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Clinical Policy: Bevacizumab (Alymsys, Avastin, <u>Avzivi</u>, Mvasi, Vegzelma, Zirabey)

Reference Number: LA.PHAR.93

Effective Date: 04.21 Last Review Date: 06.27.23 Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description

Bevacizumab (Avastin®) and its biosimilars [bevacizumab-maly (Alymsys®), bevacizumab-tnjn (Avzivi®), bevacizumab-awwb (Mvasi®), bevacizumab-bvzr (Zirabev[™]), bevacizumab-maly (Alymsys®), and bevacizumab-adcd (Vegzelma[™]), bevacizumab-bvzr (Zirabev[™])] are vascular endothelial growth factor-specific angiogenesis inhibitors.

FDA Approved Indication(s)

Avastin, Mvasi, Zirabev, Alymsys, and Avzivi, Mvasi, Vegzelma, and Zirabev are indicated for the treatment of:

- Metastatic colorectal cancer, (CRC), in combination with intravenous 5-fluorouracil (5-FU)-based chemotherapy for first- or second-line treatment
- Metastatic eolorectal cancerCRC, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC), in combination with carboplatin and paclitaxel for first-line treatment
- · Recurrent glioblastoma in adults
- Metastatic renal cell carcinoma (RCC) in combination with interferon alfa
- Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer:
 - In combination with carboplatin and paclitaxel, followed by Avastin/Mvasi/Zirabev/Vegzelma <u>Zirabev</u> as a single agent, for stage III or IV disease following initial surgical resection
 - In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens
 - In combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Avastin/Mvasi/Zirabev/Vegzelma/<u>Zirabev</u> as a single agent, for platinum-sensitive recurrent disease

Avastin is also indicated for the treatment of:

 Hepatocellular carcinoma (HCC) in combination with atezolizumab for patients with unresectable or metastatic HCC who have not yet received prior systemic therapy.

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Limitation(s) of use: Bevacizumab-_products are not indicated for adjuvant treatment of colon cancer.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Avastin, Mvasi, Zirabev, Alymsys, and Avzivi, Mvasi, Vegzelma, and Zirabev are medically necessary when the following criteria are met:

I. Initial Approval Criteria

- A. FDA-Approved Indications (must meet all):
 - 1. Diagnosis of one of the following (a-g):
 - a. Colorectal cancer;
 - b. NSCLS:
 - a. CRC;
 - b. Non-squamous NSCLC;
 - c. Glioblastoma;
 - d. Metastatic RCC;
 - e. Cervical cancer;
 - f. Epithelial ovarian, fallopian tube, or primary peritoneal cancer;
 - g. HCC;
 - 2. Prescribed by or in consultation with an oncologist;
 - 3. Age \geq 18 years;
 - 4. Member meets one of the following (a-g):
 - a. For colorectal cancer, CRC, disease is advanced, metastatic, or unresectable and bevacizumab is used in combination with one of the following (i-vi):
 - i. 5-FU/leucovorin or capecitabine-based chemotherapy;
 - ii. Irinotecan IROX (irinotecan and oxaliplatin;);
 - iii. FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin);
 - iv. Irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan);
 - v. FOLFIRINOX (fluorouracil, leucovorin, irinotecan, and oxaliplatin);
 - vi. Lonsurf® if previously progressed through all available regimens;
 - b. For recurrent, advanced, or metastatic non-squamous NSCLC, prescribed as one of the following (i-v):
 - i. Single agent therapy;
 - ii. In combination with carboplatin and paclitaxel for first line treatment;
 - iii. In combination with pemetrexed;
 - iv. In combination with Tecentriq®;
 - v. In combination with erlotinib for sensitizing EGFR mutation-positive histology;

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 For glioblastoma, member has recurrent disease or requires symptom management;

