

Medical Policy:

Erbitux® (cetuximab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.79	April 10, 2025	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Length of Authorization

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

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

CRC, Head and Neck, Squamous Cell Skin, Penile: Weekly	NSCLC- Every two weeks
– Load: 100 billable units x 1 dose	120 billable units every 14 days
– Maintenance Dose: 60 billable units every 7 days	120 billable dilits every 14 days

Guideline

I. Initial Approval Criteria

Coverage is provided in the following conditions:

1. Patient is 18 years or older; AND

1. Colorectal Cancer (CRC) †

- A. Patient meets ONE of the following (i, ii, **OR** iii):
 - i. Patient has advanced or metastatic disease and meets ONE of the following (a, b, c, **OR** d):
 - a. Patient meets ALL of the following [(1), (2), (3), AND (4)]:
 - 1) Tumor or metastases are KRAS, NRAS, and BRAF wild-type; **AND**Note: The tumor or metastases are KRAS/NRAS/BRAF mutation negative.
 - 2) The primary tumor originated on the left side of the colon; **AND**Note: Primary tumor originated from the splenic flexure to the rectum.
 - 3) Medication is used for initial treatment; AND
 - 4) Medication is used as a single agent or in combination with FOLFOX, CapeOX, or FOLFIRI; **OR**

<u>Note</u>: FOLFOX includes 5-fluorouracil; leucovorin, and oxaliplatin; CapeOX included capecitabine and oxaliplatin; and FOLFIRI includes 5-fluorouracil, leucovorin, and irinotecan.

- b. Patient meets ALL of the following [(1), (2), AND (3):
 - 1) Tumor or metastases are KRAS/NRAS/BRAF wild-type; **AND**Note: The tumor or metastases are KRAS, NRAS, and BRAF mutation negative.
 - 2) Medication is used for subsequent treatment; AND
 - 3) Medication is used as a single agent or in combination with irinotecan, FOLFOX, CapeOX, or FOLFIRI; **OR**

<u>Note</u>: FOLFOX includes 5-fluorouracil; leucovorin, and oxaliplatin; CapeOX included capecitabine and oxaliplatin; and FOLFIRI includes 5-fluorouracil, leucovorin, and irinotecan.

- c. Patient meets BOTH of the following [(1) AND (2)]:
 - 1) Tumor or metastases are BRAF V600E mutation-positive; AND
 - 2) Medication is used in combination with Braftovi (encorafenib capsules); OR
- d. Patient meets ALL of the following [(1), (2), AND (3)]:
 - 1) Tumor or metastases are KRAS G12C mutation positive; AND
 - Medication is used for subsequent therapy; AND
 <u>Note</u>: This is subsequent therapy following the initial diagnosis of colon or rectal cancer.
 - 3) Medication is used in combination with Lumakras (sotorasib tablets) or Krazati (adagrasib tablets); **OR**
- ii. Patient has unresectable synchronous liver and/or lung metastases and meets ALL of the following [(1), (2), (3), **AND** (4)]:

<u>Note</u>: Synchronous metastases are metastases that are diagnosed at the same time as or within a few months of the initial diagnosis of colon or rectal cancer.

- 1) Metastases are KRAS/NRAS/BRAF wild-type; **AND**Note: The metastases are KRAS, NRAS, and BRAF mutation negative.
- 2) The primary tumor originated on the left side of the colon; **AND**Note: Primary tumor originated from the splenic flexure to the rectum.
- 3) Medication is used for primary treatment; AND
- 4) Medication is used in combination with FOLFOX or FOLFIRI; **OR**<u>Note</u>: FOLFOX includes 5-fluorouracil, leucovorin, and oxaliplatin and FOLFIRI includes fluorouracil, leucovorin, and irinotecan.
- iii. Patient has unresectable metachronous metastases and meets ONE of the following (a, b, <u>OR</u> c):

<u>Note</u>: Metachronous metastases are metastases that are diagnosed months to years after the initial diagnosis of colon or rectal cancer.

