

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	Congenital Cardiac Malformation Algorithm Defined in "Congenital Malformations Observed in the Mother's Records Following Fingolimod Use During Pregnancy: A Descriptive Analysis"
Request ID	cder_mpl1p_wp072
Description	<p>This report lists International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes and algorithms used to define congenital cardiac malformation 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 analysis, see the analysis page here: https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/congenital-malformations-observed-mother-s-records-following</p>
Outcome	Congenital cardiac malformation
Algorithm to Define Outcome	Congenital cardiac malformations were identified using ICD-9-CM or ICD-10-CM codes appearing in any care setting or position during the first, second, or third trimesters of pregnancy in the mothers' records or within 30 days of delivery in the mothers' records.
Query Period	January 1, 2011 - August 1, 2022
Request Send Date	January 9, 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 Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Congenital Cardiac Malformation in this Request

Code	Description	Code Category	Code Type
Cardiac Malformation			
745	Bulbus cordis anomalies and anomalies of cardiac septal closure	Diagnosis	ICD-9-CM
745.0	Bulbus cordis anomalies and anomalies of cardiac septal closure, common truncus	Diagnosis	ICD-9-CM
745.1	Transposition of great vessels	Diagnosis	ICD-9-CM
745.10	Complete transposition of great vessels	Diagnosis	ICD-9-CM
745.11	Transposition of great vessels, double outlet right ventricle	Diagnosis	ICD-9-CM
745.12	Corrected transposition of great vessels	Diagnosis	ICD-9-CM
745.19	Other transposition of great vessels	Diagnosis	ICD-9-CM
745.2	Tetralogy of Fallot	Diagnosis	ICD-9-CM
745.3	Bulbus cordis anomalies and anomalies of cardiac septal closure, common ventricle	Diagnosis	ICD-9-CM
745.4	Ventricular septal defect	Diagnosis	ICD-9-CM
745.5	Ostium secundum type atrial septal defect	Diagnosis	ICD-9-CM
745.6	Endocardial cushion defects	Diagnosis	ICD-9-CM
745.60	Unspecified type congenital endocardial cushion defect	Diagnosis	ICD-9-CM
745.61	Ostium primum defect	Diagnosis	ICD-9-CM
745.69	Other congenital endocardial cushion defect	Diagnosis	ICD-9-CM
745.7	Cor biloculare	Diagnosis	ICD-9-CM
745.8	Other bulbus cordis anomalies and anomalies of cardiac septal closure	Diagnosis	ICD-9-CM
745.9	Unspecified congenital defect of septal closure	Diagnosis	ICD-9-CM
746	Other congenital anomalies of heart	Diagnosis	ICD-9-CM
746.0	Congenital anomalies of pulmonary valve	Diagnosis	ICD-9-CM
746.00	Unspecified congenital pulmonary valve anomaly	Diagnosis	ICD-9-CM
746.01	Congenital atresia of pulmonary valve	Diagnosis	ICD-9-CM
746.02	Congenital stenosis of pulmonary valve	Diagnosis	ICD-9-CM
746.09	Other congenital anomalies of pulmonary valve	Diagnosis	ICD-9-CM
746.1	Congenital tricuspid atresia and stenosis	Diagnosis	ICD-9-CM
746.2	Ebstein's anomaly	Diagnosis	ICD-9-CM
746.3	Congenital stenosis of aortic valve	Diagnosis	ICD-9-CM
