

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 Non-Cardiac/Non-Urinary Malformation Algorithm Defined in "Congenital Malformations Observed in the Mother's or Linked Infant's Records Following Fingolimod Use During Pregnancy: A Descriptive Analysis"
Request ID	cder_mpl1p_wp063
Description	<p>This report lists Current Procedural Terminology, Fourth Edition (CPT-4), 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 non-cardiac/non-urinary 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-or-linked-infant</p>
Outcome	Congenital non-cardiac/non-urinary malformation
Algorithm to Define Outcome	Congenital non-cardiac or non-urinary malformations were defined as malformations of the central nervous system, eye, ear, orofacial, respiratory, gastrointestinal, genitourinary, renal, or musculoskeletal systems. Non-cardiac or non-urinary malformations were identified using CPT-4, 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 or 90 days of delivery in the mothers' or infants' records.
Query Period	January 1, 2011 - June 30, 2022
Request Send Date	January 24, 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 Current Procedural Terminology, Fourth Edition (CPT-4), 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 Non-Cardiac/Non-Urinary Malformation in this Request

Code	Description	Code Category	Code Type
Non-Cardiac/Non-Urinary Malformation			
00102	Anesthesia for procedures involving plastic repair of cleft lip	Procedure	CPT-4
00172	Anesthesia for intraoral procedures, including biopsy; repair of cleft palate	Procedure	CPT-4
27.54	Repair of cleft lip	Procedure	ICD-9-CM
27.62	Correction of cleft palate	Procedure	ICD-9-CM
27.63	Revision of cleft palate repair	Procedure	ICD-9-CM
40700	Plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral	Procedure	CPT-4
40701	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1-stage procedure	Procedure	CPT-4
40702	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1 of 2 stages	Procedure	CPT-4
40720	Plastic repair of cleft lip/nasal deformity; secondary, by recreation of defect and reclosure	Procedure	CPT-4
40740	Plastic Repair Of Cleft Lip	Procedure	CPT-4
40761	Plastic repair of cleft lip/nasal deformity; with cross lip pedicle flap (Abbe-Estlander type), including sectioning and inserting of pedicle	Procedure	CPT-4
40799	Unlisted procedure, lips	Procedure	CPT-4
42200	Palatoplasty for cleft palate, soft and/or hard palate only	Procedure	CPT-4
42205	Palatoplasty for cleft palate, with closure of alveolar ridge; soft tissue only	Procedure	CPT-4
42210	Palatoplasty for cleft palate, with closure of alveolar ridge; with bone graft to alveolar ridge (includes obtaining graft)	Procedure	CPT-4
42215	Palatoplasty for cleft palate; major revision	Procedure	CPT-4
42220	Palatoplasty for cleft palate; secondary lengthening procedure	Procedure	CPT-4
42225	Palatoplasty for cleft palate; attachment pharyngeal flap	Procedure	CPT-4
42226	Lengthening of palate, and pharyngeal flap	Procedure	CPT-4
42227	Lengthening of palate, with island flap	Procedure	CPT-4
42235	Repair of anterior palate, including vomer flap	Procedure	CPT-4
42260	Repair of nasolabial fistula	Procedure	CPT-4
741.0	Spina bifida with hydrocephalus	Diagnosis	ICD-9-CM
741.00	Spina bifida with hydrocephalus, unspecified region	Diagnosis	ICD-9-CM
741.01	Spina bifida with hydrocephalus, cervical region	Diagnosis	ICD-9-CM
741.02	Spina bifida with hydrocephalus, dorsal (thoracic) region	Diagnosis	ICD-9-CM
741.03	Spina bifida with hydrocephalus, lumbar region	Diagnosis	ICD-9-CM
741.9	Spina bifida without mention of hydrocephalus	Diagnosis	ICD-9-CM
