

## AVASTIN (bevacizumab)

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**Line(s) of Business:**

HMO; PPO; QUEST Integration  
Medicare Advantage

**Original Effective Date:**

10/01/2015

**Current Effective Date:**

12/01/2018

### POLICY

#### A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indications

- Epithelial ovarian, fallopian tube or primary peritoneal cancer
  - In combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for stage III or IV disease following initial surgical resection
  - Platinum-resistant disease in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan
  - Platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, either in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by Avastin as a single agent
- Cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan in persistent, recurrent, or metastatic disease
- Metastatic colorectal cancer:
  - In combination with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment
  - In combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line Avastin-containing regimen
- Non-squamous non-small cell lung cancer (NSCLC), with carboplatin and paclitaxel for first line treatment of unresectable, locally advanced, recurrent or metastatic disease
- Glioblastoma, as a single agent for adult patients with recurrent disease
- Metastatic renal cell carcinoma with interferon alfa

#### Compendial Uses

- AIDS-related Kaposi Sarcoma
  - Subsequent systemic therapy given with antiretroviral therapy (ART) for relapsed/refractory advanced, cutaneous, oral, visceral, or nodal disease that has progressed on or not responded to first-line systemic therapy, and progressed on alternate first line systemic therapy
- Breast cancer

- in combination with paclitaxel for recurrent or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-negative disease
  - with symptomatic visceral disease or visceral crisis
  - that is hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory
- Central nervous system (CNS) cancers
  - Adult intracranial and spinal ependymoma, as single agent treatment for progression of recurrent disease
  - Anaplastic gliomas, treatment for recurrent disease as a single agent or in combination with irinotecan, carmustine, lomustine, or temozolomide, if bevacizumab monotherapy fails
  - Glioblastoma treatment for recurrent disease as a single agent or in combination with irinotecan, carmustine, lomustine, or temozolomide, if bevacizumab fails.
- Cervical cancer, first line or second line therapy (if not previously used as first line) in combination with paclitaxel and cisplatin, carboplatin, or topotecan or second line therapy for local regional recurrence or Stage IVB or distant metastases
- Colon/rectal cancer,
  - in combination with capecitabine or with FOLFOX (fluorouracil, leucovorin, and oxaliplatin), FOLFIRI (fluorouracil, leucovorin, and irinotecan), CapeOX (capecitabine and oxaliplatin), FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan), or 5-FU/LV (fluorouracil and leucovorin) regimen
    - as primary treatment for locally unresectable or medically inoperable disease
    - for unresectable synchronous liver and/or lung metastases that remain unresectable after primary systemic therapy
    - as primary treatment for synchronous abdominal/peritoneal metastases that are nonobstructing, or following local therapy for patients with imminent or existing obstruction
    - for synchronous unresectable metastases of other sites
    - as primary treatment for unresectable metachronous metastases in patients who have not received previous adjuvant FOLFOX or CapeOX within the past 12 months, who have received previous fluorouracil/leucovorin (%-FU/LV) or capecitabine therapy, or who have not received any previous chemotherapy
    - for unresectable metachronous metastases that remain unresectable after primary treatment
  - initial treatment for unresectable synchronous liver and/or lung metastases in combination with
    - FOLFOX (fluorouracil, leucovorin, and oxaliplatin) regimen
    - FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen
    - FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin and irinotecan) regimen
    - CapeOX (capecitabine and oxaliplatin) regimen
  - preferred anti-angiogenic therapy as primary treatment for patients with unresectable metachronous metastases and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months
    - in combination with irinotecan
    - in combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen

- subsequent therapy after first progression of unresectable advanced or metastatic disease
  - as the preferred anti-angiogenic agent in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen for disease previously treated with oxaliplatin-based therapy without irinotecan
  - in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) regimen for disease previously treated with irinotecan-based therapy without oxaliplatin
  - as the preferred anti-angiogenic agent in combination with irinotecan or FOLFIRI for patients previously treated with fluoropyrimidine therapy without irinotecan or oxaliplatin
  - in combination with FOLFOX, CapeOX, or irinotecan and oxaliplatin for patients previously treated with fluoropyrimidine therapy without irinotecan or oxaliplatin
- Endometrial carcinoma
  - Single agent for disease that has progressed on prior cytotoxic chemotherapy
- Non Squamous Non-Small Cell Lung Cancer
  - Treatment in combination with carboplatin and paclitaxel or pemetrexed or in combination with cisplatin and pemetrexed for recurrence or metastases in patients with performance status 0-1, tumors of nonsquamous cell histology, and no history of recent hemoptysis as
    - initial cytotoxic therapy for EGFR, ALK, ROS1, BRAF, and negative or unknown, and PD-L1 <50% or unknown
    - first-line or subsequent therapy for BRAF V600E-mutation positive tumors
    - subsequent therapy for sensitizing EGFR mutation-positive tumors and prior erlotinib, afatinib, gefitinib, or osimertinib therapy
    - subsequent therapy for ALK rearrangement-positive tumors and prior crizotinib, ceritinib, alectinib, or brigatinib therapy
    - subsequent therapy for ROS1 rearrangement-positive tumors and prior crizotinib or ceritinib therapy
    - subsequent therapy for PD-L1 expression-positive (≥50%) tumors and EGFR, ALK, ROS1, and BRAF negative or unknown and prior pembrolizumab therapy
  - Continuation maintenance therapy if given first line with chemotherapy for recurrence or metastasis in patients with performance status 0-2, tumors of nonsquamous cell histology, and no history of recent hemoptysis who achieve tumor response or stable disease following initial cytotoxic therapy
    - as a single agent
    - in combination with pemetrexed if previously used with a first-line pemetrexed/platinum chemotherapy regimen
- Malignant pleural mesothelioma
  - Used in combination with cisplatin and pemetrexed followed by single-agent maintenance bevacizumab as treatment of
    - unresectable clinical stage I-III disease and tumors of epithelial histology
    - clinical stage IV disease, tumors of sarcomatoid or mixed histology, or medically inoperable tumors in patients with performance status (PS) 0-2
- Epithelial Ovarian cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer

- Neoadjuvant chemotherapy in combination with paclitaxel and carboplatin for bulky stage III-IV disease or poor surgical candidates
- In combination with paclitaxel and carboplatin as
  - Primary treatment for patients with incomplete previous surgery and/or staging with stage II-IV and suspected unresectable residual disease
  - Primary adjuvant therapy for pathologic stage II-IV disease
- Postremission maintenance therapy as a single agent if used previously as part of a combination therapy, for patients with partial or complete remission following
  - Primary therapy for stage II-IV disease
  - Recurrence for platinum-sensitive disease
- Preferred therapy for persistent disease or recurrence
  - If platinum-sensitive in combination with carboplatin and gemcitabine
  - If platinum-sensitive, in combination with carboplatin and paclitaxel
  - If platinum-resistant, in combination with liposomal doxorubicin, weekly paclitaxel, or topotecan
  - As a single agent
- Preferred adjuvant treatment in combination with carboplatin and paclitaxel for pathologic stage I-IV disease or stage II-IV disease
- Adjuvant treatment for pathologic stage II-IV disease in combination with
  - Carboplatin and paclitaxel
  - Fluorouracil, leucovorin, and oxliplatin
  - Capecitabine and oxaliplatin
- Adjuvant treatment in combination with carboplatin and paclitaxel for pathologic stage II-IV low grade serous/grade 1 endometrioid epithelial carcinoma or borderline epithelial tumors with invasive implants
- Single agent for clinical relapse in patients with stage II-IV disease
- Renal Cancer
  - For relapse or stage IV disease
    - in combination with interferon alfa-2b as first-line therapy for predominant clear cell histology
    - as single-agent systemic therapy for non-clear cell histology
    - in combination with erlotinib or everolimus for selected patients with advanced papillary renal cell carcinoma including hereditary leiomyomatosis and renal cell cancer (HLRCC)
- Soft tissue sarcoma
  - Angiosarcoma as a single agent
  - Solitary Fibrous Tumor/Hemangiopericytoma in combination with temozolomide

## B. REQUIRED DOCUMENTATION

The following information may be necessary to initiate the prior authorization review:

- All approvable oncologic diagnoses
  - Current oncology notes, clinical notes (including previous treatment history), and any pertinent pathology reports and/or imaging studies
- All approvable oncologic diagnoses for continuation therapy

- Documentation demonstrating lack of disease progression on therapy
- Breast cancer
  - Human epidermal growth factor receptor 2 (*HER2*) test result
  - Hormone receptor (HR) test result
- NSCLC
  - Documentation of previous treatment history where applicable

#### **C. PRESCRIBER RESTRICTION**

- All approvable oncologic diagnoses
  - Avastin must be prescribed by an oncologist.