- 1) Patient meets ALL of the following [(1), (2), AND (3)]:
 - i. Metastases are KRAS, NRAS, and BRAF wild-type; **AND**Note: The metastases are KRAS/NRAS/BRAF mutation negative.
 - ii. Medication is used for initial treatment; AND
 - iii. Medication is used in combination with irinotecan or FOLFIRI; **OR** *Note: FOLFIRI includes fluorouracil, leucovorin, and irinotecan.*
- 2) Patient meets ALL of the following [(1), (2), AND (3)]:
 - i. Metastases are BRAF V600E mutation positive; AND
 - ii. Medication is used for initial treatment; AND
 - iii. Medication is used in combination with Braftovi; OR
- 3) Patient meets ALL of the following [(1), (2), AND (3)]:
 - i. Metastases are KRAS G12C mutation positive; AND
 - ii. Medication is used for initial treatment; AND
 - iii. Medication is used in combination with Lumakras or Krazati

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

- A. Patient meets **ONE** of the following (i, ii, iii, iv **OR** v):
 - i. Erbitux will be used in combination with radiation therapy; **OR**
 - ii. Erbitux will be used in combination with platinum-based therapy; **OR**Note: Examples of platinum chemotherapy include cisplatin and carboplatin.
 - iii. Erbitux will be used in combination with paclitaxel or docetaxel; **OR**
 - iv. Erbitux will be used in combination with Keytruda (pembrolizumab intravenous infusion) or Opdivo (nivolumab intravenous infusion); **OR**
 - v. Erbitux will be used as a single agent.

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

- A. Patient meets **ONE** of the following (i, ii, iii, or iv):
 - i. Patient has locally advanced, high-risk, or very high-risk disease; OR
 - ii. Patient has unresectable, inoperable, or incompletely resected regional disease; OR
 - iii. Patient has local or regional recurrence; OR
 - iv. Patient has distant metastases

4. Penile Cancer ‡

- A. Patient must have metastatic disease; AND
- B. Must be used for subsequent treatment; AND
- C. Must be used as a single agent

5. Non-Small Cell Lung Cancer (NSCLC) ‡

- A. Patient has recurrent, advanced, or metastatic non-small cell lung cancer; AND
- B. Patient has a known sensitizing epidermal growth factor receptor (EGFR) mutation; **AND**<u>Note</u>: Examples of EGFR mutations include EGFR exon 19 deletion, or exon 21 L858R, or EGFR S768I, L861Q, and/or G719X mutation positive.
- C. Patient has received at least ONE tyrosine kinase inhibitor; **AND**<u>Note</u>: Examples of tyrosine kinase inhibitors include erlotinib tablets, Iressa (gefitinib tablets), or Gilotrif (afatinib tablets)
- D. Erbitux will be used in combination with Gilotrif (afatinib tablets)

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

**May also be used for progression on non-intensive therapy, except if received previous fluoropyrimidine, with improvement in functional status (Note: Colon cancer patients must have left-sided tumors only).

§ Colon cancer patients must have left-sided tumors only

II. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- 1. Patient continues to meet criteria identified above; AND
- 2. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; AND
- 3. 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.

III. Dosage/Administration

Indication	Dose	
Colorectal Cancer	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	In combination with 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)	
	Sequential systemic therapy/radiation:	
	400 mg/m² loading dose intravenously, then 250 mg/m² intravenously every 7 days	
	for up to 12 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	
	<u>OR</u>	
	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
Penile Cancer	days until disease progression or unacceptable toxicity

Limitations/Exclusions

Erbitux® (cetuximab) is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

C	Code	Description
J.	9055	Injection, cetuximab, 10 mg

Applicable NDCs

Code	Description	
66733-0948-xx	Erbitux 100 mg/50 mL single-use vial; solution for injection	
66733-0958-xx	Erbitux 200 mg/100 mL single-use vial; solution for injection	

