SPECIALTY GUIDELINE MANAGEMENT

AVASTIN (bevacizumab) MVASI (bevacizumab-awwb)

POLICY

I. 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.

A. FDA-Approved Indications

- 1. Metastatic colorectal cancer (mCRC)
 - a. Avastin, in combination with intravenous 5-fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer.
 - b. Avastin, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line Avastin-containing regimen.
- 2. First-line non-squamous non-small cell lung cancer (NSCLC)
 Avastin, in combination with carboplatin and paclitaxel, is indicated for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer.
- 3. Recurrent glioblastoma (RGM)
 - Avastin is indicated for the treatment of recurrent glioblastoma in adults.
- 4. Metastatic renal cell carcinoma (mRCC)
 - Avastin, in combination with interferon alfa, is indicated for the treatment of metastatic renal cell carcinoma.
- 5. Persistent, recurrent, or metastatic cervical cancer
 - Avastin, in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer.
- 6. Epithelial ovarian, fallopian tube, or primary peritoneal cancer
 - a. Avastin, in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, is indicated for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection.
 - b. Avastin, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, is indicated for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.
 - c. Avastin, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Avastin as a single agent, is indicated for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

B. Compendial Uses

- 1. Breast cancer for recurrent or stage IV (M1) human epidermal growth factor receptor 2 (HER2)negative disease
- 2. Central nervous system (CNS) cancers
 - a. Adult low-grade (WHO Grade II) infiltrative supratentorial astrocytoma/oligodendroglioma
 - b. Adult intracranial and spinal ependymoma (excluding subependymoma)
 - c. Anaplastic gliomas
 - d. Adult medulloblastoma
 - e. Primary central nervous system lymphoma

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- f. Meningiomas
- g. Limited and extensive brain metastases
- h. Leptomeningeal metastases
- i. Metastatic spine tumors
- 3. Malignant pleural mesothelioma
- 4. Ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer
 - a. Carcinosarcoma (malignant mixed Müllerian tumors)
 - b. Clear cell carcinoma
 - c. Mucinous carcinoma
 - d. Low-grade serous/grade 1 endometrioid epithelial carcinoma
 - e. Malignant sex cord-stromal tumors
- 5. Soft tissue sarcoma
 - a. Angiosarcoma
 - b. Solitary fibrous tumor/Hemangiopericytoma
- 6. AIDS-related Kaposi sarcoma
- 7. Uterine/Endometrial cancer
- 8. Vulvar cancer
- 9. Ophthalmic disorders
 - a. Diabetic macular edema
 - b. Neovascular (wet) age-related macular degeneration (AMD)
 - c. Macular edema following retinal vein occlusion (RVO)
 - d. Proliferative diabetic retinopathy
 - e. Choroidal neovascularization (CNV)
 - f. Neovascular glaucoma; adjunct
 - g. Retinopathy of prematurity

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Ophthalmic disorders

Authorization of 24 months may be granted for the following retinal disorders:

- 1. Diabetic macular edema
- 2. Neovascular (wet) age-related macular degeneration including subtypes:
 - a. Polypoidal choroidopathy
 - b. Retinal angiomatous proliferation
- 3. Macular edema following retinal vein occlusion
- 4. Proliferative diabetic retinopathy
- 5. Choroidal neovascularization
- 6. Neovascular glaucoma
- 7. Retinopathy of prematurity

B. Colorectal cancer (CRC)

Authorization of 12 months may be granted for the treatment of colorectal cancer.

C. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for the treatment of non-squamous NSCLC.

D. CNS cancer

Authorization of 12 months may be granted for treatment of the following types of CNS cancer:

- 1. Glioblastoma
- 2. Adult intracranial and spinal ependymoma (excludes subependymoma)

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- 3. Anaplastic glioma
- 4. Adult low-grade (WHO Grade II) infiltrative supratentorial astrocytoma/oligodendroglioma
- 5. Adult medulloblastoma
- 6. Primary central nervous system lymphoma
- 7. Meningiomas
- 8. Limited and extensive brain metastases
- 9. Leptomeningeal metastases
- 10. Metastatic spine tumors

E. Ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer

Authorization of 12 months may be granted for the treatment of the following types of ovarian fallopian tube cancer/primary peritoneal cancer:

- 1. Epithelial ovarian cancer
- 2. Fallopian tube cancer
- 3. Primary peritoneal cancer
- 4. Carcinosarcoma (malignant mixed Müllerian tumors)
- 5. Clear cell carcinoma
- 6. Mucinous carcinoma
- 7. Low-grade serous/grade 1 endometrioid epithelial carcinoma
- 8. Malignant sex cord-stromal tumors

F. Uterine/Endometrial cancer

Authorization of 12 months may be granted for the treatment of uterine cancer or endometrial cancer.

G. Cervical cancer

Authorization of 12 months may be granted for the treatment of cervical cancer.

H. Breast cancer

Authorization of 12 months may be granted for treatment of breast cancer.

I. Renal cell carcinoma

Authorization of 12 months may be granted for the treatment of renal cell carcinoma.

J. Soft tissue sarcoma

Authorization of 12 months may be granted for the treatment of the following types of soft tissue sarcoma:

- 1. AIDS-related Kaposi sarcoma
- 2. Angiosarcoma
- 3. Solitary fibrous tumor/hemangiopericytoma

K. Malignant Pleural Mesothelioma

Authorization of 12 months may be granted for the treatment of malignant pleural mesothelioma.

L. AIDS-related Kaposi sarcoma

Authorization of 12 months may be granted for the treatment of AIDS-related Kaposi sarcoma.

M. Vulvar cancer

Authorization of 12 months may be granted for the treatment of vulvar cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

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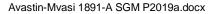
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