

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	Seizure Algorithm Defined in "Seizures following Gadolinium-Based Contrast Agents Exposure: A Self-Controlled Risk Interval Analysis"
Request ID	cder_mpl2r_wp007
Description	<p>This report lists International Classification of Disease, Ninth Revision, with Clinical Modification (ICD-9-CM) diagnosis codes, International Classification of Disease, Tenth Revision, with Clinical Modification (ICD-10-CM) diagnosis codes, and algorithms used to define seizure 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/seizures-following-gadolinium-based-contrast-agents-exposure</p>
Outcome	Seizure
Algorithm to Define Outcome	Seizure outcomes were defined using ICD-9-CM and ICD-10-CM diagnosis codes that occurred in the emergency department or the inpatient care setting in the principal diagnosis position. An outcome of interest was included if the individual had no evidence of the outcome in any care setting in the six months (183 days) prior to the outcome of interest.
Query Period	January 1, 2008 - November 30, 2016
Request Send Date	May 26, 2017

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 Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Outcomes in this Request

Code	Description	Code Type
Epilepsy and Convulsions		
345	Epilepsy and recurrent seizures	ICD-9-CM Diagnosis
345.0	Generalized nonconvulsive epilepsy	ICD-9-CM Diagnosis
345.00	Generalized nonconvulsive epilepsy without mention of intractable epilepsy	ICD-9-CM Diagnosis
345.01	Generalized nonconvulsive epilepsy with intractable epilepsy	ICD-9-CM Diagnosis
345.1	Generalized convulsive epilepsy	ICD-9-CM Diagnosis
345.10	Generalized convulsive epilepsy without mention of intractable epilepsy	ICD-9-CM Diagnosis
345.11	Generalized convulsive epilepsy with intractable epilepsy	ICD-9-CM Diagnosis
345.2	Epileptic petit mal status	ICD-9-CM Diagnosis
345.3	Epileptic grand mal status	ICD-9-CM Diagnosis
345.4	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures	ICD-9-CM Diagnosis
345.40	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures, without mention of intractable epilepsy	ICD-9-CM Diagnosis
345.41	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures, with intractable epilepsy	ICD-9-CM Diagnosis
345.5	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures	ICD-9-CM Diagnosis
345.50	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures, without mention of intractable epilepsy	ICD-9-CM Diagnosis
345.51	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures, with intractable epilepsy	ICD-9-CM Diagnosis
345.6	Infantile spasms	ICD-9-CM Diagnosis
345.60	Infantile spasms without mention of intractable epilepsy	ICD-9-CM Diagnosis
345.61	Infantile spasms with intractable epilepsy	ICD-9-CM Diagnosis
345.7	Epilepsia partialis continua	ICD-9-CM Diagnosis
345.70	Epilepsia partialis continua without mention of intractable epilepsy	ICD-9-CM Diagnosis
345.71	Epilepsia partialis continua with intractable epilepsy	ICD-9-CM Diagnosis
345.8	Other forms of epilepsy and recurrent seizures	ICD-9-CM Diagnosis
345.80	Other forms of epilepsy and recurrent seizures, without mention of intractable epilepsy	ICD-9-CM Diagnosis
345.81	Other forms of epilepsy and recurrent seizures, with intractable epilepsy	ICD-9-CM Diagnosis
345.9	Unspecified epilepsy	ICD-9-CM Diagnosis
345.90	Unspecified epilepsy without mention of intractable epilepsy	ICD-9-CM Diagnosis
345.91	Unspecified epilepsy with intractable epilepsy	ICD-9-CM Diagnosis
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus	ICD-10-CM Diagnosis

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Code	Description	Code Type
G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.501	Epileptic seizures related to external causes, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.801	Other epilepsy, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.802	Other epilepsy, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.803	Other epilepsy, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.804	Other epilepsy, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.821	Epileptic spasms, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.822	Epileptic spasms, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.823	Epileptic spasms, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.824	Epileptic spasms, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.89	Other seizures	ICD-10-CM Diagnosis
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.911	Epilepsy, unspecified, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.919	Epilepsy, unspecified, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.A01	Absence epileptic syndrome, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.A11	Absence epileptic syndrome, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.A19	Absence epileptic syndrome, intractable, without status epilepticus	ICD-10-CM Diagnosis
G40.B01	Juvenile myoclonic epilepsy, not intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus	ICD-10-CM Diagnosis

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G40.B11	Juvenile myoclonic epilepsy, intractable, with status epilepticus	ICD-10-CM Diagnosis
G40.B19	Juvenile myoclonic epilepsy, intractable, without status epilepticus	ICD-10-CM Diagnosis
780.3	Convulsions	ICD-9-CM Diagnosis
780.31	Febrile convulsions (simple), unspecified	ICD-9-CM Diagnosis
780.32	Complex febrile convulsions	ICD-9-CM Diagnosis
780.33	Post traumatic seizures	ICD-9-CM Diagnosis
780.39	Other convulsions	ICD-9-CM Diagnosis
R56.00	Simple febrile convulsions	ICD-10-CM Diagnosis
R56.01	Complex febrile convulsions	ICD-10-CM Diagnosis
R56.1	Post traumatic seizures	ICD-10-CM Diagnosis
R56.9	Unspecified convulsions	ICD-10-CM Diagnosis