741.90	Spina bifida without mention of hydrocephalus, unspecified region	Diagnosis	ICD-9-CM
741.91	Spina bifida without mention of hydrocephalus, cervical region	Diagnosis	ICD-9-CM
741.92	Spina bifida without mention of hydrocephalus, dorsal (thoracic) region	Diagnosis	ICD-9-CM
741.93	Spina bifida without mention of hydrocephalus, lumbar region	Diagnosis	ICD-9-CM

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Code	Description	Code Category	Code Type
742.0	Encephalocele	Diagnosis	ICD-9-CM
742.1	Microcephalus	Diagnosis	ICD-9-CM
742.2	Congenital reduction deformities of brain	Diagnosis	ICD-9-CM
743.00	Unspecified clinical anophthalmos	Diagnosis	ICD-9-CM
743.10	Unspecified microphthalmos	Diagnosis	ICD-9-CM
743.11	Simple microphthalmos	Diagnosis	ICD-9-CM
743.12	Microphthalmos associated with other anomalies of eye and adnexa	Diagnosis	ICD-9-CM
743.2	Buphthalmos	Diagnosis	ICD-9-CM
743.20	Unspecified buphthalmos	Diagnosis	ICD-9-CM
743.21	Simple buphthalmos	Diagnosis	ICD-9-CM
743.22	Buphthalmos associated with other ocular anomaly	Diagnosis	ICD-9-CM
743.30	Unspecified congenital cataract	Diagnosis	ICD-9-CM
743.31	Congenital capsular and subcapsular cataract	Diagnosis	ICD-9-CM
743.32	Congenital cortical and zonular cataract	Diagnosis	ICD-9-CM
743.33	Congenital nuclear cataract	Diagnosis	ICD-9-CM
743.34	Congenital total and subtotal cataract	Diagnosis	ICD-9-CM
743.35	Congenital aphakia	Diagnosis	ICD-9-CM
743.36	Congenital anomalies of lens shape	Diagnosis	ICD-9-CM
744.01	Congenital absence of external ear causing impairment of hearing	Diagnosis	ICD-9-CM
744.23	Microtia	Diagnosis	ICD-9-CM
748.0	Congenital choanal atresia	Diagnosis	ICD-9-CM
749	Cleft palate and cleft lip	Diagnosis	ICD-9-CM
749.0	Cleft palate	Diagnosis	ICD-9-CM
749.00	Unspecified cleft palate	Diagnosis	ICD-9-CM
749.01	Unilateral cleft palate, complete	Diagnosis	ICD-9-CM
749.02	Unilateral cleft palate, incomplete	Diagnosis	ICD-9-CM
749.03	Bilateral cleft palate, complete	Diagnosis	ICD-9-CM
749.04	Bilateral cleft palate, incomplete	Diagnosis	ICD-9-CM
749.1	Cleft lip	Diagnosis	ICD-9-CM
749.10	Unspecified cleft lip	Diagnosis	ICD-9-CM
749.11	Unilateral cleft lip, complete	Diagnosis	ICD-9-CM
749.12	Unilateral cleft lip, incomplete	Diagnosis	ICD-9-CM
749.13	Bilateral cleft lip, complete	Diagnosis	ICD-9-CM
749.14	Bilateral cleft lip, incomplete	Diagnosis	ICD-9-CM
749.2	Cleft palate with cleft lip	Diagnosis	ICD-9-CM
749.20	Unspecified cleft palate with cleft lip	Diagnosis	ICD-9-CM
749.21	Unilateral cleft palate with cleft lip, complete	Diagnosis	ICD-9-CM
749.22	Unilateral cleft palate with cleft lip, incomplete	Diagnosis	ICD-9-CM
749.23	Bilateral cleft palate with cleft lip, complete	Diagnosis	ICD-9-CM
749.24	Bilateral cleft palate with cleft lip, incomplete	Diagnosis	ICD-9-CM
749.25	Other combinations of cleft palate with cleft lip	Diagnosis	ICD-9-CM

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Code	Description	Code Category	Code Type
750.3	Congenital tracheoesophageal fistula, esophageal atresia and stenosis	Diagnosis	ICD-9-CM
750.5	Congenital hypertrophic pyloric stenosis	Diagnosis	ICD-9-CM
751.1	Congenital atresia and stenosis of small intestine	Diagnosis	ICD-9-CM
751.2	Congenital atresia and stenosis of large intestine, rectum, and anal canal	Diagnosis	ICD-9-CM
751.61	Congenital biliary atresia	Diagnosis	ICD-9-CM
752.61	Hypospadias	Diagnosis	ICD-9-CM
753.0	Congenital renal agenesis and dysgenesis	Diagnosis	ICD-9-CM
753.15	Congenital renal dysplasia	Diagnosis	ICD-9-CM
753.5	Exstrophy of urinary bladder	Diagnosis	ICD-9-CM
755.2	Congenital reduction deformities of upper limb	Diagnosis	ICD-9-CM
