ALYMSYS (bevacizumab-maly) AVASTIN (bevacizumab) MVASI (bevacizumab-awwb) ZIRABEV (bevacizumab-bvzr) Clover Health MedB QSet

- 1. Is the product being requested for the treatment of either of the following:
 - Ocular disorder
 - Oncology indication
 - a. Ocular disorder Go to #2
 - b. Oncology indication Go to #3
- 2. The only product for which coverage is provided for ocular indications is Avastin. Is this request for Alymsys, Mvasi, or Zirabev for an ocular disorder?
 - a. Yes Deny
 - b. No Approve for 12 months (enter authorization for Avastin only)
- 3. The preferred products for which coverage is provided for oncology indications are Mvasi and Zirabev. Can the patient's treatment be switched to a preferred product?
 - a. This request is for Mvasi and Zirabev Go to #100
 - b. Yes, the treatment can be switched to Mvasi and Zirabev Go to #100
 - c. No, proceed with Avastin or Alymsys request Go to #4
- 4. Has the patient received treatment with the requested product in the past 365 days? *Internal Note: If 'Yes,' please review the past 365 days of the patient's claim history.*
 - a. Yes Go to #100
 - b. No Go to #5
- 5. Does the patient have a documented intolerable adverse event to both of the preferred products (Mvasi and Zirabev) that was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)? **Action Required:** If 'Yes', attach supporting chart note(s).
 - a. Yes Go to #100
 - b. No Deny

Oncology

- 100. Is the patient currently receiving requested drug?
 - a. Yes \rightarrow Go to #101
 - b. No \rightarrow Go to #108

Continuation of Therapy – Oncology

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101. Is the patient participating in any of the clinical trials listed in the table below?

Study ID #	Study Title
C80405	Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5FU/Leucovorin with Bevacizumab, or Cetuximab, or with the combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum
E2204	An Intergroup Randomized Phase II Study of Bevacizumab or Cetuximab in Combination with Gemcitabine and in Combination with Chemoradiation (Capecitabine and Radiation) in Patients with Completely-Resected Pancreatic Carcinoma
E4203	Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer
E5202	Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers
E5204	Intergroup Randomized Phase III Study of Post-Operative Oxaliplatin, 5-Fluorouracil and Leucovorin with or without Bevacizumab in Patients with Stage II or III Rectal Cancer Receiving Pre-Operative Radiation and a 5-Fluorouracil-Based Regimen
NSABP-R-04	A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum
RTOG-0522	Phase III Trial of Concurrent Accelerated Radiation & Cisplatin vs Concurrent Accelerated Radiation, Cisplatin, & Cetuximab (Followed by Surgery for Selected Patients) for Stage III & IV Head & Neck Carcinomas
S0502	Phase III Randomized Study of Imatinib, with or without Bevacizumab, in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors
7325	Dose-Dense and Dose-Intense Alternating Irinotecan/Capecitabine & Oxaliplatin/Capecitabine: Phase I in Solid Tumors and Phase II with Bevacizumab as First-Line Therapy of Advanced Colorectal Cancer

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- a. Yes → Approve for 12 months
- b. No \rightarrow Go to #102
- 102. What is the patient's diagnosis?
 - a. Colorectal cancer → Go to #106
 - b. Non-small cell lung cancer → Go to #106
 - c. Central nervous system cancer → Go to #103
 - d. Central nervous system necrosis due to exposure to ionizing radiation → Go to #107
 - e. Renal cell cancer → Go to #106
 - f. Malignant pleural mesothelioma → Go to #106
 - g. Cervical cancer → Go to #106
 - h. Vaginal cancer → Go to #106
 - i. Ovarian cancer → Go to #104
 - j. Fallopian tube cancer → Go to #106
 - k. Primary peritoneal cancer → Go to #106
 - I. Soft tissue sarcoma \rightarrow Go to #105
 - m. Endometrial carcinoma→ Go to #106
 - n. Uterine neoplasms → Go to #106
 - o. Breast cancer → Go to #106
 - p. Hepatocellular carcinoma → Go to #106
 - g. Gastric cancer → Go to #106
 - r. Liver cancer → Go to #106
 - s. Small bowel adenocarcinoma, including advanced ampullary cancer → Go to #106
 - t. Vulvar squamous cell carcinoma → Go to #106
 - u. Peritoneal mesothelioma → Go to #106
 - v. Pericardial mesothelioma → Go to #106
 - w. Tunica vaginalis testis mesothelioma → Go to #106
 - x. Other \rightarrow *Deny*
- 103. Which of the following subtypes classifies the disease?
 - a. Glioblastoma→ Go to #106
 - Intracranial and spinal ependymoma (excludes subependymoma) → Go to #106
 - c. Anaplastic glioma → Go to #106
 - d. Low-grade (WHO Grade 1 or 2) glioma → Go to #106
 - e. Medulloblastoma → Go to #106
 - f. Primary central nervous system lymphoma → Go to #106
 - g. Meningiomas \rightarrow Go to #106
 - h. Limited and extensive brain metastases → Go to #106
 - i. Metastatic spine tumors → Go to #106
 - j. Other \rightarrow *Deny*
- 104. Which of the following subtypes classifies the disease?
 - a. Clear cell carcinoma → Go to #106
 - b. Epithelial ovarian cancer → Go to #106
 - c. Carcinosarcoma (malignant mixed Mullerian tumors) → Go to #106
 - d. Malignant sex cord-stromal tumors → Go to #106
 - e. Mucinous carcinoma → Go to #106

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- f. Serous carcinoma → Go to #106
- g. Endometrioid carcinoma → Go to #106
- h. Borderline epithelial tumors (low malignant potential) with invasive implants → Go to #106
- i. Other → *Deny*
- 105. Which of the following subtypes classifies the disease?
 - a. Angiosarcoma \rightarrow Go to #106
 - b. Solitary fibrous tumor/hemangiopericytoma → Go to #106
 - c. Other \rightarrow *Deny*
- 106. Is the patient receiving benefit from therapy, defined as no evidence of unacceptable toxicity and no evidence of disease progression while on the current regimen?
 - a. Yes \rightarrow Approve for 12 months
 - b. No \rightarrow *Deny*
- 107. Is the patient receiving benefit from therapy?
 - a. Yes → Approve for 3 months
 - b. No \rightarrow *Deny*

New Start - Oncology

108. Is the patient participating in any of the clinical trials listed in the table below?

Study ID #	Study Title
C80405	Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5FU/Leucovorin with Bevacizumab, or Cetuximab, or with the combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum
E2204	An Intergroup Randomized Phase II Study of Bevacizumab or Cetuximab in Combination with Gemcitabine and in Combination with Chemoradiation (Capecitabine and Radiation) in Patients with Completely-Resected Pancreatic Carcinoma
E4203	Phase II Study of Treatment Selection Based Upon Tumor Thymidylate Synthase Expression in Previously Untreated Patients with Metastatic Colorectal Cancer
E5202	Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers

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E5204	Intergroup Randomized Phase III Study of Post-Operative Oxaliplatin, 5-Fluorouracil and Leucovorin with or without Bevacizumab in Patients with Stage II or III Rectal Cancer Receiving Pre-Operative Radiation and a 5-Fluorouracil-Based Regimen
NSABP-R-04	A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum
RTOG-0522	Phase III Trial of Concurrent Accelerated Radiation & Cisplatin vs Concurrent Accelerated Radiation, Cisplatin, & Cetuximab (Followed by Surgery for Selected Patients) for Stage III & IV Head & Neck Carcinomas
S0502	Phase III Randomized Study of Imatinib, with or without Bevacizumab, in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors
7325	Dose-Dense and Dose-Intense Alternating Irinotecan/Capecitabine & Oxaliplatin/Capecitabine: Phase I in Solid Tumors and Phase II with Bevacizumab as First-Line Therapy of Advanced Colorectal Cancer

- a. Yes → Approve for 12 months
- b. No \rightarrow Go to #109

109. What is the patient's diagnosis?

- Colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma → Approve for 12 months
- b. Non-squamous non-small cell lung cancer → Go to #118
- c. Central nervous system cancer → Go to #110
- d. Central nervous system necrosis due to ionizing radiation → Approve for 3 months
- e. Renal cell cancer → Go to #119
- f. Malignant pleural mesothelioma \rightarrow Go to #122
- g. Cervical cancer \rightarrow Go to #120
- h. Vaginal cancer → Go to #120
- i. Ovarian cancer → Go to #111
- j. Fallopian tube cancer → *Approve for 12 months*
- k. Primary peritoneal cancer \rightarrow Approve for 12 months
- I. Soft tissue sarcoma \rightarrow Go to #112
- m. Endometrial carcinoma → Go to #121
- n. Uterine neoplasms→ Go to #121
- o. Breast cancer → Go to #123
- p. Hepatocellular carcinoma → Go to #115
- q. Gastric cancer \rightarrow Approve for 12 months
- r. Liver cancer → *Approve for 12 months*
- s. Small bowel adenocarcinoma, including advanced ampullary cancer \rightarrow Approve for 12 months

