

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	Syphilis Diagnosis Algorithm Defined in "Characterization of Syphilis Testing and Treatment in Infants in the Mother-Infant Linkage Table in the Sentinel Distributed Database: A Descriptive Analysis"
Request ID	cder_mpl1p_wp092
Description	<p>This report lists the International Classification of Diseases, 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 syphilis diagnosis in this request.</p> <p>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/syphilis-testing-and-treatment-infants-mother-infant-linkage</p>
Outcome	Syphilis Diagnosis
Algorithm to Define Outcome	The syphilis diagnosis outcome is defined as one ICD-9-CM or ICD-10-CM diagnosis code for syphilis diagnosis (Code List 1) within 7 days of a delivery date in the inpatient setting.
Query Period	January 1, 2010 - December 31, 2023
Request Send Date	August 1, 2024

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) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Syphilis Diagnosis in this Request

Code	Description	Code Category	Diagnosis Code Type
090.40	Unspecified juvenile neurosyphilis	Diagnosis	09
090.49	Other juvenile neurosyphilis	Diagnosis	09
091.0	Genital syphilis (primary)	Diagnosis	09
091.1	Primary anal syphilis	Diagnosis	09
091.2	Other primary syphilis	Diagnosis	09
091.3	Secondary syphilis of skin or mucous membranes	Diagnosis	09
092.0	Early syphilis, latent, serological relapse after treatment	Diagnosis	09
092.9	Early syphilis, latent, unspecified	Diagnosis	09
093.89	Other specified cardiovascular syphilis	Diagnosis	09
093.9	Unspecified cardiovascular syphilis	Diagnosis	09
094.3	Asymptomatic neurosyphilis	Diagnosis	09
094.82	Syphilitic Parkinsonism	Diagnosis	09
094.83	Syphilitic disseminated retinochoroiditis	Diagnosis	09
094.87	Syphilitic ruptured cerebral aneurysm	Diagnosis	09
094.89	Other specified neurosyphilis	Diagnosis	09
094.9	Unspecified neurosyphilis	Diagnosis	09
095.1	Syphilis of lung	Diagnosis	09
095.2	Syphilitic peritonitis	Diagnosis	09
095.3	Syphilis of liver	Diagnosis	09
095.4	Syphilis of kidney	Diagnosis	09
095.5	Syphilis of bone	Diagnosis	09
095.6	Syphilis of muscle	Diagnosis	09
095.7	Syphilis of synovium, tendon, and bursa	Diagnosis	09
095.8	Other specified forms of late symptomatic syphilis	Diagnosis	09
095.9	Unspecified late symptomatic syphilis	Diagnosis	09
096	Late syphilis, latent	Diagnosis	09
097.0	Unspecified late syphilis	Diagnosis	09
097.1	Unspecified latent syphilis	Diagnosis	09
097.9	Unspecified syphilis	Diagnosis	09
104.0	Nonvenereal endemic syphilis	Diagnosis	09
647.00	Maternal syphilis, complicating pregnancy, childbirth, or the puerperium, unspecified as	Diagnosis	09
647.01	Maternal syphilis, complicating pregnancy, with delivery	Diagnosis	09
647.02	Maternal syphilis, complicating pregnancy, with delivery, with current postpartum comp	Diagnosis	09
647.03	Maternal syphilis, antepartum	Diagnosis	09
647.04	Maternal syphilis complicating pregnancy, childbirth, or the puerperium, postpartum cor	Diagnosis	09
A51	Early syphilis	Diagnosis	10
A51.0	Primary genital syphilis	Diagnosis	10
A51.1	Primary anal syphilis	Diagnosis	10
A51.2	Primary syphilis of other sites	Diagnosis	10