755.3	Congenital reduction deformities of lower limb	Diagnosis	ICD-9-CM
755.4	Congenital reduction deformities, unspecified limb	Diagnosis	ICD-9-CM
755.5	Other congenital anomalies of upper limb, including shoulder girdle	Diagnosis	ICD-9-CM
755.6	Other congenital anomaly of lower limb, including pelvic girdle	Diagnosis	ICD-9-CM
755.8	Other specified congenital anomalies of unspecified limb	Diagnosis	ICD-9-CM
755.9	Unspecified congenital anomaly of unspecified limb	Diagnosis	ICD-9-CM
756.13	Congenital absence of vertebra	Diagnosis	ICD-9-CM
756.6	Congenital anomaly of diaphragm	Diagnosis	ICD-9-CM
756.71	Prune belly syndrome	Diagnosis	ICD-9-CM
756.72	Omphalocele	Diagnosis	ICD-9-CM
756.73	Gastroschisis	Diagnosis	ICD-9-CM
756.79	Other congenital anomalies of abdominal wall	Diagnosis	ICD-9-CM
Q01.0	Frontal encephalocele	Diagnosis	ICD-10-CM
Q01.1	Nasofrontal encephalocele	Diagnosis	ICD-10-CM
Q01.2	Occipital encephalocele	Diagnosis	ICD-10-CM
Q01.8	Encephalocele of other sites	Diagnosis	ICD-10-CM
Q01.9	Encephalocele, unspecified	Diagnosis	ICD-10-CM
Q02	Microcephaly	Diagnosis	ICD-10-CM
Q04.0	Congenital malformations of corpus callosum	Diagnosis	ICD-10-CM
Q04.1	Arhinencephaly	Diagnosis	ICD-10-CM
Q04.2	Holoprosencephaly	Diagnosis	ICD-10-CM
Q04.3	Other reduction deformities of brain	Diagnosis	ICD-10-CM
Q05.0	Cervical spina bifida with hydrocephalus	Diagnosis	ICD-10-CM
Q05.1	Thoracic spina bifida with hydrocephalus	Diagnosis	ICD-10-CM
Q05.2	Lumbar spina bifida with hydrocephalus	Diagnosis	ICD-10-CM
Q05.3	Sacral spina bifida with hydrocephalus	Diagnosis	ICD-10-CM
Q05.4	Unspecified spina bifida with hydrocephalus	Diagnosis	ICD-10-CM
Q05.5	Cervical spina bifida without hydrocephalus	Diagnosis	ICD-10-CM
Q05.6	Thoracic spina bifida without hydrocephalus	Diagnosis	ICD-10-CM
Q05.7	Lumbar spina bifida without hydrocephalus	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Q05.8	Sacral spina bifida without hydrocephalus	Diagnosis	ICD-10-CM
Q05.9	Spina bifida, unspecified	Diagnosis	ICD-10-CM
Q07.00	Arnold-Chiari syndrome without spina bifida or hydrocephalus	Diagnosis	ICD-10-CM
Q07.01	Arnold-Chiari syndrome with spina bifida	Diagnosis	ICD-10-CM
Q07.02	Arnold-Chiari syndrome with hydrocephalus	Diagnosis	ICD-10-CM
Q07.03	Arnold-Chiari syndrome with spina bifida and hydrocephalus	Diagnosis	ICD-10-CM
Q11.1	Other anophthalmos	Diagnosis	ICD-10-CM
Q11.2	Microphthalmos	Diagnosis	ICD-10-CM
Q12.0	Congenital cataract	Diagnosis	ICD-10-CM
Q12.2	Coloboma of lens	Diagnosis	ICD-10-CM
Q12.3	Congenital aphakia	Diagnosis	ICD-10-CM
Q12.4	Spherophakia	Diagnosis	ICD-10-CM
Q12.8	Other congenital lens malformations	Diagnosis	ICD-10-CM
Q15.0	Congenital glaucoma	Diagnosis	ICD-10-CM
Q16.0	Congenital absence of (ear) auricle	Diagnosis	ICD-10-CM
Q17.2	Microtia	Diagnosis	ICD-10-CM
Q30.0	Choanal atresia	Diagnosis	ICD-10-CM
Q35.1	Cleft hard palate	Diagnosis	ICD-10-CM
Q35.3	Cleft soft palate	Diagnosis	ICD-10-CM
Q35.5	Cleft hard palate with cleft soft palate	Diagnosis	ICD-10-CM
Q35.7	Cleft uvula	Diagnosis	ICD-10-CM
Q35.9	Cleft palate, unspecified	Diagnosis	ICD-10-CM
Q36.0	Cleft lip, bilateral	Diagnosis	ICD-10-CM
Q36.1	Cleft lip, median	Diagnosis	ICD-10-CM
Q36.9	Cleft lip, unilateral	Diagnosis	ICD-10-CM
Q37.0	Cleft hard palate with bilateral cleft lip	Diagnosis	ICD-10-CM
Q37.1	Cleft hard palate with unilateral cleft lip	Diagnosis	ICD-10-CM
Q37.2	Cleft soft palate with bilateral cleft lip	Diagnosis	ICD-10-CM
Q37.3	Cleft soft palate with unilateral cleft lip	Diagnosis	ICD-10-CM
Q37.4	Cleft hard and soft palate with bilateral cleft lip	Diagnosis	ICD-10-CM