746.4	Congenital insufficiency of aortic valve	Diagnosis	ICD-9-CM
746.5	Congenital mitral stenosis	Diagnosis	ICD-9-CM
746.6	Congenital mitral insufficiency	Diagnosis	ICD-9-CM
746.7	Hypoplastic left heart syndrome	Diagnosis	ICD-9-CM
746.8	Other specified congenital anomaly of heart	Diagnosis	ICD-9-CM
746.81	Congenital subaortic stenosis	Diagnosis	ICD-9-CM
746.82	Cor triatriatum	Diagnosis	ICD-9-CM
746.83	Congenital infundibular pulmonic stenosis	Diagnosis	ICD-9-CM
746.84	Congenital obstructive anomalies of heart, not elsewhere classified	Diagnosis	ICD-9-CM
746.85	Congenital coronary artery anomaly	Diagnosis	ICD-9-CM
746.86	Congenital heart block	Diagnosis	ICD-9-CM

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Code	Description	Code Category	Code Type
746.87	Congenital malposition of heart and cardiac apex	Diagnosis	ICD-9-CM
746.89	Other specified congenital anomaly of heart	Diagnosis	ICD-9-CM
746.9	Unspecified congenital anomaly of heart	Diagnosis	ICD-9-CM
747	Other congenital anomalies of circulatory system	Diagnosis	ICD-9-CM
747.0	Patent ductus arteriosus	Diagnosis	ICD-9-CM
747.1	Coarctation of aorta	Diagnosis	ICD-9-CM
747.10	Coarctation of aorta (preductal) (postductal)	Diagnosis	ICD-9-CM
747.11	Congenital interruption of aortic arch	Diagnosis	ICD-9-CM
747.2	Other congenital anomaly of aorta	Diagnosis	ICD-9-CM
747.20	Unspecified congenital anomaly of aorta	Diagnosis	ICD-9-CM
747.21	Congenital anomaly of aortic arch	Diagnosis	ICD-9-CM
747.22	Congenital atresia and stenosis of aorta	Diagnosis	ICD-9-CM
747.29	Other congenital anomaly of aorta	Diagnosis	ICD-9-CM
747.3	Anomalies of pulmonary artery	Diagnosis	ICD-9-CM
747.31	Pulmonary artery coarctation and atresia	Diagnosis	ICD-9-CM
747.32	Pulmonary arteriovenous malformation	Diagnosis	ICD-9-CM
747.39	Other anomalies of pulmonary artery and pulmonary circulation	Diagnosis	ICD-9-CM
747.4	Congenital anomalies of great veins	Diagnosis	ICD-9-CM
747.40	Congenital anomaly of great veins unspecified	Diagnosis	ICD-9-CM
747.41	Total congenital anomalous pulmonary venous connection	Diagnosis	ICD-9-CM
747.42	Partial congenital anomalous pulmonary venous connection	Diagnosis	ICD-9-CM
747.49	Other congenital anomalies of great veins	Diagnosis	ICD-9-CM
747.5	Congenital absence or hypoplasia of umbilical artery	Diagnosis	ICD-9-CM
747.6	Other congenital anomaly of peripheral vascular system	Diagnosis	ICD-9-CM
747.60	Congenital anomaly of the peripheral vascular system, unspecified site	Diagnosis	ICD-9-CM
747.61	Congenital gastrointestinal vessel anomaly	Diagnosis	ICD-9-CM
747.62	Congenital renal vessel anomaly	Diagnosis	ICD-9-CM
747.63	Congenital upper limb vessel anomaly	Diagnosis	ICD-9-CM
747.64	Congenital lower limb vessel anomaly	Diagnosis	ICD-9-CM
747.69	Congenital anomaly of other specified site of peripheral vascular system	Diagnosis	ICD-9-CM
747.8	Other specified congenital anomalies of circulatory system	Diagnosis	ICD-9-CM
747.81	Congenital anomaly of cerebrovascular system	Diagnosis	ICD-9-CM
747.82	Congenital spinal vessel anomaly	Diagnosis	ICD-9-CM
747.83	Persistent fetal circulation	Diagnosis	ICD-9-CM
