

ANJESO is indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics. <u>Limitation of Use</u>: Because of delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS Cardiovascular Risk

- Non-steroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- ANJESO is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

• NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Please scroll down to see Important Safety Information. Please see full Prescribing Information, including Boxed Warning, at www.anjeso.com.



TABLE OF CONTENTS

Introduction	
Overview of ANJESO	
Coding	
— HCPCS and NDC Codes	5
Medicare Pass-Through Status for ANJESO	6
ANJESO Use in the Ambulatory Surgical Center (ASC)	7
— Billing, Coding, and Reimbursement Highlights for the ASC — Sample Claim Form for the ASC	
ANJESO Use in the Hospital Outpatient Department (HOPD)	10
— Billing, Coding, and Reimbursement Highlights for the HOPD — Sample Claim Form for the HOPD	10
ANJESO Use in the Physician Office	13
— Physician Office: ANJESO Use for Postsurgical Pain Management — Physician Office: ANJESO Use for Non-Surgical Pain Management — Sample Claim Form for Use in the Physician Office	14
Appendix	17
— ASC and HOPD Medicare Pass-Through Payment Indicators and Rates — Abbreviations Used in This Guide	
— Baudax Reimbursement HUB	2





INTRODUCTION

Baudax Bio, Inc., is committed to providing you with information to assist in obtaining reimbursement for ANJESO.

This billing and coding guide is intended to supply you with general coding, coverage, and reimbursement information to help with the reimbursement process for ANJESO. Information in this guide reflects information available regarding polices in effect as of January 1, 2021.

Additional, complimentary reimbursement support is available by contacting the Baudax Reimbursement HUB. See page 21 of this guide for contact information, availability, and services offered by the Baudax Reimbursement HUB.

DISCLAIMER: The details provided in this resource are for general reimbursement information only and are not legal advice nor are they advice about how to code, complete, or submit any particular claim for payment. Information provided is not intended to increase or maximize reimbursement by any payer. The information provided represents Baudax's understanding of current coverage and reimbursement policies as of January 1, 2021. It is a facility's and physician's responsibility to determine appropriate codes, charges, and modifiers, and submit bills for items and services consistent with the patient insurer requirements. Third-party payers may have different policies and coding requirements. Such policies can change over time. Baudax disclaims any responsibility for claims submitted by facilities or physicians. Providers should check and verify current policies and requirements with the payer for any particular patient.

IMPORTANT SAFETY INFORMATION (CONT'D) CONTRAINDICATIONS

ANJESO is contraindicated in patients with:

- Known hypersensitivity (eg, anaphylactic reactions and serious skin reactions) to meloxicam or any components of the drug product.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.
- Moderate to severe renal insufficiency patients who are at risk for renal failure due to volume depletion.





NON-OPIOID ANJESO: THE FIRST AND ONLY ONCE-DAILY IV ANALGESIC¹



Up to 24 hour pain relief1,*



COX-2 preferential IV NSAID^{1-3,†}



Demonstrated safety and tolerability¹



Once-daily IV push¹

OVERVIEW OF ANJESO¹

Indication

ANJESO is indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics. Limitation of Use: Because of delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required.

Dosing and Administration

- The approved dose of ANJESO is 30 mg once daily
- ANJESO is administered by intravenous bolus push injection over 15 seconds
- For more information, please refer to the Dosage and Administration section of the Full Prescribing Information for ANJESO

How Supplied

- ANJESO is available as a ready-to-use, single-use vial
- Each vial contains 30 mg of ANJESO
- Each vial is supplied as a 1 mL fill (30 mg/mL) in a clear 2 mL vial
- No refrigeration or reconstitution is required

*When initiating ANJESO, monitor patient pain response. If patient experiences inadequate analgesia during the 24-hour dosing interval, consider adding a short-acting, non-NSAID, immediate-release analgesic.

'The mechanism of action of ANJESO, like other NSAIDs, is not completely understood, but involves inhibition of both COX-1 and COX-2 pathways. COX-2 activity is based on in vitro data, not clinical trial data.

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS

<u>Hepatotoxicity</u>: Elevations of ALT or AST have been reported in patients with NSAIDs. In addition, rare, sometimes fatal, cases of severe hepatic injury including fulminant hepatitis, liver necrosis, and hepatic failure have been reported. Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue ANJESO immediately if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Please scroll down to see Important Safety Information.
Please see full Prescribing Information, including Boxed Warning, at www.anjeso.com.





