

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 <u>Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data</u> guidance document provided by the FDA.



Title Basal Cell Carcinoma Algorithm Defined in "Non-Melanoma Skin Cancer following Hydrochlorothiazide Use: A Propensity Score Matched Analysis" **Request ID** cder_mpl2p_wp016_nsdp_v01 Description This report lists International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis codes, Current Procedural Terminology, Fourth Edition (CPT-4) procedure codes, generic names, and algorithms used to define basal cell carcinoma in this request. 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: https://www.sentinelinitiative.org/drugs/assessments/risk-non-melanomaskin-cancer-patients-treated-hydrochlorothiazide. Outcome Basal cell carcinoma Evidence of an ICD-9-CM or ICD-10-CM code used to define basal cell Algorithm to Define Outcome carcinoma in any care setting AND either a CPT-4 procedure code for tumor removal OR evidence of topical chemotherapy within 30 days of the diagnosis code defined by the generic name days supply. The date of the outcome algorithm was assigned to the date of basal cell carcinoma diagnosis. Query Period January 1, 2000 - August 31, 2018 **Request Send Date** April 12, 2019

Overview



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



International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Basal Cell Carcinoma in this Request

Codes	Description	Code Type
173.11	Basal cell carcinoma of eyelid, including canthus	ICD-9-CM
173.21	Basal cell carcinoma of skin of ear and external auditory canal	ICD-9-CM
173.31	Basal cell carcinoma of skin of other and unspecified parts of face	ICD-9-CM
173.41	Basal cell carcinoma of scalp and skin of neck	ICD-9-CM
173.51	Basal cell carcinoma of skin of trunk, except scrotum	ICD-9-CM
173.61	Basal cell carcinoma of skin of upper limb, including shoulder	ICD-9-CM
173.71	Basal cell carcinoma of skin of lower limb, including hip	ICD-9-CM
173.81	Basal cell carcinoma of other specified sites of skin	ICD-9-CM
173.91	Basal cell carcinoma of skin, site unspecified	ICD-9-CM
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus	ICD-10-CM
C44.112	Basal cell carcinoma of skin of right eyelid, including canthus	ICD-10-CM
C44.119	Basal cell carcinoma of skin of left eyelid, including canthus	ICD-10-CM
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal	ICD-10-CM
C44.212	Basal cell carcinoma of skin of right ear and external auricular canal	ICD-10-CM
C44.219	Basal cell carcinoma of skin of left ear and external auricular canal	ICD-10-CM
C44.310	Basal cell carcinoma of skin of unspecified parts of face	ICD-10-CM
C44.311	Basal cell carcinoma of skin of nose	ICD-10-CM
C44.319	Basal cell carcinoma of skin of other parts of face	ICD-10-CM
C44.41	Basal cell carcinoma of skin of scalp and neck	ICD-10-CM
C44.510	Basal cell carcinoma of anal skin	ICD-10-CM
C44.511	Basal cell carcinoma of skin of breast	ICD-10-CM
C44.519	Basal cell carcinoma of skin of other part of trunk	ICD-10-CM
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder	ICD-10-CM
C44.612	Basal cell carcinoma of skin of right upper limb, including shoulder	ICD-10-CM
C44.619	Basal cell carcinoma of skin of left upper limb, including shoulder	ICD-10-CM
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip	ICD-10-CM
C44.712	Basal cell carcinoma of skin of right lower limb, including hip	ICD-10-CM
C44.719	Basal cell carcinoma of skin of left lower limb, including hip	ICD-10-CM
C44.81	Basal cell carcinoma of overlapping sites of skin	ICD-10-CM
C44.91	Basal cell carcinoma of skin, unspecified	ICD-10-CM



Current Procedural Terminology, Fourth Edition (CPT-4) Procedure Codes Used to Define Tumor Removal in this

	Description	Code Type
	Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 0.5 cm or less	CPT-4
	Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 0.6 to 1.0 cm	CPT-4
	Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 1.1 to 2.0 cm	CPT-4
	Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 2.1 to 3.0 cm	CPT-4
	Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 3.1 to 4.0 cm	CPT-4
	Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter over 4.0 cm	CPT-4
	Excision, malignant lesion including margins, scalp, neck, hands, feet, genitalia; excised diameter 0.5 cm or less	CPT-4
11621	Excision, malignant lesion including margins, scalp, neck, hands, feet, genitalia; excised diameter 0.6 to 1.0 cm	CPT-4
11622	Excision, malignant lesion including margins, scalp, neck, hands, feet, genitalia; excised diameter 1.1 to 2.0 cm	CPT-4
11623	Excision, malignant lesion including margins, scalp, neck, hands, feet, genitalia; excised diameter 2.1 to 3.0 cm	CPT-4
11624	Excision, malignant lesion including margins, scalp, neck, hands, feet, genitalia; excised diameter 3.1 to 4.0 cm	CPT-4
11626	Excision, malignant lesion including margins, scalp, neck, hands, feet, genitalia; excised diameter over 4.0 cm	CPT-4
11640	Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 0.5 cm or less	CPT-4
11641	Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 0.6 to 1.0 cm	CPT-4
11642	Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 1.1 to 2.0 cm	CPT-4
11643	Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 2.1 to 3.0 cm	CPT-4
11644	Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 3.1 to 4.0 cm	CPT-4
11646	Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter over 4.0 cm	CPT-4
17260	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 0.5 cm or less	CPT-4
17261	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 0.6 to 1.0 cm	CPT-4
17262	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 1.1 to 2.0 cm	CPT-4
17263	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 2.1 to 3.0 cm	CPT-4
17264	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 3.1 to 4.0 cm	CPT-4
17266	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter over 4.0 cm	CPT-4



Current Procedural Terminology, Fourth Edition (CPT-4) Procedure Codes Used to Define Tumor Removal in this

Codes	Description	Code Type
17270	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical	CPT-4
	curettement), scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less	
17271	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical	CPT-4
	curettement), scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm	
17272	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical	CPT-4
	curettement), scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm	
17273	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 2.1 to 3.0 cm	CPT-4
17274	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 3.1 to 4.0 cm	CPT-4
17276	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter over 4.0 cm	CPT-4
17280	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less	CPT-4
17281	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm	CPT-4
17282	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm	CPT-4
17283	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 2.1 to 3.0 cm	CPT-4
17284	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 3.1 to 4.0 cm	CPT-4
17286	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter over 4.0 cm	CPT-4
17304	Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); first stage, fresh tissue technique, up to 5 specimens	CPT-4
17305	Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); second stage, fixed or fresh tissue, up to 5 specimens	CPT-4



Current Procedural Terminology, Fourth Edition (CPT-4) Procedure Codes Used to Define Tumor Removal in this

odes	Description	Code Typ
7306	Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); third stage, fixed or fresh tissue, up to 5 specimens	CPT-4
7307	Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); additional stage(s), up to 5 specimens, each stage	CPT-4
7310	Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histopathologic preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); each additional specimen, after the first 5 specimens, fixed or fresh tissue, any stage (List separately in addition to code for primary procedure)	CPT-4
7311	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks	CPT-4
7312	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; each additional stage after the first stage, up to 5 tissue blocks (List separately in addition to code for primary procedure)	CPT-4
7313	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; first stage, up to 5 tissue blocks	CPT-4
7314	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; each additional stage after the first stage, up to 5 tissue blocks (List separately in addition to code for primary procedure)	CPT-4
7315	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), each additional block after the first 5 tissue blocks, any stage (List separately in addition to code for primary procedure)	CPT-4



Generic Names Used to Define Topical Chemotherapy in this Request

Generic Name

alitretinoin aminolevulinic acid HCl bexarotene diclofenac sodium fluorouracil fluorouracil/adhesive bandage imiquimod mechlorethamine HCl methyl aminolevulinate HCl