ATRIO HEALTH PLANS

Chemotherapy: Colorectal Cancer Drugs
Erbitux (cetuximab) J9055, Vectibix (panitumumab) J9303, Zaltrap (ziv-aflibercept) J9400
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

Zaltrap

- ☐ Patient has a diagnosis of metastatic colon, rectal, colorectal, appendiceal, or anal adenocarcinoma;
- ☐ The Patient is resistant to or has disease progression following treatment with an oxaliplatin-containing regimen;
- ☐ Ziv-aflibercept will be used in combination with an irinotecan based regimen;
- ☐ Ziv-aflibercept will be given in a single line of therapy.

- Requests for Zaltrap (ziv-aflibercept) may not be approved for the following:
  - Ziv-aflibercept is given concomitantly with cetuximab, panitumumab, or bevacizumab (or bevacizumab biosimilar); OR
  - Ziv-aflibercept is used in combination with the same irinotecan-based regimen that was previously used in combination with bevacizumab (or bevacizumab biosimilar);

Erbitux

- ☐ Diagnosis of colon, rectal, colorectal, appendix or anal adenocarcinoma and the following are met:
  - ☐ Individual has advanced or metastatic disease;
  - ☐ Extended RAS gene mutation testing is confirmed and the tumor is determined to be RAS wild-type+;
  - ☐ Cetuximab is used as a single agent or as part of combination therapy;
  - ☐ Individual has not received prior treatment with panitumumab*;
  - ☐ Cetuximab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab);
  - ☐ Cetuximab is used in a single line of therapy**;

  +Note: RAS wild-type means that the KRAS and NRAS genes are normal or lacking mutations

- ☐ Diagnosis of colon, rectal, colorectal, appendix or anal adenocarcinoma and the following are met:
  - ☐ Individual has advanced or metastatic disease;
  - ☐ Gene mutation testing is confirmed, and the tumor is determined to be BRAF wild-type ++;
  - ☐ Individual is being treated for left-sided only tumors;
  - ☐ Cetuximab is used as a single agent or as part of combination therapy;
  - ☐ Individual has not received prior treatment with panitumumab*;
  - ☐ Cetuximab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab);
  - ☐ Cetuximab is used in a single line of therapy **;

  ++Note: BRAF wild-type means that the BRAF gene is normal or lacking mutations

- ☐ Diagnosis of unresectable, advanced, or metastatic colorectal cancer and the following are met:
  - ☐ Individual has BRAF V600E mutation with test results confirmed;
  - ☐ Cetuximab is used in combination with encorafenib;
  - ☐ Individual has demonstrated disease progression after one or more prior lines of systemic therapy;
  - ☐ Individual has not received prior treatment with panitumumab*;
  - ☐ Cetuximab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab);
  - ☐ Cetuximab is used in a single line of therapy **;

- ☐ Diagnosis of squamous cell carcinoma of the head and neck (SCCHN), and the following are met:
  - ☐ Individual has not received prior treatment with panitumumab*;
  - ☐ Cetuximab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab);
  - ☐ Cetuximab is used in a single line of therapy**;
  - ☐ Cetuximab is used in one of the following indications:
    - ☐ In combination with radiation therapy, for the initial treatment of locally or regionally advanced disease; OR
    - ☐ As a single agent for the treatment of individuals with recurrent or metastatic disease for whom prior platinum-based therapy has failed; OR
    - ☐ In combination with platinum-based therapy with 5-FU (fluorouracil) as first-line treatment for individuals with recurrent locoregional disease or metastatic SCCHN; OR
    - ☐ As a single agent or in combination therapy with or without radiation therapy for any of the following indications:
      - ☐ Unresectable locoregional recurrence; OR
      - ☐ Second primary in individuals who have received prior radiation therapy; OR

☐ Resectable locoregional recurrence in individuals who have not received prior radiation therapy; OR

☐ Distant metastases;

☐ Diagnosis of squamous cell skin carcinoma, and the following are met:

- ☐ Individual has unresectable or locally advanced disease, regional recurrence, or distant metastatic disease;
- ☐ Individual has not received prior treatment with panitumumab*;
- ☐ Cetuximab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab);
- ☐ Cetuximab is used in a single line of therapy**

Vectibix

☐ Diagnosis of stage IV colon, rectal, colorectal, appendiceal, or anal adenocarcinoma & the following are met:

- ☐ Panitumumab is used as a single agent or as part of combination therapy;
- ☐ Extended RAS gene mutation testing with an FDA approved test is confirmed and the tumor is determined to be RAS wild-type (RAS wild-type means that the KRAS and NRAS genes are normal or lacking muctations);
- ☐ Panitumumab is used in a single line of therapy;
- ☐ Panitumumab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab);

☐ Diagnosis of unresectable, advanced, or metastatic colorectal cancer and the following are met:

- ☐ Individual has BRAF V600E mutation with test results confirmed;
- ☐ Individual has demonstrated disease progression after one or more prior lines of systemic therapy;
- ☐ Panitumumab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab);
- ☐ Panitumumab is used in a single line of therapy

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Oncology: Colorectal Cancer Drugs PA

Drug Name(s):

ERBITUX	**CETUXIMAB**
VECTIBIX	**PANITUMUMAB**
ZALTRAP	**ZIV-AFLIBERCEPT**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months
Continuation: Approval will be for 12 months

FDA Indications:

Erbitux

- Metastatic colorectal cancer, KRAS wild-type, EGFR-expressing, as monotherapy, in patients intolerant to irinotecan-based chemotherapy
- Metastatic colorectal cancer, KRAS wild-type, EGFR-expressing, as monotherapy in patients who failed both irinotecan- and oxaliplatin-based regimens
- Metastatic colorectal cancer, KRAS wild-type, EGFR-expressing, first-line therapy, in combination with FOLFIRI (irinotecan, 5-fluorouracil, and leucovorin)
- Metastatic colorectal cancer, KRAS wild-type, EGFR-expressing, in combination with irinotecan, in patients refractory to irinotecan-based chemotherapy
- Squamous cell carcinoma of head and neck, Locally or regionally advanced disease, in combination with radiation therapy
- Squamous cell carcinoma of head and neck, Metastatic or recurrent disease, as monotherapy, in patients who failed prior platinum-based therapy
- Squamous cell carcinoma of head and neck, Metastatic or recurrent disease, first-line therapy, in combination with platinum-based chemotherapy with 5-fluorouracil

Vectibix

- Metastatic colorectal cancer, Wild-type RAS (wild-type in both KRAS and NRAS), first-line therapy, in combination with infusional fluorouracil, leucovorin, and oxaliplatin (FOLFOX regimen)
- Metastatic colorectal cancer, Wild-type RAS (wild-type in both KRAS and NRAS), progression following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

Zaltrap

- Metastatic colorectal cancer, In combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), in patients whose disease is resistant to or has progressed following an oxaliplatin-based regimen

Off-Label Uses:

Erbitux

- Gastric cancer
- Malignant neoplasm of cardio-esophageal junction of stomach
- Metastatic colorectal cancer, EGFR-expressing, in combination with irinotecan, in patients who failed both fluoropyrimidine- and oxaliplatin-based regimens
- Metastatic colorectal cancer, Refractory, non-epidermal growth factor receptor (EGFR) expressing
- Squamous cell carcinoma of head and neck, Metastatic or recurrent disease, refractory to platinum-based therapy, as combination therapy

Vectibix

- Metastatic colorectal cancer, Wild-type KRAS mutation, second-line therapy following fluoropyrimidine-containing chemotherapy, in combination with fluorouracil, leucovorin, and irinotecan (FOLFIRI regimen)
- Non-small cell lung cancer, Advanced

Age Restrictions:

Safety and effectiveness not established in pediatric patients

Other Clinical Considerations:

Cancer diagnoses: Criteria as per NCCN or other FDA-approved cancer related guidelines.

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/50B6A9/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/304A33/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=928013&contentSetId=100&title=Cetuximab&servicesTitle=Cetuximab&brandName=Erbitux&UserMdxSearchTerm=ERBITUX&=null#

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