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	Complex Regional Pain Syndrome (CRPS), Uveitis, Acute Disseminated Encephalomyelitis (ADEM), and Acute Pericarditis Algorithms Defined in "Sequential Analysis of Gardasil 9 Safety"
Description	This report lists International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) and ICD-10-CM diagnosis codes and algorithms used to define complex regional pain syndrome (CRPS), uveitis, acute disseminated encephalomyelitis (ADEM), and acute pericarditis 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 Modular Program reports here: https://www.sentinelinitiative.org/vaccines-blood-biologics/assessments/sequential-analysis-gardasil-9-safety.
Outcome	CRPS, uveitis, ADEM, and acute pericarditis
Algorithm to Define Outcome	Outcome 1: Evidence of an ICD-9-CM or ICD-10-CM code used to define CRPS in any care setting (Inpatient, Non-Acute Institutional Stay, Emergency Department, or Other Ambulatory Visit) in any diagnosis position. Outcome 2: Evidence of an ICD-9-CM or ICD-10-CM code used to define uveitis in any care setting (Inpatient, Non-Acute Institutional Stay, Emergency Department, or Other Ambulatory Visit) in any diagnosis position. Outcome 3: Evidence of an ICD-9-CM or ICD-10-CM code used to define ADEM in the Inpatient or Emergency Department care setting in any diagnosis position. Outcome 4: Evidence of an ICD-9-CM or ICD-10-CM code used to define acute pericarditis in the Inpatient care setting in any diagnosis position.

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

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) and ICD-10-CM Diagnosis Codes Used to Define Complex Regional Pain Syndrome (CRPS) in this Request

Codes	Code Type	Description
337.20	ICD-9-CM	Reflex sympathetic dystrophy, unspecified
337.21	ICD-9-CM	Reflex sympathetic dystrophy of the upper limb
337.22	ICD-9-CM	Reflex sympathetic dystrophy of the lower limb
337.29	ICD-9-CM	Reflex sympathetic dystrophy of other specified site
G90.50	ICD-10-CM	Complex regional pain syndrome I, unspecified
G90.511	ICD-10-CM	Complex regional pain syndrome I of right upper limb
G90.512	ICD-10-CM	Complex regional pain syndrome I of left upper limb
G90.513	ICD-10-CM	Complex regional pain syndrome I of upper limb, bilateral
G90.519	ICD-10-CM	Complex regional pain syndrome I of unspecified upper limb
G90.521	ICD-10-CM	Complex regional pain syndrome I of right lower limb
G90.522	ICD-10-CM	Complex regional pain syndrome I of left lower limb
G90.523	ICD-10-CM	Complex regional pain syndrome I of lower limb, bilateral
G90.529	ICD-10-CM	Complex regional pain syndrome I of unspecified lower limb
G90.59	ICD-10-CM	Complex regional pain syndrome I of other specified site

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) and ICD-10-CM Diagnosis Codes Used to Define Uveitis in this Request

