

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 F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-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 Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
Skin Biopsy			
11100	Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion	CPT-4	Procedure
11101	Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; each separate/additional lesion (List separately in addition to code for primary procedure)	CPT-4	Procedure
11300	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.5 cm or less	CPT-4	Procedure
24065	Biopsy, soft tissue of upper arm or elbow area; superficial	CPT-4	Procedure
24066	Biopsy, soft tissue of upper arm or elbow area; deep (subfascial or intramuscular)	CPT-4	Procedure
25065	Biopsy, soft tissue of forearm and/or wrist; superficial	CPT-4	Procedure
25066	Biopsy, soft tissue of forearm and/or wrist; deep (subfascial or intramuscular)	CPT-4	Procedure
83.21	Open biopsy of soft tissue	ICD-9-CM	Diagnosis
83.39	Excision of lesion of other soft tissue	ICD-9-CM	Diagnosis
83.49	Other excision of soft tissue	ICD-9-CM	Diagnosis
86.11	Closed biopsy of skin and subcutaneous tissue	ICD-9-CM	Diagnosis
0HB0XZX	Excision of Scalp Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HB1XZX	Excision of Face Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HB4XZX	Excision of Neck Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HB5XZX	Excision of Chest Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HB6XZX	Excision of Back Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HB7XZX	Excision of Abdomen Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HB8XZX	Excision of Buttock Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HB9XZX	Excision of Perineum Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBAXZX	Excision of Inguinal Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBBXZX	Excision of Right Upper Arm Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBCXZX	Excision of Left Upper Arm Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBDXZX	Excision of Right Lower Arm Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBEXZX	Excision of Left Lower Arm Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBFXZX	Excision of Right Hand Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBGXZX	Excision of Left Hand Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBHXZX	Excision of Right Upper Leg Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBJXZX	Excision of Left Upper Leg Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBKXZX	Excision of Right Lower Leg Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBLXZX	Excision of Left Lower Leg Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBMXZX	Excision of Right Foot Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBNXZX	Excision of Left Foot Skin, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBQXZX	Excision of Finger Nail, External Approach, Diagnostic	ICD-10-PCS	Procedure
0HBRXZX	Excision of Toe Nail, External Approach, Diagnostic	ICD-10-PCS	Procedure
0JB00ZZ	Excision of Scalp Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JB03ZX	Excision of Scalp Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JB03ZZ	Excision of Scalp Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JB10ZZ	Excision of Face Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-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 Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
0JB13ZX	Excision of Face Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JB13ZZ	Excision of Face Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JB40ZZ	Excision of Right Neck Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JB43ZX	Excision of Right Neck Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JB43ZZ	Excision of Right Neck Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JB50ZZ	Excision of Left Neck Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JB53ZX	Excision of Left Neck Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JB53ZZ	Excision of Left Neck Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JB60ZZ	Excision of Chest Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JB63ZX	Excision of Chest Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JB63ZZ	Excision of Chest Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JB70ZZ	Excision of Back Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JB73ZX	Excision of Back Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JB73ZZ	Excision of Back Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JB80ZZ	Excision of Abdomen Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JB83ZX	Excision of Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JB83ZZ	Excision of Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JB90ZZ	Excision of Buttock Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JB93ZX	Excision of Buttock Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JB93ZZ	Excision of Buttock Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBB0ZZ	Excision of Perineum Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBB3ZX	Excision of Perineum Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBB3ZZ	Excision of Perineum Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBC0ZZ	Excision of Pelvic Region Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBC3ZX	Excision of Pelvic Region Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBC3ZZ	Excision of Pelvic Region Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBD0ZZ	Excision of Right Upper Arm Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBD3ZX	Excision of Right Upper Arm Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBD3ZZ	Excision of Right Upper Arm Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBF0ZZ	Excision of Left Upper Arm Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBF3ZX	Excision of Left Upper Arm Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBF3ZZ	Excision of Left Upper Arm Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBG0ZZ	Excision of Right Lower Arm Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBG3ZX	Excision of Right Lower Arm Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBG3ZZ	Excision of Right Lower Arm Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBH0ZZ	Excision of Left Lower Arm Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure

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Code	Description	Code Type	Code Category
0JBH3ZX	Excision of Left Lower Arm Subcutaneous Tissue and Fascia, Percutaneous Approach,	ICD-10-PCS	Procedure
0JBH3ZZ	Excision of Left Lower Arm Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBJ3ZX	Excision of Right Hand Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBK3ZX	Excision of Left Hand Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBL0ZZ	Excision of Right Upper Leg Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBL3ZX	Excision of Right Upper Leg Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBL3ZZ	Excision of Right Upper Leg Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBM0ZZ	Excision of Left Upper Leg Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBM3ZX	Excision of Left Upper Leg Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBM3ZZ	Excision of Left Upper Leg Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBN0ZZ	Excision of Right Lower Leg Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBN3ZX	Excision of Right Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBN3ZZ	Excision of Right Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBP0ZZ	Excision of Left Lower Leg Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBP3ZX	Excision of Left Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBP3ZZ	Excision of Left Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBQ0ZZ	Excision of Right Foot Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBQ3ZX	Excision of Right Foot Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBQ3ZZ	Excision of Right Foot Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0JBR0ZZ	Excision of Left Foot Subcutaneous Tissue and Fascia, Open Approach	ICD-10-PCS	Procedure
0JBR3ZX	Excision of Left Foot Subcutaneous Tissue and Fascia, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0JBR3ZZ	Excision of Left Foot Subcutaneous Tissue and Fascia, Percutaneous Approach	ICD-10-PCS	Procedure
0KB00ZX	Excision of Head Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB10ZX	Excision of Facial Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB20ZX	Excision of Right Neck Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB30ZX	Excision of Left Neck Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB40ZX	Excision of Tongue, Palate, Pharynx Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB50ZX	Excision of Right Shoulder Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB60ZX	Excision of Left Shoulder Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB70ZX	Excision of Right Upper Arm Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB80ZX	Excision of Left Upper Arm Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KB90ZX	Excision of Right Lower Arm and Wrist Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KBB0ZX	Excision of Left Lower Arm and Wrist Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KBC0ZX	Excision of Right Hand Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KBD0ZX	Excision of Left Hand Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0KBF0ZX	Excision of Right Trunk Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure

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Code	Description	Code Type	Code Category
OKBG0ZX	Excision of Left Trunk Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBH0ZX	Excision of Right Thorax Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBJ0ZX	Excision of Left Thorax Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBK0ZX	Excision of Right Abdomen Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBL0ZX	Excision of Left Abdomen Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBM0ZX	Excision of Perineum Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBN0ZX	Excision of Right Hip Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBP0ZX	Excision of Left Hip Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBQ0ZX	Excision of Right Upper Leg Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBR0ZX	Excision of Left Upper Leg Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBS0ZX	Excision of Right Lower Leg Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBT0ZX	Excision of Left Lower Leg Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBV0ZX	Excision of Right Foot Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OKBW0ZX	Excision of Left Foot Muscle, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB00ZX	Excision of Head and Neck Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB10ZX	Excision of Right Shoulder Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB20ZX	Excision of Left Shoulder Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB30ZX	Excision of Right Upper Arm Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB40ZX	Excision of Left Upper Arm Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB50ZX	Excision of Right Lower Arm and Wrist Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB60ZX	Excision of Left Lower Arm and Wrist Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB70ZX	Excision of Right Hand Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB80ZX	Excision of Left Hand Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLB90ZX	Excision of Right Trunk Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBB0ZX	Excision of Left Trunk Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBC0ZX	Excision of Right Thorax Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBD0ZX	Excision of Left Thorax Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBF0ZX	Excision of Right Abdomen Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBG0ZX	Excision of Left Abdomen Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBH0ZX	Excision of Perineum Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBJ0ZX	Excision of Right Hip Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBK0ZX	Excision of Left Hip Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBL0ZX	Excision of Right Upper Leg Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBM0ZX	Excision of Left Upper Leg Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBN0ZX	Excision of Right Lower Leg Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBP0ZX	Excision of Left Lower Leg Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBQ0ZX	Excision of Right Knee Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBR0ZX	Excision of Left Knee Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBS0ZX	Excision of Right Ankle Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBT0ZX	Excision of Left Ankle Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBV0ZX	Excision of Right Foot Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OLBW0ZX	Excision of Left Foot Tendon, Open Approach, Diagnostic	ICD-10-PCS	Procedure
OMB00ZX	Excision of Head and Neck Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure

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Code	Description	Code Type	Code Category
0MB10ZX	Excision of Right Shoulder Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MB20ZX	Excision of Left Shoulder Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MB30ZX	Excision of Right Elbow Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MB40ZX	Excision of Left Elbow Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MB50ZX	Excision of Right Wrist Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MB60ZX	Excision of Left Wrist Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MB70ZX	Excision of Right Hand Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MB80ZX	Excision of Left Hand Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MB90ZX	Excision of Right Upper Extremity Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBB0ZX	Excision of Left Upper Extremity Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBC0ZX	Excision of Upper Spine Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBD0ZX	Excision of Lower Spine Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBF0ZX	Excision of Sternum Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBG0ZX	Excision of Rib(s) Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBH0ZX	Excision of Right Abdomen Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBJ0ZX	Excision of Left Abdomen Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBK0ZX	Excision of Perineum Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBL0ZX	Excision of Right Hip Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBM0ZX	Excision of Left Hip Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBN0ZX	Excision of Right Knee Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBP0ZX	Excision of Left Knee Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBQ0ZX	Excision of Right Ankle Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBR0ZX	Excision of Left Ankle Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBS0ZX	Excision of Right Foot Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBT0ZX	Excision of Left Foot Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBV0ZX	Excision of Right Lower Extremity Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0MBW0ZX	Excision of Left Lower Extremity Bursa and Ligament, Open Approach, Diagnostic	ICD-10-PCS	Procedure
0WB03ZX	Excision of Head, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0WB04ZX	Excision of Head, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0WB0XZX	Excision of Head, External Approach, Diagnostic	ICD-10-PCS	Procedure
0WB23ZX	Excision of Face, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0WB24ZX	Excision of Face, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0WB2XZX	Excision of Face, External Approach, Diagnostic	ICD-10-PCS	Procedure
0WB43ZX	Excision of Upper Jaw, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0WB44ZX	Excision of Upper Jaw, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0WB4XZX	Excision of Upper Jaw, External Approach, Diagnostic	ICD-10-PCS	Procedure
0WB53ZX	Excision of Lower Jaw, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0WB54ZX	Excision of Lower Jaw, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0WB5XZX	Excision of Lower Jaw, External Approach, Diagnostic	ICD-10-PCS	Procedure
0WB63ZX	Excision of Neck, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0WB64ZX	Excision of Neck, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0WB6XZX	Excision of Neck, External Approach, Diagnostic	ICD-10-PCS	Procedure
0WBK3ZX	Excision of Upper Back, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure

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Code	Description	Code Type	Code Category
0WBK4ZX	Excision of Upper Back, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0WBKXZX	Excision of Upper Back, External Approach, Diagnostic	ICD-10-PCS	Procedure
0WBL3ZX	Excision of Lower Back, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0WBL4ZX	Excision of Lower Back, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0WBLLZX	Excision of Lower Back, External Approach, Diagnostic	ICD-10-PCS	Procedure
0WBM3ZX	Excision of Male Perineum, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0WBM4ZX	Excision of Male Perineum, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0WBMXZX	Excision of Male Perineum, External Approach, Diagnostic	ICD-10-PCS	Procedure
0XB23ZX	Excision of Right Shoulder Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XB24ZX	Excision of Right Shoulder Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XB33ZX	Excision of Left Shoulder Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XB34ZX	Excision of Left Shoulder Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XB43ZX	Excision of Right Axilla, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XB44ZX	Excision of Right Axilla, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XB53ZX	Excision of Left Axilla, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XB54ZX	Excision of Left Axilla, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XB63ZX	Excision of Right Upper Extremity, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XB64ZX	Excision of Right Upper Extremity, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XB73ZX	Excision of Left Upper Extremity, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XB74ZX	Excision of Left Upper Extremity, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XB83ZX	Excision of Right Upper Arm, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XB84ZX	Excision of Right Upper Arm, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XB93ZX	Excision of Left Upper Arm, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XB94ZX	Excision of Left Upper Arm, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XBB3ZX	Excision of Right Elbow Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XBB4ZX	Excision of Right Elbow Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XBC3ZX	Excision of Left Elbow Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XBC4ZX	Excision of Left Elbow Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XBD3ZX	Excision of Right Lower Arm, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XBD4ZX	Excision of Right Lower Arm, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XBF3ZX	Excision of Left Lower Arm, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XBF4ZX	Excision of Left Lower Arm, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XBG3ZX	Excision of Right Wrist Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XBG4ZX	Excision of Right Wrist Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XBH3ZX	Excision of Left Wrist Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XBH4ZX	Excision of Left Wrist Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XBJ3ZX	Excision of Right Hand, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XBJ4ZX	Excision of Right Hand, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0XBK3ZX	Excision of Left Hand, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0XBK4ZX	Excision of Left Hand, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YB03ZX	Excision of Right Buttock, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YB04ZX	Excision of Right Buttock, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YB13ZX	Excision of Left Buttock, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-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 Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
0YB14ZX	Excision of Left Buttock, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YB93ZX	Excision of Right Lower Extremity, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YB94ZX	Excision of Right Lower Extremity, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBB3ZX	Excision of Left Lower Extremity, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBB4ZX	Excision of Left Lower Extremity, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBC3ZX	Excision of Right Upper Leg, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBC4ZX	Excision of Right Upper Leg, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBD3ZX	Excision of Left Upper Leg, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBD4ZX	Excision of Left Upper Leg, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBF3ZX	Excision of Right Knee Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBF4ZX	Excision of Right Knee Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBG3ZX	Excision of Left Knee Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBG4ZX	Excision of Left Knee Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBH3ZX	Excision of Right Lower Leg, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBH4ZX	Excision of Right Lower Leg, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBJ3ZX	Excision of Left Lower Leg, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBJ4ZX	Excision of Left Lower Leg, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBK3ZX	Excision of Right Ankle Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBK4ZX	Excision of Right Ankle Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBL3ZX	Excision of Left Ankle Region, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBL4ZX	Excision of Left Ankle Region, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBM3ZX	Excision of Right Foot, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBM4ZX	Excision of Right Foot, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure
0YBN3ZX	Excision of Left Foot, Percutaneous Approach, Diagnostic	ICD-10-PCS	Procedure
0YBN4ZX	Excision of Left Foot, Percutaneous Endoscopic Approach, Diagnostic	ICD-10-PCS	Procedure

Appendix G. Specifications Defining Parameters in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) tool, version 6.0.0 to estimate rates of cutaneous small vessel vasculitis (CSVV) or acute kidney injury (AKI) in patients with prior direct-acting oral anticoagulant (DOAC) exposure and no prior autoimmune disease in the Sentinel Distributed Database (SDD). We additionally estimated rates of CSVV among patients with prior atrial fibrillation diagnoses and no prior autoimmune disease.

Query period: January 1, 2010 - June 30, 2018
Coverage requirement: Medical & Drug Coverage
Enrollment gap: 45 days
Age groups: 30-39, 40-49, 50-59, 60-69, 70+ years
Stratifications: Age group, Sex, Calendar year
Envelope macro: Reclassify encounters during inpatient stay as inpatient; *No reclassification on inpatient Adate; or *No reclassification

Scenario	Index Exposure/Event	Exposure/Event						Inclusion/Exclusion Criteria					
		Pre-Index Enrollment Requirement (days)	Post-Index Enrollment Requirement (days)	Cohort Definition	Washout Period (days)	Incident with Respect to:	Care Setting	Principal Diagnosis Position	Censor Enrollment at Evidence of:	Criteria	Inclusion/Exclusion	Evaluation Window (days)	Minimum Number of Instances the Criteria Should be Found in Evaluation Period
1	Cutaneous Small Vessel Vasculitis (CSVV)	183	90	First valid index date during query period	183	CSVV	Any care setting	Any diagnosis position	Data Partner End Date; Query End Date; Death Date	1. Any NOAC dispensing	Inclusion	-90, 0	1
										2. Select Autoimmune Disorders (Rheumatoid Arthritis, Lupus, Crohn's Disease, Sjogren's Syndrome, Dermatomyositis, Polymyositis, Cryoglobulinemia)	Exclusion	-183, 0	1
2	Cutaneous Small Vessel Vasculitis (CSVV)	183	90	First valid index date during query period	183	CSVV	Any care setting	Any diagnosis position	Data Partner End Date; Query End Date; Death Date	1. Atrial Fibrillation	Inclusion	-183, 0	1
										2. Select Autoimmune Disorders (Rheumatoid Arthritis, Lupus, Crohn's Disease, Sjogren's Syndrome, Dermatomyositis, Polymyositis, Cryoglobulinemia)	Exclusion	-183, 0	1

3	Acute Kidney Injury (AKI)	183	0	First valid index date during query period	183	AKI	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	Data Partner End Date; Query End Date; Death Date	1. Any NOAC dispensing	Inclusion	-183, 0	1
4	Acute Kidney Injury (AKI)	365	0	First valid index date during query period	183	AKI	In-patient; Emergency Department	IP: limit to Principal; Secondary ED: any care setting	Data Partner End Date; Query End Date; Death Date	1. Any NOAC dispensing	Inclusion	-365, 0	1

Characteristic

Scenario	Characteristic	Care setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Number of Instances the Covariate Should be Found in Evaluation Period
1	See Appendix H	Any care setting	Only applicable for Inpatient and Institutional stays: *Any; *Principal; *Secondary; *Unknown	See Appendix H	See Appendix H	Numeric specified (Code days)
2	See Appendix H	Any care setting	Only applicable for Inpatient and Institutional stays: *Any; *Principal; *Secondary; *Unknown	See Appendix H	See Appendix H	Numeric specified (Code days)
3	See Appendix I	See Appendix I	Only applicable for Inpatient and Institutional stays: *Any; *Principal; *Secondary; *Unknown	See Appendix I	See Appendix I	Numeric specified (Code days)
4	See Appendix I	See Appendix I	Only applicable for Inpatient and Institutional stays: *Any; *Principal; *Secondary; *Unknown	See Appendix I	See Appendix I	Numeric specified (Code days)
<p>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), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360. National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."</p>						

Appendix H. List of Baseline Characteristics Examined in this Request for Cutaneous Small Vessel Vasculitis (CSVV) and the Corresponding Periods in Which They Were Assessed, Relative to the Index Date

Characteristic	Evaluation Period Start (days)	Evaluation Period End (days)	Number of Instances the Covariate Should be Found in Evaluation Period
Skin biopsy	-14	14	Numeric specified (Code days)
Atrial fibrillation	-183	0	Numeric specified (Code days)
Prednisone and/or prednisolone	0	90	
DOAC1 (CSVV Cohorts)	-90	0	Numeric specified (Code days)
DOAC2 (CSVV Cohorts)	-90	0	
DOAC3 (CSVV Cohorts)	-90	0	Numeric specified (Code days)
DOAC4 (CSVV Cohorts)	-90	0	
ANY_DOAC (CSVV Cohorts)	-10	0	
Skin biopsy AND prednisone/prednisolone treatment	-14	14	
Hypersensitivity angiitis, unspecified	0	0	
Other specified hypersensitivity angiitis	0	0	
Henoch-Schonlein allergic purpura	0	0	
Vascular disorders of skin	0	0	
Hypersensitivity angiitis	0	0	
Allergic purpura	0	0	
Vasculitis limited to the skin, unspecified	0	0	
Other vasculitis limited to the skin, specified NEC	0	0	
Hypersensitivity angiitis	0	0	
Hypersensitivity angiitis, unspecified AND prednisone/prednisolone treatment	0	0	
	0	90	
Other specified hypersensitivity angiitis AND prednisone/prednisolone treatment	0	0	
	0	90	
Henoch-Schonlein allergic purpura AND prednisone/prednisolone treatment	0	0	
	0	90	
Vascular disorders of skin AND prednisone/prednisolone treatment	0	0	
Hypersensitivity angiitis AND prednisone/prednisolone treatment	0	0	
Allergic purpura AND prednisone/prednisolone treatment	0	0	
Vasculitis limited to the skin, unspecified AND prednisone/prednisolone treatment	0	0	
	0	90	
Other vasculitis limited to the skin, specified NEC AND prednisone/prednisolone treatment	0	0	
	0	90	
Hypersensitivity angiitis AND prednisone/prednisolone Treatment	0	0	
Charlson comorbidity index	-183	0	
Healthcare utilization	-183	0	

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