

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 Treatment for Pregnant Women and Non-Standard Syphilis Treatment 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 treatment for pregnant women and non-standard syphilis treatment 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	<p>Syphilis Treatment for Pregnant Women</p> <p>Non-Standard Syphilis Treatment</p>
Algorithm to Define Outcome	The syphilis treatment for pregnant women outcome is defined as one HCPCS code defined as benzathine penicillin G. Non-standard treatment outcome was defined as one HCPCS code for other antibiotics sometimes given for syphilis, and required that a syphilis diagnosis code occurred within 30 days prior to the antibiotic dispensing to count as an alternative treatment.
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) Codes Used to Define Standard Syphilis Treatment for Pregnant Individuals in This Request

Code	Description	Code Category	Code Type
J0580	Injection, penicillin G benzathine, up to 2,400,000 units	PX	HC
J0560	Injection, penicillin G benzathine, up to 600,000 units	PX	HC
J0561	Injection, penicillin G benzathine, 100,000 units	PX	HC

Code List 2. List of Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Non-Standard Syphilis Treatment in This Request

Code	Description	Code Category	Code Type
J0540	Injection, penicillin G benzathine and penicillin G procaine, up to 1,200,000 units	PX	HC
J0530	Injection, penicillin G benzathine and penicillin G procaine, up to 600,000 units	PX	HC
J0550	Injection, penicillin G benzathine and penicillin G procaine, up to 2,400,000 units	PX	HC
J0559	Injection, penicillin G benzathine and penicillin G procaine, 2500 units	PX	HC
J0558	Injection, penicillin G benzathine and penicillin G procaine, 100,000 units	PX	HC
J2510	Injection, penicillin G procaine, aqueous, up to 600,000 units	PX	HC
J0696	Injection, ceftriaxone sodium, per 250 mg	PX	HC