Erbitux® (cetuximab)

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

<table>
<thead>
<tr>
<th></th>
<th>Weekly</th>
<th>Every two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erbitux 100 mg solution for injection</td>
<td>1 vial every 7 days</td>
<td>1 vial every 14 days</td>
</tr>
<tr>
<td>Erbitux 200 mg solution for injection</td>
<td>3 vials every 7 days (5 vials for first dose only)</td>
<td>6 vials every 14 days</td>
</tr>
</tbody>
</table>

B. Max Units (per dose and over time) [Medical Benefit]:

<table>
<thead>
<tr>
<th></th>
<th>Weekly</th>
<th>Every two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Load: 100 billable units x 1 dose</td>
<td></td>
<td>120 billable units every 14 days</td>
</tr>
<tr>
<td>– Maintenance Dose: 60 billable units every 7 days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Used in combination with irinotecan- or oxaliplatin-based regimens‡: OR
Used in combination with a vemurafenib-based regimen in patients with BRAF V600E mutations: OR

- Used as a single agent therapy for metastatic disease †; AND
- Patient has previously failed on an oxaliplatin- and irinotecan-based regimen: OR
- Patient is unable to tolerate irinotecan

Squamous Cell Carcinoma of the Head and Neck (SCCHN) †

- Used in one of the following regimens: †
  - In combination with radiation therapy for regionally or locally advanced disease: OR
  - As a single agent in recurrent or metastatic disease after failure on platinum-based therapy: OR
  - In combination with platinum-based therapy for first-line treatment of recurrent, loco-regional, or metastatic disease: AND
- Patient has one of the following sub-types of SCCHN: ‡
  - Cancer of the Glottic Larynx
  - Cancer of the Hypopharynx
    - Cetuximab may also be used as a single agent for sequential chemoradiation ‡
  - Cancer of the Lip
  - Cancer of the Nasopharynx
  - Cancer of the Oropharynx
    - Cetuximab may also be used as a single agent for sequential chemoradiation ‡
  - Cancer of the Supraglottic Larynx
  - Ethmoid Sinus Tumors
  - Maxillary Sinus Tumors
  - Very advanced and recurrent/persistent head and neck cancer
    - Cetuximab may also be used as a single agent for sequential chemoradiation ‡

Occult Primary Head and Neck Cancers ‡

- Must be used as initial treatment as a single agent with sequential chemoradiation

Non-melanoma Skin Cancer (Basal Cell Skin Cancer and Squamous Cell Skin Cancer) ‡

- For regional recurrence or distant metastases

Penile Cancer ‡

- Patient must have metastatic disease: AND
- Must be used for subsequent treatment: AND
- Must be used as a single agent

Non-Small Cell Lung Cancer (NSCLC) ‡
- Patient must have metastatic disease; **AND**
- Must be used in combination with afatinib; **AND**
- Must be used as subsequent therapy for sensitizing EGFR mutation-positive tumors; **AND**
- Patient has progressed on EGFR tyrosine kinase inhibitor therapy (e.g. erlotinib, afatinib, or gefitinib, etc); **AND**
  - Patient has asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**
  - Patient is T790M negative and has multiple symptomatic systemic lesions

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

IV. **Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Tumor response with 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 the following: severe infusion reactions, cardiopulmonary arrest, pulmonary toxicity/interstitial lung disease, dermatologic toxicity, electrolyte abnormalities, etc.

V. **Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal Cancer</td>
<td>400 mg/m² loading dose, then 250 mg/m² every 7 days; <strong>OR</strong> 500 mg/m² every 14 days</td>
</tr>
<tr>
<td>All other indications</td>
<td>400 mg/m² loading dose, then 250 mg/m² every 7 days</td>
</tr>
</tbody>
</table>

