Jobevne™
(bevacizumab-nwgd) Injection

CODING & BILLING GUIDE

For Jobevne™ (bevacizumab-nwgd) Injection

Please see full Indications and Limitations of Use on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

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OVERVIEW

PURPOSE OF THIS GUIDE

This Coding and Billing Guide for Jobevne™ (bevacizumab-nwgd) is intended to support medically appropriate patient access by providing general information on coding, coverage, billing, and reimbursement to healthcare professionals and their staff who prescribe and administer JOBEVNE at physician office and hospital outpatient sites of care. JOBEVNE is a biosimilar to AVASTIN® (bevacizumab) for the indications listed on pages 5 and 22.

DISCLAIMER

The content provided in this guide is for informational purposes only. It is not intended as legal advice or to replace a medical provider's professional judgment.

It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure JOBEVNE claims are accurate, complete, and supported by documentation in the patient's medical record.

Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios, and Biocon Biologics does not guarantee coverage or reimbursement for JOBEVNE. Please note that information specific to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information in this guide is current as of May 2025.

HOW SUPPLIED

JOBEVNE is available as a 100 mg/4 mL and 400 mg/16 mL solution in a single-dose vial. Each mL of concentrate contains 25 mg of JOBEVNE.

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INDICATIONS AND USAGE[1]

Metastatic Colorectal Cancer (mCRC)

JOBEVNE combined with intravenous fluorouracil-based chemotherapy for first- or second-line treatment of patients with mCRC.

JOBEVNE combined with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for the second-line treatment of patients with mCRC who have progressed on a first-line treatment containing bevacizumab

Limitations of Use: JOBEVNE is not approved for use if surgery was used as the primary treatment in patients with colon cancer which has not spread to other parts of the body.

First-Line Non-Squamous Non-Small Cell Lung Cancer (NSCLC):

JOBEVNE combined with carboplatin and paclitaxel is approved for first-line treatment in patients with unresectable, locally advanced, recurrent or metastatic NSCLC.

Recurrent Glioblastoma (rGBM):

JOBEVNE is approved to treat rGBM in adults.

Metastatic Renal Cell Carcinoma (mRCC):

JOBEVNE combined with interferon alfa, is approved to treat mRCC.

Persistent, Recurrent or Metastatic Cervical Cancer (CC):

JOBEVNE combined with paclitaxel and cisplatin or paclitaxel and topotecan, is approved to treat patients with persistent, recurrent, or metastatic cervical cancer.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer:

JOBEVNE combined with carboplatin and paclitaxel, followed by JOBEVNE alone, is used for the treatment of patients with advanced (Stage III or IV) epithelial ovarian, fallopian tube or primary peritoneal cancer following initial surgical resection.

JOBEVNE combined with paclitaxel, pegylated liposomal doxorubicin or topotecan, is approved to treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.

JOBEVNE combined with carboplatin and paclitaxel or with carboplatin and gemcitabine, followed by JOBEVNE alone, is approved for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Please see full Indications and Limitations of Use on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

CODING

This section lists some of the billing codes that may be appropriate to report services provided to patients undergoing treatment with Jobevne™ (bevacizumab-nwgd).

REPORTING USE OF JOBEVNE

Healthcare Common Procedure Coding System (HCPCS) Level II Codes

The Centers for Medicare & Medicaid Services (CMS) has not yet assigned JOBEVNE a permanent, unique HCPCS code. Until a permanent code is assigned, healthcare professionals may bill using a miscellaneous (unclassified) HCPCS code such as one of the following:

Table 1. Miscellaneous HCPCS Codes That May Be Appropriate for JOBEVNE[2]

Code	Description	Sites of Service
J9999	Not otherwise classified, antineoplastic drugs	• Physician office • Hospital outpatient
J3590	Unclassified biologics	
J3490	Unclassified drugs	
C9399	Unclassified drugs or biologicals	• Hospital outpatient

HCPCS codes must be accompanied by a billing unit value. Miscellaneous codes such as those in the above table are generally reported with "1 unit" in the units field of the CMS-1500 (physician office) and CMS-1450 (facility) claim forms.

Please check individual payer guidelines for how to report units when billing JOBEVNE with an unclassified code, or call My Biocon Biologics™ at 1-833-247-2756 Monday-Friday 9 AM-8 PM ET.*

*My Biocon Biologics support services will be available starting in July 2025.

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Reporting Discarded Medication (Wastage)

Payers typically cover and pay for both the amount of medication that is administered to a patient and the amount of discarded drug or biologic, called wastage, that is left over from a single-use vial.[3] The amount of medication that was administered to the patient and the amount that was discarded should be documented in the Comment field (Item 19) of the CMS-1 500 claim form or Remarks section (Field 80) of the CMS-1450 claim form (or their electronic equivalents). These amounts should also be documented in the patient's medical record.

HCPCS Modifiers for Product Acquired Via 340B Drug Discount Program

CMS has established modifiers that must be reported on claims for drugs and biologics that meet the following criteria[4]:

- Furnished to a patient enrolled in fee-for-service (FFS) Medicare Part B
- Administered in the hospital outpatient setting
- Acquired via the 340B Drug Discount Program

The following modifiers may be appropriate to bill along with the HCPCS code for JOBEVNE for certain claims:

Table 2. Medicare Modifiers for 340B Products[4]

Modifier	Description	Sites of Service
-JG	Drug or biological acquired with 340B drug pricing program discount	Hospital outpatient
-TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	

Please see full Indications and Limitations of Use on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

National Drug Codes (NDCs)

The United States Food and Drug Administration (FDA) assigns approved medications a 3-segment number known as the NDC that is specific to the labeler (manufacturer), product (identifies a specific drug, strength, and dosage formulation), and package size. Jobevne™ (bevacizumab-nwgd) has been assigned a 10-digit NDC as listed in the prescribing information.[1] The 11-digit format is required by HIPAA (the Health Insurance Portability and Accountability Act) for claims submission. It is typically reported on claims without hyphens or other punctuation marks and preceded by the qualifier "N4." Payers may also require the unit of measure (UoM) after the NDC, to include the qualifier "ML" and NDC quantity (eg, N4XXXXXXXXXXX MLx):

Table 3. NDCs for JOBEVNE

Product	10-Digit NDC	11-Digit NDC and UoM
JOBEVNE (bevacizumab-nwgd) 100 mg/4 mL single-dose vial	83257-009-11	83257-0009-11 eg, N483257000911 ML4
JOBEVNE (bevacizumab-nwgd) 400 mg/16 mL single-dose vial	83257-010-11	83257-0010-11 eg, N483257001011 ML16

When reported with a miscellaneous code, the NDC is critical in order for payers to identify JOBEVNE as the medication administered. It should be reported on medical claims along with the most appropriate HCPCS code. The NDC location on the claim form may vary by payer.

Additional Identifying Information on Claims for Miscellaneous-Coded Drugs and Biologics

Most payers will require physicians and facilities to submit drug-identifying information on the claim form when JOBEVNE is billed with a miscellaneous HCPCS code. Submitting payer-specific information that is complete and accurate in the Comment or Remarks fields on the claim may facilitate timely coverage and reimbursement.

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Payers may request the following types of drug-identifying information on claim forms for JOBEVNE:

Table 4. Drug-Identifying Information for JOBEVNE

Type of Information	Specifics for JOBEVNE
11-digit NDC and UoM	N483257000911 ML4 or N483257001011 ML16
Drug name (brand/generic)	JOBEVNE (bevacizumab-nwgd)
Dose/dosage	XX mg/kg
Amount administered vs discarded	XX mg administered and XX mg discarded from a 100 mg/4 mL or 400 mg/16 mL single-dose vial
Route of administration	Intravenous infusion

REPORTING THE INTRAVENOUS INFUSION PROCEDURE

If a treating healthcare professional decides to administer JOBEVNE in a physician's office or hospital outpatient department, the infusion service is typically reported to a payer using a Current Procedural Terminology (CPT®)[5] or HCPCS code, such as the following:

Table 5. Possible CPT and HCPCS Codes for JOBEVNE Intravenous (IV) Infusion Procedure

Code	Description	Sites of Service
96413[5]	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	• Physician office • Hospital outpatient
96415[5]	Chemotherapy administration, intravenous infusion technique; each additional hour	
96417[5]	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour	
Q0081[2]	Infusion therapy, using other than chemotherapeutic drugs, per visit	

Please see full Indications and Limitations of Use on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

REPORTING DIAGNOSIS

The medical necessity for treatment with Jobevne™ (bevacizumab-nwgd) is reported on physician and hospital claims with *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) codes.[6] ICD-10-CM diagnosis codes for cancer indications vary by type and anatomical location. ICD-10-CM codes have 3 to 7 digits and must be reported to the highest level of specificity. This means that if there is a fifth-digit option in the diagnosis category, the code must be reported out to the fifth digit. Allowable ICD-10-CM diagnosis code may vary by payer.

Table 6. Possible ICD-10-CM Diagnosis Codes for JOBEVNE[6]

Code		Description
Metastatic colorectal cancer	C18.2-C18.9	Malignant neoplasm of colon
	C19	Malignant neoplasm of rectosigmoid junction
	C20	Malignant neoplasm of rectum
	Z92.22	Personal history of monoclonal drug therapy
First-line, non-squamous, non–small cell lung cancer	C30.10-C34.92	Malignant neoplasm of bronchus or lung
Recurrent glioblastoma	C71.0-C71.9	Malignant neoplasm of brain
Metastatic renal cell carcinoma	C64.1-C65.9	Malignant neoplasm of kidney
Persistent, recurrent, or metastatic cervical cancer	C53.0-C53.9	Malignant neoplasm of cervix uteri
Epithelial ovarian, fallopian tube, or primary peritoneal cancer	C48.0-C48.8	Malignant neoplasm of retroperitoneum and peritoneum
	C56.1-C56.9	Malignant neoplasm of ovary
	C57.00-C57.02	Malignant neoplasm of fallopian tube

REPORTING REVENUE CODES

Revenue codes categorize hospital services by revenue center to capture cost data. Many payers require claims to include a revenue code for each service provided in the hospital. The following table shows sample revenue codes that may be relevant for JOBEVNE and its infusion service in hospital outpatient departments.

Table 7. Sample Revenue Codes[7]

Code	Description	Appropriate Use
0636	Drugs requiring detailed coding	Use in combination with HCPCS drug code
0250	Pharmacy, general	
0258	Pharmacy, IV solutions	
0260	IV therapy, general	Use in combination with CPT injection code
0261	IV therapy, IV pump	
0330	Chemotherapy administration, general	
0335	Chemotherapy administration IV	

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COVERAGE

IMPORTANCE OF BENEFITS VERIFICATION

Verifying a patient's health insurance plan coverage prior to receiving an infusion of Jobevne™ (bevacizumab-nwgd) will identify coding requirements for the product and infusion procedure, coverage guidelines, and claims submission criteria.

With a typical response time of 1 business day, My Biocon Biologics:

- Verifies the patient's insurance benefits
- Prepares a detailed Summary of Benefits and shares it with the requester via fax or online, depending on preference

The Summary of Benefits provides details on:

- The patient's health plan eligibility
- Coverage for the biosimilar and its administration
- Acquisition options
- Prior authorization (PA) requirements
- The patient's out-of-pocket financial responsibility
- The patient's eligibility for assistance (eg, co-pay assistance)

My Biocon Biologics™

Contact My Biocon Biologics for assistance with benefits verification or other coverage and coding-related questions.*

Monday-Friday
9 AM-8 PM ET

Call
1-833-695-2623

COVERAGE FOR MEDICARE

Medicare Part B Coverage

JOBEVNE is covered under the Part B benefit when it is reasonable and medically necessary for the beneficiary and certain criteria are met.[8] It may be subject to coverage restrictions spelled out in local or national Medicare coverage guidance.

*My Biocon Biologics support services will be available starting in July 2025.

In general, Medicare coverage for drugs and biologics under the Part B benefit includes the following requirements:

The drug or biologic must be furnished "incident to" a physician's service,[8] meaning it must be furnished by a physician and administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision. In addition, the charge for the product must be included in the physician's bill, representing an expense to the physician

The product must **meet the definition of a drug or biological**

The treatment must be **reasonable and necessary for the diagnosis or treatment of the illness or injury for which it is administered**, according to accepted standards of medical practice

The product is **not usually self-administered**

The product must **be safe and effective**

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REIMBURSEMENT

MEDICARE

Medicare provides separate payment for Part B-covered drugs and biologics in outpatient settings.

Physician Office

Medicare reimbursement for biosimilars administered in the physician's office is typically based on the average sales price (ASP) of the biosimilar + 6% of the reference product's ASP.[8] The reference product for Jobevne™ (bevacizumab-nwgd) is Avastin.[1] However, because JOBEVNE is a newly approved product, its ASP will not be immediately available. Until ASP is established, reimbursement is based on 103% of JOBEVNE's wholesale acquisition cost (WAC).[9]

Table 8. Medicare Reimbursement Methodology for a Part B-Covered Biosimilar in the Physician Office Setting[9,10]

At Launch and Until ASP Is Established	Once ASP Is Established
103% WAC of biosimilar	ASP of biosimilar + 6% of reference product's ASP

Hospital Outpatient Department

Medicare payment for Part B-covered biosimilars administered in hospital outpatient clinics varies based on multiple factors, including whether the biosimilar[11]:

- Has an established ASP
- Has temporary pass-through status
- Is acquired under the 340B Drug Discount Program

Table 9. Medicare Reimbursement Methodology for a Part B-Covered Biosimilar in the Hospital Outpatient Setting[11,12]

At Launch and Until ASP Is Established	Once ASP Is Established
95% of biosimilar average wholesale price (AWP) or 103% of biosimilar WAC	ASP of biosimilar + 6% of reference product's ASP*

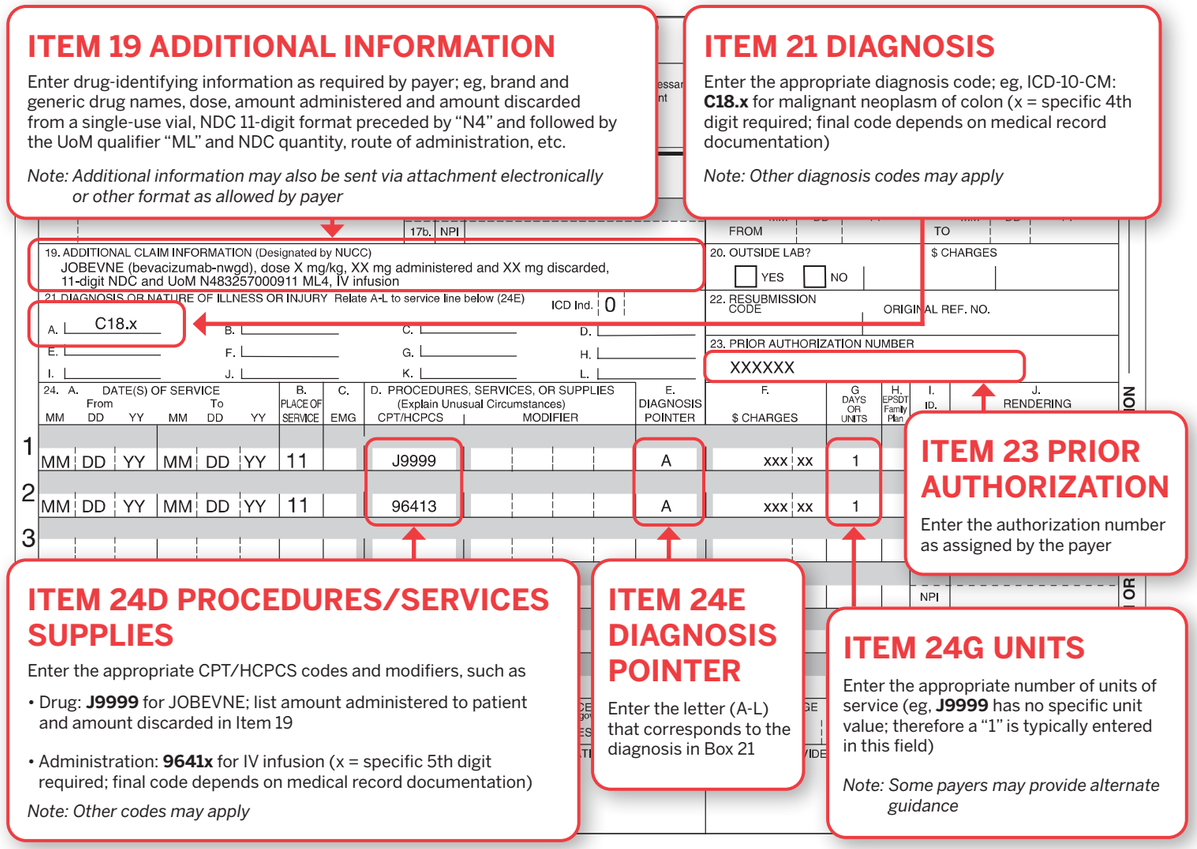
*Applies if product has temporary pass-through status. Medicare payment policies vary based on multiple factors.

For more information, please refer to the flashcard "Medicare Payment for Biosimilars in Outpatient Settings" or contact your My Biocon Biologics Field Reimbursement Specialist. You may also contact your Medicare Administrative Contractor for more information on Medicare policies that may affect reimbursement for JOBEVNE.

CLAIMS

SAMPLE CMS-1500 CLAIM FORM

Products and services provided in the physician office setting are billed using the CMS-1500 claim form or the electronic claim file (837P). A sample CMS-1500 claim form for billing Jobevne™ (bevacizumab-nwgd) is provided below.



ITEM 19 ADDITIONAL INFORMATION

Enter drug-identifying information as required by payer; eg, brand and generic drug names, dose, amount administered and amount discarded from a single-use vial, NDC 11-digit format preceded by "N4" and followed by the UoM qualifier "ML" and NDC quantity, route of administration, etc.

Note: Additional information may also be sent via attachment electronically or other format as allowed by payer

ITEM 21 DIAGNOSIS

Enter the appropriate diagnosis code; eg, ICD-10-CM: **C18.x** for malignant neoplasm of colon (x = specific 4th digit required; final code depends on medical record documentation)

Note: Other diagnosis codes may apply

ITEM 23 PRIOR AUTHORIZATION

Enter the authorization number as assigned by the payer

ITEM 24D PROCEDURES/SERVICES SUPPLIES

Enter the appropriate CPT/HCPCS codes and modifiers, such as

- Drug: **J9999** for JOBEVNE; list amount administered to patient and amount discarded in Item 19
- Administration: **9641x** for IV infusion (x = specific 5th digit required; final code depends on medical record documentation)

Note: Other codes may apply

ITEM 24E DIAGNOSIS POINTER

Enter the letter (A-L) that corresponds to the diagnosis in Box 21

ITEM 24G UNITS

Enter the appropriate number of units of service (eg, **J9999** has no specific unit value; therefore a "1" is typically entered in this field)

Note: Some payers may provide alternate guidance

The content provided on these sample claim forms is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure JOBEVNE injection claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios, and Biocon Biologics does not guarantee JOBEVNE coverage or reimbursement.

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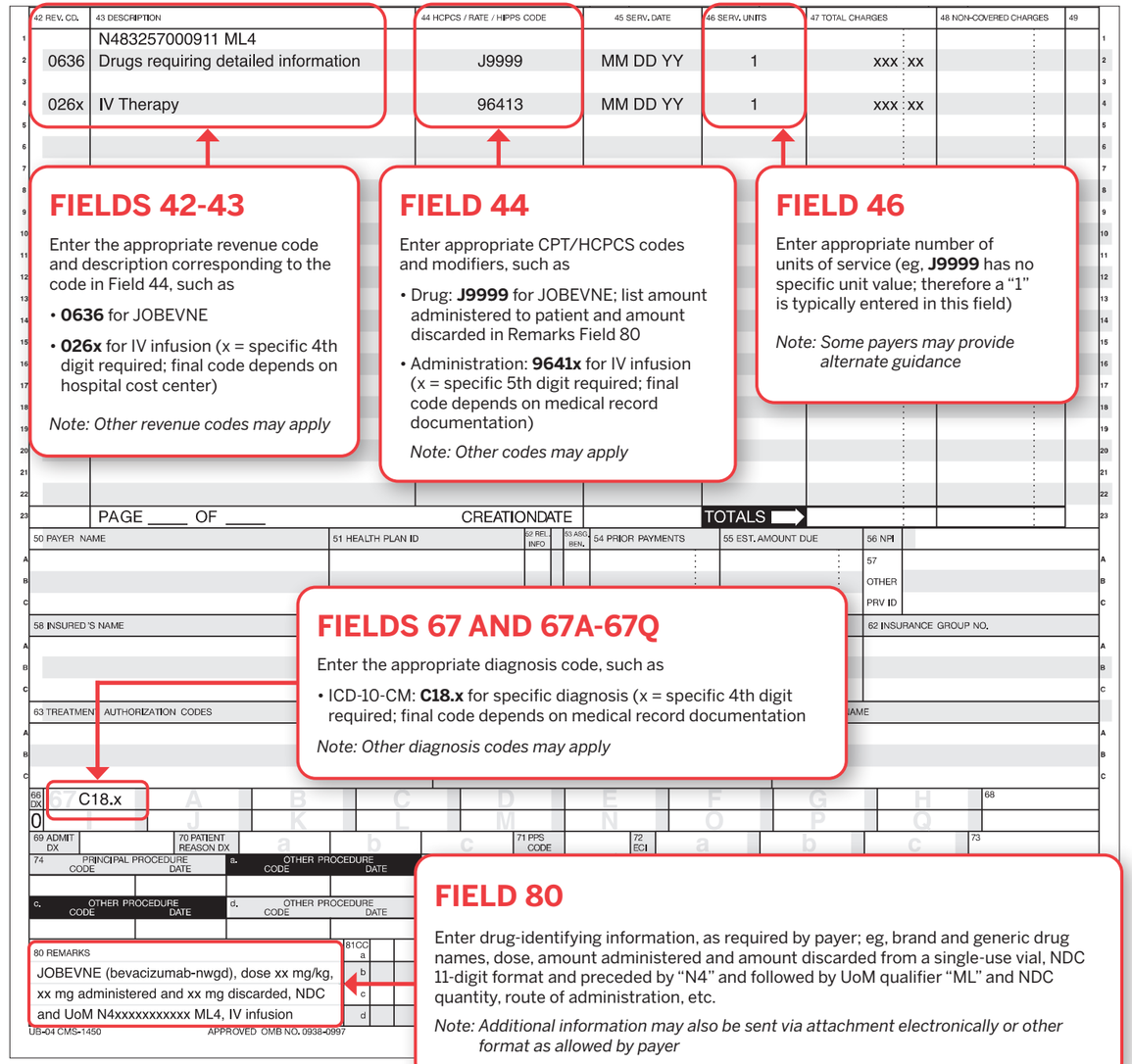
SAMPLE CMS-1450 (UB-04) CLAIM FORM

Products and services provided in the hospital outpatient facility are billed using the CMS-1450 institutional claim form or the electronic claim file (837I). A sample CMS-1450 claim form for billing JOBEVNE administered to a Medicare patient is provided.



FIELDS 42-43

Enter the appropriate revenue code and description corresponding to the code in Field 44, such as

- **0636** for JOBEVNE
- **026x** for IV infusion (x = specific 4th digit required; final code depends on hospital cost center)

Note: Other revenue codes may apply

FIELD 44

Enter appropriate CPT/HCPCS codes and modifiers, such as

- Drug: **J9999** for JOBEVNE; list amount administered to patient and amount discarded in Remarks Field 80
- Administration: **9641x** for IV infusion (x = specific 5th digit required; final code depends on medical record documentation)

Note: Other codes may apply

FIELD 46

Enter appropriate number of units of service (eg, **J9999** has no specific unit value; therefore a "1" is typically entered in this field)

Note: Some payers may provide alternate guidance

FIELDS 67 AND 67A-67Q

Enter the appropriate diagnosis code, such as

- ICD-10-CM: **C18.x** for specific diagnosis (x = specific 4th digit required; final code depends on medical record documentation

Note: Other diagnosis codes may apply

FIELD 80

Enter drug-identifying information, as required by payer; eg, brand and generic drug names, dose, amount administered and amount discarded from a single-use vial, NDC 11-digit format and preceded by "N4" and followed by UoM qualifier "ML" and NDC quantity, route of administration, etc.

Note: Additional information may also be sent via attachment electronically or other format as allowed by payer

Please see full Indications and Limitations of Use on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

CLEAN CLAIMS SUBMISSION

Submitting an error-free or "clean" claim that has all of the required information necessary may facilitate timely and accurate reimbursement for services rendered. The following are some considerations for preparing and submitting claims for Jobevne™ (bevacizumab-nwgd):

Include the correct patient/subscriber information Patient—name, date of birth, and member identification number; provider—provider name, identifier (tax identification number, National Provider Identifier, or other payer-specific identifier), clinic demographic information, and required signatures

Report all of the necessary payer-specific, drug-identifying information for JOBEVNE (eg, correct codes, modifiers, units, NDC, brand and generic name, and dose)

Report a primary diagnosis code (and secondary code, if applicable) to the highest level of specificity

Include payer-specific required supplemental information (eg, letter of medical necessity, PA number, chart notes, laboratory tests)

When filing a claim electronically, stay within any payer-mandated character limits for completing the sections that correspond to Item 19 (CMS-1500) or Field 80 (CMS-1450)

File the claim within the payer's required time frame for submission

You may contact My Biocon Biologics for additional information about claims submissions.*

*My Biocon Biologics support services will be available starting in July 2025.

SAMPLE LETTER OF MEDICAL NECESSITY

Payers may request a letter of medical necessity to support coverage for JOBEVNE. The letter explains why the drug was medically necessary for the specific patient and may include supporting documentation. The letter may be submitted as part of a PA request, in tandem with the claim form, or in response to a payer's request for additional documentation.

The following is a sample letter of medical necessity; you may use another form or format. The letter should include patient-specific information, be on your letterhead, and be signed by the prescriber.

<Date>
<Contact Name> <Title>
<Name of Health Insurance Company>
<Address> <City, State Zip>

Insured: <Name>
Policy Number; <Number>
Group Number: <Number>

Dear <Contact's Name>:
I am writing on behalf of my patient, <name of patient>, to request that <name of health insurance company> approve coverage and appropriate reimbursement associated with <name of patient>'s treatment with JOBEVNE (bevacizumab-nwgd), which is biosimilar to reference product Avastin. JOBEVNE is approved by the FDA for <indication relevant to patient's diagnosis>.

Patient History and Diagnosis
<Name of patient> is a<n> <age>-year-old <indicate gender> born <MM-DD-YEAR> who was diagnosed on <date> with <patient's diagnosis>. <Provide a brief description of patient's symptoms, diagnostic test results, and therapy to date. Describe any surgical procedures, prior treatments, and underlying medical complications.>

Treatment Rationale and Plan
My planned course of treatment is <include detailed information such as regimen, dose, frequency, and duration of treatment, etc>. Based on the above facts, I am confident you will agree that JOBEVNE is medically necessary for this patient. If you have any further questions, please call me at <physician's phone number (XXX) XXX-XXXX> to discuss. Thank you in advance for your prompt attention to this request.

Sincerely,

<Physician's name>
<Physician's practice name>
<Phone number>

Enclosures <supporting documentation, such as FDA approval letter and prescribing information, pathology and surgical reports, clinical notes, computerized tomography scans and other imaging reports, additional supporting documentation, as applicable>

Please see full Indications and Limitations of Use on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

APPEALS FOR DENIED CLAIMS

If a payer improperly reimburses or denies a claim for Jobevne™ (bevacizumab-nwgd), you may submit an appeal. Many claim denials occur because of incorrect codes, incorrect policy numbers, or missing supplemental documentation, such as a letter of medical necessity.

Many claims issues can be resolved with a single phone call to a payer representative who may be able to reprocess a corrected claim. If not, you may have to carefully craft an appeal letter.

This list offers considerations that may be helpful for appealing denied claims:

Determine the Payer's Process for Filing Appeals

- Use a designated form for the appeal if such a form is required by the payer
- Determine the timely filing limit

Understand the Reason for the Denial

- Read the explanation of benefits (EOB) to find the reason for the claim denial. Payers use remittance advice codes for the service in question. Remittance advice code descriptions are usually included at the bottom of the page
- If the payer needs additional information, compile and submit the necessary documentation as soon as possible
- If you receive a claim denial due to a lack of medical necessity, submit additional documentation that helps to support the physician's clinical decision to prescribe JOBEVNE

Draft the Appeal Letter

- Make sure the appeal letter responds to the denial code reason
- Submit a corrected claim if the denial was due to a technical billing error (eg, incorrect patient identifier, missing diagnosis). Write "Corrected Copy" at the top
- Include a copy of the original claim and related denial notification (EOB)
- You may need to include the patient's relevant medical records, prescribing information, FDA approval letter, relevant compendia listings, or journal articles supporting the use of JOBEVNE
- Request that an oncology specialist who is familiar with JOBEVNE review the appeal letter and additional documentation

Submit and Track Appeal Status

- Submit the appeal as soon as possible and within the required time limits
- Track claims appeal responses to ensure appeals have been processed appropriately
- Document the result (eg, payment made or if further action is required)

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SAMPLE LETTER OF APPEAL

Payers may require a written appeal in cases where they have denied a claim. You may submit an appeal letter in response to a payer's decision for underpayment or nonpayment. Understanding the reason the payer denied the claim is critical for filing a successful appeal; this information can usually be found in the EOB or remittance advice. You may use the sample letter below or another form to appeal a denied claim for JOBEVNE. If you use the sample letter here, be sure to customize it with patient-specific details and submit it with additional documentation, as requested by the payer.

<Date>
<Contact Name> <Title>
<Name of Health Insurance Company>
<Address> <City, State Zip>

Insured: <Name>
Policy Number; <Number>
Group Number: <Number>
Claim Control Number: <Number>

Dear <Contact's Name>:
This letter serves as a request for reconsideration for payment of a denied claim representing charges for JOBEVNE (bevacizumab-nwgd), a biosimilar to reference product Avastin, which was administered to <name of patient> on <date(s) of service>. <Name of patient> is a<n> <age>-year-old <indicate gender> born <MM-DD-YEAR> who has been under my care for <his/her/their> diagnosis of <patient's diagnosis>. You have indicated that JOBEVNE is not covered by <insurance name> because <reason for denial>.

<Provide a brief description of patient's symptoms and therapy to date, and any other pertinent information.>

Treatment with JOBEVNE has resulted in <list documented outcomes> for this patient. JOBEVNE is approved by the FDA for <indication relevant to patient's diagnosis>. JOBEVNE has been administered to <name of patient> per the FDA-approved prescribing information dosing instructions.

JOBEVNE is a medically necessary part of <name of patient>'s treatment. I request that an oncology specialist who is familiar with JOBEVNE review this appeal letter with the additional enclosed documentation, as I am confident your reconsideration of this claim will yield appropriate coverage for my patient. Please contact me at <physician's phone number (XXX) XXX-XXXX> if you require additional information. Thank you in advance for your prompt attention to this request.

Sincerely,

<Physician's name>
<Physician's practice name>
<Phone number>

Enclosures <supporting documentation, such as FDA approval letter and prescribing information, pathology and surgical reports, clinical notes, computerized tomography scans and other imaging reports, additional supporting documentation, as applicable>

Please see full Indications and Limitations of Use on page 5, Important Safety Information on page 22, and accompanying Full Prescribing Information.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

IMPORTANT SAFETY INFORMATION

JOBEVNE can cause serious side effects, including:

Gastrointestinal (GI) perforations and fistulae: Serious, and sometimes fatal, gastrointestinal perforation occurred at a higher incidence in patients receiving bevacizumab products compared to patients receiving chemotherapy. The incidence ranged from 0.3% to 3% across clinical studies, with the highest incidence in patients with a history of prior pelvic radiation. Serious fistulae ranged from < 1% to 1.8% across clinical studies, with the highest incidence in patients with cervical cancer. Avoid JOBEVNE in patients with ovarian cancer who have evidence of recto-sigmoid involvement by pelvic examination or bowel involvement on CT scan or clinical symptoms of bowel obstruction. Discontinue in patients who develop gastrointestinal perforation, tracheoesophageal fistula, or any Grade 4 fistula. Discontinue in patients with fistula formation involving any internal organ.

Surgery and Wound Healing Complications: The incidence of surgery and wound healing complications, including serious and fatal complications, was increased in patients receiving bevacizumab products. In patients who experience wound healing complications during treatment, withhold JOBEVNE until adequate wound healing. Do not use JOBEVNE for at least 28 days following major surgery, to allow time for the wound to heal. Discontinue JOBEVNE in patients who develop necrotizing fasciitis.

Hemorrhage: Severe or fatal hemorrhage including hemoptysis, gastrointestinal bleeding, hematemesis, CNS hemorrhage, epistaxis, and vaginal bleeding, occurred up to 5-fold more frequently in patients receiving bevacizumab products vs chemotherapy alone. Discontinue JOBEVNE in patients who develop a Grades 3-4 hemorrhage.

Arterial Thromboembolic Events: Serious, sometimes fatal, arterial thromboembolic events (ATE) including cerebral infarction, transient ischemic attacks, myocardial infarction, and angina, occurred at a higher incidence in patients receiving bevacizumab vs chemotherapy. Discontinue JOBEVNE in patients who develop severe ATE. The safety of reinitiating bevacizumab products after an ATE is resolved is not known.

Venous Thromboembolic Events: An increased risk of venous thromboembolic events (VTE) was observed across clinical studies. Discontinue JOBEVNE in patients with a Grade 4 VTE, including pulmonary embolism.

Hypertension: Severe hypertension occurred at a higher incidence in patients receiving bevacizumab products as compared to chemotherapy alone. Monitor blood pressure every two to three weeks during treatment with JOBEVNE. Treat with appropriate anti-hypertensive therapy and monitor blood pressure regularly. Discontinue in patients who develop hypertensive crisis or hypertensive encephalopathy.

Posterior Reversible Encephalopathy Syndrome (PRES): PRES was reported in < 0.5% of patients across clinical studies. Discontinue JOBEVNE in patients who develop PRES.

Renal Injury and Proteinuria: The incidence and severity of proteinuria was higher in patients receiving bevacizumab as compared to patients receiving chemotherapy. Nephrotic syndrome occurred in < 1% of patients receiving bevacizumab products across clinical studies, in some instances with fatal outcome. Discontinue JOBEVNE in patients who develop nephrotic syndrome.

Infusion-related reactions: Infusion-related reactions reported across clinical studies and post marketing experience include hypertension, hypertensive crises associated with neurologic signs and symptoms, wheezing, oxygen desaturation, Grade 3 hypersensitivity, anaphylactoid/anaphylactic reactions, chest pain, headaches, rigors, and diaphoresis. In clinical studies, infusion-related reactions with the first dose of bevacizumab products occurred in < 3% of patients and severe reactions occurred in 0.4% of patients. Decrease the rate of infusion for mild, clinically insignificant infusion-related reactions. Interrupt the infusion in patients with clinically significant infusion-related reactions and consider resuming at a slower rate following resolution. Discontinue JOBEVNE in patients who develop a severe infusion-related reaction and administer appropriate medical therapy.

Embryo-Fetal Toxicity: Bevacizumab products may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JOBEVNE and for 6 months after the last dose.

Ovarian Failure: The incidence of ovarian failure was 34% vs 2% in premenopausal women receiving bevacizumab with chemotherapy vs chemotherapy alone for adjuvant treatment of a solid tumor. Inform females of reproductive potential of the risk of ovarian failure prior to initiating JOBEVNE.

Congestive Heart Failure (CHF): JOBEVNE is not indicated for use with anthracycline-based chemotherapy. Discontinue JOBEVNE in patients who develop CHF.

Most common adverse reactions incidence (incidence >10%): epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis.

Across clinical studies, bevacizumab was discontinued in 8% to 22% of patients because of adverse reactions.

Most Common Adverse Reactions by Indication

Metastatic Colorectal Cancer:

- **in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment (Study AVF2107g):** Grades 3-4 adverse reactions occurring at higher incidence (≥2%) in patients receiving bevacizumab with IFL (N=392) vs placebo with IFL (N=396) were leukopenia (37% vs 31%), neutropenia (21% vs 14%), diarrhea (34% vs 25%), abdominal pain (8% vs 5%), constipation (4% vs 2%), hypertension (12% vs 2%), deep vein thrombosis (9% vs 5%), intra-abdominal thrombosis (3% vs 1%), syncope (3% vs 1%), asthenia (10% vs 7%), and pain (8% vs 5%).
- **Metastatic colorectal cancer, 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 (Study E3200):** Selected Grades 3–5 (non-hematologic) and Grades 4–5 (hematologic) occurring at a higher incidence (≥ 2%) in patients (N=521) receiving bevacizumab with FOLFOX4 compared to FOLFOX4 alone were fatigue (19% vs. 13%), diarrhea (18% vs. 13%), sensory neuropathy (17% vs. 9%), nausea (12% vs. 5%), vomiting (11% vs. 4%), dehydration (10% vs. 5%), hypertension (9% vs. 2%), abdominal pain (8% vs. 5%), hemorrhage (5% vs. 1%), other neurological (5% vs. 3%), ileus (4% vs. 1%) and headache (3% vs. 0%).

First-Line Non-Squamous Non–Small Cell Lung Cancer (NSCLC)

- **Study E4599:**, grades 3–5 (non-hematologic) and grade 4–5 (hematologic) adverse reactions in a clinical study occurred at ≥ 2% higher incidence in patients (N=422) receiving

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IMPORTANT SAFETY INFORMATION AND INDICATIONS (cont'd)

First-Line Non-Squamous Non–Small Cell Lung Cancer (NSCLC) (cont'd)

bevacizumab with paclitaxel and carboplatin vs. patients receiving chemotherapy alone were neutropenia (27% vs. 17%), fatigue (16% vs. 13%), hypertension (8% vs. 0.7%), infection without neutropenia (7% vs. 3%), venous thromboembolism (5% vs. 3%), febrile neutropenia (5% vs. 2%), pneumonitis/pulmonary infiltrates (5% vs. 3%), infection with Grade 3 or 4 neutropenia (4% vs. 2%), hyponatremia (4% vs. 1%), headache (3% vs. 1%) and proteinuria (3% vs. 0%).

Recurrent Glioblastoma

- **Study EORTC 26101:** In patients (N=278) with recurrent GBM following radiotherapy and temozolomide, patients received bevacizumab with lomustine or lomustine alone, 22% of patients discontinued treatment in the bevacizumab with the lomustine arm compared with 10% of patients in the lomustine arm. In patients receiving bevacizumab with lomustine, the adverse reaction profile was similar to that observed in other approved indications.