ICD-10 Diagnoses

Code	Description		
C00.0	Malignant neoplasm of external upper lip		
C00.1	Malignant neoplasm of external lower lip		
C00.2	Malignant neoplasm of external lip, unspecified		
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		
C05.0	Malignant neoplasm of hard palate		
C05.1	Malignant neoplasm of soft palate		
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 foid, 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		
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		
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		
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C21.8 Malignant neoplasm of overlapping sites of rectum, anus and anal canal C31.0 Malignant neoplasm of nasal cavity C31.0 Malignant neoplasm of maxiliary sinus C31.1 Malignant neoplasm of ethmoidal sinus C32.0 Malignant neoplasm of ethmoidal sinus C32.0 Malignant neoplasm of supragiottis C32.1 Malignant neoplasm of supragiottis C32.2 Malignant neoplasm of supragiottis C32.3 Malignant neoplasm of supragiottis C32.3 Malignant neoplasm of laryngeal cartilage C32.8 Malignant neoplasm of laryngeal cartilage C32.9 Malignant neoplasm of overlapping sites of larynx C32.9 Malignant neoplasm of overlapping sites of larynx C32.9 Malignant neoplasm of siryngeal cartilage C32.0 Malignant neoplasm of rostabea C32.0 Malignant neoplasm of inaryngeal cartilage C32.0 Malignant neoplasm of inaryngeal cartilage C32.0 Malignant neoplasm of inaryngeal cartilage C34.00 Malignant neoplasm of upper lobe, unspecified C34.01 Malignant neoplasm of upper lobe, unspecified bronchus or lung C34.10 Malignant neoplasm of upper lobe, unspecified bronchus or lung C34.11 Malignant neoplasm of upper lobe, ight bronchus or lung C34.2 Malignant neoplasm of word upper lobe, unspecified bronchus or lung C34.30 Malignant neoplasm of lower lobe, unspecified bronchus or lung C34.31 Malignant neoplasm of overlobe punspecified bronchus and lung C34.32 Malignant neoplasm of lower lobe, left bronchus or lung C34.33 Malignant neoplasm of lower lobe, left bronchus or lung C34.34 Malignant neoplasm of overlapping sites of right bronchus and lung C34.80 Malignant neoplasm of overlapping sites of right bronchus and lung C34.90 Malignant neoplasm of overlapping sites of right bronchus and lung C34.91 Malignant neoplasm of overlapping sites of right bronchus and lung C34.92 Malignant neoplasm of overlapping sites of right bronchus or lung C34.91 Malignant neoplasm of overlapping sites of right bronchus or lung C34.92 Malignant neoplasm of overlapping sites of right bronchus or lung C34.92 Malignant neoplasm of overlapping sites of right bronchus or lung C34.91 Ma				
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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 C33.0 Malignant neoplasm of trachea C34.00 Malignant neoplasm of unspecified main bronchus 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 C34.13 Malignant neoplasm of indel lobe, bronchus or lung C34.2 Malignant neoplasm of lower lobe, left bronchus or lung C34.30 Malignant neoplasm of lower lobe, left bronchus or lung C34.31 Malignant neoplasm of lower lobe, left bronchus or lung C34.32 Malignant neoplasm of lower lobe, left bronchus or lung C34.33 Malignant neoplasm of lower lobe, left bronchus or lung C34.34 Malignant neoplasm of lower lobe, left bronchus or lung C34.30 Malignant neoplasm of lower lobe, left bronchus and lung C34.31 Malignant neoplasm of overlapping sites of right bronchus and lung C34.32 Malignant neoplasm of overlapping sites of right bronchus and lung C34.39 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 skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.03 Squamous cell carcinoma of skin of lip C44.04 Squamous cell carcinoma of skin of lip C44.05 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1221 Squamous cell carcinoma of skin of lipst eyelid, including canthus C44.1221 Squamous cell carcinoma of skin of right eyelid, including canthus C44.222 Squamous cell carcinoma of skin of right eyelid, including canthus	C32.0	Malignant neoplasm of glottis		
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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 C34.01 Malignant neoplasm of right main bronchus C34.02 Malignant neoplasm of left main bronchus C34.10 Malignant neoplasm of left main bronchus C34.11 Malignant neoplasm of upper lobe, unspecified bronchus or lung C34.12 Malignant neoplasm of upper lobe, left bronchus or lung C34.13 Malignant neoplasm of indele lobe, bronchus or lung C34.14 Malignant neoplasm of lower lobe, left bronchus or lung C34.15 Malignant neoplasm of lower lobe, unspecified bronchus or lung C34.16 Malignant neoplasm of lower lobe, right bronchus or lung C34.17 Malignant neoplasm of lower lobe, left bronchus or lung C34.20 Malignant neoplasm of lower lobe, left bronchus or lung C34.30 Malignant neoplasm of lower lobe, left bronchus or lung C34.31 Malignant neoplasm of lower lobe, left bronchus or lung C34.32 Malignant neoplasm of overlapping sites of unspecified bronchus and lung C34.33 Malignant neoplasm of overlapping sites of left bronchus and lung C34.40 Malignant neoplasm of unspecified part of unspecified bronchus or lung C34.90 Malignant neoplasm of unspecified part of left bronchus or lung C34.91 Malignant neoplasm of unspecified part of left bronchus or lung C34.92 Malignant neoplasm of unspecified part of left bronchus or lung C34.00 Unspecified malignant neoplasm of skin of lip C44.01 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.122 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.122 Squamous cell carcinoma of skin of unspecified ear and external auricular canal C44.222 Squamous cell carcinoma of skin of right eyelid, including canthus C44.222 Squamous cell carcinoma of skin of right eyelid, including canthus	C32.2	Malignant neoplasm of subglottis		
