

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 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 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 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 urinary malformation
Algorithm to Define Outcome	Congenital urinary 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 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 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 Urinary Malformation in this Request

Code	Description	Code Category	Code Type
Urinary Malformation			
753	Congenital anomalies of urinary system	Diagnosis	ICD-9-CM
753.0	Congenital renal agenesis and dysgenesis	Diagnosis	ICD-9-CM
753.1	Congenital cystic kidney disease	Diagnosis	ICD-9-CM
753.10	Unspecified congenital cystic kidney disease	Diagnosis	ICD-9-CM
753.11	Congenital single renal cyst	Diagnosis	ICD-9-CM
753.12	Congenital polycystic kidney, unspecified type	Diagnosis	ICD-9-CM
753.13	Congenital polycystic kidney, autosomal dominant	Diagnosis	ICD-9-CM
753.14	Congenital polycystic kidney, autosomal recessive	Diagnosis	ICD-9-CM
753.15	Congenital renal dysplasia	Diagnosis	ICD-9-CM
753.16	Congenital medullary cystic kidney	Diagnosis	ICD-9-CM
753.17	Congenital medullary sponge kidney	Diagnosis	ICD-9-CM
753.19	Other specified congenital cystic kidney disease	Diagnosis	ICD-9-CM
753.2	Congenital obstructive defects of renal pelvis and ureter	Diagnosis	ICD-9-CM
753.20	Unspecified obstructive defect of renal pelvis and ureter	Diagnosis	ICD-9-CM
753.21	Congenital obstruction of ureteropelvic junction	Diagnosis	ICD-9-CM
753.22	Congenital obstruction of ureterovesical junction	Diagnosis	ICD-9-CM
753.23	Congenital ureterocele	Diagnosis	ICD-9-CM
753.29	Other obstructive defect of renal pelvis and ureter	Diagnosis	ICD-9-CM
753.3	Other specified congenital anomalies of kidney	Diagnosis	ICD-9-CM
753.4	Other specified congenital anomalies of ureter	Diagnosis	ICD-9-CM
753.5	Exstrophy of urinary bladder	Diagnosis	ICD-9-CM
753.6	Congenital atresia and stenosis of urethra and bladder neck	Diagnosis	ICD-9-CM
753.7	Congenital anomalies of urachus	Diagnosis	ICD-9-CM
753.8	Other specified congenital anomaly of bladder and urethra	Diagnosis	ICD-9-CM
753.9	Unspecified congenital anomaly of urinary system	Diagnosis	ICD-9-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
Q61.00	Congenital renal cyst, unspecified	Diagnosis	ICD-10-CM
Q61.01	Congenital single renal cyst	Diagnosis	ICD-10-CM
Q61.02	Congenital multiple renal cysts	Diagnosis	ICD-10-CM
Q61.11	Cystic dilatation of collecting ducts	Diagnosis	ICD-10-CM
Q61.19	Other polycystic kidney, infantile type	Diagnosis	ICD-10-CM
Q61.2	Polycystic kidney, adult type	Diagnosis	ICD-10-CM
Q61.3	Polycystic kidney, unspecified	Diagnosis	ICD-10-CM
Q61.4	Renal dysplasia	Diagnosis	ICD-10-CM
Q61.5	Medullary cystic kidney	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Q61.8	Other cystic kidney diseases	Diagnosis	ICD-10-CM
Q61.9	Cystic kidney disease, unspecified	Diagnosis	ICD-10-CM
Q62.0	Congenital hydronephrosis	Diagnosis	ICD-10-CM
Q62.10	Congenital occlusion of ureter, unspecified	Diagnosis	ICD-10-CM
Q62.11	Congenital occlusion of ureteropelvic junction	Diagnosis	ICD-10-CM
Q62.12	Congenital occlusion of ureterovesical orifice	Diagnosis	ICD-10-CM
Q62.2	Congenital megaureter	Diagnosis	ICD-10-CM
Q62.31	Congenital ureterocele, orthotopic	Diagnosis	ICD-10-CM
Q62.32	Cecoureterocele	Diagnosis	ICD-10-CM
Q62.39	Other obstructive defects of renal pelvis and ureter	Diagnosis	ICD-10-CM
Q62.4	Agenesis of ureter	Diagnosis	ICD-10-CM
Q62.5	Duplication of ureter	Diagnosis	ICD-10-CM
Q62.60	Malposition of ureter, unspecified	Diagnosis	ICD-10-CM
Q62.61	Deviation of ureter	Diagnosis	ICD-10-CM
Q62.62	Displacement of ureter	Diagnosis	ICD-10-CM
Q62.63	Anomalous implantation of ureter	Diagnosis	ICD-10-CM
Q62.69	Other malposition of ureter	Diagnosis	ICD-10-CM
Q62.7	Congenital vesico-uretero-renal reflux	Diagnosis	ICD-10-CM
Q62.8	Other congenital malformations of ureter	Diagnosis	ICD-10-CM
Q63.0	Accessory kidney	Diagnosis	ICD-10-CM
Q63.1	Lobulated, fused and horseshoe kidney	Diagnosis	ICD-10-CM
Q63.2	Ectopic kidney	Diagnosis	ICD-10-CM
Q63.3	Hyperplastic and giant kidney	Diagnosis	ICD-10-CM
Q63.8	Other specified congenital malformations of kidney	Diagnosis	ICD-10-CM
Q63.9	Congenital malformation of kidney, unspecified	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
Q64.2	Congenital posterior urethral valves	Diagnosis	ICD-10-CM
Q64.31	Congenital bladder neck obstruction	Diagnosis	ICD-10-CM
Q64.32	Congenital stricture of urethra	Diagnosis	ICD-10-CM
Q64.33	Congenital stricture of urinary meatus	Diagnosis	ICD-10-CM
Q64.39	Other atresia and stenosis of urethra and bladder neck	Diagnosis	ICD-10-CM
Q64.4	Malformation of urachus	Diagnosis	ICD-10-CM
Q64.5	Congenital absence of bladder and urethra	Diagnosis	ICD-10-CM
Q64.6	Congenital diverticulum of bladder	Diagnosis	ICD-10-CM
Q64.70	Unspecified congenital malformation of bladder and urethra	Diagnosis	ICD-10-CM
Q64.71	Congenital prolapse of urethra	Diagnosis	ICD-10-CM
Q64.72	Congenital prolapse of urinary meatus	Diagnosis	ICD-10-CM
Q64.73	Congenital urethrorectal fistula	Diagnosis	ICD-10-CM
Q64.74	Double urethra	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Q64.75	Double urinary meatus	Diagnosis	ICD-10-CM
Q64.79	Other congenital malformations of bladder and urethra	Diagnosis	ICD-10-CM
Q64.8	Other specified congenital malformations of urinary system	Diagnosis	ICD-10-CM
Q64.9	Congenital malformation of urinary system, unspecified	Diagnosis	ICD-10-CM