#### **D. CRITERIA FOR APPROVAL**

##### **1. Breast cancer**

Authorization of 3 months may be granted to members who are prescribed Avastin in combination with paclitaxel for the treatment of *HER2*-negative recurrent or stage IV (M1) breast cancer when members have ANY of the following types of disease:

- a. Symptomatic visceral disease
- b. Disease with visceral crisis
- c. HR-negative disease
- d. HR-positive disease refractory to endocrine therapy

##### **2. Cervical cancer**

Authorization of 3 months may be granted for the treatment of persistent, recurrent, or metastatic cervical cancer when Avastin is prescribed in ONE of the following regimens:

- a. Avastin, cisplatin and paclitaxel
- b. Avastin, topotecan and paclitaxel

Authorization of 3 months may be granted for the treatment of local regional recurrence or Stage IVB or distant metastases cervical cancer in ONE of the following regimens:

- a. Second line (if not used previously as first line) for Avastin with paclitaxel and cisplatin
- b. Second line (if not used previously as first line) for Avastin with paclitaxel and carboplatin
- c. Second line (if not used previously as first line) for Avastin with topotecan

##### **3. CNS cancer**

###### **3.1. Glioblastoma and anaplastic glioma**

Authorization of 3 months may be granted to members who are prescribed Avastin as a single agent for recurrent disease or in combination with irinotecan, carmustine, lomustine, or temozolomide, if bevacizumab monotherapy fails.

###### **3.2. Adult intracranial and spinal ependymoma (excludes subependymoma)**

Authorization of 3 months may be granted to members who are prescribed Avastin as a single agent for disease progression.

##### **4. Colorectal cancer**

- a. Authorization of 3 months may be granted to members who are prescribed Avastin as adjuvant therapy in combination with FOLFOX, FOLFIRI, CapeOX, FOLFOXIRI, or 5-FU with leucovorin.

- b. Authorization of 3 months may be granted to members who are prescribed Avastin in combination with irinotecan or FOLFIRI for unresectable metastases with previous adjuvant FOLFOX or CapeOX therapy within the past 12 months.
- c. Authorization of 3 months may be granted to members who are prescribed Avastin in combination with capecitabine, FOLFOX, CapeOX, FOLFIRI, FOLFOXIRI, or 5-FU with leucovorin for advanced or metastatic disease.
- d. Authorization of 3 months may be granted when Avastin is prescribed after first progression of unresectable advanced or metastatic disease as ONE of the following:
  - i. In combination with FOLFIRI or irinotecan for members who were previously treated with an oxaliplatin-based regimen without irinotecan,
  - ii. In combination with FOLFOX or CapeOX for members who were previously treated with an irinotecan-based regimen without oxaliplatin,
  - iii. In combination with FOLFOX, CapeOX, irinotecan, irinotecan and oxaliplatin, or FOLFIRI for members who were treated with 5-FU with leucovorin or capecitabine regimen.

CapeOX = capecitabine and oxaliplatin; FOLFIRI = leucovorin, fluorouracil, and irinotecan; FOLFOX = leucovorin, fluorouracil, and oxaliplatin; FOLFOXIRI = leucovorin, fluorouracil, oxaliplatin, and irinotecan.

## 5. Endometrial cancer

Authorization of 3 months may be granted to members who are prescribed Avastin as a single agent and who have progressed on prior cytotoxic chemotherapy.

## 6. Ovarian cancer

### 6.1 Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer

- a. Authorization of 3 months may be granted to members who have persistent or recurrent disease and Avastin will be used in ONE of the following regimens:
  - i. In combination with carboplatin and paclitaxel, for stage III or IV disease following initial surgical resection or
  - ii. As a single agent
  - iii. In combination with liposomal doxorubicin, paclitaxel, or topotecan, or
  - iv. In combination with carboplatin and either paclitaxel or gemcitabine
- b. Authorization of 3 months may be granted to members who are using Avastin in combination with paclitaxel and carboplatin as neoadjuvant chemotherapy in bulky stage III-IV disease or poor surgical candidates
- c. Authorization of 3 months may be granted to members who are using Avastin in combination with paclitaxel and carboplatin as primary treatment for patients with incomplete previous surgery and/or staging with stage II-IV and suspected unresectable residual disease or primary adjuvant therapy for pathologic stage II-IV disease
- d. Authorization of 3 months may be granted to members who are using Avastin as a single agent if previously as part of a combination therapy for patients with partial or complete remission following primary therapy for stage II-IV disease or recurrence for platinum-sensitive disease
- e. Authorization of 3 months may be granted when Avastin is used as preferred therapy for persistent disease or recurrence in ONE of the following regimens:

- i. If platinum sensitive with Avastin in combination with carboplatin and gemcitabine
  - ii. If platinum sensitive with Avastin in combination with carboplatin and paclitaxel
  - iii. If platinum resistant with Avastin in combination with liposomal doxorubicin, weekly paclitaxel, or topotecan
  - iv. Avastin as a single agent
- f. Authorization of 3 months may be granted when Avastin is used in combination with carboplatin and paclitaxel as preferred adjuvant therapy in pathological stage I-IV disease or stage II-IV disease
- g. Authorization of 3 months may be granted when Avastin is used for adjuvant treatment for pathological stage II-IV disease when used in ONE of the following regimens:
  - i. Avastin and carboplatin with paclitaxel
  - ii. Avastin and fluorouracil, leucovorin with oxaliplatin
  - iii. Avastin and capecitabine with oxaliplatin
- h. Authorization of 3 months may be granted when Avastin is used for pathologic stage II-IV low grade serous/grade 1 endometrial epithelial carcinoma or borderline epithelial tumors with invasive implants as adjuvant treatment in combination with carboplatin and paclitaxel
- i. Authorization of 3 months may be granted when Avastin is used as a single agent for clinical relapse in patients with stage II-IV disease.

## 6.2 Malignant sex cord-stromal tumors

Authorization of 3 months may be granted to members in clinical relapse with stage II-IV disease.

## 7. NSCLC

- a. The disease is unresectable, locally advanced, recurrent, or metastatic.
- b. Member has ECOG performance status (PS) 0-1 (first-line/subsequent therapy) or PS 0-2 (continuation maintenance), tumors of non-squamous cell histology, and no history of recent hemoptysis.
- c. Authorization of 3 months may be granted to members who are prescribed Avastin in combination with carboplatin and paclitaxel or pemetrexed or with cisplatin and pemetrexed who meet one of the following:
  - i. For tumors with negative/unknown EGFR mutations, ALK gene rearrangements, ROS1 rearrangements or PD-L1 expression ( $\geq 50\%$ ) Avastin will be used as a first-line therapy (see section d. below for continuation maintenance).
  - ii. For tumors with sensitizing EGFR mutations:
    - 1) Avastin will be used as a subsequent therapy AND
    - 2) Member experienced disease progression on prior erlotinib (Tarceva), afatinib (Gilotrif), gefitinib (Iressa) or osimertinib (Tagrisso) therapy.
  - iii. For ALK-positive tumors:
    - 1) Avastin will be used as a subsequent therapy AND
    - 2) Member experienced disease progression on prior crizotinib (Xalkori), ceritinib (Zykadia), brigatinib (Alunbrig) or alectinib (Alecensa) therapy.
  - iv. For ROS1-positive tumors:
    - 1) Avastin will be used as a subsequent therapy AND
    - 2) Member experienced disease progression on prior crizotinib (Xalkori) therapy.
  - v. For PD-L1 expression-positive ( $\geq 50\%$ ) tumors:
    - 1) Avastin will be used as a subsequent therapy AND
    - 2) Member experienced disease progression on prior pembrolizumab (Keytruda) therapy.