HCPCS CODE

Unique J-code

CMS has established a unique, Level II HCPCS code, which identifies ANJESO (meloxicam) injection:

• J1738: Injection, meloxicam, 1 mg⁴

As of October 1, 2020, J1738 should be used for all commercial, Medicare, and Medicaid claims. It replaces all previously used codes for ANJESO, including J3490, C9399, and C9059.⁴

INTRODUCTION



May not reflect actual size

Important Coding Notes

- One unit of J1738 is 1 mg of ANJESO, not the entire vial⁴
- A vial of ANJESO contains 30 mg, which is the recommended daily dose of ANJESO¹
- If a patient is administered 30 mg of ANJESO (1 vial), it would be billed as 30 units of J1738

NDC CODES

The NDC is a unique number that identifies a drug's labeler, product, and package size.

Payer requirements regarding the use of the 10 or 11-digit NDC may vary. Consult individual payers to learn about their billing requirements. Medicaid fee-for-service programs, Medicare crossover claims for dual-eligible beneficiaries (Medicare and Medicaid), and some private payers also require the NDC for billing instead of, or in addition to, the HCPCS code. Information on the use of line item NDC is provided in the claim form examples on pages 9, 12, and 16 of this guide.

FOR ORDERING: 10-DIGIT NDC ⁵	FOR BILLING: 11-DIGIT NDC	DESCRIPTION ⁵
71518-001-01	71518-0001-01	1 vial, single-dose in 1 carton

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS (CONT'D)

<u>Hypertension</u>: NSAIDs including ANJESO can lead to new onset of hypertension or worsening of preexisting hypertension, which may contribute to the increased incidence of cardiovascular (CV) events. Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.





APPENDIX

ANIESO HAS MEDICARE PASS-THROUGH STATUS

In July 2020, ANJESO received Medicare transitional pass-through payment status for use in the HOPD and Medicare-certified ASC settings of care.⁶⁷

What Is Medicare Transitional Pass-Through Status?8-10

The Centers for Medicare and Medicaid Services (CMS) established transitional pass-through status in 2000 for innovative products such as new drugs, devices, and biological agents as part of the Medicare Hospital Outpatient Prospective Payment System (OPPS). Medicare also allows separate drug payment in the ASC Payment System when the drug is provided as part of a covered surgery.

What Is the Purpose of Medicare Pass-Through Status?¹⁰

The purpose of the provision, which lasts for a 3-year period, is to provide adequate, separate payment for new drugs to allow HOPDs and ASCs time to incorporate the new drug into their protocols. The provision also allows CMS to collect claims data to determine appropriate reimbursement after the pass through period.

Why Is This Important?

(meloxicam) injection

Medicare pass-through status enables ANJESO be reimbursed separately from the payment for the procedure. CMS pass-through payments allow your patients to have access to new drugs, like ANJESO, by reimbursing facilities separately for those drugs when administered as part of a procedure.

What Hospital Departments Might Be Relevant for the ANJESO Medicare Pass-Through Status?

In settings in which a hospital bills OPPS, Medicare pass-through status may apply if the patient receives care as an outpatient and is not subsequently admitted as an inpatient within a 1- or 3-day window depending on the type of hospital. For example, pass-through status could be applicable for hospital outpatient surgeries and observation stays as long as the patient has not been admitted as an inpatient. Likewise, in the hospital emergency department (ED) if billing OPPS and if the patient is discharged from the ED, pass-through status is applicable. However, if the patient is admitted to the hospital as an inpatient, Medicare pass-through status does not apply as the patient is not considered an outpatient.

What Is the Medicare Facility Payment?

The total Medicare facility payment, including beneficiary cost sharing, is based on the ANJESO Wholesale Acquisition Cost (WAC) + 3% until an Average Sales Price (ASP) is established by CMS. Once the ASP is published by CMS, the Medicare payment amount is based on ASP + 6%. See the ASC section for patient copayment information.

Where Can I Find the Medicare Payment Amount?

See the Appendix for information on how to locate this information on the CMS website.

How Do I Bill for Pass-Through Payment?

Providers should use one claim form, but should bill Medicare for ANJESO separately from the procedure(s), using a separate line on the claim form, as shown in the ASC and HOPD sections of this guide.

Is Medicare Pass-Through Applicable for Physician Offices?

Medicare pass-through status is applicable when billing the OPPS or the ASC payment system, and is not applicable in the physician office (place of service 11). In the office setting, post-surgical pain management is typically included in the surgical payment. Physicians may bill separately for ANJESO when used for medically necessary, non-surgical pain management administered in the physician office (see Physician Office section of this guide).

Please scroll down to see Important Safety Information.

Please see full Prescribing Information, including Boxed Warning, at www.anjeso.com.





ANJESO USE IN THE ASC

Applicable for ANJESO use in a Medicare-certified ASC when the drug is provided as part of a covered ASC surgery.

Billing and Coding Points

PRODUCT	ANJESO® (meloxicam) Injection 30 mg/mL
11-DIGIT NDC	71518-0001-01
HCPCS PRODUCT CODE	J1738
DESCRIPTION	Injection, meloxicam, 1 mg
UNITS IN VIAL*	30
PLACE OF SERVICE	24: Ambulatory surgical center

INTRODUCTION

Reimbursement Highlights

Medicare

In the ASC Payment System, ANJESO has pass-through status for Part B claims and is reimbursed separately from the payment for the procedure.¹²

- The Medicare payment amount for ANJESO is based on the drug's WAC + 3% until an ASP is established by CMS. Once the ASP is published by CMS, the Medicare payment amount is based on ASP + 6%¹¹
- Facility reimbursement is 80% of the Medicare payment amount. The patient or secondary/supplemental insurance responsibility covers the remaining 20% after the deductible is met¹²
- Medicare's share of payment may be reduced by sequestration if applicable on the date of service
- See the Appendix for information on how to find the quarterly updated Medicare payment amount on the CMS website

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS (CONT'D)

<u>Heart Failure and Edema</u>: NSAID use increased the risk of myocardial infarction (MI), hospitalization for heart failure, and death. Avoid use of ANJESO in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. If ANJESO is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Please scroll down to see Important Safety Information.
Please see full Prescribing Information, including Boxed Warning, at www.anjeso.com.



^{*}See Important Coding Notes in the Coding section of this guide.



ANJESO USE IN THE ASC (CONT.)

Reimbursement Highlights

Medicare Advantage*

For Medicare Advantage (Part C) claims, ANJESO reimbursement and patient co-pay may vary from traditional Medicare Part B plans.

- Medicare Advantage plans may or may not follow traditional CMS reimbursement guidelines
- Contact local Medicare Advantage payers in advance to determine coverage and reimbursement for ANJESO

Commercial and Medicaid*

Commercial and Medicaid payers may use different payment methods for ANJESO than Medicare. Commercial and Medicaid payers may:

- Determine payment based on percent of charges
- Follow Medicare pass-through status and provide separate payment for ANJESO outside of the surgical bundle
- Bundle pain management with the surgical procedure reimbursement

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS (CONT'D)

Post MI Patients: Avoid the use of ANJESO in patients with recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ANJESO is used in these patients, monitor for signs of cardiac ischemia.





^{*}Prior authorizations and/or predeterminations may be required. Prior to administering, verify individual contracted rates by reviewing the facility's contracts or contacting the payer's provider relations representative.



SAMPLE CMS-1500 CLAIM FORM FOR USE IN THE ASC

• As noninstitutional providers, ASCs use the ANSI 837P electronic or the CMS-1500 paper claim form. A CMS-1500 claim form with relevant excerpts is shown below¹⁴

INTRODUCTION

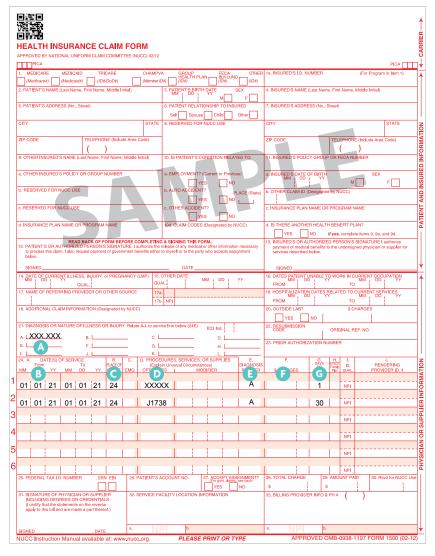
- In this example, the provider administered 30 mg of ANJESO as per the approved dose for use in adults
- Item 21: Diagnosis Code(s) Enter the appropriate ICD-10-CM ICD-10-CM diagnosis code(s)
- Item 24A: Date of Service Enter the date of the procedure and drug administration

Note: If line item NDC is required by a payer, for example dual-eligible Medicare and Medicaid beneficiaries, enter in the shaded area of Item 24A:

• Qualifier "N4" before the 11-digit ANJESO NDC (71518-0001-01), followed by 3 spaces, the unit of measure (UN for units), and ANJESO units administered

24. A.	. D/	ATE(S) C	F SER	VICE	
	From			To	
MM	DD	YY	MM	DD	YY
N471518000101 UN30					
01	01	21	01	01	21

- **Item 24B: Place of Service Code** Enter 24 for ASC setting of care
- Item 24D: HCPCS Code Enter the CPT procedure code(s) provided on the day of service per payer policy On a separate line, enter J1738 for ANJESO (Injection, meloxicam, 1 mg)
- **Item 24E: Diagnosis Pointer** Enter the diagnosis code reference letter from Item 21. Enter only one diagnosis pointer
- **Item 24F: Charges** Enter the amount of your charge for the procedure and for ANJESO
- Item 24G: Units Enter the appropriate units for the procedure, then enter the units of ANJESO administered. In this example, enter 30 to describe 30 mg administered





Applicable for ANJESO use in the HOPD. See page 6 for examples where ANJESO Medicare pass-through status may apply when billing OPPS.

Billing and Coding Points

PRODUCT	ANJESO® (meloxicam) Injection 30 mg/mL
11-DIGIT NDC	71518-0001-01
HCPCS PRODUCT CODE	J1738
DESCRIPTION	Injection, meloxicam, 1 mg
UNITS IN VIAL*	30
REVENUE CODE	0636: Drugs requiring detailed coding

^{*}See Important Coding Notes in the Coding section of this guide.

Reimbursement Highlights

Medicare

In the OPPS Payment System, ANJESO has pass-through status for Part B claims and is reimbursed separately from the payment for the procedure.¹³

- The Medicare payment amount for ANJESO is based on the drug's WAC +3% until an ASP is established by CMS. Once the ASP is published by CMS, the Medicare payment amount is based on ASP + 6%11
- Facility reimbursement is 100% of the Medicare payment amount¹⁵
- Medicare's share of payment may be reduced by sequestration if applicable on the date of service
- See the Appendix for information on how to find the quarterly updated Medicare payment amount on the CMS website

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS (CONT'D)

Renal Toxicity: Long-term administration of NSAIDs has resulted in renal papillary necrosis, renal insufficiency, acute renal failure, and other renal injury. ANJESO is not recommended in patients with moderate to severe renal insufficiency and is contraindicated in patients with moderate to severe renal insufficiency who are at risk for renal failure due to volume depletion. Correct volume status in dehydrated or hypovolemic patients prior to initiating ANJESO. Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of ANJESO in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. If ANJESO is used in patients with advanced renal disease, monitor patients for signs of worsening renal function.





ANJESO USE IN THE HOPD (CONT.)

Reimbursement Highlights (cont.)

Medicare Advantage*

For Medicare Advantage (Part C) claims, ANJESO reimbursement and patient co-pay may vary from traditional Medicare Part B fee for service (FFS).

- Medicare Advantage plans may or may not follow traditional Medicare FFS reimbursement guidelines
- Contact local Medicare Advantage payers in advance to determine coverage and reimbursement for ANJESO

Commercial and Medicaid*

Commercial and Medicaid payers may use different payment methods for ANJESO than Medicare. Commercial and Medicaid payers may:

- Determine payment based on percent of charges
- Follow Medicare pass-through status and provide separate payment for ANJESO outside of the surgical bundle
- Bundle pain management with the surgical procedure reimbursement

*Prior authorizations and/or predeterminations may be required. Prior to administering, verify individual contracted rates by reviewing the facility's contracts or contacting the payer's provider relations representative.

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS (CONT'D)

<u>Anaphylactic Reactions</u>: Meloxicam has been associated with anaphylactic reactions in patients with and without known hypersensitivity to meloxicam and in patients with aspirin-sensitive asthma. Seek emergency help if an anaphylactic reaction occurs.