C32.9 Malignant neoplasm of larynx, unspecified C33 Malignant neoplasm of trachea C34.00 Malignant neoplasm of unspecified main bronchus C34.01 Malignant neoplasm of right main bronchus C34.02 Malignant neoplasm of left main bronchus C34.03 Malignant neoplasm of upper lobe, unspecified bronchus or lung C34.10 Malignant neoplasm of upper lobe, right bronchus or lung C34.11 Malignant neoplasm of upper lobe, left bronchus or lung C34.12 Malignant neoplasm of upper lobe, left bronchus or lung C34.2 Malignant neoplasm of lower lobe, unspecified bronchus or lung C34.30 Malignant neoplasm of lower lobe, right 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 C34.33 Malignant neoplasm of overlapping sites of unspecified bronchus and lung C34.80 Malignant neoplasm of overlapping sites of unspecified bronchus and lung C34.81 Malignant neoplasm of overlapping sites of left bronchus and lung C34.82 Malignant neoplasm of unspecified part of unspecified bronchus or lung C34.90 Malignant neoplasm of unspecified part of unspecified bronchus or lung C34.91 Malignant neoplasm of unspecified part of left bronchus or lung C34.92 Malignant neoplasm of unspecified part of left bronchus or lung C34.00 Unspecified malignant neoplasm of skin of lip C34.01 Squamous cell carcinoma of skin of lip C34.02 Squamous cell carcinoma of skin of lip C34.03 Squamous cell carcinoma of skin of lip C34.04 Squamous cell carcinoma of skin of lip C34.122 Squamous cell carcinoma of skin of left eyelid, including canthus C34.122 Squamous cell carcinoma of skin of left eyelid, including canthus C34.122 Squamous cell carcinoma of skin of left eyelid, including canthus C34.122 Squamous cell carcinoma of skin of right ear and external auricular canal	C32.3	Malignant neoplasm of laryngeal cartilage		
C33 Malignant neoplasm of trachea C34.00 Malignant neoplasm of unspecified main bronchus C34.01 Malignant neoplasm of right main bronchus C34.02 Malignant neoplasm of left main bronchus C34.00 Malignant neoplasm of left main bronchus C34.10 Malignant neoplasm of upper lobe, unspecified bronchus or lung C34.11 Malignant neoplasm of upper lobe, left bronchus or lung C34.12 Malignant neoplasm of upper lobe, left bronchus or lung C34.2 Malignant neoplasm of indidle lobe, bronchus or lung C34.30 Malignant neoplasm of lower lobe, unspecified bronchus or lung C34.31 Malignant neoplasm of lower lobe, left bronchus or lung C34.32 Malignant neoplasm of lower lobe, left bronchus or lung C34.33 Malignant neoplasm of lower lobe, left bronchus or lung C34.40 Malignant neoplasm of overlapping sites of unspecified bronchus and lung C34.80 Malignant neoplasm of overlapping sites of inght bronchus and lung C34.81 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 inght bronchus or lung C34.92 Malignant neoplasm of unspecified part of left bronchus or lung C34.00 Unspecified malignant neoplasm of skin of lip C34.01 Squamous cell carcinoma of skin of lip C34.02 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C34.122 Squamous cell carcinoma of skin of left eyelid, including canthus C34.122 Squamous cell carcinoma of skin of left eyelid, including canthus C34.122 Squamous cell carcinoma of skin of left eyelid, including canthus C34.122 Squamous cell carcinoma of skin of unspecified ear and external auricular canal	C32.8	Malignant neoplasm of overlapping sites of larynx		
C34.00 Malignant neoplasm of unspecified main bronchus 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 C34.3 Malignant neoplasm of lower lobe, unspecified bronchus or lung C34.3 Malignant neoplasm of lower lobe, ight bronchus or lung C34.3 Malignant neoplasm of lower lobe, left bronchus or lung C34.3 Malignant neoplasm of lower lobe, left bronchus or lung C34.3 Malignant neoplasm of overlapping sites of unspecified bronchus and lung C34.8 Malignant neoplasm of overlapping sites of left bronchus and lung C34.8 Malignant neoplasm of overlapping sites of left bronchus and lung C34.9 Malignant neoplasm of unspecified part of unspecified bronchus or lung C34.9 Malignant neoplasm of unspecified part of right bronchus or lung C34.9 Malignant neoplasm of unspecified part of left bronchus or lung C34.9 Malignant neoplasm of skin of lip C34.0 Unspecified malignant neoplasm of skin of lip C34.0 Squamous cell carcinoma of skin of lip C44.0 Squamous cell carcinoma of skin of lip C44.12 Squamous cell carcinoma of skin of right eyelid, including canthus C34.12 Squamous cell carcinoma of skin of left eyelid, including canthus C44.12 Squamous cell carcinoma of skin of left eyelid, including canthus C44.22 Squamous cell carcinoma of skin of unspecified ear and external auricular canal	C32.9	Malignant neoplasm of larynx, unspecified		
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, left 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, unspecified bronchus or lung C34.32 Malignant neoplasm of lower lobe, left bronchus or lung C34.33 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 left bronchus or lung C34.92 Malignant neoplasm of unspecified part of left bronchus or lung C34.00 Unspecified malignant neoplasm of skin of lip C44.00 Squamous cell carcinoma of skin of lip C44.122 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.122 Squamous cell carcinoma of skin of left eyelid, including canthus C44.222 Squamous cell carcinoma of skin of unspecified ear and external auricular canal	C33	Malignant neoplasm of trachea		