- d. Authorization of 3 months may be granted to members who are prescribed Avastin as a continuation maintenance therapy when ALL of the following criteria are met:
  - i. Members have achieved tumor response or stable disease following first-line chemotherapy.
  - ii. Avastin will be used as a single agent or in combination with pemetrexed if previously used with a first-line pemetrexed/platinum chemotherapy regimen.

## **8. Renal cell carcinoma**

Authorization of 3 months may be granted for the treatment of relapsed, metastatic, or stage IV renal cell carcinoma when Avastin will be used as ONE of the following:

- a. Avastin in combination with interferon alfa-2
- b. Avastin monotherapy for disease with non-clear cell histology
- c. Avastin in combination with interferon alfa-2b for predominant clear cell histology
- d. Avastin in combination with erlotinib or everolimus for advanced papillary renal cell carcinoma including hereditary leiomyomatosis and renal cell cancer (HLRCC)

## **9. Soft tissue sarcoma**

### **9.1. Angiosarcoma**

Authorization of 3 months may be granted to members who are prescribed Avastin as a single agent.

### **9.2. Solitary fibrous tumor/hemangiopericytoma**

Authorization of 3 months may be granted to members who are prescribed Avastin in combination with temozolomide.

## **10. Malignant pleural mesothelioma**

Authorization of 3 months may be granted to members who are prescribed Avastin for the treatment of malignant pleural mesothelioma when criteria a. and b. below are met:

- a. Member has one of the following:
  - Unresectable or medically in operable clinical stage I to III disease with epithelial or mixed histology
  - Clinical stage IV disease
  - Tumor with sarcomatoid histology
  - Medically inoperable disease in patients with an ECOG Performance status of 0 - 2
- b. Avastin is used as a single agent for maintenance therapy or is used in combination with pemetrexed (Alimta) and cisplatin

## **11. AIDS-related Kaposi Sarcoma**

Authorization of 3 months may be granted to members using Avastin as subsequent therapy with antiretroviral therapy (ART) for relapsed, refractory advanced, cutaneous, oral, visceral, or nodal disease that has progressed on or not responded to first line systemic therapy and progressed on alternate first line systemic therapy.

## **E. CONTINUATION OF THERAPY**

1. No previous authorization/precertification:

All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.

2. Reauthorization:



a. **All approvable oncologic diagnosis except colorectal cancer**

Members who were previously approved for Avastin by HMSA/CVS may request reauthorizations after their initial approval. Approval for an additional 3 months may be granted if the following information is supplied:

- A current oncology note documenting the patient's response to treatment showing no progression of disease
- Current imaging studies and other objective measures showing no progression of disease when compared with previous results

b. **Colorectal cancer**

Authorization of 3 months may be granted to members requesting continuation of therapy when Avastin was previously authorized by HMSA/CVS and after first progression of unresectable advanced or metastatic disease and cancer progressed on a first-line Avastin-containing regimen as ONE of the following:

- i. In combination with FOLFIRI or irinotecan for members who were previously treated with an oxaliplatin-based regimen,
- ii. In combination with FOLFOX or CapeOX for members who were previously treated with an irinotecan-based regimen, OR
- iii. In combination with FOLFOX, CapeOX, irinotecan, irinotecan and oxaliplatin, or FOLFIRI for members who were treated with 5-FU with leucovorin or capecitabine regimen.

**F. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**G. PROGRAM EXCEPTION – MEDICARE ADVANTAGE**

For Medicare Advantage members, the following National Coverage Determination (NCD) applies:

- Anti-Cancer Chemotherapy for Colorectal Cancer (110.17).

**H. ADMINISTRATIVE GUIDELINES**

Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

**I. IMPORTANT REMINDER**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes 432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with

HMSA/CVS's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

## J. REFERENCES

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## Document History

10/01/2015	Original effective date
12/07/2016	Annual update/label update (expanded ovarian cancer indications)
05/01/2017	Revision effective date
08/2017	Annual Review
03/01/2018	Revision effective date
06/11/2018	Updated Policy/label update
07/18/2018	Removed ophthalmic disorders
08/2018	Annual Review date
12/01/2018	Revision effective date
12/01/2018	NO PA required for ophthalmic disorders