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	Oral Clefts Algorithm Defined in "Risk of Cardiac Malformations and Oral Clefts in Infants Following in Utero Exposure to Cyclobenzaprine: A Sensitivity Analysis"
Request ID	cder_mpl2p_wp067
Description	This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes, International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes, Current Procedural Terminology, Fourth Revision (CPT-4) Procedure Codes, and Healthcare Common Procedure Coding System (HCPCS) procedure codes and algorithms used to define oral clefts in this request. For additional information about the algorithm and how it was defined relative to the cohort and exposure(s) of interest in the analysis, refer to the analysis webpage here: https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/risk-cardiac-malformations-and-oral-clefts-infants-following
Outcome	Oral Clefts
Algorithm to Define Outcome	The oral clefts outcome is defined as the presence of ≥2 dates with diagnostic codes for cleft lip, cleft palate, or cleft palate with cleft lip (Code List 1) from date of birth (DOB) to DOB + 365 days or maternal claims from delivery and delivery + 30 days, OR ≥1 date with a diagnostic code for oral clefts (Code List 1) and a oral cleft correction procedure code (Code List 2) from date of birth (DOB) to DOB + 365 days or maternal claims from delivery and delivery + 30 days, OR ≥1 date with a diagnostic code for oral clefts from date of birth (DOB) to DOB + 365 days or maternal claims from delivery and delivery + 30 days and infant death within 90 days of delivery (Code List 1).
Query Period	January 1, 2010 - December 31, 2022
Request Send Date	July 16, 2026

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

Code List 1. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes, International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes, Current Procedural Terminology, Fourth Revision (CPT-4) Procedure Codes, and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Outcomes in this Request

Code	Description	Code Category	Code Type
	Oral Clefts		
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
Q35.9	Cleft palate, unspecified	Diagnosis	ICD-10-CM
Q35.7	Cleft uvula	Diagnosis	ICD-10-CM
Q36.9	Cleft lip, unilateral	Diagnosis	ICD-10-CM
Q36.0	Cleft lip, bilateral	Diagnosis	ICD-10-CM
Q37.9	Unspecified cleft palate with unilateral cleft lip	Diagnosis	ICD-10-CM
Q37.8	Unspecified cleft palate with bilateral cleft lip	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
Q36.1	Cleft lip, median	Diagnosis	ICD-10-CM
Q37.3	Cleft soft palate with unilateral cleft lip	Diagnosis	ICD-10-CM
Q37.5	Cleft hard and soft palate with unilateral cleft lip	Diagnosis	ICD-10-CM
Q37.1	Cleft hard palate with unilateral cleft lip	Diagnosis	ICD-10-CM
Q37.0	Cleft hard palate with bilateral cleft lip	Diagnosis	ICD-10-CM
Q37.4	Cleft hard and soft palate with bilateral cleft lip	Diagnosis	ICD-10-CM
Q37.2	Cleft soft palate with bilateral cleft lip	Diagnosis	ICD-10-CM

Code List 2. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes, International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) Procedure Codes, Current Procedural Terminology, Fourth Revision (CPT-4) Procedure Codes, and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Oral Clefts in this Request

Code	Description	Code Category	Code Type
	Oral Clefts Procedures		
27.62	Correction of cleft palate	Procedure	ICD-9-PCS
75.36	Correction of fetal defect	Procedure	ICD-9-PCS
27.69	Other plastic repair of palate	Procedure	ICD-9-PCS
27.54	Repair of cleft lip	Procedure	ICD-9-PCS
27.63	Revision of cleft palate repair	Procedure	ICD-9-PCS
27.61	Suture of laceration of palate	Procedure	ICD-9-PCS
00172	Anesthesia for intraoral procedures, including biopsy; repair of cleft palate	Procedure	CPT-4
00102	Anesthesia for procedures involving plastic repair of cleft lip	Procedure	CPT-4
42226	Lengthening of palate, and pharyngeal flap	Procedure	CPT-4
42227	Lengthening of palate, with island flap	Procedure	CPT-4
42225	Palatoplasty for cleft palate; attachment pharyngeal flap	Procedure	CPT-4
42215	Palatoplasty for cleft palate; major revision	Procedure	CPT-4
42220	Palatoplasty for cleft palate; secondary lengthening procedure	Procedure	CPT-4
40702	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1 of 2 stages	Procedure	CPT-4
40701	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1-stage procedure	Procedure	CPT-4
40700	Plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral	Procedure	CPT-4
42235	Repair of anterior palate, including vomer flap	Procedure	CPT-4
30580	Repair fistula; oromaxillary (combine with 31030 if antrotomy is included)	Procedure	CPT-4
30600	Repair fistula; oronasal	Procedure	CPT-4
42260	Repair of nasolabial fistula	Procedure	CPT-4
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies	Procedure	CPT-4
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only	Procedure	CPT-4
0CQ00ZZ	Repair Upper Lip, Open Approach	Procedure	ICD-10-PCS
0CQ03ZZ	Repair Upper Lip, Percutaneous Approach	Procedure	ICD-10-PCS
0CQ0XZZ	Repair Upper Lip, External Approach	Procedure	ICD-10-PCS
0CQ10ZZ	Repair Lower Lip, Open Approach	Procedure	ICD-10-PCS
0CQ13ZZ	Repair Lower Lip, Percutaneous Approach	Procedure	ICD-10-PCS
0CQ1XZZ	Repair Lower Lip, External Approach	Procedure	ICD-10-PCS
0CQ20ZZ	Repair Hard Palate, Open Approach	Procedure	ICD-10-PCS
0CQ23ZZ	Repair Hard Palate, Percutaneous Approach	Procedure	ICD-10-PCS
0CQ2XZZ	Repair Hard Palate, External Approach	Procedure	ICD-10-PCS
0CQ30ZZ	Repair Soft Palate, Open Approach	Procedure	ICD-10-PCS
0CQ33ZZ	Repair Soft Palate, Percutaneous Approach	Procedure	ICD-10-PCS
0CQ3XZZ	Repair Soft Palate, External Approach	Procedure	ICD-10-PCS
0CR207Z	Replacement of Hard Palate with Autologous Tissue Substitute, Open Approach	Procedure	ICD-10-PCS
0CR20JZ	Replacement of Hard Palate with Synthetic Substitute, Open Approach	Procedure	ICD-10-PCS
0CR20KZ	Replacement of Hard Palate with Nonautologous Tissue Substitute, Open Approach	Procedure	ICD-10-PCS
0CR237Z	Replacement of Hard Palate with Autologous Tissue Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CR23JZ	Replacement of Hard Palate with Synthetic Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CR23KZ	Replacement of Hard Palate with Nonautologous Tissue Substitute, Percutaneous Approach	Procedure	ICD-10-PCS