747.89	Other specified congenital anomaly of circulatory system	Diagnosis	ICD-9-CM
747.9	Unspecified congenital anomaly of circulatory system	Diagnosis	ICD-9-CM
I27.83	Eisenmenger's syndrome	Diagnosis	ICD-10-CM
P29.30	Pulmonary hypertension of newborn	Diagnosis	ICD-10-CM
P29.38	Other persistent fetal circulation	Diagnosis	ICD-10-CM
Q20.0	Common arterial trunk	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Q20.1	Double outlet right ventricle	Diagnosis	ICD-10-CM
Q20.2	Double outlet left ventricle	Diagnosis	ICD-10-CM
Q20.3	Discordant ventriculoarterial connection	Diagnosis	ICD-10-CM
Q20.4	Double inlet ventricle	Diagnosis	ICD-10-CM
Q20.5	Discordant atrioventricular connection	Diagnosis	ICD-10-CM
Q20.6	Isomerism of atrial appendages	Diagnosis	ICD-10-CM
Q20.8	Other congenital malformations of cardiac chambers and connections	Diagnosis	ICD-10-CM
Q20.9	Congenital malformation of cardiac chambers and connections, unspecified	Diagnosis	ICD-10-CM
Q21.0	Ventricular septal defect	Diagnosis	ICD-10-CM
Q21.1	Atrial septal defect	Diagnosis	ICD-10-CM
Q21.2	Atrioventricular septal defect	Diagnosis	ICD-10-CM
Q21.3	Tetralogy of Fallot	Diagnosis	ICD-10-CM
Q21.4	Aortopulmonary septal defect	Diagnosis	ICD-10-CM
Q21.8	Other congenital malformations of cardiac septa	Diagnosis	ICD-10-CM
Q21.9	Congenital malformation of cardiac septum, unspecified	Diagnosis	ICD-10-CM
Q22.0	Pulmonary valve atresia	Diagnosis	ICD-10-CM
Q22.1	Congenital pulmonary valve stenosis	Diagnosis	ICD-10-CM
Q22.2	Congenital pulmonary valve insufficiency	Diagnosis	ICD-10-CM
Q22.3	Other congenital malformations of pulmonary valve	Diagnosis	ICD-10-CM
Q22.4	Congenital tricuspid stenosis	Diagnosis	ICD-10-CM
Q22.5	Ebstein's anomaly	Diagnosis	ICD-10-CM
Q22.6	Hypoplastic right heart syndrome	Diagnosis	ICD-10-CM
Q22.8	Other congenital malformations of tricuspid valve	Diagnosis	ICD-10-CM
Q22.9	Congenital malformation of tricuspid valve, unspecified	Diagnosis	ICD-10-CM
Q23.0	Congenital stenosis of aortic valve	Diagnosis	ICD-10-CM
Q23.1	Congenital insufficiency of aortic valve	Diagnosis	ICD-10-CM
Q23.2	Congenital mitral stenosis	Diagnosis	ICD-10-CM
Q23.3	Congenital mitral insufficiency	Diagnosis	ICD-10-CM
Q23.4	Hypoplastic left heart syndrome	Diagnosis	ICD-10-CM
Q23.8	Other congenital malformations of aortic and mitral valves	Diagnosis	ICD-10-CM
Q23.9	Congenital malformation of aortic and mitral valves, unspecified	Diagnosis	ICD-10-CM
Q24.0	Dextrocardia	Diagnosis	ICD-10-CM
Q24.1	Levocardia	Diagnosis	ICD-10-CM
Q24.2	Cor triatriatum	Diagnosis	ICD-10-CM
Q24.3	Pulmonary infundibular stenosis	Diagnosis	ICD-10-CM
Q24.4	Congenital subaortic stenosis	Diagnosis	ICD-10-CM
Q24.5	Malformation of coronary vessels	Diagnosis	ICD-10-CM
Q24.6	Congenital heart block	Diagnosis	ICD-10-CM
Q24.8	Other specified congenital malformations of heart	Diagnosis	ICD-10-CM
Q24.9	Congenital malformation of heart, unspecified	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Q25.0	Patent ductus arteriosus	Diagnosis	ICD-10-CM
Q25.1	Coarctation of aorta	Diagnosis	ICD-10-CM
Q25.21	Interruption of aortic arch	Diagnosis	ICD-10-CM
Q25.29	Other atresia of aorta	Diagnosis	ICD-10-CM