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Code	Description	Code Category	Diagnosis Code Type
A51.3	Secondary syphilis of skin and mucous membranes	Diagnosis	10
A51.39	Other secondary syphilis of skin	Diagnosis	10
A51.4	Other secondary syphilis	Diagnosis	10
A51.5	Early syphilis, latent	Diagnosis	10
A51.9	Early syphilis, unspecified	Diagnosis	10
A52	Late syphilis	Diagnosis	10
A52.0	Cardiovascular and cerebrovascular syphilis	Diagnosis	10
A52.00	Cardiovascular syphilis, unspecified	Diagnosis	10
A52.05	Other cerebrovascular syphilis	Diagnosis	10
A52.09	Other cardiovascular syphilis	Diagnosis	10
A52.1	Symptomatic neurosyphilis	Diagnosis	10
A52.10	Symptomatic neurosyphilis, unspecified	Diagnosis	10
A52.12	Other cerebrospinal syphilis	Diagnosis	10
A52.19	Other symptomatic neurosyphilis	Diagnosis	10
A52.2	Asymptomatic neurosyphilis	Diagnosis	10
A52.3	Neurosyphilis, unspecified	Diagnosis	10
A52.7	Other symptomatic late syphilis	Diagnosis	10
A52.72	Syphilis of lung and bronchus	Diagnosis	10
A52.73	Symptomatic late syphilis of other respiratory organs	Diagnosis	10
A52.74	Syphilis of liver and other viscera	Diagnosis	10
A52.75	Syphilis of kidney and ureter	Diagnosis	10
A52.76	Other genitourinary symptomatic late syphilis	Diagnosis	10
A52.77	Syphilis of bone and joint	Diagnosis	10
A52.78	Syphilis of other musculoskeletal tissue	Diagnosis	10
A52.79	Other symptomatic late syphilis	Diagnosis	10
A52.8	Late syphilis, latent	Diagnosis	10
A52.9	Late syphilis, unspecified	Diagnosis	10
A53	Other and unspecified syphilis	Diagnosis	10
A53.0	Latent syphilis, unspecified as early or late	Diagnosis	10
A53.9	Syphilis, unspecified	Diagnosis	10
A65	Nonvenereal syphilis	Diagnosis	10
O98.1	Syphilis complicating pregnancy, childbirth and the puerperium	Diagnosis	10
O98.11	Syphilis complicating pregnancy	Diagnosis	10
O98.111	Syphilis complicating pregnancy, first trimester	Diagnosis	10
O98.112	Syphilis complicating pregnancy, second trimester	Diagnosis	10
O98.113	Syphilis complicating pregnancy, third trimester	Diagnosis	10
O98.119	Syphilis complicating pregnancy, unspecified trimester	Diagnosis	10
O98.12	Syphilis complicating childbirth	Diagnosis	10
O98.13	Syphilis complicating the puerperium	Diagnosis	10

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Code	Description	Code Category	Diagnosis Code Type
090.0	Early congenital syphilis, symptomatic	Diagnosis	09
090.1	Early congenital syphilis, latent	Diagnosis	09
090.2	Early congenital syphilis, unspecified	Diagnosis	09
090.3	Syphilitic interstitial keratitis	Diagnosis	09
090.41	Congenital syphilitic encephalitis	Diagnosis	09
090.42	Congenital syphilitic meningitis	Diagnosis	09
090.5	Other late congenital syphilis, symptomatic	Diagnosis	09
090.6	Late congenital syphilis, latent	Diagnosis	09
090.7	Late congenital syphilis, unspecified	Diagnosis	09
090.9	Congenital syphilis, unspecified	Diagnosis	09
091.4	Adenopathy due to secondary syphilis	Diagnosis	09
091.50	Syphilitic uveitis, unspecified	Diagnosis	09
091.51	Syphilitic chorioretinitis (secondary)	Diagnosis	09
091.52	Syphilitic iridocyclitis (secondary)	Diagnosis	09
091.61	Secondary syphilitic periostitis	Diagnosis	09
091.62	Secondary syphilitic hepatitis	Diagnosis	09
091.69	Secondary syphilis of other viscera	Diagnosis	09
091.7	Secondary syphilis, relapse	Diagnosis	09
091.81	Acute syphilitic meningitis (secondary)	Diagnosis	09
091.82	Syphilitic alopecia	Diagnosis	09
091.89	Other forms of secondary syphilis	Diagnosis	09
091.9	Unspecified secondary syphilis	Diagnosis	09
093.0	Aneurysm of aorta, specified as syphilitic	Diagnosis	09
093.1	Syphilitic aortitis	Diagnosis	09
093.20	Syphilitic endocarditis of valve, unspecified	Diagnosis	09
093.21	Syphilitic endocarditis of mitral valve	Diagnosis	09
093.22	Syphilitic endocarditis of aortic valve	Diagnosis	09
093.23	Syphilitic endocarditis of tricuspid valve	Diagnosis	09
093.24	Syphilitic endocarditis of pulmonary valve	Diagnosis	09
093.81	Syphilitic pericarditis	Diagnosis	09
093.82	Syphilitic myocarditis	Diagnosis	09
094.0	Tabes dorsalis	Diagnosis	09
094.1	General paresis	Diagnosis	09
094.2	Syphilitic meningitis	Diagnosis	09
094.81	Syphilitic encephalitis	Diagnosis	09
094.84	Syphilitic optic atrophy	Diagnosis	09
094.85	Syphilitic retrobulbar neuritis	Diagnosis	09
094.86	Syphilitic acoustic neuritis	Diagnosis	09
095.0	Syphilitic episcleritis	Diagnosis	09