- d. For metastatic RCC, used as a single-agent or in combination with interferon alfa, everolimus, or erlotinib (for advanced papillary renal cell carcinoma RCC including hereditary leiomyomatosis and renal cell cancer-);
- e. For persistent, recurrent, or metastatic cervical cancer, used in one of the following ways (i, ii or iiii):
 - i. As a single agent;
 - i-ii. In combination with paclitaxel and cisplatin, carboplatin, or topotecan;
 - iii. In combination with Keytruda®, paclitaxel, and cisplatin/carboplatin for PD-L1-postive disease;
- f. For epithelial ovarian, fallopian tube, or primary peritoneal cancer, one of the following (i-vi):
 - Prescribed in combination with <u>a platinum agent (e.g., carboplatin, oxaliplatin)</u> and paclitaxelchemotherapy, followed by bevacizumab as a single agent, for one of the following (1 or 2):Stage IB-IV disease;
 - 1) Stage III or IV disease following initial surgical resection;
 - Stage II IV high grade serous, low grade serous, endometroid (Grade 1/2/3), clear cell carcinoma, or carcinosarcoma;
 - ii. Prescribed for maintenance in combination with Lynparza[®] for stage II-IV disease;
 - iii. Prescribed as targeted therapy in combination with Zejula[®] as targeted therapy for platinum-sensitive persistent disease or recurrence;
 - iv. For platinum-resistant disease, prescribed in combination with paclitaxel, pegylated liposomal doxorubicin, topotecan, <u>gemcitabine</u>, or cyclophosphamide;
 - v. For platinum-sensitive disease, prescribed in combination with carboplatin and paclitaxel, or carboplatin and gemcitabine, or carboplatin and liposomal doxorubicin, followed by bevacizumab as a single agent;
 - vi. Prescribed as a single agent;
- g. For unresectable or metastatic HCC, used in combination with Tecentriq as first-line systemic therapy, and:
 - i. HCC is classified as Child-Pugh class A or B;
- For Alymsys, Avastin. <u>Avzivi</u>, or Vegzelma requests, member meets one of the following (a or b):
 - a. Member must use Mvasi or Zirabev, unless both are contraindicated or clinically significant adverse effects are experienced;*
 - *Prior authorization may be required for Mvasi and Zirabev
 - b. Request is for Stage IV or metastatic cancer or treatment associated conditions.

 Exception if "clinically equivalent with cancer for a State with regulations against step therapy, contains identical active ingredient(s), and proven to have same efficacy. in certain oncology settings (see Appendix E);
- 6. Request meets one of the following (a or b):*
 - a. Dose does not exceed 15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks (see Appendix F for dose rounding guidelines);

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b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*). **Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 6 months

B. Oncology - Non-FDA-Approved Adult Indications (off-label) (must meet all):

- 1. Diagnosis of one of the following conditions (a-nm):
 - a. Adult glioma of one of the following types (Hi, ii, or iii):
 - i. Oligodendroglioma that is IDH-mutant, 1p19q codeleted;
 - ii. IDH-mutant astrocytoma;
 - iii. Low-grade (WHO Grade I)Circumscribed glioma;
 - b. Ampullary adenocarcinoma intestinal type;
 - c. Endometrial carcinoma;
 - d. Intracranial and spinal ependymoma;
 - e. Malignant peritoneal Peritoneal mesothelioma;
 - f. Malignant pleural Pleural mesothelioma;
 - g. Medulloblastoma;
 - h. Meningioma;
 - i. Metastatic spine tumors or brain metastases;
 - j. Pediatric diffuse high-grade glioma;
 - k.j. Primary central nervous system cancers lymphoma;
 - <u>Lk.</u> Small bowel adenocarcinoma;
 - m.l. Soft tissue sarcoma solitary fibrous tumor or angiosarcoma;
 - n.m. Vulvar cancer <u>adenocarcinoma or</u> squamous cell carcinoma;
- 2. Prescribed by or in consultation with an oncologist;
- 3. Age \geq 18 years;
- 4. For Alymsys, Avastin, <u>Avzivi</u>, or Vegzelma requests, member meets one of the following (a or b):
 - Member must use Mvasi or Zirabev, unless both are contraindicated or clinically significant adverse effects are experienced;*
 - *Prior authorization may be required for Mvasi and Zirabev
 - Request is for Stage IV or metastatic cancer or treatment associated conditions.
 Exception if "clinically equivalent with cancer for a State with regulations against step therapy, contains identical active ingredient(s), and proven to have same efficacy. in certain oncology settings (see Appendix E);
- 5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