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Code	Description	Code Category	Code Type
0CR2X7Z	Replacement of Hard Palate with Autologous Tissue Substitute, External Approach	Procedure	ICD-10-PCS
0CR2XJZ	Replacement of Hard Palate with Synthetic Substitute, External Approach	Procedure	ICD-10-PCS
0CR2XKZ	Replacement of Hard Palate with Nonautologous Tissue Substitute, External Approach	Procedure	ICD-10-PCS
0CR307Z	Replacement of Soft Palate with Autologous Tissue Substitute, Open Approach	Procedure	ICD-10-PCS
0CR30JZ	Replacement of Soft Palate with Synthetic Substitute, Open Approach	Procedure	ICD-10-PCS
0CR30KZ	Replacement of Soft Palate with Nonautologous Tissue Substitute, Open Approach	Procedure	ICD-10-PCS
0CR337Z	Replacement of Soft Palate with Autologous Tissue Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CR33JZ	Replacement of Soft Palate with Synthetic Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CR33KZ	Replacement of Soft Palate with Nonautologous Tissue Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CR3X7Z	Replacement of Soft Palate with Autologous Tissue Substitute, External Approach	Procedure	ICD-10-PCS
0CR3XJZ	Replacement of Soft Palate with Synthetic Substitute, External Approach	Procedure	ICD-10-PCS
0CR3XKZ	Replacement of Soft Palate with Nonautologous Tissue Substitute, External Approach	Procedure	ICD-10-PCS
0CS20ZZ	Reposition Hard Palate, Open Approach	Procedure	ICD-10-PCS
0CS2XZZ	Reposition Hard Palate, External Approach	Procedure	ICD-10-PCS
0CS30ZZ	Reposition Soft Palate, Open Approach	Procedure	ICD-10-PCS
0CS3XZZ	Reposition Soft Palate, External Approach	Procedure	ICD-10-PCS
0CU207Z	Supplement Hard Palate with Autologous Tissue Substitute, Open Approach	Procedure	ICD-10-PCS
0CU20JZ	Supplement Hard Palate with Synthetic Substitute, Open Approach	Procedure	ICD-10-PCS
0CU20KZ	Supplement Hard Palate with Nonautologous Tissue Substitute, Open Approach	Procedure	ICD-10-PCS
0CU237Z	Supplement Hard Palate with Autologous Tissue Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CU23JZ	Supplement Hard Palate with Synthetic Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CU23KZ	Supplement Hard Palate with Nonautologous Tissue Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CU2X7Z	Supplement Hard Palate with Autologous Tissue Substitute, External Approach	Procedure	ICD-10-PCS
0CU2XJZ	Supplement Hard Palate with Synthetic Substitute, External Approach	Procedure	ICD-10-PCS
0CU2XKZ	Supplement Hard Palate with Nonautologous Tissue Substitute, External Approach	Procedure	ICD-10-PCS
0CU307Z	Supplement Soft Palate with Autologous Tissue Substitute, Open Approach	Procedure	ICD-10-PCS
0CU30JZ	Supplement Soft Palate with Synthetic Substitute, Open Approach	Procedure	ICD-10-PCS
0CU30KZ	Supplement Soft Palate with Nonautologous Tissue Substitute, Open Approach	Procedure	ICD-10-PCS
0CU337Z	Supplement Soft Palate with Autologous Tissue Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CU33JZ	Supplement Soft Palate with Synthetic Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CU33KZ	Supplement Soft Palate with Nonautologous Tissue Substitute, Percutaneous Approach	Procedure	ICD-10-PCS
0CU3X7Z	Supplement Soft Palate with Autologous Tissue Substitute, External Approach	Procedure	ICD-10-PCS
0CU3XJZ	Supplement Soft Palate with Synthetic Substitute, External Approach	Procedure	ICD-10-PCS
0CU3XKZ	Supplement Soft Palate with Nonautologous Tissue Substitute, External Approach	Procedure	ICD-10-PCS

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Code	Description	Code Category	Code Type
2769	OTHER PLASTIC REPAIR OF PALATE	Procedure	ICD-9-PCS
2754	Repair of cleft lip	Procedure	ICD-9-PCS
2761	Suture of laceration of palate	Procedure	ICD-9-PCS
2762	Correction of cleft palate	Procedure	ICD-9-PCS
2763	Revision of cleft palate repair	Procedure	ICD-9-PCS
7536	CORRECTION OF FETAL DEFECT	Procedure	ICD-9-PCS