspecified carotid siphon and bifurcation	ICD-10-CM	Diagnosis
I60.01	Nontraumatic subarachnoid hemorrhage from right carotid siphon and bifurcation	ICD-10-CM	Diagnosis
I60.02	Nontraumatic subarachnoid hemorrhage from left carotid siphon and bifurcation	ICD-10-CM	Diagnosis
I60.10	Nontraumatic subarachnoid hemorrhage from unspecified middle cerebral artery	ICD-10-CM	Diagnosis
I60.11	Nontraumatic subarachnoid hemorrhage from right middle cerebral artery	ICD-10-CM	Diagnosis
I60.12	Nontraumatic subarachnoid hemorrhage from left middle cerebral artery	ICD-10-CM	Diagnosis
I60.2	Nontraumatic subarachnoid hemorrhage from anterior communicating artery	ICD-10-CM	Diagnosis
I60.30	Nontraumatic subarachnoid hemorrhage from unspecified posterior communicating artery	ICD-10-CM	Diagnosis
I60.31	Nontraumatic subarachnoid hemorrhage from right posterior communicating artery	ICD-10-CM	Diagnosis
I60.32	Nontraumatic subarachnoid hemorrhage from left posterior communicating artery	ICD-10-CM	Diagnosis
I60.4	Nontraumatic subarachnoid hemorrhage from basilar artery	ICD-10-CM	Diagnosis
I60.50	Nontraumatic subarachnoid hemorrhage from unspecified vertebral artery	ICD-10-CM	Diagnosis
I60.51	Nontraumatic subarachnoid hemorrhage from right vertebral artery	ICD-10-CM	Diagnosis
I60.52	Nontraumatic subarachnoid hemorrhage from left vertebral artery	ICD-10-CM	Diagnosis
I60.6	Nontraumatic subarachnoid hemorrhage from other intracranial arteries	ICD-10-CM	Diagnosis
I60.7	Nontraumatic subarachnoid hemorrhage from unspecified intracranial artery	ICD-10-CM	Diagnosis
I60.8	Other nontraumatic subarachnoid hemorrhage	ICD-10-CM	Diagnosis
I60.9	Nontraumatic subarachnoid hemorrhage, unspecified	ICD-10-CM	Diagnosis
I61.0	Nontraumatic intracerebral hemorrhage in hemisphere, subcortical	ICD-10-CM	Diagnosis
I61.1	Nontraumatic intracerebral hemorrhage in hemisphere, cortical	ICD-10-CM	Diagnosis
I61.2	Nontraumatic intracerebral hemorrhage in hemisphere, unspecified	ICD-10-CM	Diagnosis
I61.3	Nontraumatic intracerebral hemorrhage in brain stem	ICD-10-CM	Diagnosis
I61.4	Nontraumatic intracerebral hemorrhage in cerebellum	ICD-10-CM	Diagnosis
I61.5	Nontraumatic intracerebral hemorrhage, intraventricular	ICD-10-CM	Diagnosis
I61.6	Nontraumatic intracerebral hemorrhage, multiple localized	ICD-10-CM	Diagnosis
I61.8	Other nontraumatic intracerebral hemorrhage	ICD-10-CM	Diagnosis
I61.9	Nontraumatic intracerebral hemorrhage, unspecified	ICD-10-CM	Diagnosis
I62.00	Nontraumatic subdural hemorrhage, unspecified	ICD-10-CM	Diagnosis
I62.01	Nontraumatic acute subdural hemorrhage	ICD-10-CM	Diagnosis
I62.02	Nontraumatic subacute subdural hemorrhage	ICD-10-CM	Diagnosis
I62.03	Nontraumatic chronic subdural hemorrhage	ICD-10-CM	Diagnosis
I62.1	Nontraumatic extradural hemorrhage	ICD-10-CM	Diagnosis
I62.9	Nontraumatic intracranial hemorrhage, unspecified	ICD-10-CM	Diagnosis
S06.340A	Traumatic hemorrhage of right cerebrum without loss of consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.341A	Traumatic hemorrhage of right cerebrum with loss of consciousness of 30 minutes or less, initial encounter	ICD-10-CM	Diagnosis
S06.342A	Traumatic hemorrhage of right cerebrum with loss of consciousness of 31 minutes to 59 minutes, initial encounter	ICD-10-CM	Diagnosis

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

Code	Description	Code Type	Code Category
S06.343A	Traumatic hemorrhage of right cerebrum with loss of consciousness of 1 hours to 5 hours 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.344A	Traumatic hemorrhage of right cerebrum with loss of consciousness of 6 hours to 24 hours, initial encounter	ICD-10-CM	Diagnosis
S06.345A	Traumatic hemorrhage of right cerebrum with loss of consciousness greater than 24 hours with return to pre-existing conscious level, initial encounter	ICD-10-CM	Diagnosis
S06.346A	Traumatic hemorrhage of right cerebrum with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, initial encounter	ICD-10-CM	Diagnosis
S06.347A	Traumatic hemorrhage of right cerebrum with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.348A	Traumatic hemorrhage of right cerebrum with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.349A	Traumatic hemorrhage of right cerebrum with loss of consciousness of unspecified duration, initial encounter	ICD-10-CM	Diagnosis
S06.350A	Traumatic hemorrhage of left cerebrum without loss of consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.351A	Traumatic hemorrhage of left cerebrum with loss of consciousness of 30 minutes or less, initial encounter	ICD-10-CM	Diagnosis
S06.352A	Traumatic hemorrhage of left cerebrum with loss of consciousness of 31 minutes to 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.353A	Traumatic hemorrhage of left cerebrum with loss of consciousness of 1 hours to 5 hours 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.354A	Traumatic hemorrhage of left cerebrum with loss of consciousness of 6 hours to 24 hours, initial encounter	ICD-10-CM	Diagnosis
S06.355A	Traumatic hemorrhage of left cerebrum with loss of consciousness greater than 24 hours with return to pre-existing conscious level, initial encounter	ICD-10-CM	Diagnosis
S06.356A	Traumatic hemorrhage of left cerebrum with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, initial encounter	ICD-10-CM	Diagnosis
S06.357A	Traumatic hemorrhage of left cerebrum with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.358A	Traumatic hemorrhage of left cerebrum with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.359A	Traumatic hemorrhage of left cerebrum with loss of consciousness of unspecified duration, initial encounter	ICD-10-CM	Diagnosis
S06.360A	Traumatic hemorrhage of cerebrum, unspecified, without loss of consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.361A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of 30 minutes or less, initial encounter	ICD-10-CM	Diagnosis
S06.362A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of 31 minutes to 59 minutes, initial encounter	ICD-10-CM	Diagnosis