VI. **Billing Code/Availability Information**

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

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

VII. **References**

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cetuximab. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL
COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C00.0</td>
<td>Malignant neoplasm of external upper lip</td>
</tr>
<tr>
<td>C00.1</td>
<td>Malignant neoplasm of lower lip</td>
</tr>
<tr>
<td>C00.2</td>
<td>Malignant neoplasm of external lip, unspecified</td>
</tr>
<tr>
<td>C00.3</td>
<td>Malignant neoplasm of upper lip, inner aspect</td>
</tr>
<tr>
<td>C00.4</td>
<td>Malignant neoplasm of lower lip, inner aspect</td>
</tr>
<tr>
<td>C00.5</td>
<td>Malignant neoplasm of lip, unspecified, inner aspect</td>
</tr>
<tr>
<td>C00.6</td>
<td>Malignant neoplasm of commissure of lip, unspecified</td>
</tr>
<tr>
<td>C00.8</td>
<td>Malignant neoplasm of overlapping sites of lip</td>
</tr>
<tr>
<td>C00.9</td>
<td>Malignant neoplasm of lip, unspecified</td>
</tr>
<tr>
<td>C01</td>
<td>Malignant neoplasm of base of tongue</td>
</tr>
<tr>
<td>C02.0</td>
<td>Malignant neoplasm of dorsal surface of tongue</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>C02.1</td>
<td>Malignant neoplasm of border of tongue</td>
</tr>
<tr>
<td>C02.2</td>
<td>Malignant neoplasm of ventral surface of tongue</td>
</tr>
<tr>
<td>C02.3</td>
<td>Malignant neoplasm of anterior two-thirds of tongue, part unspecified</td>
</tr>
<tr>
<td>C02.4</td>
<td>Malignant neoplasm of lingual tonsil</td>
</tr>
<tr>
<td>C02.8</td>
<td>Malignant neoplasm of overlapping sites of tongue</td>
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<tr>
<td>C02.9</td>
<td>Malignant neoplasm of tongue, unspecified</td>
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<tr>
<td>C03.0</td>
<td>Malignant neoplasm of upper gum</td>
</tr>
<tr>
<td>C03.1</td>
<td>Malignant neoplasm of lower gum</td>
</tr>
<tr>
<td>C03.9</td>
<td>Malignant neoplasm of gum, unspecified</td>
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<tr>
<td>C04.0</td>
<td>Malignant neoplasm of anterior floor of mouth</td>
</tr>
<tr>
<td>C04.1</td>
<td>Malignant neoplasm of lateral floor of mouth</td>
</tr>
<tr>
<td>C04.8</td>
<td>Malignant neoplasm of overlapping sites of floor of mouth</td>
</tr>
<tr>
<td>C04.9</td>
<td>Malignant neoplasm of floor of mouth, unspecified</td>
</tr>
<tr>
<td>C05.0</td>
<td>Malignant neoplasm of hard palate</td>
</tr>
<tr>
<td>C05.1</td>
<td>Malignant neoplasm of soft palate</td>
</tr>
<tr>
<td>C06.0</td>
<td>Malignant neoplasm of cheek mucosa</td>
</tr>
<tr>
<td>C06.2</td>
<td>Malignant neoplasm of retromolar area</td>
</tr>
<tr>
<td>C06.80</td>
<td>Malignant neoplasm of overlapping sites of unspecified parts of mouth</td>
</tr>
<tr>
<td>C06.89</td>
<td>Malignant neoplasm of overlapping sites of other parts of mouth</td>
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<td>C06.9</td>
<td>Malignant neoplasm of mouth, unspecified</td>
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<tr>
<td>C09.0</td>
<td>Malignant neoplasm of tonsillar fossa</td>
</tr>
<tr>
<td>C09.1</td>
<td>Malignant neoplasm of tonsillar pillar (anterior) (posterior)</td>
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<td>Malignant neoplasm of overlapping sites of tonsil</td>
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<td>Malignant neoplasm of lateral wall of oropharynx</td>
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<td>C10.3</td>
<td>Malignant neoplasm of posterior wall of oropharynx</td>
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<td>Malignant neoplasm of hypopharynx, unspecified</td>
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<tr>
<td>C14.0</td>
<td>Malignant neoplasm of pharynx, unspecified</td>
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<td>Malignant neoplasm of Waldeyer's ring</td>
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<td>Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx</td>
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<td>C17.0</td>
<td>Malignant neoplasm duodenum</td>
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<td>C17.1</td>
<td>Malignant neoplasm jejunum</td>
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<td>Malignant neoplasm ileum</td>
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<td>C17.8</td>
<td>Malignant neoplasm of overlapping sites of small intestines</td>
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<td>Malignant neoplasm of cecum</td>
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<td>Malignant neoplasm of appendix</td>
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<td>Malignant neoplasm of ascending colon</td>
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<td>Malignant neoplasm of hepatic flexure</td>
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<td>Malignant neoplasm of transverse colon</td>
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<td>Malignant neoplasm of splenic flexure</td>
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<td>C18.9</td>
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<td>C19</td>
<td>Malignant neoplasm of rectosigmoid junction</td>
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<td>C20</td>
<td>Malignant neoplasm of rectum</td>
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<td>C21.8</td>
<td>Malignant neoplasm of overlapping sites of rectum, anus and anal canal</td>
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<td>C30.0</td>
<td>Malignant neoplasm of nasal cavity</td>
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<td>C31.0</td>
<td>Malignant neoplasm of maxillary sinus</td>
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<td>Malignant neoplasm of ethmoidal sinus</td>
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<td>C32.0</td>
<td>Malignant neoplasm of glottis</td>
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<td>Malignant neoplasm of supraglottis</td>
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<tr>
<td>C32.2</td>
<td>Malignant neoplasm of subglottis</td>
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<tr>
<td>C32.3</td>
<td>Malignant neoplasm of laryngeal cartilage</td>
</tr>
<tr>
<td>C32.8</td>
<td>Malignant neoplasm of overlapping sites of larynx</td>
</tr>
<tr>
<td>C32.9</td>
<td>Malignant neoplasm of larynx, unspecified</td>
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<tr>
<td>C33</td>
<td>Malignant neoplasm of trachea</td>
</tr>
<tr>
<td>C34.00</td>
<td>Malignant neoplasm of unspecified main bronchus</td>
</tr>
<tr>
<td>C34.01</td>
<td>Malignant neoplasm of right main bronchus</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------</td>
</tr>
<tr>
<td>C34.02</td>
<td>Malignant neoplasm of left main bronchus</td>
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<tr>
<td>C34.10</td>
<td>Malignant neoplasm of upper lobe, unspecified bronchus or lung</td>
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<tr>
<td>C34.11</td>
<td>Malignant neoplasm of upper lobe, right bronchus or lung</td>
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<td>C34.12</td>
<td>Malignant neoplasm of upper lobe, left bronchus or lung</td>
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<tr>
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<td>Malignant neoplasm of lower lobe, unspecified bronchus or lung</td>
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<td>C34.31</td>
<td>Malignant neoplasm of lower lobe, right bronchus or lung</td>
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<td>C34.32</td>
<td>Malignant neoplasm of lower lobe, left bronchus or lung</td>
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<td>C34.80</td>
<td>Malignant neoplasm of overlapping sites of unspecified bronchus and lung</td>
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<tr>
<td>C34.81</td>
<td>Malignant neoplasm of overlapping sites of right bronchus and lung</td>
</tr>
<tr>
<td>C34.82</td>
<td>Malignant neoplasm of overlapping sites of left bronchus and lung</td>
</tr>
<tr>
<td>C34.90</td>
<td>Malignant neoplasm of unspecified part of unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.91</td>
<td>Malignant neoplasm of unspecified part of right bronchus or lung</td>
</tr>
<tr>
<td>C34.92</td>
<td>Malignant neoplasm of unspecified part of left bronchus or lung</td>
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<tr>
<td>C44.00</td>
<td>Unspecified malignant neoplasm of skin of lip</td>
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<tr>
<td>C44.02</td>
<td>Squamous cell carcinoma of skin of lip</td>
</tr>
<tr>
<td>C44.09</td>
<td>Other specified malignant neoplasm of skin of lip</td>
</tr>
<tr>
<td>C44.121</td>
<td>Squamous cell carcinoma of skin of unspecified eyelid, including canthus</td>
</tr>
<tr>
<td>C44.122</td>
<td>Squamous cell carcinoma of skin of right eyelid, including canthus</td>
</tr>
<tr>
<td>C44.129</td>
<td>Squamous cell carcinoma of skin of left eyelid, including canthus</td>
</tr>
<tr>
<td>C44.221</td>
<td>Squamous cell carcinoma of skin of unspecified ear and external auricular canal</td>
</tr>
<tr>
<td>C44.222</td>
<td>Squamous cell carcinoma of skin of right ear and external auricular canal</td>
</tr>
<tr>
<td>C44.229</td>
<td>Squamous cell carcinoma of skin of left ear and external auricular canal</td>
</tr>
<tr>
<td>C44.320</td>
<td>Squamous cell carcinoma of skin of unspecified parts of face</td>
</tr>
<tr>
<td>C44.321</td>
<td>Squamous cell carcinoma of skin of nose</td>
</tr>
<tr>
<td>C44.329</td>
<td>Squamous cell carcinoma of skin of other parts of face</td>
</tr>
<tr>
<td>C44.42</td>
<td>Squamous cell carcinoma of skin of scalp and neck</td>
</tr>
<tr>
<td>C44.520</td>
<td>Squamous cell carcinoma of anal skin</td>
</tr>
<tr>
<td>C44.521</td>
<td>Squamous cell carcinoma of skin of breast</td>
</tr>
<tr>
<td>C44.529</td>
<td>Squamous cell carcinoma of skin of other part of trunk</td>
</tr>
<tr>
<td>C44.621</td>
<td>Squamous cell carcinoma of skin of unspecified upper limb, including shoulder</td>
</tr>
<tr>
<td>C44.622</td>
<td>Squamous cell carcinoma of skin of right upper limb, including shoulder</td>
</tr>
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<td>Squamous cell carcinoma of skin of left upper limb, including shoulder</td>
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<tr>
<td>C44.721</td>
<td>Squamous cell carcinoma of skin of unspecified lower limb, including hip</td>
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<td>C44.729</td>
<td>Squamous cell carcinoma of skin of left lower limb, including hip</td>
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<tr>
<td>C44.82</td>
<td>Squamous cell carcinoma of overlapping sites of skin</td>
</tr>
<tr>
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<td>Squamous cell carcinoma of skin, unspecified</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------------------------</td>
</tr>
<tr>
<td>C60.0</td>
<td>Malignant neoplasm of prepuce</td>
</tr>
<tr>
<td>C60.1</td>
<td>Malignant neoplasm of glans penis</td>
</tr>
<tr>
<td>C60.2</td>
<td>Malignant neoplasm of body of penis</td>
</tr>
<tr>
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<td>Malignant neoplasm of overlapping sites of penis</td>
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<td>Malignant neoplasm of penis, unspecified</td>
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<tr>
<td>C63.7</td>
<td>Malignant neoplasm of other specified male genital organs</td>
</tr>
<tr>
<td>C63.8</td>
<td>Malignant neoplasm of overlapping sites of male genital organs</td>
</tr>
<tr>
<td>C76.0</td>
<td>Malignant neoplasm of head, face and neck</td>
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<tr>
<td>C77.0</td>
<td>Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck</td>
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<tr>
<td>C78.00</td>
<td>Secondary malignant neoplasm of unspecified lung</td>
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<tr>
<td>C78.01</td>
<td>Secondary malignant neoplasm of right lung</td>
</tr>
<tr>
<td>C78.02</td>
<td>Secondary malignant neoplasm of left lung</td>
</tr>
<tr>
<td>C78.6</td>
<td>Secondary malignant neoplasm of retroperitoneum and peritoneum</td>
</tr>
<tr>
<td>C78.7</td>
<td>Secondary malignant neoplasm of liver and intrahepatic bile duct</td>
</tr>
<tr>
<td>C78.89</td>
<td>Secondary malignant neoplasm of other digestive organs</td>
</tr>
<tr>
<td>D37.01</td>
<td>Neoplasm of uncertain behavior of lip</td>
</tr>
<tr>
<td>D37.02</td>
<td>Neoplasm of uncertain behavior of tongue</td>
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<tr>
<td>D37.05</td>
<td>Neoplasm of uncertain behavior of pharynx</td>
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<td>D37.09</td>
<td>Neoplasm of uncertain behavior of other specified sites of the oral cavity</td>
</tr>
<tr>
<td>D38.0</td>
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<tr>
<td>D38.5</td>
<td>Neoplasm of uncertain behavior of other respiratory organs</td>
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<td>Personal history of other malignant neoplasm of large intestine</td>
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<tr>
<td>Z85.068</td>
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<tr>
<td>Z85.118</td>
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<td>Z85.22</td>
<td>Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses</td>
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<td>Personal history of malignant neoplasm of other male genital organs</td>
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<td>Z85.818</td>
<td>Personal history of malignant neoplasm of other sites of lip, oral cavity and pharynx</td>
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<tr>
<td>Z85.819</td>
<td>Personal history of malignant neoplasm of unspecified site of lip, oral cavity and pharynx</td>
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<td>Z85.828</td>
<td>Personal history of other malignant neoplasm of skin</td>
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**Appendix 2 – Centers for Medicare and Medicaid Services (CMS)**

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-](http://www.cms.gov/medicare-)_
coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

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

<table>
<thead>
<tr>
<th>Jurisdiction(s): N</th>
<th>NCD/LCD Document (s): L33278</th>
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<th>Applicable State/US Territory</th>
<th>Contractor</th>
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<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
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<td>Noridian Healthcare Solutions, LLC</td>
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<td>5</td>
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</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
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<td>Novitas Solutions, Inc.</td>
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<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<td>First Coast Service Options, Inc.</td>
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<tr>
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<td>M (11)</td>
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<td>CGS Administrators, LLC</td>
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