

## 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

<b>Title</b>	Cutaneous Small-Vessel Vasculitis Algorithm Defined in "Cutaneous Small-Vessel Vasculitis following Dabigatran, Rivaroxaban, and Apixaban Use in Patients with Atrial Fibrillation: A Propensity Score Matched Analysis"
<b>Request ID</b>	cder_mpl2r_wp014
<b>Description</b>	<p>This report lists International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis codes, generic and brand names of medical products, and algorithms used to define cutaneous small-vessel vasculitis 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:  <a href="https://www.sentinelinitiative.org/assessments/drugs/cutaneous-small-vessel-vasculitis-following-dabigatran-rivaroxaban-and-apixaban">https://www.sentinelinitiative.org/assessments/drugs/cutaneous-small-vessel-vasculitis-following-dabigatran-rivaroxaban-and-apixaban</a></p>
<b>Outcome</b>	Cutaneous small-vessel vasculitis
<b>Algorithm to Define Outcome</b>	The cutaneous small-vessel vasculitis (CSVV) outcome is defined as evidence of one ICD-9-CM or ICD-10-CM diagnosis code from Code List 1 for hypersensitivity angitis, vasculitis of the skin, or allergic purpura in the ambulatory visit (AV), other ambulatory visit (OA), or emergency department (ED) care settings AND one code from Code List 2 for oral or topical dispensing of steroid treatment within 90 days of qualifying CSVV diagnosis, including the date of diagnosis.
<b>Query Period</b>	October 19, 2010 - February 29, 2020
<b>Request Send Date</b>	September 15, 2020

## 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 and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Cutaneous Small-Vessel Vasculitis in this Request**

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<b>Code</b>	<b>Description</b>	<b>Care Setting<sup>1</sup></b>	<b>Code Type</b>	<b>Code Category</b>
287.0	Allergic purpura	AV, OA, or ED	ICD-9-CM	Diagnosis
446.2	Hypersensitivity angiitis	AV, OA, or ED	ICD-9-CM	Diagnosis
446.20	Unspecified hypersensitivity angiitis	AV, OA, or ED	ICD-9-CM	Diagnosis
446.29	Other specified hypersensitivity angiitis	AV, OA, or ED	ICD-9-CM	Diagnosis
709.1	Vascular disorder of skin	AV, OA, or ED	ICD-9-CM	Diagnosis
D69.0	Allergic purpura	AV, OA, or ED	ICD-10-CM	Diagnosis
L95.0	Livedoid vasculitis	AV, OA, or ED	ICD-10-CM	Diagnosis
L95.8	Other vasculitis limited to the skin	AV, OA, or ED	ICD-10-CM	Diagnosis
L95.9	Vasculitis limited to the skin, unspecified	AV, OA, or ED	ICD-10-CM	Diagnosis
M31.0	Hypersensitivity angiitis	AV, OA, or ED	ICD-10-CM	Diagnosis

<sup>1</sup>Ambulatory visit (AV), other ambulatory visit (OA), or emergency department (ED) care setting.

**Code List 2. List of Generic and Brand Names of Medical Products Used to Define Steroid Treatment for Cutaneous Small-Vessel Vasculitis in this Request**

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<b>Generic Name</b>	<b>Brand Name</b>
alclometasone dipropionate	Aclovate
alclometasone dipropionate	alclometasone
amcinonide	amcinonide
betamethasone	Celestone
betamethasone dipropionate	betamethasone dipropionate
betamethasone dipropionate	betamethasone, augmented
betamethasone dipropionate	Diprosone
betamethasone dipropionate	Sernivo
betamethasone dipropionate/propylene glycol	betamethasone, augmented
betamethasone dipropionate/propylene glycol	Diprolene
betamethasone dipropionate/propylene glycol	Diprolene AF
betamethasone valerate	betamethasone valerate
betamethasone valerate	Beta-Val
betamethasone valerate	Luxiq
clobetasol propionate	clobetasol
clobetasol propionate	Clobex
clobetasol propionate	Clodan
clobetasol propionate	Cormax
clobetasol propionate	Embeline
clobetasol propionate	Impoyz
clobetasol propionate	Olux
clobetasol propionate	Temovate
clobetasol propionate/calcipotriene	clobetasol-calcipotriene
clobetasol propionate/coal tar	Clobeta+Plus
clobetasol propionate/coal tar	clobetasol-coal tar
clobetasol propionate/emollient base	clobetasol-emollient
clobetasol propionate/emollient base	Olux-E
clobetasol propionate/emollient base	Olux-Olux-E (100/10)
clobetasol propionate/emollient base	Olux-Olux-E (50/50)
clobetasol propionate/emollient base	Temovate E
clobetasol propionate/emollient base	Tovet Emollient
clobetasol propionate/emollient combination no.65	Tovet Kit
clobetasol propionate/levocetirizine dihydrochloride	clobetasol-levocetirizine
clobetasol propionate/niacinamide	clobetasol-niacinamide
clobetasol propionate/skin cleanser combination no.28	Clodan Kit
clocortolone pivalate	clocortolone pivalate
clocortolone pivalate	Cloderm
cortisone acetate	cortisone
deflazacort	Emflaza
desonide	Desonate
desonide	desonide
desonide	DesOwen
desonide	Tridesilon
desonide	Verdeso

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<b>Generic Name</b>	<b>Brand Name</b>
desonide/emollient combination no. 28	DesOwen
desonide/emollient combination no.3	Desonil
desonide/emollient combination no.3	Desonil + Plus
desonide/emollient combination no.30	DesOwen Cream and Lotion
desonide/emollient combination no.30	DesOwen Ointment and Lotion
desoximetasone	desoximetasone
desoximetasone	Topicort
dexamethasone	Baycadron
dexamethasone	Decadron
dexamethasone	Dexabliss
dexamethasone	dexamethasone
dexamethasone	Dexamethasone Intensol
dexamethasone	DexPak 10 day
dexamethasone	DexPak 13 Day
dexamethasone	DexPak 6 Day
dexamethasone	Dxevo
dexamethasone	HiDex
dexamethasone	LoCort
dexamethasone	TaperDex
dexamethasone	Zema-Pak
dexamethasone	ZoDex
dexamethasone	ZonaCort
diflorasone diacetate	ApexiCon
diflorasone diacetate	diflorasone
diflorasone diacetate	Psorcon
diflorasone diacetate/emollient base	ApexiCon E
diphenhydramine HCl/hydrocortisone	HC Derma-Pax
fluocinolone acetonide	Capex
fluocinolone acetonide	Derma-Smoothe/FS Body Oil
fluocinolone acetonide	Derma-Smoothe/FS Eczema
fluocinolone acetonide	fluocinolone
fluocinolone acetonide	Synalar
fluocinolone acetonide/emollient combination no.65	Synalar Cream Kit
fluocinolone acetonide/emollient combination no.65	Synalar Ointment Kit
fluocinolone acetonide/niacinamide	fluocinolone-niacinamide
fluocinolone acetonide/skin cleanser comb no.28	Synalar TS
fluocinolone acetonide/skin cleanser no.10/silicone, tape	Xilapak
fluocinolone acetonide/urea/silicone, adhesive	Noxipak
fluocinonide	fluocinonide
fluocinonide	Lidex
fluocinonide	Vanos
fluocinonide/emollient base	Fluocinonide-E
fluocinonide/emollient base	fluocinonide-emollient
fluocinonide/silicone, adhesive	Fluovix