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Code	Description	Code Category	Diagnosis Code Type
A50.01	Early congenital syphilitic oculopathy	Diagnosis	10
A50.02	Early congenital syphilitic osteochondropathy	Diagnosis	10
A50.03	Early congenital syphilitic pharyngitis	Diagnosis	10
A50.04	Early congenital syphilitic pneumonia	Diagnosis	10
A50.05	Early congenital syphilitic rhinitis	Diagnosis	10
A50.06	Early cutaneous congenital syphilis	Diagnosis	10
A50.07	Early mucocutaneous congenital syphilis	Diagnosis	10
A50.08	Early visceral congenital syphilis	Diagnosis	10
A50.09	Other early congenital syphilis, symptomatic	Diagnosis	10
A50.1	Early congenital syphilis, latent	Diagnosis	10
A50.2	Early congenital syphilis, unspecified	Diagnosis	10
A50.30	Late congenital syphilitic oculopathy, unspecified	Diagnosis	10
A50.31	Late congenital syphilitic interstitial keratitis	Diagnosis	10
A50.32	Late congenital syphilitic chorioretinitis	Diagnosis	10
A50.39	Other late congenital syphilitic oculopathy	Diagnosis	10
A50.40	Late congenital neurosyphilis, unspecified	Diagnosis	10
A50.41	Late congenital syphilitic meningitis	Diagnosis	10
A50.42	Late congenital syphilitic encephalitis	Diagnosis	10
A50.43	Late congenital syphilitic polyneuropathy	Diagnosis	10
A50.44	Late congenital syphilitic optic nerve atrophy	Diagnosis	10
A50.45	Juvenile general paresis	Diagnosis	10
A50.49	Other late congenital neurosyphilis	Diagnosis	10
A50.51	Clutton's joints	Diagnosis	10
A50.52	Hutchinson's teeth	Diagnosis	10
A50.53	Hutchinson's triad	Diagnosis	10
A50.54	Late congenital cardiovascular syphilis	Diagnosis	10
A50.55	Late congenital syphilitic arthropathy	Diagnosis	10
A50.56	Late congenital syphilitic osteochondropathy	Diagnosis	10
A50.57	Syphilitic saddle nose	Diagnosis	10
A50.59	Other late congenital syphilis, symptomatic	Diagnosis	10
A50.6	Late congenital syphilis, latent	Diagnosis	10
A50.7	Late congenital syphilis, unspecified	Diagnosis	10
A50.9	Congenital syphilis, unspecified	Diagnosis	10
A51.31	Condyloma latum	Diagnosis	10
A51.32	Syphilitic alopecia	Diagnosis	10
A51.41	Secondary syphilitic meningitis	Diagnosis	10
A51.42	Secondary syphilitic female pelvic disease	Diagnosis	10
A51.43	Secondary syphilitic oculopathy	Diagnosis	10
A51.44	Secondary syphilitic nephritis	Diagnosis	10

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Code	Description	Code Category	Diagnosis Code Type
A51.45	Secondary syphilitic hepatitis	Diagnosis	10
A51.46	Secondary syphilitic osteopathy	Diagnosis	10
A51.49	Other secondary syphilitic conditions	Diagnosis	10
A52.01	Syphilitic aneurysm of aorta	Diagnosis	10
A52.02	Syphilitic aortitis	Diagnosis	10
A52.03	Syphilitic endocarditis	Diagnosis	10
A52.04	Syphilitic cerebral arteritis	Diagnosis	10
A52.06	Other syphilitic heart involvement	Diagnosis	10
A52.11	Tabes dorsalis	Diagnosis	10
A52.13	Late syphilitic meningitis	Diagnosis	10
A52.14	Late syphilitic encephalitis	Diagnosis	10
A52.15	Late syphilitic neuropathy	Diagnosis	10
A52.16	Charcot's arthropathy (tabetic)	Diagnosis	10
A52.17	General paresis	Diagnosis	10