



NOW APPROVED

Avastin[®] (bevacizumab), solution for intravenous infusion, is now approved in combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.¹

Avastin plus chemotherapy demonstrated statistically significant overall survival (OS) in the GOG 240 study.

With a 16.8-month median OS (vs 12.9 months), Avastin plus chemotherapy* demonstrated a statistically significant increase in OS vs chemotherapy alone in the GOG 240 study (HR=0.74 [95% CI, 0.58-0.94], P=0.0132)¹

*Chemotherapy included either paclitaxel and cisplatin or paclitaxel and topotecan.

Select Codes for Your Reference ¹⁻⁶	
NDC	50242-060-01 – 100 mg/4 mL single-use vial 50242-061-01 – 400 mg/16 mL single-use vial
ICD-9 Codes	 180.0 – Malignant neoplasm of the endocervix 180.1 – Malignant neoplasm of the exocervix 180.8 – Malignant neoplasm of other specified sites of cervix 180.9 – Malignant neoplasm of cervix uteri, unspecified site
CPT [®] Codes	 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug 96415 - Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure) 96417 - Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (list separately in addition to code for primary procedure)
HCPCS Code	J9035 – Injection, bevacizumab, 10 mg

CPT, Current Procedural Terminology (CPT®); HCPCS, Healthcare Common Procedure Coding System; ICD-9, International Classification of Diseases, Ninth Revision, Clinical Modification; NDC, National Drug Code.

These codes are provided for informational purposes only. Correct coding is the responsibility of the provider submitting the claim for the item or service.

- Avastin Access Solutions[®] offers services to help you navigate the access and reimbursement process. Our dedicated, in-house specialists help bring patient treatment and practice solutions together
- Customers can access Avastin through authorized specialty pharmacies and freestanding infusion centers if a patient is covered by a commercial healthcare plan. To find out which specialty pharmacies may be available based on the patient's insurance, please contact Avastin Access Solutions at (888) 249-4918
- Avastin is available through an authorized network of specialty distributors and wholesalers via the Avastin distribution model. Please visit <u>http://www.Genentech-Access.com/Avastin</u> for more information on the network
- For more information, please contact your Field Reimbursement Manager or submit your inquiry at <u>http://www.gene.com/contact-us/email-us</u>



To speak live with one of our dedicated Specialists for patient access support, please call (888) 249-4918, 6 a.m. – 5 p.m. PT, Monday through Friday. Or, visit Genentech-Access.com/Avastin for more information.

IMPORTANT SAFETY INFORMATION

Boxed WARNINGS

- Gastrointestinal (GI) perforation
 - Serious and sometimes fatal GI perforation occurs at a higher incidence in
 - Avastin-treated patients compared to controls
 - The incidences of GI perforation ranged from 0.3% to 3.2% across clinical studies
 - $-\,$ Discontinue Avastin in patients with GI perforation
- Surgery and wound healing complications
 - The incidence of wound healing and surgical complications, including serious and fatal complications, is increased in Avastin-treated patients
 - Do not initiate Avastin for at least 28 days after surgery and until the surgical wound is fully healed. The appropriate interval between termination of Avastin and subsequent elective surgery required to reduce the risks of impaired wound healing/wound dehiscence has not been determined
 - Discontinue Avastin at least 28 days prior to elective surgery and in patients with wound healing complications requiring medical intervention

Hemorrhage

- Severe or fatal hemorrhage, including hemoptysis,
 GI bleeding, hematemesis, central nervous system
 hemorrhage, epistaxis, and vaginal bleeding, occurred up to
 5-fold more frequently in patients receiving Avastin. Across
 indications, the incidence of grade ≥3 hemorrhagic events
 among patients receiving Avastin ranged from 0.4% to 6.9%
- − Do not administer Avastin to patients with serious hemorrhage or recent hemoptysis (\geq 1/2 tsp of red blood)
- Discontinue Avastin in patients with serious hemorrhage (ie, requiring medical intervention)

Please see following page and accompanying Prescribing Information for additional important safety information.

IMPORTANT SAFETY INFORMATION (continued)

Additional serious adverse events

- · Additional serious and sometimes fatal adverse events with increased incidence in the Avastin-treated arm vs control included
 - GI fistulae (up to 2%)
 - Non-GI fistulae (≤1.8%)
 - − Arterial thromboembolic events (grade \geq 3, 2.6%)
 - Proteinuria (nephrotic syndrome, <1%)
- Additional serious adverse events with increased incidence in the Avastin-treated arm vs control included
 - GI-vaginal fistulae occurred in 8.2% of patients in a cervical cancer trial
 - Venous thromboembolism (grade 3–4, up to 10.6%) in patients with persistent, recurrent, or metastatic cervical cancer treated with Avastin
 - Hypertension (grade 3-4, 5%-18%)
 - Posterior reversible encephalopathy syndrome (PRES) (<0.5%)

- Proteinuria

Back pain

- Infusion reactions with the first dose of Avastin were uncommon (<3%), and severe reactions occurred in 0.2% of patients
- Inform females of reproductive potential of the risk of ovarian failure prior to starting treatment with Avastin

Most common adverse events

- Across indications, the most common adverse reactions observed in Avastin patients at a rate >10% and at least twice the control
 arm rate were
 - Epistaxis
 - Taste alteration

- Lacrimation disorder
 Hypertension
- Dry skin

Headache

- Exfoliative dermatitis Rhinitis
- Rectal hemorrhage
- Across all studies, Avastin was discontinued in 8.4% to 21% of patients because of adverse reactions

Pregnancy warning

- Avastin may impair fertility
- Based on animal data, Avastin may cause fetal harm
- Advise patients of the potential risk to the fetus during and following Avastin and the need to continue adequate contraception for at least 6 months following the last dose of Avastin
- For nursing mothers, discontinue nursing or Avastin, taking into account the importance of Avastin to the mother

Indication-specific adverse events

In CC, grade 3 or 4 adverse reactions in study GOG 240, occurring at a higher incidence (≥2%) in 218 patients receiving chemotherapy plus Avastin compared to 222 patients receiving chemotherapy alone, were abdominal pain (11.9% vs 9.9%), diarrhea (5.5% vs 2.7%), anal fistula (3.7% vs 0%), proctalgia (2.8% vs 0%), urinary tract infection (8.3% vs 6.3%), cellulitis (3.2% vs 0.5%), fatigue (14.2% vs 9.9%), hypertension (11.5% vs 0.5%), thrombosis (8.3% vs 2.7%), hypokalemia (7.3% vs 4.5%), hyponatremia (3.7% vs 1.4%), dehydration (4.1% vs 0.5%), neutropenia (7.8% vs 4.1%), lymphopenia (6.0% vs 3.2%), back pain (5.5% vs 3.2%), and pelvic pain (5.5% vs 1.4%). There were no grade 5 adverse reactions occurring at a higher incidence (≥2%) in patients receiving chemotherapy plus Avastin compared to patients receiving chemotherapy alone

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Please see accompanying full Prescribing Information, including **Boxed WARNINGS**, for additional important safety information.

References: 1. Avastin® (bevacizumab) full prescribing information. Genentech, Inc., August 2014. 2. ICD9Data. Malignant neoplasm of cervix uteri. http://www.icd9data .com/2014/Volume1/140-239/179-189/180/default.htm. ICD9Data Website. Accessed August 7, 2014. 3. American Medical Association. https://ocm.ama-assn.org/OCM /CPTRelativeValueSearchResults.do?locality=7&keyword=96413. American Medical Association CodeManager Website. Accessed August 7, 2014. 4. American Medical Association. https://ocm.ama-assn.org/OCM/CPTRelativeValueSearchResults.do?locality=7.keyword=96415. American Medical Association CodeManager Website. Accessed August 7, 2014. 5. American Medical Association. https://ocm.ama-assn.org/OCM/CPTRelativeValueSearchResults.do?locality=7.keyword=96415. American Medical Association CodeManager Website. Accessed August 7, 2014. 6. ICD9Data. 2013 HCPCS J9035. http://www.icd9data.com/HCPCS/2014/J/J9035.htm. ICD9Data Website. Accessed August 7, 2014.