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, eright bronchus or lung C34.32 Malignant neoplasm of lower lobe, left bronchus or lung C34.33 Malignant neoplasm of lower lobe, left bronchus or lung C34.30 Malignant neoplasm of overlapping sites of unspecified bronchus and lung C34.80 Malignant neoplasm of overlapping sites of right bronchus and lung C34.81 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 C34.93 Malignant neoplasm of unspecified part of left bronchus or lung C34.90 Unspecified malignant neoplasm of skin of lip C34.00 Unspecified malignant neoplasm of skin of lip C34.01 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C34.02 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C34.122 Squamous cell carcinoma of skin of left eyelid, including canthus C34.122 Squamous cell carcinoma of skin of unspecified ear and external auricular canal	C34.00	Malignant neoplasm of unspecified 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 C34.30 Malignant neoplasm of overlapping sites of unspecified bronchus and lung C34.31 Malignant neoplasm of overlapping sites of right bronchus and lung C34.80 Malignant neoplasm of overlapping sites of left bronchus and lung C34.81 Malignant neoplasm of overlapping sites of left bronchus and lung C34.92 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 C34.92 Malignant neoplasm of skin of lip C44.00 Unspecified malignant neoplasm of skin of lip C44.01 Squamous cell carcinoma of skin of lip C44.02 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.122 Squamous cell carcinoma of skin of right eyelid, including canthus C44.122 Squamous cell carcinoma of skin of unspecified ear and external auricular canal C44.22 Squamous cell carcinoma of skin of unspecified ear and external auricular canal	C34.01	Malignant neoplasm of right main bronchus		
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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left 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	C34.02	Malignant neoplasm of left main bronchus		
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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left 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	C34.10	Malignant neoplasm of upper lobe, unspecified 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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left 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	C34.11	Malignant neoplasm of upper lobe, right 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 C44.00 Unspecified malignant neoplasm of skin of lip C44.01 Squamous cell carcinoma of skin of lip C44.02 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1221 Squamous cell carcinoma of skin of left eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left 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	C34.12	Malignant neoplasm of upper lobe, left 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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left eyelid, including canthus C44.129 Squamous cell carcinoma of skin of left 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	C34.2	Malignant neoplasm of middle lobe, bronchus or lung		
C34.80 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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.09 Other specified malignant neoplasm of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left eyelid, including canthus C44.1292 Squamous cell carcinoma of skin of left 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	C34.30	Malignant neoplasm of lower lobe, unspecified 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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left eyelid, including canthus C44.1292 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	C34.31	Malignant neoplasm of lower lobe, right bronchus or 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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.09 Other specified malignant neoplasm of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left eyelid, including canthus C44.1292 Squamous cell carcinoma of skin of left 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	C34.32	Malignant neoplasm of lower lobe, left bronchus or 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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.09 Other specified malignant neoplasm of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of right eyelid, including canthus C44.1292 Squamous cell carcinoma of skin of unspecified ear and external auricular canal C44.221 Squamous cell carcinoma of skin of right ear and external auricular canal	C34.80	Malignant neoplasm of overlapping sites of unspecified 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 C44.00 Unspecified malignant neoplasm of skin of lip C44.02 Squamous cell carcinoma of skin of lip C44.09 Other specified malignant neoplasm of skin of lip C44.1221 Squamous cell carcinoma of skin of unspecified eyelid, including canthus C44.1222 Squamous cell carcinoma of skin of left eyelid, including canthus C44.1292 Squamous cell carcinoma of skin of unspecified ear and external auricular canal C44.221 Squamous cell carcinoma of skin of right ear and external auricular canal	C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung		
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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	C44.1222	Squamous cell carcinoma of skin of right eyelid, including canthus		
C44.222 Squamous cell carcinoma of skin of right ear and external auricular canal	C44.1292	Squamous cell carcinoma of skin of left eyelid, including canthus		
<u> </u>	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	C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal		
C44.320 Squamous cell carcinoma of skin of unspecified parts of face	C44.320	Squamous cell carcinoma of skin of unspecified parts of face		
C44.321 Squamous cell carcinoma of skin of nose	C44.321	Squamous cell carcinoma of skin of nose		
C44.329 Squamous cell carcinoma of skin of other parts of face	C44.329	·		
C44.42 Squamous cell carcinoma of skin of scalp and neck	C44.42	Squamous cell carcinoma of skin of scalp and neck		
C44.520 Squamous cell carcinoma of anal skin	C44.520	Squamous cell carcinoma of anal skin		
C44.521 Squamous cell carcinoma of skin of breast	C44.521	Squamous cell carcinoma of skin of breast		
C44.529 Squamous cell carcinoma of skin of other part of trunk	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	C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder		

