

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	Interstitial Lung Disease (ILD) Algorithm Defined in "Interstitial Lung Disease (ILD) in Patients with Inflammatory Bowel Disease (IBD) and Following Vedolizumab or Natalizumab Initiation: A Descriptive Analysis"
Request ID	cder_mpl1r_wp258
Description	<p>This report lists 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 interstitial lung disease (ILD) 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/interstitial-lung-disease-ild-patients-inflammatory-bowel</p>
Outcome	Interstitial lung disease (ILD)
Algorithm to Define Outcome	The interstitial lung disease (ILD) outcome was defined using ICD-9-CM and ICD-10-CM codes that occurred in any care setting, with follow up for this outcome starting on day one after the index date, and washing out any prior history of these ILD diagnosis codes in all available history.
Query Period	January 1, 2006 - April 30, 2023
Request Send Date	October 12, 2023

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 Interstitial Lung Disease (ILD) in this Request

Code	Description	Code Category	Code Type
515	Postinflammatory pulmonary fibrosis	Diagnosis	ICD-9-CM
516.30	Idiopathic interstitial pneumonia, not otherwise specified	Diagnosis	ICD-9-CM
516.31	Idiopathic pulmonary fibrosis	Diagnosis	ICD-9-CM
516.32	Idiopathic non-specific interstitial pneumonitis	Diagnosis	ICD-9-CM
516.33	Acute interstitial pneumonitis	Diagnosis	ICD-9-CM
516.34	Respiratory bronchiolitis interstitial lung disease	Diagnosis	ICD-9-CM
516.35	Idiopathic lymphoid interstitial pneumonia	Diagnosis	ICD-9-CM
516.36	Cryptogenic organizing pneumonia	Diagnosis	ICD-9-CM
516.37	Desquamative interstitial pneumonia	Diagnosis	ICD-9-CM
516.8	Other specified alveolar and parietoalveolar pneumonopathies	Diagnosis	ICD-9-CM
516.9	Unspecified alveolar and parietoalveolar pneumonopathy	Diagnosis	ICD-9-CM
J80	Acute respiratory distress syndrome	Diagnosis	ICD-10-CM
J84	Other interstitial pulmonary diseases	Diagnosis	ICD-10-CM
J84.1	Other interstitial pulmonary diseases with fibrosis	Diagnosis	ICD-10-CM
J84.10	Pulmonary fibrosis, unspecified	Diagnosis	ICD-10-CM
J84.11	Idiopathic interstitial pneumonia	Diagnosis	ICD-10-CM
J84.111	Idiopathic interstitial pneumonia, not otherwise specified	Diagnosis	ICD-10-CM
J84.112	Idiopathic pulmonary fibrosis	Diagnosis	ICD-10-CM
J84.113	Idiopathic non-specific interstitial pneumonitis	Diagnosis	ICD-10-CM
J84.114	Acute interstitial pneumonitis	Diagnosis	ICD-10-CM
J84.115	Respiratory bronchiolitis interstitial lung disease	Diagnosis	ICD-10-CM
J84.116	Cryptogenic organizing pneumonia	Diagnosis	ICD-10-CM
J84.117	Desquamative interstitial pneumonia	Diagnosis	ICD-10-CM
J84.17	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere	Diagnosis	ICD-10-CM
J84.2	Lymphoid interstitial pneumonia	Diagnosis	ICD-10-CM
J84.8	Other specified interstitial pulmonary diseases	Diagnosis	ICD-10-CM
J84.89	Other specified interstitial pulmonary diseases	Diagnosis	ICD-10-CM
J84.9	Interstitial pulmonary disease, unspecified	Diagnosis	ICD-10-CM