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Diagnosis Codes Used to Define Intracranial Hemorrhage in this Request**

Code	Description	Code Type	Code Category
S06.363A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of 1 hours to 5 hours 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.364A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of 6 hours to 24 hours, initial encounter	ICD-10-CM	Diagnosis
S06.365A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness greater than 24 hours with return to pre-existing conscious level, initial encounter	ICD-10-CM	Diagnosis
S06.366A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, initial encounter	ICD-10-CM	Diagnosis
S06.367A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.368A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.369A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of unspecified duration, initial encounter	ICD-10-CM	Diagnosis
S06.4X0A	Epidural hemorrhage without loss of consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.4X1A	Epidural hemorrhage with loss of consciousness of 30 minutes or less, initial encounter	ICD-10-CM	Diagnosis
S06.4X2A	Epidural hemorrhage with loss of consciousness of 31 minutes to 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.4X3A	Epidural hemorrhage with loss of consciousness of 1 hour to 5 hours 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.4X4A	Epidural hemorrhage with loss of consciousness of 6 hours to 24 hours, initial encounter	ICD-10-CM	Diagnosis
S06.4X5A	Epidural hemorrhage with loss of consciousness greater than 24 hours with return to pre-existing conscious level, initial encounter	ICD-10-CM	Diagnosis
S06.4X6A	Epidural hemorrhage with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, initial encounter	ICD-10-CM	Diagnosis
S06.4X7A	Epidural hemorrhage with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.4X8A	Epidural hemorrhage with loss of consciousness of any duration with death due to other causes prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.4X9A	Epidural hemorrhage with loss of consciousness of unspecified duration, initial encounter	ICD-10-CM	Diagnosis
S06.5X0A	Traumatic subdural hemorrhage without loss of consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.5X1A	Traumatic subdural hemorrhage with loss of consciousness of 30 minutes or less, initial encounter	ICD-10-CM	Diagnosis
S06.5X2A	Traumatic subdural hemorrhage with loss of consciousness of 31 minutes to 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.5X3A	Traumatic subdural hemorrhage with loss of consciousness of 1 hour to 5 hours 59 minutes, initial encounter	ICD-10-CM	Diagnosis

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Diagnosis Codes Used to Define Intracranial Hemorrhage in this Request**

Code	Description	Code Type	Code Category
S06.5X4A	Traumatic subdural hemorrhage with loss of consciousness of 6 hours to 24 hours, initial encounter	ICD-10-CM	Diagnosis
S06.5X5A	Traumatic subdural hemorrhage with loss of consciousness greater than 24 hours with return to pre-existing conscious level, initial encounter	ICD-10-CM	Diagnosis
S06.5X6A	Traumatic subdural hemorrhage with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, initial encounter	ICD-10-CM	Diagnosis
S06.5X7A	Traumatic subdural hemorrhage with loss of consciousness of any duration with death due to brain injury before regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.5X8A	Traumatic subdural hemorrhage with loss of consciousness of any duration with death due to other cause before regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.5X9A	Traumatic subdural hemorrhage with loss of consciousness of unspecified duration, initial encounter	ICD-10-CM	Diagnosis
S06.6X0A	Traumatic subarachnoid hemorrhage without loss of consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.6X1A	Traumatic subarachnoid hemorrhage with loss of consciousness of 30 minutes or less, initial encounter	ICD-10-CM	Diagnosis
S06.6X2A	Traumatic subarachnoid hemorrhage with loss of consciousness of 31 minutes to 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.6X3A	Traumatic subarachnoid hemorrhage with loss of consciousness of 1 hour to 5 hours 59 minutes, initial encounter	ICD-10-CM	Diagnosis
S06.6X4A	Traumatic subarachnoid hemorrhage with loss of consciousness of 6 hours to 24 hours, initial encounter	ICD-10-CM	Diagnosis
S06.6X5A	Traumatic subarachnoid hemorrhage with loss of consciousness greater than 24 hours with return to pre-existing conscious level, initial encounter	ICD-10-CM	Diagnosis
S06.6X6A	Traumatic subarachnoid hemorrhage with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, initial encounter	ICD-10-CM	Diagnosis
S06.6X7A	Traumatic subarachnoid hemorrhage with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.6X8A	Traumatic subarachnoid hemorrhage with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter	ICD-10-CM	Diagnosis
S06.6X9A	Traumatic subarachnoid hemorrhage with loss of consciousness of unspecified duration, initial encounter	ICD-10-CM	Diagnosis