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- t. Vulvar cancer → Go to #124
- u. Peritoneal mesothelioma → Approve for 12 months
- v. Pericardial mesothelioma → Approve for 12 months
- w. Tunica vaginalis testis mesothelioma → Approve for 12 months
- x. Other \rightarrow *Deny*
- 110. Which of the following subtypes classifies the disease?
 - a. Glioblastoma→ Approve for 12 months
 - b. Intracranial and spinal ependymoma (excludes subependymoma) → Approve for 12 months
 - c. Anaplastic glioma → Approve for 12 months
 - d. Low-grade (WHO Grade 1 or 2) glioma→ Approve for 12 months
 - e. Medulloblastoma → *Approve for 12 months*
 - f. Primary central nervous system lymphoma → *Approve for 12 months*
 - g. Meningiomas \rightarrow *Approve for 12 months*
 - h. Limited and extensive brain metastases → *Approve for 12 months*
 - i. Metastatic spine tumors → *Approve for 12 months*
 - j. Other \rightarrow **Deny**
- 111. Which of the following subtypes classifies the disease?
 - a. Clear cell carcinoma → Approve for 12 months
 - b. Epithelial ovarian cancer → *Approve for 12 months*
 - c. Carcinosarcoma (malignant mixed Mullerian tumors) → *Approve for 12 months*
 - d. Malignant sex cord-stromal tumors → Approve for 12 months
 - e. Mucinous carcinoma → *Approve for 12 months*
 - f. Serous carcinoma \rightarrow Approve for 12 months
 - g. Endometrioid carcinoma → *Approve for 12 months*
 - h. Borderline epithelial tumors (low malignant potential) with invasive implants → Approve for 12 months
 - i. Other → *Deny*
- 112. Which of the following subtypes classifies the disease?
 - a. Angiosarcoma \rightarrow Go to #113
 - b. Solitary fibrous tumor/hemangiopericytoma → Go to #114
 - c. Other \rightarrow *Deny*
- 113. Will the requested medication be given as single agent therapy?
 - a. Yes \rightarrow Approve for 12 months
 - b. No \rightarrow *Deny*
- 114. Will the requested medication be given in combination with temozolomide?
 - a. Yes \rightarrow Approve for 12 months
 - b. No \rightarrow *Deny*
- 115. Will the requested drug be used in combination with atezolizumab?
 - a. Yes \rightarrow Go to #116
 - b. No \rightarrow *Deny*
- 116. What is the place in therapy in which the requested drug will be used?

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- a. Initial treatment \rightarrow Go to #117
- b. Subsequent treatment \rightarrow *Deny*
- 117. Does the patient have unresectable or metastatic disease?
 - a. Unresectable disease → *Approve for 12 months*
 - b. Metastatic disease → *Approve for 12 months*
 - c. None of the above $\rightarrow Deny$
- 118. Does the patient have recurrent, unresectable, advanced, or metastatic disease?
 - a. Recurrent disease → *Approve for 12 months*
 - b. Unresectable disease → *Approve for 12 months*
 - c. Advanced disease → Approve for 12 months
 - d. Metastatic disease → *Approve for 12 months*
 - e. None of the above $\rightarrow Deny$
- 119. Does the patient have relapsed or stage IV disease?
 - a. Relapsed disease → *Approve for 12 months*
 - b. Stage IV disease → Approve for 12 months
 - c. None of the above \rightarrow *Deny*
- 120. Does the patient have persistent, recurrent, or metastatic disease?
 - a. Persistent disease → Approve for 12 months
 - b. Recurrent disease → *Approve for 12 months*
 - c. Metastatic disease → Approve for 12 months
 - d. None of the above $\rightarrow Deny$
- 121. Does the patient have progressive, advanced, recurrent, or metastatic disease?
 - a. Progressive disease → Approve for 12 months
 - b. Advanced disease → *Approve for 12 months*
 - c. Recurrent disease → Approve for 12 months
 - d. Metastatic disease → Approve for 12 months
 - e. None of the above \rightarrow *Deny*
- 122. Will the requested medication be given for first-line treatment in combination with pemetrexed and either cisplatin or carboplatin, followed by single agent maintenance therapy?
 - a. Yes \rightarrow Approve for 12 months
 - b. No \rightarrow *Deny*
- 123. Does the patient have recurrent or metastatic disease?
 - a. Recurrent disease → *Approve for 12 months*
 - b. Metastatic disease → *Approve for 12 months*
 - c. None of the above $\rightarrow Deny$
- 124. Does the patient have unresectable locally advanced, recurrent, or metastatic disease?

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C22121-A

- a. Unresectable locally advanced disease → Approve for 12 months
- b. Recurrent disease → Approve for 12 months
- c. Metastatic disease → Approve for 12 months
- d. None of the above \rightarrow *Deny*

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