Codes	Code Type	Description
360.11	ICD-9-CM	Sympathetic uveitis
363.00	ICD-9-CM	Focal chorioretinitis, unspecified
363.01	ICD-9-CM	Focal choroiditis and chorioretinitis, juxtapapillary
363.03	ICD-9-CM	Focal choroiditis and chorioretinitis of other posterior pole
363.04	ICD-9-CM	Focal choroiditis and chorioretinitis, peripheral
363.05	ICD-9-CM	Focal retinitis and retinochoroiditis, juxtapapillary
363.06	ICD-9-CM	Focal retinitis and retinochoroiditis, macular or paramacular
363.07	ICD-9-CM	Focal retinitis and retinochoroiditis of other posterior pole
363.08	ICD-9-CM	Focal retinitis and retinochoroiditis, peripheral
363.10	ICD-9-CM	Disseminated chorioretinitis, unspecified
363.11	ICD-9-CM	Disseminated choroiditis and chorioretinitis, posterior pole
363.12	ICD-9-CM	Disseminated choroiditis and chorioretinitis, peripheral
363.13	ICD-9-CM	Disseminated choroiditis and chorioretinitis, generalized
363.14	ICD-9-CM	Disseminated retinitis and retinochoroiditis, metastatic
363.20	ICD-9-CM	Chorioretinitis, unspecified
364.00	ICD-9-CM	Acute and subacute iridocyclitis, unspecified
364.01	ICD-9-CM	Primary iridocyclitis
364.04	ICD-9-CM	Secondary iridocyclitis, noninfectious
364.3	ICD-9-CM	Unspecified iridocyclitis
H20.00	ICD-10-CM	Unspecified acute and subacute iridocyclitis
H20.011	ICD-10-CM	Primary iridocyclitis, right eye
H20.012	ICD-10-CM	Primary iridocyclitis, left eye
H20.013	ICD-10-CM	Primary iridocyclitis, bilateral
H20.019	ICD-10-CM	Primary iridocyclitis, unspecified eye
H20.041	ICD-10-CM	Secondary noninfectious iridocyclitis, right eye
H20.042	ICD-10-CM	Secondary noninfectious iridocyclitis, left eye
H20.043	ICD-10-CM	Secondary noninfectious iridocyclitis, bilateral
H20.049	ICD-10-CM	Secondary noninfectious iridocyclitis, unspecified eye
H20.9	ICD-10-CM	Unspecified iridocyclitis
H30.001	ICD-10-CM	Unspecified focal chorioretinal inflammation, right eye
H30.002	ICD-10-CM	Unspecified focal chorioretinal inflammation, left eye
H30.003	ICD-10-CM	Unspecified focal chorioretinal inflammation, bilateral
H30.009	ICD-10-CM	Unspecified focal chorioretinal inflammation, unspecified eye
H30.011	ICD-10-CM	Focal chorioretinal inflammation, juxtapapillary, right eye
H30.012	ICD-10-CM	Focal chorioretinal inflammation, juxtapapillary, left eye
H30.013	ICD-10-CM	Focal chorioretinal inflammation, juxtapapillary, bilateral
H30.019	ICD-10-CM	Focal chorioretinal inflammation, juxtapapillary, unspecified eye
H30.021	ICD-10-CM	Focal chorioretinal inflammation of posterior pole, right eye
H30.022	ICD-10-CM	Focal chorioretinal inflammation of posterior pole, left eye
H30.023	ICD-10-CM	Focal chorioretinal inflammation of posterior pole, bilateral

H30.029	ICD-10-CM	Focal chorioretinal inflammation of posterior pole, unspecified eye
H30.031	ICD-10-CM	Focal chorioretinal inflammation, peripheral, right eye
H30.032	ICD-10-CM	Focal chorioretinal inflammation, peripheral, left eye
H30.033	ICD-10-CM	Focal chorioretinal inflammation, peripheral, bilateral
H30.039	ICD-10-CM	Focal chorioretinal inflammation, peripheral, unspecified eye
H30.041	ICD-10-CM	Focal chorioretinal inflammation, macular or paramacular, right eye
H30.042	ICD-10-CM	Focal chorioretinal inflammation, macular or paramacular, left eye
H30.043	ICD-10-CM	Focal chorioretinal inflammation, macular or paramacular, bilateral
H30.049	ICD-10-CM	Focal chorioretinal inflammation, macular or paramacular, unspecified eye
H30.101	ICD-10-CM	Unspecified disseminated chorioretinal inflammation, right eye
H30.102	ICD-10-CM	Unspecified disseminated chorioretinal inflammation, left eye
H30.103	ICD-10-CM	Unspecified disseminated chorioretinal inflammation, bilateral
H30.109	ICD-10-CM	Unspecified disseminated chorioretinal inflammation, unspecified eye
H30.111	ICD-10-CM	Disseminated chorioretinal inflammation of posterior pole, right eye
H30.112	ICD-10-CM	Disseminated chorioretinal inflammation of posterior pole, left eye
H30.113	ICD-10-CM	Disseminated chorioretinal inflammation of posterior pole, bilateral
H30.119	ICD-10-CM	Disseminated chorioretinal inflammation of posterior pole, unspecified eye
H30.121	ICD-10-CM	Disseminated chorioretinal inflammation, peripheral right eye
H30.122	ICD-10-CM	Disseminated chorioretinal inflammation, peripheral, left eye
H30.123	ICD-10-CM	Disseminated chorioretinal inflammation, peripheral, bilateral
H30.129	ICD-10-CM	Disseminated chorioretinal inflammation, peripheral, unspecified eye
H30.131	ICD-10-CM	Disseminated chorioretinal inflammation, generalized, right eye
H30.132	ICD-10-CM	Disseminated chorioretinal inflammation, generalized, left eye
H30.133	ICD-10-CM	Disseminated chorioretinal inflammation, generalized, bilateral
H30.139	ICD-10-CM	Disseminated chorioretinal inflammation, generalized, unspecified eye
H30.891	ICD-10-CM	Other chorioretinal inflammations, right eye
H30.892	ICD-10-CM	Other chorioretinal inflammations, left eye
H30.893	ICD-10-CM	Other chorioretinal inflammations, bilateral
H30.899	ICD-10-CM	Other chorioretinal inflammations, unspecified eye
H30.90	ICD-10-CM	Unspecified chorioretinal inflammation, unspecified eye
H30.91	ICD-10-CM	Unspecified chorioretinal inflammation, right eye
H30.92	ICD-10-CM	Unspecified chorioretinal inflammation, left eye
H30.93	ICD-10-CM	Unspecified chorioretinal inflammation, bilateral
H44.131	ICD-10-CM	Sympathetic uveitis, right eye
H44.132	ICD-10-CM	Sympathetic uveitis, left eye
H44.133	ICD-10-CM	Sympathetic uveitis, bilateral
H44.139	ICD-10-CM	Sympathetic uveitis, unspecified eye

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) and ICD-10-CM Diagnosis Codes Used to Define Acute Disseminated Encephalomylelitis (ADEM) in this Request

Codes	Code Type	Description
323.51	ICD-9-CM	ENCEPHALITIS AND ENCEPHALOMYELITIS FOLLOWING IMMUNIZATION PROCEDURES
323.52	ICD-9-CM	MYELITIS FOLLOWING IMMUNIZATION PROCEDURES
323.61	ICD-9-CM	INFECTIOUS ACUTE DISSEMINATED ENCEPHALOMYELITIS (ADEM)
323.62	ICD-9-CM	OTHER POSTINFECTIOUS ENCEPHALITIS AND ENCEPHALOMYELITIS
323.81	ICD-9-CM	OTHER CAUSES OF ENCEPHALITIS AND ENCEPHALOMYELITIS
323.9	ICD-9-CM	UNSPECIFIED CAUSES OF ENCEPHALITIS, MYELITIS, AND ENCEPHALOMYELITIS
G04.00	ICD-10-CM	Acute disseminated encephalitis and encephalomyelitis, unspecified
G04.01	ICD-10-CM	Postinfectious acute disseminated encephalitis and encephalomyelitis (postinfectious ADEM
G04.02	ICD-10-CM	Postimmunization acute disseminated encephalitis, myelitis and encephalomyelitis
G04.30	ICD-10-CM	Acute necrotizing hemorrhagic encephalopathy, unspecified
G04.31	ICD-10-CM	Postinfectious acute necrotizing hemorrhagic encephalopathy
G04.32	ICD-10-CM	Postimmunization acute necrotizing hemorrhagic encephalopathy
G04.39	ICD-10-CM	Other acute necrotizing hemorrhagic encephalopathy
G04.81	ICD-10-CM	Other encephalitis and encephalomyelitis
G04.90	ICD-10-CM	Encephalitis and encephalomyelitis, unspecified

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) and ICD-10-CM Diagnosis Codes Used to Define Acute Pericarditis in this Request

Codes	Code Type	Description
074.21	ICD-9-CM	Coxsackie pericarditis
420.91	ICD-9-CM	Acute idiopathic pericarditis
420.90	ICD-9-CM	Acute pericarditis, unspecified
420.99	ICD-9-CM	Other acute pericarditis
B33.23	ICD-10-CM	Viral pericarditis
I30.0	ICD-10-CM	Acute nonspecific idiopathic pericarditis
I30.1	ICD-10-CM	Infective pericarditis
I30.8	ICD-10-CM	Other forms of acute pericarditis
I30.9	ICD-10-CM	Acute pericarditis, unspecified