Q25.3	Supravalvular aortic stenosis	Diagnosis	ICD-10-CM
Q25.40	Congenital malformation of aorta unspecified	Diagnosis	ICD-10-CM
Q25.41	Absence and aplasia of aorta	Diagnosis	ICD-10-CM
Q25.42	Hypoplasia of aorta	Diagnosis	ICD-10-CM
Q25.43	Congenital aneurysm of aorta	Diagnosis	ICD-10-CM
Q25.44	Congenital dilation of aorta	Diagnosis	ICD-10-CM
Q25.45	Double aortic arch	Diagnosis	ICD-10-CM
Q25.46	Tortuous aortic arch	Diagnosis	ICD-10-CM
Q25.47	Right aortic arch	Diagnosis	ICD-10-CM
Q25.48	Anomalous origin of subclavian artery	Diagnosis	ICD-10-CM
Q25.49	Other congenital malformations of aorta	Diagnosis	ICD-10-CM
Q25.5	Atresia of pulmonary artery	Diagnosis	ICD-10-CM
Q25.6	Stenosis of pulmonary artery	Diagnosis	ICD-10-CM
Q25.71	Coarctation of pulmonary artery	Diagnosis	ICD-10-CM
Q25.72	Congenital pulmonary arteriovenous malformation	Diagnosis	ICD-10-CM
Q25.79	Other congenital malformations of pulmonary artery	Diagnosis	ICD-10-CM
Q25.8	Other congenital malformations of other great arteries	Diagnosis	ICD-10-CM
Q25.9	Congenital malformation of great arteries, unspecified	Diagnosis	ICD-10-CM
Q26.0	Congenital stenosis of vena cava	Diagnosis	ICD-10-CM
Q26.1	Persistent left superior vena cava	Diagnosis	ICD-10-CM
Q26.2	Total anomalous pulmonary venous connection	Diagnosis	ICD-10-CM
Q26.3	Partial anomalous pulmonary venous connection	Diagnosis	ICD-10-CM
Q26.4	Anomalous pulmonary venous connection, unspecified	Diagnosis	ICD-10-CM
Q26.5	Anomalous portal venous connection	Diagnosis	ICD-10-CM
Q26.6	Portal vein-hepatic artery fistula	Diagnosis	ICD-10-CM
Q26.8	Other congenital malformations of great veins	Diagnosis	ICD-10-CM
Q26.9	Congenital malformation of great vein, unspecified	Diagnosis	ICD-10-CM
Q27.0	Congenital absence and hypoplasia of umbilical artery	Diagnosis	ICD-10-CM
Q27.1	Congenital renal artery stenosis	Diagnosis	ICD-10-CM
Q27.2	Other congenital malformations of renal artery	Diagnosis	ICD-10-CM
Q27.30	Arteriovenous malformation, site unspecified	Diagnosis	ICD-10-CM
Q27.31	Arteriovenous malformation of vessel of upper limb	Diagnosis	ICD-10-CM
Q27.32	Arteriovenous malformation of vessel of lower limb	Diagnosis	ICD-10-CM
Q27.33	Arteriovenous malformation of digestive system vessel	Diagnosis	ICD-10-CM
Q27.34	Arteriovenous malformation of renal vessel	Diagnosis	ICD-10-CM
Q27.39	Arteriovenous malformation, other site	Diagnosis	ICD-10-CM
Q27.4	Congenital phlebectasia	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Q27.8	Other specified congenital malformations of peripheral vascular system	Diagnosis	ICD-10-CM
Q27.9	Congenital malformation of peripheral vascular system, unspecified	Diagnosis	ICD-10-CM
Q28.0	Arteriovenous malformation of precerebral vessels	Diagnosis	ICD-10-CM
Q28.1	Other malformations of precerebral vessels	Diagnosis	ICD-10-CM
Q28.2	Arteriovenous malformation of cerebral vessels	Diagnosis	ICD-10-CM
Q28.3	Other malformations of cerebral vessels	Diagnosis	ICD-10-CM
Q28.8	Other specified congenital malformations of circulatory system	Diagnosis	ICD-10-CM
Q28.9	Congenital malformation of circulatory system, unspecified	Diagnosis	ICD-10-CM