

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	Hysterectomy Algorithm Defined in "Gynecologic Surgery following Permanent Sterilization: A Propensity Score Matched Analysis"
Request ID	cdrh_mpl2r_wp001
Description	<p>This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) procedure codes and algorithms used to define hysterectomy 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 inferential analysis, see the analysis page here: https://www.sentinelinitiative.org/assessments/devices-radiological-health/gynecologic-surgery-following-permanent-sterilization.</p>
Outcome	Hysterectomy
Algorithm to Define Outcome	Evidence of an ICD-9-CM, CPT-4, or HCPCS procedure code used to define hysterectomy in any care setting in any diagnosis position.
Query Period	January 1, 2008 - September 30, 2015
Request Send Date	March 6, 2018

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

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Hysterectomy in This Request

Code	Description	Code Type	Code Category
68.31	Laparoscopic supracervical hysterectomy [LSH]	ICD-9-CM	Procedure
68.39	Other and unspecified subtotal abdominal hysterectomy	ICD-9-CM	Procedure
68.41	Laparoscopic total abdominal hysterectomy	ICD-9-CM	Procedure
68.49	Other and unspecified total abdominal hysterectomy	ICD-9-CM	Procedure
68.51	Laparoscopically assisted vaginal hysterectomy (LAVH)	ICD-9-CM	Procedure
68.59	Other and unspecified vaginal hysterectomy	ICD-9-CM	Procedure
68.9	Other and unspecified hysterectomy	ICD-9-CM	Procedure
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s);	CPT-4	Procedure
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)	CPT-4	Procedure
58260	Vaginal hysterectomy, for uterus 250 g or less;	CPT-4	Procedure
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	CPT-4	Procedure
58290	Vaginal hysterectomy, for uterus greater than 250 g;	CPT-4	Procedure
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	CPT-4	Procedure
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;	CPT-4	Procedure
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	CPT-4	Procedure
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;	CPT-4	Procedure
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	CPT-4	Procedure
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less;	CPT-4	Procedure
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	CPT-4	Procedure
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g;	CPT-4	Procedure
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	CPT-4	Procedure
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;	CPT-4	Procedure
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	CPT-4	Procedure
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g;	CPT-4	Procedure
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	CPT-4	Procedure
S2078	Laparoscopic supracervical hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)	HCPC	Procedure