**Cetuximab (Erbitux®)**

**Place of Service**

**Office Administration**
**Outpatient Facility Infusion Administration**
**Infusion Center Administration**

**HCPCS: J9055** per 10 mg

**Condition(s) listed in policy (*see criteria for details*)**

- Colorectal or appendiceal carcinoma
- Non-small cell lung cancer
- Penile cancer
- Squamous cell carcinoma of the head and neck
- Squamous cell skin cancer

**AHFS therapeutic class:** Antineoplastic

**Mechanism of action:** recombinant chimeric (human-murine) monoclonal antibody that binds to epidermal growth factor receptors (EGFR)

## (1) Special Instructions and pertinent Information

**Covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax.

## (2) Prior Authorization/Medical Review is required for the following condition(s)

**All requests for Erbitux® (cetuximab) must be sent for clinical review and receive authorization prior to drug administration or claim payment**

**Colorectal or appendiceal cancer**

1. Diagnosis of metastatic, unresectable, unresectable metachronous metastatic, or medically inoperable disease, **AND**
2. One of the following:
    a. Patient is **BRAF V600E wild type** *(negative for mutation)*, and meets either of the following:
        i. Being used in combination with either an irinotecan- or oxaliplatin-containing regimen, OR
        ii. Being used as a single agent in patient who is unable to tolerate irinotecan or has experienced disease progression following oxaliplatin- and irinotecan-containing regimens

    **OR**

    b. Patient is **BRAF positive** and being used in combination with Braftovi (encorafenib), **OR**
    c. Cancer is **KRAS G12C mutation positive**, and being used with either Lumakras or Krazati

**Covered Doses**

Up to 400 mg/m$^2$ IV infusion as initial dose, followed by up to 250 mg/m$^2$ IV infusion weekly or 500 mg/m$^2$ IV infusion every 2 weeks

**Coverage Period**

Indefinite

**ICD-10:**
C17.0-C17.2, C17.8, C17.9, C18.0-C18.9, C19, C20, C21.8, C78.00-C78.02, C78.6, C78.7, Z85.038

**Non-small cell lung cancer (NSCLC)**

1. Disease is recurrent, unresectable or metastatic, **AND**
2. Used as subsequent therapy for recurrent, unresectable or metastatic NSCLC, **AND**
3. Used in combination with Gilotrif (afatinib), **AND**
4. Patient has a sensitizing EGFR mutation, **AND**
5. Patient has progressed on EGFR tyrosine kinase inhibitor therapy

**Covered Doses**
Up to 500 mg/$m^2$ IV every 2 weeks (in combination with afatinib 40 mg daily)

**Coverage Period**
Indefinite

**ICD-10:**
C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.118

**Penile cancer**

1. Metastatic or recurrent disease, **AND**
2. Used as a single agent, **AND**
3. Used as subsequent-line therapy for metastatic or recurrent disease

**Covered Doses**
Up to 400 mg/$m^2$ IV infusion as initial dose, followed by up to 250 mg/$m^2$ IV infusion weekly.

**Coverage Period**
Indefinite

**ICD-10:**
C60.0-C60.2, C60.8, C60.9, C63.7, C63.8

**Squamous cell cancer of the head and neck (SCCHN)**

1. Either of the following:
    a. Used as a single agent, OR
    b. Used in combination with radiation and/or one of the following regimens:
        i. Platinum-based chemotherapy, or
        ii. Opdivo

**Covered Doses**
Up to 400 mg/$m^2$ IV infusion as initial dose, followed by up to 250 mg/$m^2$ IV infusion weekly or 500 mg/$m^2$ IV infusion every 2 weeks

**Coverage Period**
Indefinite

**ICD-10:**
C00.0-C00.6, C00.8, C00.9, C01, C02.0-C02.4, C02.8, C02.9, C03.0, C03.1, C03.9, C04.0, C04.1, C04.8, C04.9, C05.0, C05.1, C06.0, C06.2, C06.80, C06.89, C06.9, C09.0, C09.1, C09.8, C09.9, C10.0-C10.4, C10.8, C10.9, C11.0-C11.3, C11.8, C11.9, C12, C13.0-C13.2, C13.8, C13.9, C14.0, C14.2, C14.8, C30.0-C31.1, C32.0-C32.3, C32.8, C32.9, C44.00, C44.02, C44.09, C76.0, C77.0, C78.89, D37.01, D37.02, D37.05, D37.09, D38.0, D38.5, D38.6, Z85.21, Z85.22, Z85.810, Z85.818, Z85.819

**Squamous cell skin cancer**

1. Patient has regional recurrence, distant metastases, or disease is inoperable or not fully resectable.
   **AND**
2. Being used as a single agent or concurrently with radiation

**Covered Doses**
Up to 400 mg/m$^2$ IV infusion as initial dose, followed by up to 250 mg/m$^2$ IV infusion weekly

**Coverage Period**
Indefinite

**ICD-10:**
C44.02, C44.121, C44.1221, C44.1222, C44.1291, C44.221, C44.222, C44.229, C44.320, C44.321, C44.329, C44.42, C44.520, C44.521, C44.529, C44.621, C44.622, C44.629, C44.721, C44.722, C44.729, C44.82, C44.92, Z85.828

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**
**All requests for Erbitux® (cetuximab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s)**
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**
How supplied:
100 mg (single-use vial)
200 mg (single-use vial)

**(6) References**


- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- Erbitux® (cetuximab) [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; 9/2021.
- Janjigian YY, Smit EF, Groen HJ et al. Dual inhibition of EGFR with afatinib and cetuximab in kinase

inhibitor resistant EGFR-mutant lung cancer with and without T790M mutations. Cancer Discov 2014; 4:1036-1045.
- National Comprehensive Cancer Network. Colon Cancer (Version 1.2022). Available at www.nccn.org.
- National Comprehensive Cancer Network. Head and Neck Cancers (Version 1.2023). Available at www.nccn.org.
- National Comprehensive Cancer Network. Non-small Cell Lung Cancer (Version 5.2022). Available at www.nccn.org.
- National Comprehensive Cancer Network. Penile Cancer (Version 2.2022). Available at www.nccn.org.
- National Comprehensive Cancer Network. Rectal Cancer (Version 2.2022). Available at www.nccn.org.
- National Comprehensive Cancer Network. Squamous Cell Skin Cancer (Version 2.2022). Available at www.nccn.org.

## (7) Policy Update

Date of last revision: 1Q2024
Date of next review: 3Q2024
Changes from previous policy version:

- Section (2): Colorectal or appendiceal cancer - Added coverage for initial treatment and subsequent therapy when used in combination with sotorasib or adagrasib for KRAS G12C mutation positive disease. *Rationale: NCCN category 2A support.*

*BSC Drug Coverage Criteria to Determine Medical Necessity*
*Reviewed by P&T Committee*