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 I. List of Baseline Characteristics Examined in this Request for Acute Kidney Injury (AKI) and the Corresponding Periods in Which They Were Assessed, Relative to the Index Date

Characteristic	Care setting	Principal diagnosis position	Evaluation period start (days)	Evaluation period end (days)
Atrial Fibrillation (AKI, 183-day Cohort)	Any	Any	-183	0
Atrial Fibrillation (AKI, 365-day Cohort)	Any	Any	-365	0
DOAC1 (AKI, 183-day Cohort)	Any	Any	-183	0
DOAC2 (AKI, 183-day Cohort)	Any	Any	-183	0
DOAC3 (AKI, 183-day Cohort)	Any	Any	-183	0
DOAC4 (AKI, 183-day Cohort)	Any	Any	-183	0
DOAC1 (AKI, 365-day Cohort)	Any	Any	-365	0
DOAC2 (AKI, 365-day Cohort)	Any	Any	-365	0
DOAC3 (AKI, 365-day Cohort)	Any	Any	-365	0
DOAC4 (AKI, 365-day Cohort)	Any	Any	-365	0
Charlson Comorbidity Index	Any	Any	-183	0
Healthcare Utilization	Any		-183	0
Acute kidney failure with lesion of tubular necrosis	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Acute kidney failure with lesion of renal cortical necrosis	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Acute kidney failure with lesion of renal medullary (papillary) necrosis	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Acute kidney failure with other specified pathological lesion in kidney	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Acute kidney failure, unspecified	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Acute kidney failure with tubular necrosis	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Acute kidney failure with acute cortical necrosis	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Acute kidney failure with medullary necrosis	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Other acute kidney failure	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0
Acute kidney failure, unspecified	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	0	0