C44.622 Squamous cell carcinoma of skin of right upper limb, including shoulder 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 C60.0 Malignant neoplasm of prepuce C60.1 Malignant neoplasm of glans penis C60.2 Malignant neoplasm of body of penis C60.8 Malignant neoplasm of overlapping sites of penis C60.9 Malignant neoplasm of penis, unspecified C63.7 Malignant neoplasm of other specified male genital organs C63.8 Malignant neoplasm of overlapping sites of male genital organs C76.0 Malignant neoplasm of head, face and neck	
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C63.8 Malignant neoplasm of overlapping sites of male genital organs C76.0 Malignant neoplasm of head, face and neck	
C76.0 Malignant neoplasm of head, face and neck	
C77.0 Secondary and unspecified malignant neoplasm of lymph nodes 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	
D37.01 Neoplasm of uncertain behavior of lip	
D37.02 Neoplasm of uncertain behavior of tongue	
D37.05 Neoplasm of uncertain behavior of pharynx	
D37.09 Neoplasm of uncertain behavior of other specified sites of the oral cavity	·
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	
Z85.118 Personal history of other malignant neoplasm of bronchus and lung	

Revision History

Company(ies)	DATE	REVISION
EmblemHealth &	4/10/2025	Annual Review:
ConnectiCare		Updated dosages/administration Colon and Rectal Cancer: Add new option for approval for patients with unresectable synchronous liver and/or lung metastases. Added new option for approval for patients with unresectable metachronous metastases. Removed criterion that the tumor or metastases are wild-type BRAF and criterion that the patient has previously received a chemotherapy regimen for colon or rectal cancer. Removed unresectable from criterion that the patient has advanced or metastatic disease and meets one of the following. Added BRAF to criterion that the tumor or metastases are KRAS/NRAS/BRAF mutation negative; and added medication is for initial therapy and medication is used in combination with FOLFOX, CapeOX, or FOLFIRI to condition of approval. Added condition of approval for the subsequent treatment of KRAS/NRAS/BRAF mutation negative disease. Added condition of approval for BRAF V600E mutation positive disease. Added condition of approval for KRAS G12C mutation positive disease. As a single

agent added to the requirement that the medication is used as a single agent or in combination with FOLFOX, CapeOX, or FOLFIRI. Removed requirement that the medication is used for subsequent treatment. This is subsequent therapy following the initial diagnosis of colon or rectal cancer added as a Note. Added synchronous metastases are metastases that are diagnosed at the same time as or within a few months of the initial diagnosis of colon or rectal cancer as a Note. Added metachronous metastases are metastases that are diagnosed months to years after the initial diagnosis of colon or rectal cancer.