Q37.5	Cleft hard and soft palate with unilateral cleft lip	Diagnosis	ICD-10-CM
Q37.8	Unspecified cleft palate with bilateral cleft lip	Diagnosis	ICD-10-CM
Q37.9	Unspecified cleft palate with unilateral cleft lip	Diagnosis	ICD-10-CM
Q39.0	Atresia of esophagus without fistula	Diagnosis	ICD-10-CM
Q39.1	Atresia of esophagus with tracheo-esophageal fistula	Diagnosis	ICD-10-CM
Q39.2	Congenital tracheo-esophageal fistula without atresia	Diagnosis	ICD-10-CM
Q39.3	Congenital stenosis and stricture of esophagus	Diagnosis	ICD-10-CM
Q39.4	Esophageal web	Diagnosis	ICD-10-CM
Q40.0	Congenital hypertrophic pyloric stenosis	Diagnosis	ICD-10-CM
Q41.0	Congenital absence, atresia and stenosis of duodenum	Diagnosis	ICD-10-CM
Q41.1	Congenital absence, atresia and stenosis of jejunum	Diagnosis	ICD-10-CM
Q41.2	Congenital absence, atresia and stenosis of ileum	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Q41.8	Congenital absence, atresia and stenosis of other specified parts of small	Diagnosis	ICD-10-CM
Q41.9	Congenital absence, atresia and stenosis of small intestine, part unspecified	Diagnosis	ICD-10-CM
Q42.0	Congenital absence, atresia and stenosis of rectum with fistula	Diagnosis	ICD-10-CM
Q42.1	Congenital absence, atresia and stenosis of rectum without fistula	Diagnosis	ICD-10-CM
Q42.2	Congenital absence, atresia and stenosis of anus with fistula	Diagnosis	ICD-10-CM
Q42.3	Congenital absence, atresia and stenosis of anus without fistula	Diagnosis	ICD-10-CM
Q42.8	Congenital absence, atresia and stenosis of other parts of large intestine	Diagnosis	ICD-10-CM
Q42.9	Congenital absence, atresia and stenosis of large intestine, part unspecified	Diagnosis	ICD-10-CM
Q44.2	Atresia of bile ducts	Diagnosis	ICD-10-CM
Q44.3	Congenital stenosis and stricture of bile ducts	Diagnosis	ICD-10-CM
Q54.0	Hypospadias, balanic	Diagnosis	ICD-10-CM
Q54.1	Hypospadias, penile	Diagnosis	ICD-10-CM
Q54.2	Hypospadias, penoscrotal	Diagnosis	ICD-10-CM
Q54.3	Hypospadias, perineal	Diagnosis	ICD-10-CM
Q54.8	Other hypospadias	Diagnosis	ICD-10-CM
Q54.9	Hypospadias, unspecified	Diagnosis	ICD-10-CM
Q60.0	Renal agenesis, unilateral	Diagnosis	ICD-10-CM
Q60.1	Renal agenesis, bilateral	Diagnosis	ICD-10-CM
Q60.2	Renal agenesis, unspecified	Diagnosis	ICD-10-CM
Q60.3	Renal hypoplasia, unilateral	Diagnosis	ICD-10-CM
Q60.4	Renal hypoplasia, bilateral	Diagnosis	ICD-10-CM
Q60.5	Renal hypoplasia, unspecified	Diagnosis	ICD-10-CM
Q60.6	Potter's syndrome	Diagnosis	ICD-10-CM
Q61.4	Renal dysplasia	Diagnosis	ICD-10-CM
Q64.10	Exstrophy of urinary bladder, unspecified	Diagnosis	ICD-10-CM
Q64.11	Supravesical fissure of urinary bladder	Diagnosis	ICD-10-CM
Q64.12	Cloacal exstrophy of urinary bladder	Diagnosis	ICD-10-CM
Q64.19	Other exstrophy of urinary bladder	Diagnosis	ICD-10-CM
Q73.0	Congenital absence of unspecified limb(s)	Diagnosis	ICD-10-CM
Q73.1	Phocomelia, unspecified limb(s)	Diagnosis	ICD-10-CM
Q73.8	Other reduction defects of unspecified limb(s)	Diagnosis	ICD-10-CM
Q74.8	Other specified congenital malformations of limb(s)	Diagnosis	ICD-10-CM
Q74.9	Unspecified congenital malformation of limb(s)	Diagnosis	ICD-10-CM
Q76.49	Other congenital malformations of spine, not associated with scoliosis	Diagnosis	ICD-10-CM
Q79.0	Congenital diaphragmatic hernia	Diagnosis	ICD-10-CM
Q79.1	Other congenital malformations of diaphragm	Diagnosis	ICD-10-CM
Q79.2	Exomphalos	Diagnosis	ICD-10-CM
Q79.3	Gastroschisis	Diagnosis	ICD-10-CM

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Q79.4	Prune belly syndrome	Diagnosis	ICD-10-CM
Q79.51	Congenital hernia of bladder	Diagnosis	ICD-10-CM
Q79.59	Other congenital malformations of abdominal wall	Diagnosis	ICD-10-CM