

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 Testing Algorithm Defined in "Characterization of Syphilis Testing and Treatment in Pregnant Women: A Descriptive Analysis"
Request ID	cder_mpl1p_wp090
Description	<p>This report lists Healthcare Common Procedure Coding System (HCPCS)codes and algorithms used to define syphilis testing 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/characterization-syphilis-testing-and-treatment-pregnant</p>
Outcome	Syphilis Testing
Algorithm to Define Outcome	The syphilis testing outcome is defined as one HCPCS code (Code List 1) in pregnant women from LMP through pregnancy outcome.
Query Period	January 1, 2010 - December 31, 2023
Request Send Date	September 17, 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 Healthcare Common Procedure Coding System (HCPCS) Used to Define Syphilis Testing in this Request

Code	Description	Code Category	Procedure Code Type
80055	Obstetric panel This panel must include the following: Blood count, complete (CBC), automated and automated differential WBC count (85025 or 85027 and 85004) OR Blood count, complete (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009) Hepatitis B surface antigen (HBsAg) (87340) Antibody, rubella (86762) Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART) (86592) Antibody screen, RBC, each serum technique (86850) Blood typing, ABO (86900) AND Blood typing, Rh (D) (86901) Screening for sexually transmitted infections, includes laboratory tests for chlamydia, gonorrhea, syphilis and hepatitis B	PX	C4
G0450	gonorrhea, syphilis and hepatitis B	PX	HC
3512F	Syphilis screening documented as performed (HIV)	PX	C2
86592	Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART)	PX	C4
86593	Syphilis test, non-treponemal antibody; quantitative	PX	C4
0065U	Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR)	PX	C4
0210U	Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)	PX	C4
86780	Antibody; Treponema pallidum	PX	C4
86781	Antibody; treponema pallidum	PX	C4
87285	Infectious agent antigen detection by immunofluorescent technique; Treponema pallidum Antibody, Treponema pallidum, total and rapid plasma reagin (RPR), immunoassay, qualitative	PX	C4
0064U	Obstetric panel (includes HIV testing) This panel must include the following. Blood count, complete (CBC), and automated differential WBC count (85025 or 85027 and 85004) OR Blood count, complete (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009) Hepatitis B surface antigen (HBsAg) (87340) HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result (87389) Antibody, rubella (86762) Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART) (86592) Antibody screen, RBC, each serum technique (86850) Blood typing, ABO (86900) AND	PX	C4
80081	Blood typing, Rh (D) (86901)	PX	C4