



Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Appendix G. Specifications Defining Parameters in this Request: cder_mpl1r_wp166									
Scenario	Exposure/Event				Exclude evidence of days supply if exposure washout includes dispensings	Care setting	Follow-up		Baseline characteristics
	Index Exposure/Event	Cohort definition	Washout period	Incident with respect to:			Follow-up Start	Censor enrollment at evidence of	Baseline characteristics
12	Edaravone	First valid index date during query period	183	Edaravone	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
13	Etelcalcetide	First valid index date during query period	183	Etelcalcetide	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
14	Midostaurin	First valid index date during query period	183	Midostaurin	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
15	Naldemedine	First valid index date during query period	183	Naldemedine	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
16	Niraparib	First valid index date during query period	183	Niraparib	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
17	Ocrelizumab	First valid index date during query period	183	Ocrelizumab	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
18	Plecanatide	First valid index date during query period	183	Plecanatide	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
19	Ribociclib	First valid index date during query period	183	Ribociclib	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
20	Safinamide	First valid index date during query period	183	Ribociclib	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
21	Sarilumab	First valid index date during query period	183	Sarilumab	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
22	Telotristat ethyl	First valid index date during query period	183	Telotristat ethyl	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D
23	Valbenazine	First valid index date during query period	183	Valbenazine	Washout lookback period should search for evidence of days supply	Any	First exposure	Disenrollment, Death, Data Partner End Date, Query End Date	See Appendix D

International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum 360.

National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus.