Erbitux® (cetuximab)
(Intravenous)

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I. Length of Authorization [1,30]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), unless otherwise specified.
  - Head and Neck Cancer (with concurrent radiation therapy): Prior authorization validity will be provided starting one week prior and for the duration of radiation therapy (up to 8 total weeks).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
  - Head and Neck Cancer (with concurrent radiation therapy): Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- Small Bowel Adenocarcinoma, Colorectal Cancer, Appendiceal Neoplasms and Cancers, & Head and Neck Cancer:
  - Loading Dose: 100 billable units for 1 dose
  - Maintenance Dose: 130 billable units every 14 days
- NSCLC: 130 billable units every 14 days
- Squamous Cell Skin Cancer:
  - Loading Dose: 100 billable units for 1 dose
  - Maintenance Dose: 60 billable units every 7 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Colorectal Cancer (CRC) ¥ † ‡ [1,2,12,13,17,19,32,37,2e,5e-8e,10e-12e,15e]

- Will not be used as part of an adjuvant treatment regimen; **AND**
- Member has not been previously treated with cetuximab or panitumumab; **AND**
- Will not be used in combination with an anti-VEGF agent (e.g., bevacizumab, ramucirumab); **AND**
  - Member has both KRAS and NRAS negative (wild-type [WT]) and BRAF V600E mutation negative (WT) disease as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test❖; **AND**
    - Used as primary treatment for metastatic or unresectable (or medically inoperable) disease **§**; **AND**
      - Used in combination with FOLFIRI **†**; **OR**
      - Used in combination with CapeOX or FOLFOX; **OR**
      - Used in combination with irinotecan; **AND**
        - Member previously received FOLFOX or CapeOX within the past 12 months; **OR**
    - Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any, or locally unresectable or medically inoperable rectal cancer; **AND**
      - Used in combination with CapeOX, FOLFOX, or FOLFIRI; **AND**
        - Used if resection is contraindicated following total neoadjuvant therapy; **OR**
        - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **OR**
    - Used as subsequent therapy for advanced or metastatic disease; **AND**
      - Used as a single agent; **AND**
        - Member has oxaliplatin- and irinotecan-refractory disease **†**; **OR**
        - Member has irinotecan-intolerant disease **†**; **OR**
      - Used in combination with irinotecan; **AND**
        - Member has irinotecan-refractory disease **†**; **OR**
        - Member has oxaliplatin-refractory disease; **OR**
      - Used in combination with FOLFIRI for oxaliplatin-refractory disease; **OR**
      - Used in combination with FOLFOX or CapeOX for irinotecan-refractory disease; **OR**
  - Member has BRAF V600E mutation positive disease (KRAS WT/NRAS WT) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used in combination with encorafenib; **AND**
      - Used as initial or subsequent therapy (if not previously given); **AND**

        - Used for advanced or metastatic disease; **OR**
    - Used in combination with encorafenib and fluorouracil-based chemotherapy regimen; **AND**
        - Member has previously untreated metastatic disease; **OR**
        - Used as primary treatment for unresectable or medically inoperable disease; **OR**
        - Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any, or locally unresectable or medically inoperable rectal cancer; **AND**
            - Used if resection is contraindicated following total neoadjuvant therapy; **OR**
            - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **OR**
- Member has KRAS G12C mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖ ‡; **AND**
    - Used in combination with adagrasib; **AND**
        - Used as initial treatment for unresectable metastatic disease after previous FOLFOX or CapeOX within the past 12 months; **OR**
        - Used as subsequent therapy, if not previously given, for progression of advanced or metastatic disease; **AND**
            - Member has received prior treatment with fluoropyrimidine-based therapy AND oxaliplatin- or irinotecan-based chemotherapy, unless contraindicated

§ *Colon cancer members must have left-sided tumors only.*

¥ *Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed members. If deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB>50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the member is a candidate.*

Appendiceal Neoplasms and Cancers ‡ [2,32,39]

- Member has not been previously treated with cetuximab or panitumumab; **AND**
    - Member has BRAF V600E mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
        - Used in combination with encorafenib; **AND**
            - Used as subsequent therapy for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease; **OR**
        - Used in combination with encorafenib and FOLFOX; **AND**
            - Used as initial treatment for recurrent or extraperitoneal disease; **OR**

- Member has KRAS G12C mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used in combination with adagrasib; **AND**
  - Used as subsequent therapy, if not previously given, for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease; **AND**
  - Member has received prior treatment with fluoropyrimidine-based therapy AND oxaliplatin- or irinotecan-based chemotherapy, unless contraindicated; **OR**
- Member has both KRAS and NRAS negative (wild-type) and BRAF V600E mutation negative (wild-type) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used as subsequent therapy for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease; **AND**
    - Used as a single agent; **AND**
      - Member has irinotecan-intolerant disease; **OR**
    - Used in combination with irinotecan; **OR**
    - Used in combination with FOLFOX, CapeOX, or FOLFIRI