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<b>Generic Name</b>	<b>Brand Name</b>
flurandrenolide	Cordran
flurandrenolide	Cordran SP
flurandrenolide	Cordran Tape Large Roll
flurandrenolide	Cordran Tape Small Roll
flurandrenolide	flurandrenolide
flurandrenolide	Nolix
fluticasone propionate	Beser
fluticasone propionate	Cutivate
fluticasone propionate	fluticasone propionate
fluticasone propionate/emollient combination no.65	Beser Kit
halcinonide	halcinonide
halcinonide	Halog
halobetasol propionate	Bryhali
halobetasol propionate	halobetasol propionate
halobetasol propionate	Lexette
halobetasol propionate	Ultravate
halobetasol propionate/ammonium lactate	Halac
halobetasol propionate/ammonium lactate	Halonate
halobetasol propionate/ammonium lactate	Halonate Pac
halobetasol propionate/ammonium lactate	Ultravate PAC
halobetasol propionate/lactic acid	Ultravate X
hydrocortisone	Advanced Allergy Collect Kit
hydrocortisone	Ala-Cort
hydrocortisone	Ala-Scalp
hydrocortisone	Anti-Itch (HC)
hydrocortisone	Anusol-HC
hydrocortisone	Aquanil HC
hydrocortisone	Beta-HC
hydrocortisone	Cortaid
hydrocortisone	Cortaid FastStick Max St
hydrocortisone	Cortaid Intensive Therapy
hydrocortisone	Cortaid Maximum Strength
hydrocortisone	Cortef
hydrocortisone	Corticool
hydrocortisone	Cortisone (hydrocortisone)
hydrocortisone	Cortisone Cooling
hydrocortisone	Cortizone-10
hydrocortisone	Cortizone-10 Plus
hydrocortisone	Dermarest Eczema (hydrocort)
hydrocortisone	Eczema Anti-Itch
HYDROCORTISONE	First-Hydrocortisone
hydrocortisone	hydrocortisone
hydrocortisone	Hydrocortisone Plus
hydrocortisone	Hydrocortisone Plus 12

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<b>Generic Name</b>	<b>Brand Name</b>
hydrocortisone	Hydrocream
hydrocortisone	HydroSkin
hydrocortisone	ITCH-X
hydrocortisone	Itch-X HC
hydrocortisone	Neosporin Anti-Itch
hydrocortisone	Noble Formula HC
hydrocortisone	Obagi Nu-Derm Tolereen
hydrocortisone	Preparation H Hydrocortisone
hydrocortisone	Proctocort
hydrocortisone	Procto-Med HC
hydrocortisone	Procto-Pak
hydrocortisone	Proctosol HC
hydrocortisone	Proctozone-HC
hydrocortisone	Recort Plus
hydrocortisone	Sarnol-HC
hydrocortisone	Scalacort
hydrocortisone	Scalp Relief
hydrocortisone	Scalpicin Anti-Itch
hydrocortisone	Soothing Care (hydrocortisone)
hydrocortisone	Texacort
hydrocortisone acetate	Cortaid Maximum Strength
hydrocortisone acetate	hydrocortisone acetate
hydrocortisone acetate	Medi-Cortisone
hydrocortisone acetate	MiCort-HC
hydrocortisone acetate	Vanicream HC
hydrocortisone acetate/aloe vera	Cortaid with Aloe
hydrocortisone acetate/aloe vera	Cortalo
hydrocortisone acetate/aloe vera	hydrocortisone acet-aloe vera
hydrocortisone acetate/aloe vera	Hydrocortisone Acetate-Aloe
hydrocortisone acetate/aloe vera	Nucort
hydrocortisone acetate/aloe vera	Nuzon
hydrocortisone acetate/pramoxine HCl	Analpram-HC
hydrocortisone acetate/pramoxine HCl	Epifoam
hydrocortisone acetate/pramoxine HCl	hydrocortisone-pramoxine
hydrocortisone acetate/pramoxine HCl	Mezparox-HC
hydrocortisone acetate/pramoxine HCl	Novacort
hydrocortisone acetate/pramoxine HCl	Pramosone
hydrocortisone acetate/pramoxine HCl/aloe polysaccharide	Novacort (with aloe)
hydrocortisone acetate/pramoxine HCl/emollient base	Pramosone E
hydrocortisone acetate/urea	CARMOL HC
hydrocortisone acetate/urea	U-Cort
hydrocortisone butyrate	hydrocortisone butyrate
hydrocortisone butyrate	Locoid
hydrocortisone butyrate/emollient base	hydrocortisone butyr-emollient



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<b>Generic Name</b>	<b>Brand Name</b>
hydrocortisone butyrate/emollient base	Locoid Lipocream
hydrocortisone probutate	Pandel
hydrocortisone valerate	hydrocortisone valerate
hydrocortisone valerate	Westcort
hydrocortisone/aloe vera	Anti-Itch(hydrocortisone)-Aloe
hydrocortisone/aloe vera	Cortisone with Aloe
hydrocortisone/aloe vera	Cortizone-10 with aloe
hydrocortisone/aloe vera	Hydrocortisone Plus
hydrocortisone/aloe vera	hydrocortisone-aloe vera
hydrocortisone/aloe vera	Hydroskin with Aloe
hydrocortisone/aloe vera/vitamin E acetate/vitamins A and	Anti-Itch (HC) with Aloe-Vit E
hydrocortisone/aloe vera/vitamin E acetate/vitamins A and	Anti-Itch Plus
hydrocortisone/colloidal oatmeal/aloe/vitamin E	Anti-Itch (HC) with Oatmeal
hydrocortisone/colloidal oatmeal/aloe/vitamin E	Aveeno Anti-Itch (hydrocortsn)
hydrocortisone/emollient combination no.45	Pediaderm HC
hydrocortisone/mineral oil/petrolatum,white	hydrocortisone-min oil-wht pet
hydrocortisone/salicylic acid/sulfur/shampoo no. 1	Scalacort DK
hydrocortisone/skin cleanser combination no.25	Aqua Glycolic HC
hydrocortisone/skin cleanser combination no.35	Dermasorb HC Complete Kit
lidocaine HCl/hydrocortisone acetate	LidaMantle HC
lidocaine HCl/hydrocortisone acetate	lidocaine HCl-hydrocortison ac
lidocaine HCl/hydrocortisone acetate	Lidocaine-HC
methylprednisolone	Medrol
methylprednisolone	Medrol (Pak)
methylprednisolone	Meprolone Unipak
methylprednisolone	Methylpred DP
methylprednisolone	methylprednisolone
mometasone furoate	Elocon
mometasone furoate	mometasone
mometasone furoate/ammonium lactate	Momexin
mometasone furoate/ammonium lactate	Quinosone
mometasone furoate/dimethicone	Quinixil
prednicarbate	Dermatop
prednicarbate	prednicarbate
prednisolone	Millipred
prednisolone	Millipred DP
prednisolone	prednisolone
prednisolone	Prelone
prednisolone acetate	Flo-Pred
prednisolone sodium phosphate	Millipred
prednisolone sodium phosphate	Orapred
prednisolone sodium phosphate	Orapred ODT
prednisolone sodium phosphate	Pediapred
prednisolone sodium phosphate	prednisolone sodium phosphate

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<b>Generic Name</b>	<b>Brand Name</b>
prednisolone sodium phosphate	Veripred 20
Prednisolone Sodium Phosphate/Peak Flow Meter	Asmalpred
Prednisolone Sodium Phosphate/Peak Flow Meter	Asmalpred Plus
prednisone	Deltasone
prednisone	prednisone
prednisone	Prednisone Intensol
prednisone	Rayos
prednisone	Sterapred
triamcinolone acetonide	Kenalog
triamcinolone acetonide	triamcinolone acetonide
triamcinolone acetonide	Trianex
triamcinolone acetonide	Triderm
triamcinolone acetonide/dimethicone	Ellzia Pak
triamcinolone acetonide/dimethicone/silicone, adhesive	DermacinRx SilaPak
triamcinolone acetonide/dimethicone/silicone, adhesive	DermaSilkRx SDS
triamcinolone acetonide/dimethicone/silicone, adhesive	DermaWerx SDS
triamcinolone acetonide/dimethicone/silicone, adhesive	NuTriaRx
triamcinolone acetonide/dimethicone/silicone, adhesive	SanaDermRx
triamcinolone acetonide/dimethicone/silicone, adhesive	Sure Result Tac Pak
triamcinolone acetonide/dimethicone/silicone, adhesive	Tri-Sila
triamcinolone acetonide/dimethicone/silicone, adhesive	Whytederm TDPak
triamcinolone acetonide/dimethicone/silicone, adhesive	Whytederm Trilasil Pak
triamcinolone acetonide/emollient combination no.45	Pediaderm TA
triamcinolone acetonide/emollient combination no.86	Dermasorb TA Complete Kit
triamcinolone acetonide/gauze bandage/silicone, adhesive	Sila III
triamcinolone acetonide/niacinamide	triamcinolone-niacinamide
triamcinolone acetonide/silicones	DermacinRx SilaZone
triamcinolone acetonide/silicones	Dermazone
triamcinolone acetonide/silicones	SilaLite Pak
triamcinolone acetonide/silicones	Silazone-II