 $*Prescribed\ regimen\ must\ be\ FDA-approved\ or\ recommended\ by\ NCCN$

Approval duration: 6 months

C. Oncology - Non-FDA-Approved Pediatric Indications (off-label) (must meet all):

- 1. Diagnosis of difuse high-grade glioma;
- 2. Prescribed by or in consultation with an oncologist;
- 3. Age < 18 years;

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- 4. For Alymsys, Avastin, Avzivi, or Vegzelma requests, member meets one of the following (a or b):
 - Member must use Myasi or Zirabey, unless both are contraindicated or clinically significant adverse effects are experienced;* *Prior authorization may be required for Mvasi and Zirabev
 - Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (see Appendix E);
- Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 6 months

Ophthalmology—_ Non-FDA-Approved Indications (off-label) (must meet C.D.

1. Diagnosis of one of the following conditions (a-g):

- a. Neovascular (wet) age-related macular degeneration;
- b. Macular edema following retinal vein occlusion;
- c. Diabetic macular edema;
- d. Proliferative diabetic retinopathy;
- e. Neovascular glaucoma;
- Choroidal neovascularization associated with: angioid streaks, no known cause, inflammatory conditions, high pathologic myopia, or ocular histoplasmosis syndrome;
- g. Diabetic retinopathy associated with ocular neovascularization (choroidal, retinal, iris);
- 2. Age \geq 18 years;
- 3. Request is for bevacizumab intravitreal solution; *Requests for IV formulations of Avastin, Mvasi, Zirabev, Alymsys, and Avzivi, Mvasi, Vegzelma, and Zirabev will not be approved
- 4. Request meets one of the following (a or b):
 - a. Dose does not exceed 2.5 mg per dose;
 - b. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant offlabel use (prescriber must submit supporting evidence).

Approval duration: 6 months

Other diagnoses/indications (must meet all):

- 1. For Alymsys, Avastin, Avzivi, or Vegzelma requests for non-ophthalmology uses, member meets one of the following (a or b):
 - a. Member must use Mvasi or Zirabev, unless both are contraindicated or clinically significant adverse effects are experienced;*
 - *Prior authorization may be required for Mvasi and Zirabev
 - b. Request is for Stage IV or metastatic cancer or treatment associated conditions. Exception if "clinically equivalentwith cancer for a State with regulations against

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step therapy, contains identical active ingredient(s), and proven to have same efficacy" in certain oncology settings (see Appendix E);

- If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
- 3. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy LA.PMN.53

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II. Continued Therapy

A. All Indications in Section I (must meet all):

- 1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
 - Documentation supports that member is currently receiving Alymsys, Avastin.
 <u>Avzivi</u>, Mvasi, Vegzelma, or Zirabev for a covered oncology indication listed in section I and has received this medication for at least 30 days;
- 2. Member is responding positively to therapy;
- 3. For Alymsys, Avastin, <u>Avzivi</u>, or Vegzelma requests for non-ophthalmology uses, member meets one of the following (a or b):
 - Member must use Mvasi or Zirabev, unless both are contraindicated or clinically adverse effects are experienced;*

*Prior authorization may be required for Mvasi and Zirabev

- Request is for Stage IV or metastatic cancer or treatment associated conditions.
 Exception if "clinically equivalent with cancer for a State with regulations against step therapy, contains identical active ingredient(s), and proven to have same efficacy. in advanced oncology settings (see Appendix E);
- 4. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks (see Appendix F for dose rounding guidelines);
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed chemotherapy regimen must be FDA-approved or recommended by NCCN

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 and either 2 or 3):

- For Alymsys, Avastin, <u>Avzivi</u> or Vegzelma requests for non-ophthalmology uses, member meets one of the following (a or b):
 - Member must use Mvasi or Zirabev, unless both are contraindicated or clinically significant adverse effects are experienced;*

*Prior authorization may be required for Mvasi and Zirabev

Request is for Stage IV or metastatic cancer or treatment associated conditions.
 Exception if "clinically equivalentwith cancer for a State with regulations against step therapy, contains identical active ingredient(s), and proven to have same efficacy.

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2. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

3. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy LA.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy LA.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

5-FU: fluorouracil

CapeOX: capecitabine, oxaliplatin

CRC: colorectal cancer

FDA: Food and Drug Administration FOLFIRI: fluorouracil, leucovorin,

irinotecan

FOLFIRINOX: fluorouracil, leucovorin,

irinotecan, oxaliplatin

FOLFOX: fluorouracil, leucovorin,

oxaliplatin

HCC: hepatocellular carcinoma IDH: isocitrate dehydrogenase gene IROX: irinotecan, oxaliplatin

NCCN: National Comprehensive Cancer

Network

NSCLC: non-small cell lung cancer PD-L1: programmed death-ligand 1

RCC: renal cell carcinoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Metastatic carcinoma of the colon of	or rectum	
FOLFOX4 = Infusional 5-	Oxaliplatin 85 mg/m ² IV over 2	Varies
FU/leucovorin/ oxaliplatin	hours day 1; leucovorin 200	
_	mg/m ² IV over 2 hours days 1 &	
	2, followed by 5-FU 400 mg/m ²	
	IV bolus over 2-4 minutes,	
	followed by 600 mg/m ² IV 5-FU	
	continuous infusion over 22	
	hours on days 1 & 2. Repeat	
	cycle every 14 days.	
FOLFIRI =	Camptosar 180 mg/m ² IV over 90	Varies
Infusional 5-FU/	minutes day 1; Leucovorin 400	
leucovorin/Camptosar® (irinotecan)	mg/m ²	
	IV over 2 hours day 1 followed	
	by 5- FU 400 mg/m ² IV bolus	

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Drug Name	Dosing Regimen	Dose Limit/
		Maximum Dose
	over 2-4 minutes, followed by	
	2.4 gm/m ² IV 5- FU continuous	
	infusion over 46 hours. Repeat	
	cycle every 14 days.	
capecitabine (Xeloda®)	2500 mg/m ² PO BID for 2 weeks;	Varies
	repeat cycles of 2 weeks on	
	and 1 week off.	
	For patients who cannot	
	tolerate intensive therapy.	
IROX = oxaliplatin/-Camptosar	Oxaliplatin 85 mg/m ² IV followed	Varies
(irinotecan)	by Camptosar 200 mg m ² IV over	
	30-90 minutes every 3 weeks	
Camptosar (irinotecan)	180 mg/m ² IV every 2 weeks or	Varies
	$300-350 \text{ mg/m}^2 \text{ IV every 3 weeks}$	
Lonsurf® (trifluridine and tipiracil)	35 mg/m ² (based on trifluridine	Trifluridine 80
	component) PO BID on days 1-5	mg/dose
NGCLC	and 8-12, repeated every 28 days	
NSCLC Examples of drugs used in single- or	Various doses	Varies
multi-drug chemotherapy regimens:	Various doses	varies
Cisplatin, carboplatin, paclitaxel		
docetaxel, vinorelbine,		
gemcitabine, etoposide,		
irinotecan, vinblastine,		
mitomycin, ifosfamide,		
pemetrexed disodium, (Alimta®)		
erlotinib (Tarceva®), Tecentriq®		
(atezolizumab)		
Ovarian Cancer	77 ' 1	¥7 '
Examples of drugs used in single-	Various doses	Varies
or multi-drug chemotherapy regimens:		
 carboplatin and paclitaxel, 		
docetaxel and carboplatin,		
	Maintenance phase cycles: 150	Varies
(Temodal)	mg- 200 mg/m² PO days 1-5	
carmustine (Bicnu®)		Varies
,		
	one year or tumor progression.	
docetaxel and carboplatin, Lynparza® (olaparib), Zejula® (niraparib) Glioblastoma Multiforme temozolomide (Temodar®) carmustine (Bicnu®)	Maintenance phase cycles: 150 mg- 200 mg/m² PO days 1-5. Repeat every 28 days. 150 mg to 200 mg/m² IV on day 1. Repeat every 6-8 weeks for	Varies Varies

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cervical Cancer		
Examples of drugs used in multi- drug chemotherapy regimens: • cisplatin/paclitaxel, carboplatin/paclitaxel,	Various doses	Varies
cisplatin/topotecan (Hycamtin [®]), topotecan/paclitaxel		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings None reported

Appendix D: General Information

• Fatal pulmonary hemorrhage can occur in patients with NSCLC treated with chemotherapy and bevacizumab. The incidence of severe or fatal hemoptysis was 31% in patients with squamous histology and 2.3% with NSCLC excluding predominant squamous histology. Patients with recent hemoptysis should not receive bevacizumab.

Appendix E: States with Regulations against Redirections in Certain Oncology Settings

State	Step Therapy Prohibited?	Notes
<u>LA</u>	Yes	For stage 4 advanced, metastatic cancer or associated conditions. Exception if "clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.

Appendix F: Dose Rounding Guidelines

Weight-based Dose Range	Vial Quantity Recommendation
≤ 104.99 mg	1 vial of 100 mg/4 mL
105 mg-209.99 mg	2 vials of 100 mg/4 mL
210 mg-314.99 mg	3 vials of 100 mg/4 mL
315 mg-419.99 mg	1 vial of 400 mg/16 mL
420 mg-524.99 mg	1 vial of 100 mg/4 mL and 1 vial of 400 mg/16 mL
525 mg-629.99 mg	2 vials of 100 mg/4 mL and 1 vial of 400 mg/16 mL
630 mg-734.99 mg	3 vials of 100 mg/4 mL and 1 vial of 400 mg/16 mL
735 mg-839.99 mg	2 vials of 400 mg/16 mL
840 mg-944.99 mg	1 vials of 100 mg/4 mL and 2 vials of 400 mg/16 mL
945 mg-1,049.99 mg	2 vials of 100 mg/4 mL and 2 vials of 400 mg/16 mL
1,050 mg-1,154.99 mg	3 vials of 100 mg/4 mL and 2 vials of 400 mg/16 mL
1,155 mg-1,259.99 mg	3 vials of 400 mg/16 mL
1,260 mg-1,364.99 mg	1 vials of 100 mg/4 mL and 3 vials of 400 mg/16 mL

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Weight-based Dose Range	Vial Quantity Recommendation
1,365 mg-1,469.99 mg	2 vials of 100 mg/4 mL and 3 vials of 400 mg/16 mL
1,470 mg-1,574.99 mg	3 vials of 100 mg/4 mL and 3 vials of 400 mg/16 mL
1,575 mg-1,679.99 mg	4 vials of 400 mg/16 mL
1,680 mg-1,784.99 mg	1 vials of 100 mg/4 mL and 4 vials of 400 mg/16 mL
1,785 mg-1,889.99 mg	2 vials of 100 mg/4 mL and 4 vials of 400 mg/16 mL
1,890 mg-1,994.99 mg	3 vials of 100 mg/4 mL and 4 vials of 400 mg/16 mL
1,995 mg-2,099.99 mg	5 vials of 400 mg/16 mL

V. Do

Dosage and Administration		
Indication	Dosing Regimen	Maximum Dose
Metastatic colorectal cancerCRC	5 mg/kg or 10 mg/kg once every 14 days as an IV infusion in combination with a 5-FU based chemotherapy regimen until disease progression is detected. 5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks when used in combination with a fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin based chemotherapy regimen in patients who have progressed on a first-line Avastincontaining regimen	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks
Non-squamous NSCLC	15 mg/kg IV infusion every 3 weeks with carboplatin/paclitaxel	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks
Ovarian cancer, stage III or IV disease following initial surgical resection	15 mg/kg IV infusion every 3 weeks with carboplatin/paclitaxel for up to 6 cycles, followed by bevacizumab 15 mg/kg every 3 weeks as a single agent	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks
Platinum resistant ovarian cancer	10 mg/kg intravenously every 2weeks with weekly paclitaxel, liposomal doxorubicin, or topotecan	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks

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Indication	Dosing Regimen	Maximum Dose
Platinum sensitive ovarian cancer	15 mg/kg intravenously every 3 weeks with carboplatin and paclitaxel or with carboplatin and gemcitabine, followed by bevacizumab 15 mg/kg every 3 weeks as a single agent	15 mg/kg IV every 3 weeks
HCC	15 mg/kg IV every 3 weeks plus Tecentriq 1,200 mg IV on the same day	15 mg/kg IV every 3 weeks
Clear cell renal carcinoma	10 mg/kg IV every 2 weeks with interferon alfa	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks
Glioblastoma multiforme, anaplastic astrocytoma, anaplastic oligodendroglioma	10 mg/kg IV every 2 weeks	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks
Soft tissue sarcoma	15 mg/kg IV infusion every 3 weeks	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks
Cervical cancer	15 mg/kg IV infusion every 3 weeks (in combination with paclitaxel and either cisplatin or topotecan) until disease progression or unacceptable toxicity	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks
Neovascular (wet) macular degeneration	1.25 to 2.5 mg administered by intravitreal injection every 4 weeks	2.5 mg/dose
Neovascular glaucoma	1.25 mg administered by intravitreal injection every 4 weeks	2.5 mg/dose
Macular edema secondary to retinal vein occlusion	1 mg to 2.5 mg administered by intravitreal injection every 4 weeks	2.5 mg/dose
Proliferative diabetic retinopathy	1.25 mg administer by intravitreal injection 5 to 20 days before vitrectomy	2.5 mg/dose

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Indication	Dosing Regimen	Maximum Dose
Diabetic macular edema	1.25 mg administered by intravitreal injection	2.5 mg/dose
Malignant mesothelioma of pleura	15 mg/kg IV (plus pemetrexed 500 mg/m(2) IV and cisplatin 75 mg/m(2) IV) every 21 days for up to 6 cycles, followed by maintenance bevacizumab 15 mg/kg every 21 days until disease progression or unacceptable toxicity. All patients should receive folic acid 400 mcg orally daily and vitamin B12 1000 mcg IM every 3 weeks, both beginning 7 days prior to pemetrexed and continuing for 3 weeks following the last pemetrexed dose (off-label dosage).	2.5 mg/dose
Metastatic colorectal cancerCRC in previously untreated elderly patients ineligible for oxaliplatin- or irinotecan-based	7.5 mg/kg IV on day 1 with capecitabine 1,000 mg/m2 orally twice daily on days 1 to 14, given every 3 weeks until disease progression.	15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks.

VI. Product Availability

Single-use vials: 100 mg/4 mL, 400 mg/16 mL

VII. References

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Bevacizumab, Bevacizumab-awwb, Bevacizumab-bvzr, and Biosimil Bevacizumab maly, Bevacizumab-adcd



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- 11.12. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; September 2019. Available at: https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp. Accessed August 3, 202218, 2023
- 12.13. Fahrenbruch R, Kintzel P, Bott AM., et al. Dose rounding of biologic and cytotoxic anticancer agents: a position statement of the hematology/oncology pharmacy association. Journal of Oncology Practice. 2018;14(3)e130-e136.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Termedisen	nent of covered services.
HCPCS	Description
Codes	
C9257	Injection, bevacizumab, 0.25 mg
J9035	Injection, bevacizumab, 10 mg
J9999	Not otherwise classified, antineoplastic drugs
Q5107	Injection, bevacizumab-awwb, biosimilar, (Mvasi), 10 mg
Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg
Q5126	Injection, bevacizumab-maly, biosimilar, (alymsysAlymsys), 10 mg
05129	Injection, beyacizumab-adcd (vegzelma) biosimilar, 10 mg

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Bevacizumab, Bevacizumab-awwb, Bevacizumab-bvzr, and Biosimil Bevacizumab-maly, Bevacizumab-adcd



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ICD-10-CM Diagnosis Codes that Support Coverage Criteria

The following is a list of diagnosis codes that support coverage for the applicable covered

Al8.53 Tuberculosis chorioretinitis C17.0 - C17.9 Malignant neoplasm of small intestine C18.0 - C18.9 Malignant neoplasm of coton C19 Malignant neoplasm of rectum C21.8 Malignant neoplasm of trachea C33 Malignant neoplasm of trachea C34.00 - C34.02 Malignant neoplasm of understand trachea C34.10 - C34.12 Malignant neoplasm of unit pronchus C34.2 Malignant neoplasm of upper lobe, bronchus or lung C34.30 - C34.32 Malignant neoplasm of indide lobe, bronchus or lung C34.30 - C34.82 Malignant neoplasm of lower lobe, bronchus or lung C34.90 - C34.92 Malignant neoplasm of or unspecified part of bronchus or lung C34.90 - C34.92 Malignant neoplasm of orther some trachea C39.0 - C30.9 Malignant neoplasm of other connective and soft tissue C50.01 - C50.029 Malignant neoplasm of other connective and soft tissue C56.1 - C56.9 Malignant neoplasm of orther some trachea C56.1 - C56.9 Malignant neoplasm of other and unspecified female genital organs C64.1 - C64.9 Malignant neoplasm of other and unspecified female genital organs C65.1 - C65.9 Malignant neoplasm of other and unspecified female genital organs C63.0 - C70.0 - C70.9 Malignant neoplasm of other and unspecified female genital organs C63.1 - C65.9 Malignant neoplasm of other and unspecified female genital organs C64.1 - C64.9 Malignant neoplasm of organ of the read unspecified female genital organs C63.0 - C57.0 - C70.9 Malignant neoplasm of organ of the read unspecified female genital organs C70.0 - C70.9 Malignant neoplasm of organ of the read unspecified female genital organs C70.0 - C70.9 Malignant neoplasm of organ of the read unspecified female genital organs C70.0 - C70.9 Malignant neoplasm of organ of the read unspecified female genital organs C64.1 - C64.9 Malignant neoplasm of organ or	procedure code(s).			
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C54.0 – C55 Malignant neoplasm of corpus uteri C56.1 – C56.9 Malignant neoplasm of ovary C57.0 – C57.9 Malignant neoplasm of other and unspecified female genital organs C64.1 – C64.9 Malignant neoplasm of kidney, except renal pelvis C65.1 – C65.9 Malignant neoplasm of renal pelvis C70.0 – C70.9 Malignant neoplasm of meninges C71.0 – C71.9 Malignant neoplasm of brain C72.0 – C72.9 Malignant neoplasm of brain C72.0 – C72.9 Malignant of spinal cord, cranial neoplasm nerves and other parts of central nervous system D32.0 – D32.9 Benign neoplasm of meninges D42.0 – D42.9 Neoplasm of uncertain behavior of meninges E08.311, E08.3211 – E08.3219, E08.3311 – E08.3219, E08.3311 – E08.3319, E09.3311 – E09.3219, E09.3311 – E09.3219, E09.3311 – E09.3319, E09.3311 – E09.3319, E09.3311 – E09.3319, E09.3311 – E09.3319	C50.01 – C50.929			
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CLINICAL POLICY
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ICD 10 CM C-1	Description	
ICD-10-CM Code	Description	
E10.3311 – E10.3319,		
E10.3411 – E10.3419,		
E10.3511 – E10.3519		
E11.311,	Type 2 diabetes mellitus with diabetic retinopathy with	
E11.3211 – E11.3219,	macular edema	
E11.3311 – E11.3319,		
E11.3411 – E11.3419,		
E11.3511 – E11.3519	Other and if all dishes and like a wide dishes a set of a	
E13.311, E13.3211 – E13.3219,	Other specified diabetes mellitus with diabetic retinopathy with macular edema	
E13.3311 – E13.3319,	with macular edema	
E13.3411 – E13.3419,		
E13.3511 – E13.3519		
	Corneal neovascularization	
H16.401 – H16.449 H30.001 – H30.049	Focal chorioretinal inflammation	
	Disseminated chorioretinal inflammation	
H30.101 – H30.139		
H30.891 – H30.899	Other chorioretinal inflammations	
H30.90 – H30.93	Unspecified chorioretinal inflammations	
H32	Chorioretinal disorders in diseases classified elsewhere	
H34.8110 – H 34.8192	Central retinal vein occlusion	
H34.8310 – H34.8392	Tributary (branch) retinal vein occlusion	
H35.051 – H35.059	Retinal neovascularization, unspecified	
H35.141 – H35.169	Retinopathy of prematurity, stages 3 through 5	
H35.3210 – H35.3293	Exudative age-related macular degeneration	
H35.33	Angioid streaks of macula	
H35.81	Retinal edema	
H40.50X0H40.53X4	Glaucoma secondary to other eye disorders [associated with	
	vascular disorders of eye]	
H44.20- <u>-</u> H44.23	Degenerative myopia	
H44.2A1H44.2A9	Degenerative myopia with choroidal neovascularization	
I67.89	Other cerebrovascular disease	
Z85.038	Personal history of other malignant neoplasm of large intestine	
Z85.048	Personal history of other malignant neoplasm of	
	rectum, rectosigmoid junction, and anus	
Z85.068	Personal history of other malignant neoplasm of small intestine	
Z85.118	Personal history of other malignant neoplasm of bronchus and lung	
Z85.3	Personal history of malignant neoplasm of breast	
Z85.41	Personal history of malignant neoplasm of cervix uteri	
Z85.42	Personal history of malignant neoplasm of other parts of uterus	
Z85.43	Personal history of malignant neoplasm of ovary	
Z85.44	Personal history of malignant neoplasm of other female	
	genital organs	
Z85.528	Personal history of other malignant neoplasm of kidney	

Bevacizumab Bevacizumab awwb, Bevacizumab bvzr, and Biosimil
Bevacizumab maly, Bevacizumab adcd



ICD-10-CM Code	Description
Z85.53	Personal history of malignant neoplasm of renal pelvis
Z85.841	Personal history of malignant neoplasm of brain
Z85.848	Personal history of malignant neoplasm of other parts of
	nervous tissue

Reviews, Revisions, and Approvals	Date	LDH
		Approval
		Date
Converted corporate to local policy	01.21	04.21
FDA indication language updated for Zirabev to reflect expansion of	04.22	07.23.22
indication to include epithelial ovarian, fallopian tube, or primary		
peritoneal cancer; amended language for ophthalmology non-FDA		
approved indications to be: request is for bevacizumab intravitreal		
solution; Applied redirection of Avastin to preferred biosimilars to		
other diagnoses/indications; Added additional NCCN-supported		
regimens and classifications for colorectal cancer, NSCLC,		
glioblastoma, cervical cancer, and epithelial ovarian, fallopian tube, or		
primary peritoneal cancer; added criterion that HCC be classified as		
Child-Pugh class A disease per NCCN; added low-grade WHO grade		
I glioma to NCCNsupported off-label indication; Updated with		
Mvasi's FDAapproved indications of epithelial ovarian, fallopian		
tube, or primary peritoneal cancers.		
Added newly FDA-approved biosimilar Alymsys to policy;	06.27.23	<u>01.03.24</u>
generalized language for oncology redirection bypass.		
Added additional NCCN-supported indications of ampullary		
adenocarcinoma cancer, malignant peritoneal mesothelioma, and		
pediatric diffuse high-grade glioma; re-classified anaplastic gliomas		
to astrocytoma and oligodendroglioma per updated NCCN		
classification; removed breast cancer indication, WHO grade 2 glioma		
indication, and single-agent therapy option for cervical cancer per		
NCCN; removed "radiographic and/or clinical relapse", "recurrent",		
and "carcinosarcoma with BRCA 1/2 mutation" disease qualifiers		
for ovarian cancer as there are other clinical scenarios per NCCN;		
added new regimens for cervical and colorectal cancers per NCCN;		
references reviewed and updated. Template changes applied to other		
diagnoses/indications and continued therapy section.		
Added HCPCS codes C9142, Q5126, Q5129		
Added Vegzelma biosimilar to policy.		
Added blurb this policy is for medical benefit only.		
Annual review; per NCCN – for CRC added that disease is advanced.	05.07.24	
metastatic, or unresectable; for cervical cancer added option for		
single-agent therapy; for RCC removed combination therapy option		
with interferon alfa; for ovarian cancers simplified bevacizumab		
combination therapy criterion when used with a platinum and		

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
chemotherapy along with corresponding staging update to IB-IV		
disease, added combination therapy option with gemcitabine for		
platinum-resistant disease, and removed combination therapy with		
Zejula; for HCC added Child-Pugh class B option; clarified off-label		
indication of primary central nervous system cancer is specifically for		
lymphoma; modified low-grade (WHO Grade I) glioma to		
circumscribed glioma; revised mesotheliomas to remove "malignant"		
per terminology change; references reviewed and updated; added		
newly FDA-approved biosimilar Avzivi to policy; for ovarian		
cancers, added combination therapy with Zejula per NCCN; created		
separate section for oncology – non-FDA-approved indications for		
pediatrics to include diffuse high-grade glioma.		

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

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professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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