Small Bowel Adenocarcinoma ‡ [2,32,40]

- Member has advanced or metastatic disease; **AND**
  - Member has BRAF V600E mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used as initial therapy in combination with encorafenib and FOLFOX (fluorouracil, leucovorin, and oxaliplatin) for members with proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
    - Used as subsequent therapy (if not previously given) in combination with encorafenib; **OR**
  - Member has KRAS G12C mutation positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used as subsequent therapy (if not previously given) in combination with adagrasib; **AND**
    - Member has received prior treatment with fluoropyrimidine-based therapy AND oxaliplatin- or irinotecan-based chemotherapy, unless contraindicated

Head and Neck Cancer † ‡ Φ [1,2,14,16,25,29-31,17e-23e,25e-29e]

- Member has squamous cell carcinoma; **AND**

- Used in combination with radiation as a single agent †; **AND**

  - Use of cetuximab will be restricted to members with a contraindication or intolerance to a generically available agent/regimen (e.g., cisplatin- or carboplatin-based regimens, docetaxel, etc. *[see NCCN Head and Neck Cancers guideline for complete list of alternatives]*); **OR**

- Used as first-line therapy; **AND**
  - Used in combination with infusional fluorouracil AND either cisplatin or carboplatin for unresectable, recurrent/persistent, or metastatic disease (non-nasopharyngeal) †; **AND**
    - Use of cetuximab will be restricted to members with a contraindication or intolerance to pembrolizumab/(cisplatin or carboplatin)/infusional fluorouracil; **OR**
  - Used in combination with cisplatin for very advanced head and neck cancers* (non-nasopharyngeal); **OR**
  - Used in combination with docetaxel AND either cisplatin or carboplatin for very advanced head and neck cancers* (non-nasopharyngeal); **AND**
    - Use of cetuximab will be restricted to members with a contraindication or intolerance to one of the following regimens:
      - Pembrolizumab/(cisplatin or carboplatin)/infusional fluorouracil
      - Pembrolizumab/(cisplatin or carboplatin)/(docetaxel or paclitaxel); **OR**
  - Used in combination with paclitaxel with or without cisplatin or carboplatin for very advanced head and neck cancers* (non-nasopharyngeal); **AND**

    <u>WITH cisplatin or carboplatin:</u>
    - Use of cetuximab will be restricted to members with a contraindication or intolerance to one of the following regimens:
      - Pembrolizumab/(cisplatin or carboplatin)/infusional fluorouracil
      - Pembrolizumab/(cisplatin or carboplatin)/(docetaxel or paclitaxel); **OR**
  - Used in combination with nivolumab for very advanced head and neck cancer* (non-nasopharyngeal); **AND**
    - Use of cetuximab will be restricted to members with a contraindication or intolerance to one of the following regimens:
      - Pembrolizumab/(cisplatin or carboplatin)/infusional fluorouracil
      - Generically available agent/regimen (e.g., cisplatin/paclitaxel, cisplatin, etc. *[see NCCN Head and Neck Cancers guideline for complete list of alternatives]*); **OR**

- Used in combination with pembrolizumab for very advanced head and neck cancer* (non-nasopharyngeal); **AND**
  - Member has platinum-resistant disease or is platinum-ineligible; **OR**

- Used as subsequent therapy; **AND**
  - Used as a single agent for unresectable, recurrent/persistent, or metastatic disease after failure on platinum-based therapy †; **AND**

– Member must demonstrate an inadequate response to one of the following (if not previously used), unless there is a contraindication or intolerance, prior to approval of cetuximab: ➢ Nivolumab ➢ Pembrolizumab (PD-L1 CPS ≥1); **OR**

  - Used in combination with carboplatin for cancer of the nasopharynx (T1-4, N0-3, M1 only), if not previously used; **OR**
  - Used in combination with paclitaxel for very advanced head and neck cancers* (non-nasopharyngeal); **OR**
  - Used in combination with nivolumab or pembrolizumab for very advanced head and neck cancer* (non-nasopharyngeal); **AND**
    - Member has platinum-resistant disease or is platinum-ineligible; **OR**
  - Used in combination with carboplatin for very advanced head and neck cancer* (nasopharyngeal) AND PS 0-1

** Very Advanced Head and Neck Cancers include: newly diagnosed (M0) locally advanced T4b, N0-3; newly diagnosed unresectable regional nodal disease, or those unfit for surgery; metastatic disease at initial presentation [M1]; or recurrent or persistent disease with or without distant metastases.*

Squamous Cell Skin Cancer ‡ [2,21,27,55e,57e]

- Used as a single agent OR in combination with carboplatin and paclitaxel; **AND**
  - Member is not a candidate for or has progressed on immune checkpoint inhibitors AND clinical trials; **AND**
  - Used as first-line therapy; **AND**
    - Member has locally advanced disease; **AND**
      - Used as primary treatment if curative surgery and curative radiation therapy (RT) are not feasible; **OR**
      - Used as additional treatment if positive surgical margins and curative surgery and curative RT are not feasible; **OR**
    - Member has regional disease that is unresectable, inoperable, or incompletely resected if curative RT is not feasible; **OR**

- Member has satellitosis/in-transit metastasis that is unresectable or incompletely resected; **OR**
- Member has regional recurrence or distant metastatic disease

Non-Small Cell Lung Cancer (NSCLC) ‡ [2,24]

- Used in combination with afatinib; **AND**
- Member has recurrent, advanced, or metastatic disease; **AND**
- Used as subsequent therapy; **AND**
- Member has EGFR exon 19 deletion or L858R mutation or EGFR S768I, L861Q, and/or G719X mutation positive tumors as determined by an FDA-approved or CLIA-compliant test ❖; **AND**
- Member progressed on EGFR tyrosine kinase inhibitor therapy; **AND**
  - Member has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited* progression; **AND**
    - Used following progression on subsequent therapy with erlotinib, afatinib, gefitinib, or dacomitinib therapy for T790M negative disease; **OR**
  - Member has multiple symptomatic systemic lesions or symptomatic systemic limited* progression; **AND**
    - Used following initial therapy with erlotinib, afatinib, gefitinib, or dacomitinib therapy for T790M negative disease

** Limited progression: Clinical trials have included up to 3 to 5 progressing sites.*

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications

Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity.

Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

❖ *If confirmed using an FDA approved assay – http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,30]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions/anaphylactic reactions, cardiopulmonary arrest, pulmonary toxicity/interstitial lung disease, dermatologic toxicity, hypomagnesemia/electrolyte abnormalities, etc.

V. Dosage/Administration [1,12,13,20-23,29-36,38-40]

Indication	Dose
Small Bowel Adenocarcinoma, Colorectal Cancer & Appendiceal Neoplasms and Cancers	400 mg/m² loading dose intravenously, then 250 mg/m² intravenously every 7 days until disease progression or unacceptable toxicity **OR** 500 mg/m² intravenously every 14 days until disease progression or unacceptable toxicity
NSCLC	500 mg/m² intravenously every 14 days until disease progression or unacceptable toxicity
Head and Neck Cancer	With concurrent radiation therapy: 400 mg/m² loading dose intravenously 1 week prior to radiation therapy, then 250 mg/m² intravenously every 7 days for the duration of radiation therapy (up to 8 total weeks of therapy) Monotherapy, in combination with paclitaxel, or in combination with platinum-based therapy: 400 mg/m² loading dose intravenously, then 250 mg/m² intravenously every 7 days until disease progression or unacceptable toxicity **OR**

	500 mg/m² intravenously every 14 days until disease progression or unacceptable toxicity In combination with nivolumab: 500 mg/m² intravenously every 14 days until disease progression or unacceptable toxicity In combination with pembrolizumab: 400 mg/m² loading dose intravenously, then 250 mg/m² intravenously every 7 days until disease progression or unacceptable toxicity
Squamous Cell Skin Cancer	400 mg/m² loading dose intravenously, then 250 mg/m² intravenously every 7 days until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J9055 – Injection, cetuximab, 10 mg; 1 billable unit = 10 mg

NDC(s):

- Erbitux 100 mg/50 mL single-dose vial, solution for injection: 66733-0948-xx
- Erbitux 200 mg/100 mL single-dose vial, solution for injection: 66733-0958-xx

VII. References (STANDARD)

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder

(MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified

ICD-10	ICD-10 Description
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.2	Malignant neoplasm of uvula
C05.8	Malignant neoplasm of overlapping sites of palate
C05.9	Malignant neoplasm of palate, unspecified
C06.0	Malignant neoplasm of cheek mucosa
C06.2	Malignant neoplasm of retromolar area
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C09.9	Malignant neoplasm of tonsil, unspecified
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C10.9	Malignant neoplasm of oropharynx, unspecified
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified

ICD-10	ICD-10 Description
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of large intestines
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C30.0	Malignant neoplasm of nasal cavity
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus

ICD-10	ICD-10 Description
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C44.02	Squamous cell carcinoma of skin of lip
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.320	Squamous cell carcinoma of skin of unspecified parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder

ICD-10	ICD-10 Description
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.92	Squamous cell carcinoma of skin, unspecified
C76.0	Malignant neoplasm of head, face and neck
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
D37.02	Neoplasm of uncertain behavior of tongue
D37.04	Neoplasm of uncertain behavior of the minor salivary glands
D37.05	Neoplasm of uncertain behavior of pharynx
D37.09	Neoplasm of uncertain behavior of other specified sites of the oral cavity
D37.3	Neoplasm of uncertain behavior of appendix
D38.0	Neoplasm of uncertain behavior of larynx
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.22	Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
Z85.810	Personal history of malignant neoplasm of the tongue
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity, and pharynx

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used

to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC