izervay™
(avacincaptad pegol intravitreal solution) 2 mg

Billing and Coding Guide

Your Access and Reimbursement Manager:

Name: _____

Phone: _____ Email: _____

With just a call or click, you can get reliable assistance from a dedicated IZERVAY My Way℠ Access Coordinator.

Phone: **1-888-C5MYWAY (1-888-256-9929)**
8 AM to 8 PM ET Monday - Friday

Fax: **1-833-C5MYWAY (1-833-256-9929)**

Email: **Support@IZERVAYMyWay.com**

Website: **IZERVAYecp.com/PatientSupport**

The information in this guide is subject to change without notice and should be verified by the provider for each patient prior to treatment. Contact the patient's health plan directly for the most accurate information.

It is always the provider's responsibility to determine the appropriate codes for the products and services rendered. Iveric Bio does not guarantee payment or coverage for any product or service.

Please see Important Safety Information on page 8 and accompanying full Prescribing Information.

Codes for billing and reimbursement

The codes below are common codes that may be used when filing a claim for IZERVAY. For the most accurate codes, please contact your patient's health plan.

Current Procedural Terminology (CPT) codes for imaging[1,2]

CPT code	Description
92134	Optical coherence tomography
92235	Fluorescein angiography (FA)
92250	Fundus photography (Fundus autofluorescence)
92240	Indocyanine green angiography (ICG)
92242	FA and ICG

CPT code for injections[3]

CPT code	Site modifier	Description
67028	Apply the appropriate site modifier (LT, RT, or 50) to the end of CPT code 67028	Intravitreal injection

LT, left eye; RT, right eye; 50, both eyes.

References: 1. Centers for Medicare & Medicaid Services. Physician fee schedule search. Accessed May 18, 2023. https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=0&HT=1&CT=0&H1=92134&H2=92235&H3=92250&H4=92240&H5=92242&M=1 **2.** Asbell RL. Chart documentation for ophthalmic diagnostic tests. *Retina Today*. 2014:29-30. **3.** Medicare.gov. Intravitreal injection of a pharmacologic agent (separate procedure). Accessed May 18, 2023. https://www.medicare.gov/procedure-price-lookup/cost/67028

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Evaluation and management (E/M) codes[1]

CPT code	Description
99203	New Patient Level 3 E/M
99213	Established Patient Level 3 E/M
99204	New Patient Level 4 E/M
99214	Established Patient Level 4 E/M

Office visit modifier[2]

Modifier	Description
25	Significant, separately identifiable evaluation and management service by the same physician or other qualified healthcare professional on the same day of the procedure or other services.

Office visit modifiers help with prompt and correct payment based on evaluation and management services provided. These modifiers do not apply to services like tests or surgeries.

References: 1. American College of Obstetricians and Gynecologists. 2021 Evaluation and management summary. Accessed May 18, 2023. https://www.dph.ncdhhs.gov/lhd/docs/2021-EM-CodingSummary.pdf **2.** American Academy of Ophthalmology. Effectively use exam modifiers. Accessed May 18, 2023. https://www.aao.org/young-ophthalmologists/yo-info/article/effectively-use-exam-modifiers

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ICD-10 codes for GA[1]

	Right eye	Left eye	Bilateral
Dry (nonexudative) AMD, advanced atrophic without subfoveal involvement	H35.31**13**	H35.31**23**	H35.31**33**
Dry (nonexudative) AMD, advanced atrophic with subfoveal involvement	H35.31**14**	H35.31**24**	H35.31**34**

Key:

Blue numerals (6th position) indicate laterality.

H35.31**11**

Red numerals (7th position) indicate staging.

National Drug Code (NDC)[2]

Tradename	Package strength	10-digit format	11-digit format
IZERVAY™ (avacincaptad pegol intravitreal solution)	20 mg/mL solution in a single-dose glass vial	82829-002-01	82829-0002-01

Check with the patient's health plan to determine sequence requirements regarding the use of a 10-digit or 11-digit NDC as it may vary.

References: 1. American Academy of Ophthalmology. How to use the ICD-10 codes for age-related macular degeneration. Accessed May 18, 2023. https://www.aao.org/eyenet/article/how-to-use-the-icd-10-codes-for-amd **2.** Izervay [prescribing information]. Iveric Bio, Inc; Parsippany, NJ.

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Healthcare Common Procedure Coding System (HCPCS) code[1]

HCPCS code	Descriptor	Site of care	Billing unit
J3490	Unclassified drugs	All sites of care	1
J3590	Unclassified biologics	All sites of care	1
C9399	Unclassified drugs or biologics	Hospital outpatient department	1

Reach out to your Access and Reimbursement Manager if you have additional questions about the miscellaneous J-code. When the permanent J-code is available, billing and coding updates will be provided.

Check with the patient's health plan to determine whether J3490 or J3590 should be used when submitting a claim, as it may vary.

JZ modifier: Effective July 1, 2023, providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts.[2]

Important reminders when using a miscellaneous code

Ensure the following information is included in the claim submission when using a miscellaneous code:

- Drug name/generic name
- Strength
- Unit administered
- Route of administration
- NDC
- Appropriate codes (ICD-10, CPT, HCPCS)

Some health plans may also request the following:

- Prescribing information
- FDA approval letter
- Any relevant documentation to support medical necessity (EHR documentation, letter of medical necessity, etc)
- Drug purchase invoice

References: 1. Centers for Medicare & Medicaid Services. Billing and coding: hospital outpatient drugs and biologics under the outpatient prospective payment system (OPPS). Accessed May 18, 2023. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55913 **2.** Centers for Medicare & Medicaid Services. Medicare program: discarded drugs and biologicals–JW modifier and JZ modifier policy frequently asked questions. Accessed May 18, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf

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Sample CMS-1500 form

The sample claim form below is just an example of how services provided in a physician's office may be billed on the CMS-1500 form.

Box 19:
Product name, generic, strength, dose administered, route of administration, NDC

Box 21A:
Diagnosis code (ICD-10-CM)

Box 23:
Prior authorization number, if available

Box 24A:
List the date of service in the white space. In the red shaded area at the top of the box, insert the N4 qualifier followed by the 11-digit NDC number and unit quantity.

Box 24D:
Enter the appropriate HCPCS code, J3490/J3590 or C9399, for IZERVAY on its own line, which should correlate to the NDC in Box 24A. The HCPCS code must be accompanied by the JZ modifier.[1] Include the following on separate lines:

- CPT code to report the administration procedure, 67028, along with the correct site modifier
- CPT code to report imaging, if appropriate
- CPT E/M code, if appropriate

Box 24E:
Enter the diagnosis code reference letter as shown in Box 21 to relate the date of service and the procedures performed to the diagnosis code.

Box 24G:
Enter the appropriate number of units administered for IZERVAY. When using the miscellaneous J-code, the unit amount is 1.

Form content (selected fields):

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
IZERVAY, 2 mg, 1 unit, intravitreal injection, 82829-002-01

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)
A. H35.3123

24. Service lines:

Line	NDC (shaded)	From MM DD YY	To MM DD YY	CPT/HCPCS	MODIFIER	DIAGNOSIS POINTER	UNITS
1	N482829-0002-01ML20	01 22 23	01 22 23	J3490	JZ	A	1
2		01 22 23	01 22 23	67028	LT		

Reference: 1. Centers for Medicare & Medicaid Services. Medicare program: discarded drugs and biologicals–JW modifier and JZ modifier policy frequently asked questions. Accessed May 18, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf
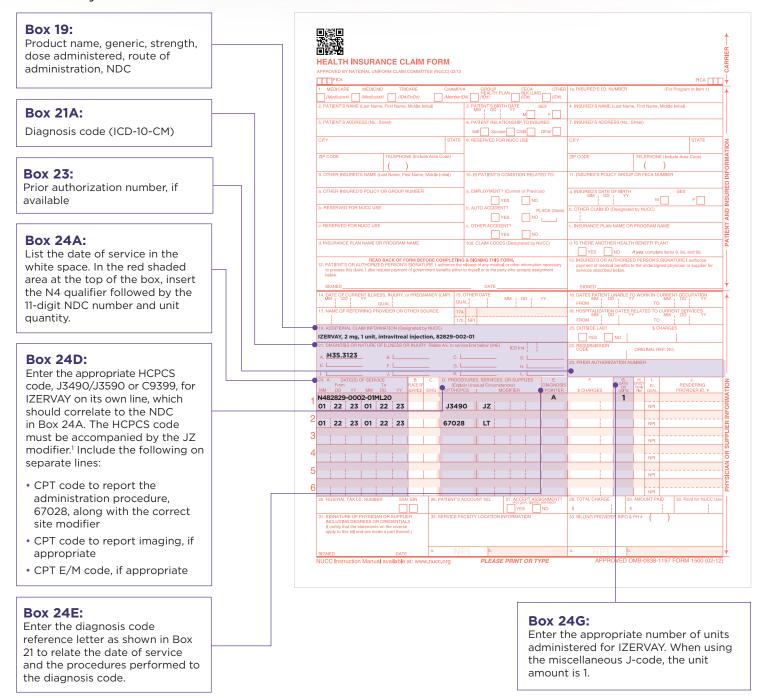
It is your responsibility to ensure that claim forms are completed accurately based on the clinical visit.

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Sample CMS-1450 form

The sample claim form below is just an example of how services provided in a hospital outpatient department may be billed on the CMS-1450 form.

Box 42:
Enter the appropriate revenue code corresponding with the HCPCS code in Box 44, which is required for billing the unclassified HCPCS code (eg, 636 revenue code for drugs requiring detailed coding, and/or 250 for general pharmacy). Then enter the appropriate revenue code corresponding with the CPT code in Box 44 (eg, 500 for general outpatient services, or 510 for general clinic services).[1]

Box 43:
Enter a detailed drug description for the payer. The N4 indicator is listed first, the 11-digit NDC number is listed second, a code describing the unit of measurement qualifier is listed third, and the unit quantity is listed at the end.

Box 44:
Enter the appropriate HCPCS code for IZERVAY as required by the payer. J3490/3590 or C9399 may be appropriate, depending on the health plan. It is your responsibility to confirm the appropriate code with the health plan and submit claims accordingly. The HCPCS code must be accompanied by the JZ modifier.[2] To report the injection procedure, enter the appropriate CPT code, 67028, along with the appropriate site modifier.

Box 46:
Enter the units of service

Box 63:
Treatment authorization codes

Box 67:
Diagnosis code (ICD-10-CM)

Box 80:
Product name, generic, strength, dose administered, route of administration

Form field values visible on the sample CMS-1450:

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	46 SERV. UNITS
250	N482829-0002-01ML20	C9399 JZ	1
500	Outpatient clinic	67028LT	

Box 67: H35.3123

Box 80 REMARKS: IZERVAY, avacincaptad pegol intravitreal solution, 2 mg, 1 unit, intravitreal injection, 82829-002-01

References: 1. Noridian Healthcare Solutions. Revenue codes. Accessed May 18, 2023. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **2.** Centers for Medicare & Medicaid Services. Medicare program: discarded drugs and biologicals–JW modifier and JZ modifier policy frequently asked questions. Accessed May 18, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf
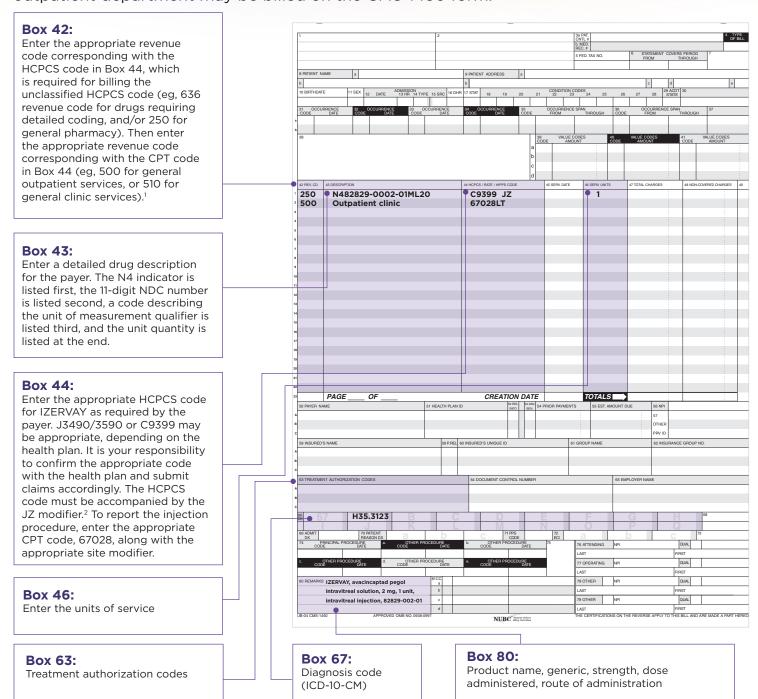
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INDICATION

IZERVAY™ (avacincaptad pegol intravitreal solution) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- IZERVAY is contraindicated in patients with ocular or periocular infections and in patients with active intraocular inflammation.

WARNINGS AND PRECAUTIONS

- Endophthalmitis and Retinal Detachments
  - Intravitreal injections, including those with IZERVAY, may be associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering IZERVAY in order to minimize the risk of endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.

- Neovascular AMD
  - In clinical trials, use of IZERVAY was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (7% when administered monthly and 4% in the sham group) by Month 12. Patients receiving IZERVAY should be monitored for signs of neovascular AMD.

- Increase in Intraocular Pressure
  - Transient increases in intraocular pressure (IOP) may occur after any intravitreal injection, including with IZERVAY. Perfusion of the optic nerve head should be monitored following the injection and managed appropriately.

ADVERSE REACTIONS

- Most common adverse reactions (incidence ≥5%) reported in patients receiving IZERVAY were conjunctival hemorrhage, increased IOP, blurred vision, and neovascular age-related macular degeneration.

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