Metastatic Renal Cell Carcinoma

- **Study BO17705:** Grades 3–5 adverse reactions occurring at a >2% higher incidence in bevacizumab with interferon alfa (N=337) compared to placebo with interferon alfa (N=304), were fatigue (13% vs. 8%), asthenia (10% vs. 7%), proteinuria (7% vs. 0%), hypertension (6% vs. 1%; including hypertension and hypertensive crisis), and hemorrhage (3% vs. 0.3%; including epistaxis, small intestinal hemorrhage, aneurysm ruptured, gastric ulcer hemorrhage, gingival bleeding, hemoptysis, hemorrhage intracranial, large intestinal hemorrhage, respiratory tract hemorrhage, and traumatic hematoma).

Persistent, Recurrent, or Metastatic Cervical Cancer

- **Study GOG-0240:** Grades 3 or 4 adverse reactions occurred at a higher incidence of ≥ 2% in patients receiving bevacizumab with chemotherapy (N = 218) compared to patients receiving chemotherapy alone (N = 222), were abdominal pain (12% vs. 10%), hypertension (11% vs. 0.5%), thrombosis (8% vs. 3%), diarrhea (6% vs. 3%), anal fistula (4% vs. 0%), proctalgia (3% vs. 0%), urinary tract infection (8% vs. 6%), cellulitis (3% vs. 0.5%), fatigue (14% vs. 10%), hypokalemia (7% vs. 4%), hyponatremia (4% vs. 1%), dehydration (4% vs. 0.5%), neutropenia (8% vs. 4%), lymphopenia (6% vs. 3%), back pain (6% vs. 3%), and pelvic pain (6% vs. 1%).

Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer

- **Combination with carboplatin and paclitaxel, followed by Bevacizumab as a single agent, for stage III or IV disease following initial surgical resection (Study BO17705):** Grades 3-4 adverse reactions occurring at a higher incidence (≥2%) in either of the bevacizumab arms vs. the control arm were fatigue (CPB15+ -9%, CPB15 -6%, CPP -6%), hypertension (CPB15+ -10%, CPB15 -6%, CPP -2%), thrombocytopenia (CPB15+ -21%, CPB15 -20%, CPP -15%) and leukopenia (CPB15+ -51%, CPB15 -53%, CPP -50%).
- **Combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens (Study MO22224):** Grades 3-4 adverse reactions occurring at a higher incidence (≥ 2%) in patients receiving bevacizumab with chemotherapy (N = 179) vs. patients receiving chemotherapy alone (N = 181) were hypertension (6.7% vs. 1.1%) and palmar-plantar erythrodysaesthesia syndrome (4.5% vs. 1.7%).
- **Combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Bevacizumab as a single agent for platinum-sensitive recurrent disease (Study AVF4095g):** Grades 3-4 adverse reactions occurring at a higher incidence (≥ 2%) in patients receiving bevacizumab with chemotherapy (N=247) compared to placebo with chemotherapy (N=233) were thrombocytopenia (40% vs. 34%), nausea (4% vs. 1.3%), fatigue (6% vs. 4%), headache (4% vs. 0.9%), proteinuria (10% vs. 0.4%), dyspnea (4% vs. 1.7%), epistaxis (5% vs. 0.4%), and hypertension (17% vs. 0.9%).
- **Patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have not received more than one previous regimen of chemotherapy (Study GOG-0213):** Grades 3-4 adverse reactions occurring at a higher incidence (≥ 2%) in patients receiving bevacizumab with chemotherapy compared to chemotherapy alone were hypertension (11% vs. 0.6%), fatigue (8% vs. 3%), febrile neutropenia (6% vs. 3%), proteinuria (8% vs. 0%), abdominal pain (6% vs. 0.9%), hyponatremia (4% vs. 0.9%), headache (3% vs. 0.9%), and pain in extremity (3% vs. 0%).

INDICATIONS

Metastatic Colorectal Cancer (mCRC)

- JOBEVNE combined with intravenous fluorouracil-based chemotherapy for first- or second-line treatment of patients with mCRC.
- JOBEVNE combined with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for the second-line treatment of patients with mCRC who have progressed on a first-line treatment containing bevacizumab.

Limitations of Use: JOBEVNE is not approved for use if surgery was used as the primary treatment in patients with colon cancer which has not spread to other parts of the body.

First-Line Non-Squamous Non-Small Cell Lung Cancer (NSCLC):

JOBEVNE combined with carboplatin and paclitaxel is approved for first-line treatment in patients with unresectable, locally advanced, recurrent or metastatic NSCLC.

Recurrent Glioblastoma (rGBM):

JOBEVNE is approved to treat rGRM in adults.

Metastatic Renal Cell Carcinoma (mRCC):

JOBEVNE combined with interferon alfa, is approved to treat mRCC.

Persistent, Recurrent or Metastatic Cervical Cancer (CC):

JOBEVNE combined with paclitaxel and cisplatin or paclitaxel and topotecan, is approved to treat patients with persistent, recurrent, or metastatic cervical cancer.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer:

- JOBEVNE combined with carboplatin and paclitaxel, followed by JOBEVNE alone, is used for the treatment of patients with advanced (Stage III or IV) epithelial ovarian, fallopian tube or primary peritoneal cancer following initial surgical resection.
- JOBEVNE combined with paclitaxel, pegylated liposomal doxorubicin or topotecan, is approved to treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.
- JOBEVNE combined with carboplatin and paclitaxel or with carboplatin and gemcitabine, followed by JOBEVNE alone, is approved for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

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NOTES

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My Biocon Biologics™

My Biocon Biologics™ provides patient access support and can assist with patient-specific verification of benefits for Jobevne™ (bevacizumab-nwgd) and its associated professional services, such as product infusion. For assistance*:

Monday-Friday
9 AM-8 PM ET

Call
1-833-695-2623

*My Biocon Biologics support services will be available starting in July 2025.

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