Head and Neck Squamous Cell Carcinoma: Added new option of approval for Erbitux to be used in combination with paclitaxel or docetaxel. Added Keytruda (pembrolizumab intravenous infusion) to option of approval Erbitux will be used in combination with Keytruda (pembrolizumab intravenous infusion) or Opdivo (nivolumab intravenous infusion).

Appendiceal Adenocarcinoma: Added new condition of approval.

Penile Cancer: Added recurrent to requirement that the patient has recurrent or metastatic disease.

EmblemHealth & ConnectiCare

3/13/2024

Annual Review: Initial Criteria: Colorectal Cancer (CRC) †

Removed and modified: "Will not be used as part of an adjuvant treatment regimen; AND Patient has not been previously treated with cetuximab or panitumumab; AND Patient must have progressive, metastatic, or unresectable advanced disease AND Used in combination with irinotecan- or oxaliplatinbased 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 Used as primary treatment; AND Used in combination with FOLFIRI †; OR Used in combination with CapeOx or FOLFOX §; AND Used in combination with an irinotecan-based regimen after previous adjuvant FOLFOX or CapeOX within the past 12 months §; OR Used as subsequent therapy; AND Used in combination with irinotecan for irinotecan-refractory disease †; OR Used in combination with irinotecan for oxaliplatin-refractory disease §; OR Used in combination with FOLFIRI for oxaliplatin-refractory disease §**; OR Used in combination with FOLFOX for irinotecan-refractory disease §**; OR Used as a single agent for oxaliplatin- and/or irinotecan-refractory disease OR irinotecan-intolerant disease; OR Patient 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 progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; ORUsed as primary treatment for unresectable metastatic disease after previous adjuvant FOLFOX or CapeOX within the past 12 months"

To Read: "The primary tumor originated on the left side of the colon (from splenic flexure to rectum); AND Patient meets ONE of the following (i or ii):

Patient's tumor or metastases are wild-type BRAF (that is, the tumor or metastases are BRAF V600E mutation-negative); OR Patient's tumor or metastases are BRAF V600E mutation-positive and the patient meets BOTH of the following (a and b): Patient has previously received a chemotherapy regimen for colon or rectal cancer; AND Note: Examples of chemotherapy regimens include a fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine, oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin). Erbitux is prescribed in combination with Braftovi (encorafenib capsules); AND" Squamous Cell Carcinoma of the Head and Neck (SCCHN) †

Modified: "Used in one of the following regimens: †" to read: "Patient meets ONE of the following (i, ii, iii, or iv):"

Added: "Erbitux will be used in combination with Opdivo (nivolumab intravenous infusion); OR" Removed: "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 Oral Cavity (including mucosal 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 ‡, Cetuximab may also be used as one of the following:— Firstline or subsequent therapy as a single agent for non-nasopharyngeal cancer, — Subsequent therapy in combination with platinum-based therapy for nonnasopharyngeal cancer, – Sequential systemic therapy/radiation as a single agent in patients with non-nasopharyngeal cancer following induction or combination systemic therapy, – Subsequent therapy in combination with carboplatin for nasopharyngeal cancer, Occult Primary, Cetuximab may also be used as a single agent as sequential systemic therapy/radiation after induction chemotherapy for one of the following:- Poorly differentiated or nonkeratinizing squamous cell, anaplastic (not thyroid), squamous cell carcinoma, or not otherwise specified (NOS) histology ‡, – p16 (HPV)-positive disease" Non-melanoma Skin Cancer (Basal Cell Skin Cancer and Squamous Cell Skin Cancer) ‡Removed or modified: "For regional recurrence or distant metastases" To read: "Patient meets ONE of the following (i, ii, iii, or iv): Patient has locally advanced, high-risk, or very high-risk disease; OR Patient has unresectable, inoperable, or incompletely resected regional disease; OR Patient has local or regional recurrence; OR Patient has distant metastases" Non-Small Cell Lung Cancer (NSCLC) ‡ Removed or modified: "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 has multiple symptomatic systemic lesions; AND Patient has T790M negative disease; OR Patient has T790M positive disease and progressed on osimertinib therapy" To Read: "Patient has recurrent, advanced, or metastatic non-small cell lung cancer; AND Patient has a known sensitizing epidermal growth factor receptor (EGFR) mutation; AND Note: Examples of EGFR mutations include EGFR exon 19 deletion, or exon 21 L858R, or EGFR S768I, L861Q, and/or G719X mutation positive. Patient has received at least ONE tyrosine kinase inhibitor; AND Note: Examples of tyrosine kinase inhibitors include erlotinib tablets, Iressa (gefitinib tablets), or Gilotrif (afatinib tablets) Erbitux will be used in combination with Gilotrif (afatinib tablets)" Jpdated dosage chart Annual Review: EmblemHealth & 7/5/2023 Colorectal Cancer (CRC) † Initial Criteria; Removed_"Patient must have ConnectiCare progressive, metastatic, or unresectable advanced disease; AND i. 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 a. Used as a single agent therapy for metastatic disease †; AND

- Patient has previously failed on an oxaliplatin- and irinotecan-based regimen; OR
- A. Patient is unable to tolerate irinotecan"

Added "Patient has metastatic, unresectable (or medically inoperable), or advanced disease that is BRAF mutation negative (wild-type); AND

- i. Used as primary treatment; AND
 - a. Used in combination with FOLFIRI †; OR
 - b. Used in combination with FOLFOX §; OR
 - Used in combination with an irinotecan-based regimen after previous adjuvant FOLFOX or CapeOX within the past 12 months §; OR
- ii. Used as subsequent therapy; AND
 - Used in combination with irinotecan for irinotecanrefractory disease †; OR
 - Used in combination with irinotecan for oxaliplatinrefractory disease §; OR
 - Used in combination with FOLFIRI for oxaliplatinrefractory disease §**; OR
 - d. Used in combination with FOLFOX for irinotecanrefractory disease §**; **OR**
 - e. Used as a single agent for oxaliplatin- and/or irinotecanrefractory disease **OR** irinotecan-intolerant disease; **OR**
- iii. Patient has BRAF V600E mutation positive disease as determined by an FDA-approved
 - or CLIA-compliant test* †; AND
 - a. Used in combination with encorafenib; AND
 - Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; OR
 - Used as primary treatment for unresectable metastatic disease after previous adjuvant FOLFOX or CapeOX within the past 12 months"

Squamous Cell Carcinoma of the Head and Neck (SCCHN) † Initial Criteria: Replaced "Cancer of the Lip" with "Cancer of the Oral Cavity (including mucosal lip)"

- a. Removed "Cetuximab may also be used as a single agent for sequential chemoradiation ‡" and added "
- a. Cetuximab may also be used as one of the following:
 - First-line or subsequent therapy as a single agent for nonnasopharyngeal cancer
 - Subsequent therapy in combination with platinum-based therapy for nonnasopharyngeal cancer
 - Sequential systemic therapy/radiation as a single agent in patients with non-nasopharyngeal cancer following induction or combination systemic therapy
 - Subsequent therapy in combination with carboplatin for nasopharyngeal cancer
- 1. Occult Primary
 - a. Cetuximab may also be used as a single agent as sequential systemic therapy/radiation after induction chemotherapy for one of the following:
 - Poorly differentiated or nonkeratinizing squamous cell, anaplastic (not thyroid), squamous cell

		carcinoma, or not otherwise specified (NOS) histology ‡ — p16 (HPV)-positive disease" Removed "Occult Primary Head and Neck Cancers ‡ 1. Must be used as initial treatment as a single agent with sequential
		Chemoradiation " Non-Small Cell Lung Cancer (NSCLC) ‡
		Removed "Patient is T790M negative and has multiple symptomatic systemic lesions"
		Added "Patient has multiple symptomatic systemic lesions; AND
		 Patient has T790M negative disease; OR
		 Patient has T790M positive disease and progressed on osimertinib therapy"
		Updated dosage chart
EmblemHealth & ConnectiCare	4/26/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	1/1/2020	Annual review

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