Clinical Policy: Cetuximab (Erbitux)

Reference Number: CP.PHAR.317
Effective Date: 02.01.17
Last Review Date: 11.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Cetuximab (Erbitux®) is an epidermal growth factor receptor (EGFR) antagonist.

FDA Approved Indication(s)

Erbitux is indicated for treatment of:

- Head and neck squamous cell carcinoma (HNSCC)
  - Locally or regionally advanced HNSCC in combination with radiation therapy for initial treatment
  - Recurrent locoregional disease or metastatic HNSCC in combination with platinum-based therapy with fluorouracil (5-FU) for first-line treatment
  - Recurrent or metastatic HNSCC progressing after platinum-based therapy, as a single agent
- Colorectal cancer (CRC)
  - K-Ras wild-type, EGFR-expressing, metastatic CRC as determined by an FDA-approved test.
    - In combination with FOLFIRI (irinotecan, fluorouracil, leucovorin) for first-line treatment
    - In combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy
    - As a single agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan
  - BRAF V600E mutation-positive metastatic CRC
    - In combination with encorafenib, for the treatment of adult patients with metastatic CRC with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.

Limitation(s) of use: Erbitux is not indicated for treatment of Ras-mutant CRC or when the results of the Ras mutation tests are unknown.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Erbitux is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Head and Neck Squamous Cell Carcinoma (must meet all)**:**

1. Diagnosis of HNSCC (*see Appendix D for subtypes by location*);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Disease is advanced, recurrent, unresectable, or metastatic;
   b. Member is receiving reirradiation with concurrent radiotherapy;
5. Prescribed in one of the following ways (a or b):
   a. As a single agent;
   b. In combination with platinum-based therapy (e.g., cisplatin or carboplatin), Opdivo®, Keytruda®, paclitaxel, or docetaxel (if cisplatin-ineligible);*
   **Prior authorization may be required for platinum-based therapies.*
6. Request meets one of the following (a, b, or c):*
   a. Dose does not exceed an initial dose of 400 mg/m^2 followed by 250 mg/m^2 weekly thereafter;
   b. Dose does not exceed 500 mg/m^2 every 2 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Colorectal Cancer (must meet all)**:**

1. Diagnosis of advanced, recurrent, or metastatic CRC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is one of the following (a, b, c, d, or e):
   a. KRAS/NRAS/BRAF wild-type (i.e., no mutations in KRAS, NRAS, or BRAF genes);
   b. BRAF V600E mutation positive;
   c. KRAS G12C mutation positive;
   d. Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H);
   e. Polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (e.g., tumor mutation burden [TMB] > 50 mut/Mb);
5. Prescribed in one of the following ways (a, b, c, d, or e):
   a. As a single agent;
   b. In combination with FOLFIRI, FOLFOX, or CapeOX;
   c. In combination with irinotecan following prior therapy;
   d. If BRAF V600E mutation positive: In combination with Braftovi® with or without FOLFOX;
   e. If KRAS G12C mutation positive: In combination with Lumakras® or Krazati® following prior therapy;
6. For colon cancer that is KRAS/NRAS/BRAF wild-type with unresectable synchronous liver and/or lung metastases or metachronous metastases: Colon cancer is left-sided only (*see Appendix E*);

7. For dMMR/MSI-H or POLE/POLD1 mutation positive cancer: Member is ineligible for or has progressed on checkpoint inhibitor immunotherapy (*see Appendix B*);
8. Request meets one of the following (a, b, or c):*
   a. Dose does not exceed an initial dose of 400 mg/m^2 followed by 250 mg/m^2 weekly thereafter;
   b. Dose does not exceed 500 mg/m^2 every 2 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Non-Small Cell Lung Cancer (off-label) (must meet all)**:**
1. Diagnosis of recurrent, advanced, or metastatic non-small cell lung cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Tumor is EGFR exon 19 deletion or exon 21 L858R, EGFR S768I, L861Q, and/or G719X mutation positive;
5. Prescribed in combination with Gilotrif® as subsequent therapy;*

   **Prior authorization may be required for Gilotrif*
6. Disease has progressed on or after an EGFR tyrosine kinase inhibitor (TKI) therapy (e.g., Tarceva®, Gilotrif, Iressa®, Tagrisso®, Lazcluze™);*

   **Prior authorization may be required for EGFR TKI therapies*
7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

D. Penile Cancer (off-label) (must meet all)**:**
1. Diagnosis of metastatic or recurrent penile cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. Prescribed as subsequent-line systemic therapy;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

E. Squamous Cell Skin Cancer (off-label) (must meet all)**:**
1. Diagnosis of squamous cell skin cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in one of the following ways (a or b):
   a. As a single agent;
   b. If member is ineligible for or progressed on immune checkpoint inhibitors (*see Appendix B*) and clinical trials: In combination with carboplatin and paclitaxel;
5. Disease is advanced, unresectable, high-risk, recurrent, metastatic, inoperable, or not fully resectable;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

F. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Erbitux for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. For HNSCC or CRC: New dose does not exceed 250 mg/m^2 weekly or 500 mg/m^2 every 2 weeks;

b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

5-FU: fluorouracil
CapeOX: capecitabine, oxaliplatin
CRC: colorectal cancer
dMMR/MSI-H: deficient mismatch repair/microsatellite instability-high
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
FOLFIRI: fluorouracil, leucovorin, irinotecan
FOLFOX: fluorouracil, leucovorin, oxaliplatin
FOLFOXIRI: fluorouracil, leucovorin, oxaliplatin, irinotecan
HER: human epidermal growth factor receptor
HNSCC: head and neck squamous cell carcinoma
KRAS: Kirsten rat sarcoma 2 viral oncogene homologue
NRAS: neuroblastoma RAS viral oncogene homologue
POLE/POLD1: polymerase epsilon/delta

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Modified FOLFOX 6	**CRC** Day 1: oxaliplatin 85 mg/m^2 IV Day 1: Folinic acid 400 mg/m^2 IV Days 1–3: 5-FU 400 mg/m^2 IV bolus on day 1, then 1,200 mg/m^2/day × 2 days (total 2,400 mg/m^2 over 46–48 hours) IV continuous infusion Repeat cycle every 2 weeks.	See dosing regimen
CapeOX	**CRC** Day 1: Oxaliplatin 130 mg/m^2 IV Days 1–14: Capecitabine 1,000 mg/m^2 PO BID Repeat cycle every 3 weeks.	See dosing regimen
FOLFIRI	**CRC** Day 1: Irinotecan 180 mg/m^2 IV Day 1: Leucovorin 400 mg/m^2 IV Day 1: Flurouracil 400 mg/m^2 IV followed by 2,400 mg/m^2 continuous IV over 46 hours Repeat cycle every 14 days.	See dosing regimen
FOLFOXIRI	**CRC** Day 1: Irinotecan 165 mg/m^2 IV, oxaliplatin 85 mg/m^2 IV, leucovorin 400 mg/m^2 IV, flurouracil 1,600 mg/m^2 continuous IV for 2 days (total 3,200 mg/m^2) Repeat cycle every 2 weeks.	See dosing regimen
Checkpoint inhibitor therapies: Opdivo® (nivolumab) ± Yervoy® (ipilimumab) or Keytruda® (pembrolizumab)	**CRC** Varies	Varies
Gilotrif (afatinib)	**Metastatic NSCLC** 40 mg PO QD	40 mg/day; 50 mg/day when on chronic concomitant therapy with a P-gp inducer

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Iressa® (gefitinib)	**Metastatic NSCLC** 250 mg PO QD	250 mg/day; 500 mg/day when used with a strong CYP3A4 inducer
Tagrisso® (osimertinib)	**NSCLC** 80 mg PO QD	80 mg/day; 160 mg/day when used with a strong CYP3A inducer
erlotinib (Tarceva®)	**Metastatic NSCLC** 150 mg PO QD	150 mg/day; 450 mg/day when used with a strong CYP3A4 inducer or 300 mg/day when used with a moderate CYP1A2 inducer
TIP (paclitaxel, ifosfamide, cisplatin)	**Penile Cancer** Paclitaxel 175 mg/m^2 IV on day 1; ifosfamide 1,200 mg/m^2 IV on day 1-3; cisplatin 25 mg/m^2 IV on day 1-3 Repeat every 3 to 4 weeks.	See dosing regimen
5-FU, cisplatin, carboplatin	**HNSCC** cisplatin 100 mg/m2 IV or carboplatin AUC 5 IV on day 1, plus 5-FU 1,000 mg/m^2 IV on days 1, 2, 3, and 4, repeated every 3 weeks **Penile Cancer** 5-FU 800 - 1,000 mg/m^2/day continuous IV on days 1-4 or 2-5; cisplatin 70-80 mg/m^2 IV on day 1 Repeat every 3 to 4 weeks.	See dosing regimen
Immune checkpoint inhibitors: Keytruda (pembrolizumab), Libtayo® (cemiplimab-rwlcf)	**Squamous Cell Skin Cancer** Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): infusions reactions, cardiopulmonary arrest

*Appendix D: Head and Neck Squamous Cell Cancers by Location**

- Paranasal sinuses (ethmoid, maxillary)
- Larynx (glottis, supraglottis)
- Pharynx (nasopharynx, oropharynx, hypopharynx)
- Lip and oral cavity
- Major salivary glands (parotid, submandibular, sublingual)
- Occult primary

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**Squamous cell carcinoma, or a variant, is the histologic type in more than 90% of head and neck cancers.*

Appendix E: KRAS/NRAS/BRAF Wild-Type Colon Cancer with Unresectable, Synchronous Liver and/or Lung Metastases or Metachronous Metastases

- The NCCN Colon Cancer Guidelines recommend that cetuximab should only be used for left-sided tumors in in KRAS/NRAS/BRAF wild-type colon cancer with unresectable, synchronous liver and/or lung metastases or metachronous metastases. The panel defines the left side of the colon as splenic flexure to rectum. Evidence suggests that patients with tumors originating on the right side of the colon (hepatic flexure through cecum) are unlikely to respond to cetuximab. Data on the response to cetuximab in patients with primary tumors originating in the transverse colon (hepatic flexure to splenic flexure) are lacking.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HNSCC, CRC	Weekly schedule: initial dose 400 mg/m^2 IV followed by 250 mg/m^2 IV weekly Biweekly schedule: initial and subsequent doses 500 mg/m^2 IV every 2 weeks	See dosing regimen

VI. Product Availability

Single-dose vials: 100 mg/50 mL, 200 mg/100 mL

VII. References

1. Erbitux Prescribing Information. Indianapolis, IN: Eli Lilly and Company; September 2021. Available at: https://erbitux.lilly.com/hcp. Accessed July 14, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 15, 2025.
3. National Comprehensive Cancer Network. Head and Neck Cancer Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed July 15, 2025.
4. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer 7.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 15, 2025.
5. National Comprehensive Cancer Network. Squamous Cell Skin Cancer 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf. Accessed July 15, 2025.

6. National Comprehensive Cancer Network. Colon Cancer 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed July 15, 2025.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9055	Injection, cetuximab, 10 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: for CRC simplified requirements for prior and combination therapy to align more closely with New Century Health criteria; updated place in therapy for penile and squamous cell skin cancer per NCCN Compendium; for brand name requests added requirement for trial of generic equivalent if available; revised reference from HIM.PHAR.21 to HIM.PA.154; RT4: updated FDA approved indications to include use in combination with encorafenib in adult patients with metastatic CRC with a BRAF V600E mutation; references reviewed and updated.	07.20.21	11.21
4Q 2022 annual review: for HNSCC, removed required 5-FU combination per NCCN; added "advanced, unresectable, or metastatic" for CRC setting and "after prior therapy" if BRAF V600E positive for CRC per NCCN; for NSCLC, removed requirement that tumor be T790M negative and added T790M positive option per NCCN; for skin cancer, added criterion that for use as a single agent and removed basal cell carcinoma indication per NCCN; removed template generic redirection language as this an injectable agent; references reviewed and updated. Template changes applied to other diagnoses/indications.	08.11.22	11.22
4Q 2023 annual review: for HNSCC added combination therapy with Opdivo per NCCN; for CRC added CapeOX as a possible combination therapy per NCCN; for colon cancer that is KRAS/NRAS/BRAF wild-type added criterion that disease is left-sided only per NCCN, along with rationale in Appendix E; for squamous cell skin cancer, removed "locally" from locally advanced disease qualifier as disease can be regional per NCCN; references reviewed and updated.	08.17.23	11.23
4Q 2024 annual review: per NCCN – for HNSCC, added qualifier of unresectable disease and added alternative combinations with Keytruda, paclitaxel, or docetaxel; for CRC, added pathways for KRAS G12C, dMMR/MSI-H, and POLE/POLD1 mutations with	08.08.24	11.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
corresponding requirements related to combination use and/or prior therapy, limited combination use with irinotecan for after prior therapy only, and modified requirement for left-sided colon cancer to only apply to unresectable synchronous liver/lung metastases; for NSCLC, specified sensitizing EGFR mutations (EGFR exon 19 deletion or exon 21 L858R, EGFR S768I, L861Q, and/or G719X mutation positive); for penile cancer, added qualifier of recurrent disease; for squamous cell skin cancer, added qualifiers of unresectable and recurrent disease, removed qualifier of very high risk, and added pathway for combination use with carboplatin and paclitaxel; references reviewed and updated.		
4Q 2025 annual review: per NCCN – for HNSCC, added option for use if member is receiving reirradiation with concurrent radiotherapy; for CRC, replaced "unresectable" with "recurrent", specified that POLE/POLD1 mutation positive disease must have ultra-hypermutated phenotype, removed prior therapy requirement when prescribed for BRAF V600E mutation positive in combination with Braftovi and added clarification that regimen may be "with or without FOLFOX", and modified requirement for left-sided colon cancer to also apply to unresectable metachronous metastases; for NSCLC, simplified criterion requiring disease progression on prior therapy to no longer call out T790M positive disease; extended initial approval duration for HIM/Medicaid from 6 to 12 months; revised approval durations for Commercial from 6/12 months to standard injectable authorization of "6 months or to the member's renewal date, whichever is longer"; references reviewed and updated.	07.15.25	11.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage

decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.