SAMPLE UB-04/CMS-1450 CLAIM FORM FOR USE IN THE HOPD

• As institutional providers, HOPDs use the ANSI 8371 electronic claim form or the UB-04 claim form, also known as the CMS-1450. Relevant excerpts of the UB-04/CMS1450 claim form as shown below. In this example, the provider administered 30 mg of ANJESO as per the approved dose for use in adults¹⁶

FL (Form Locator) 42: Revenue Code Enter appropriate revenue code for the procedure, then Enter 0636 for "drugs requiring detailed coding"

FL 43: Description Enter description for revenue code for the procedure, then **Enter Drugs requiring detailed coding**

Note: If line item NDC is required, for example dual-eligible Medicare and Medicaid beneficiaries, enter in FL 43:

• Qualifier "N4" before the 11-digit ANJESO NDC (71518-0001-01), followed by the unit of measure (UN for units), and the ANJESO units administered"

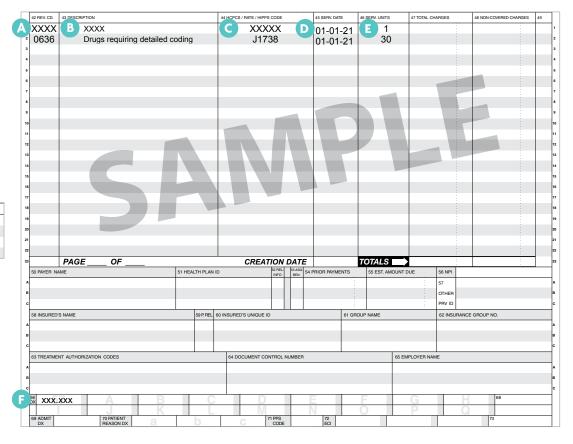
	42 REV. CD.	43 DESCRIPTION
1	XXXX	XXXX
2		
3	0636	N471518000101UN30
4		

FL 44: HCPCS Code Enter the appropriate CPT procedure code, then Enter J1738 for ANJESO (Injection, meloxicam, 1 mg)

FL45: Service Date Enter date of the service for the procedure and ANJESO administration

FL 46: Service Units Enter the service units for the procedure, then Enter 30 to describe 30 mg of ANJESO (a service unit = mg)

FL 66: Diagnosis Code(s) Enter the appropriate ICD-10-CM diagnosis code(s)





ANJESO USE IN THE PHYSICIAN OFFICE

ANJESO is indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics. ANJESO labeling is not specific to postsurgical pain management.

When ANJESO is administered in the physician office setting of care (Place of Service: 11), reimbursement may differ depending on whether the drug is administered as:

- Pain management as part of a surgical procedure
- Pain management not associated with a surgical procedure

PHYSICIAN OFFICE: ANJESO USE FOR POSTSURGICAL PAIN MANAGEMENT

INTRODUCTION

Medicare

- When used integral to a surgical procedure performed in a physician office (Place of Service 11), ANJESO may be considered as part of the Medicare global surgical payment and not reimbursed separately¹⁷
- Medicare considers post-surgical pain management provided by the surgeon to be part of the global surgical payment provided by the surgeon to be part of the global surgical payment
- Medicare utilizes correct coding initiative (CCI) edits to prevent the billing of an infusion administration code (e.g. 96374) and a surgical procedure CPT code performed in the physician office. If the infusion procedure cannot be billed, typically the drug will not be reimbursed either¹⁹

Other Payers

- Other payers may or may not follow Medicare policy. If a payer considers post-surgical pain management provided by a surgeon to be part of a global surgery payment, ANJESO may not be separately reimbursed
- Contact the payer to obtain individual payment policies, payer specific claim forms, and whether CPT codes for infusion services can be billed

PHYSICIAN OFFICE: ANJESO USE FOR NON-SURGICAL PAIN MANAGEMENT

• Medicare and other payers may allow coverage for ANJESO as a Part B drug for medically necessary management of moderate-to-severe pain use not associated with postsurgical pain management.

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS (CONT'D)

<u>Exacerbation of Asthma Related to Aspirin Sensitivity</u>: ANJESO is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

Please scroll down to see Important Safety Information.
Please see full Prescribing Information, including Boxed Warning, at www.anjeso.com.





PHYSICIAN OFFICE: ANJESO USE FOR NON-SURGICAL PAIN MANAGEMENT

Billing and Coding Points

PRODUCT	ANJESO® (meloxicam) Injection 30 mg/mL
11-DIGIT NDC	71518-0001-01
HCPCS PRODUCT CODE	J1738
DESCRIPTION	Injection, meloxicam, 1 mg
UNITS IN VIAL*	30
PLACE OF SERVICE	11: Physician Office

ADMINISTRATION CODES

For non-surgical use, one of the following infusion CPT codes is used for ANJESO administration, dependent on other drugs infused the same day:

- **CPT 96374** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
- **CPT 96375** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS AND PRECAUTIONS (CONT'D)

<u>Serious Skin Reactions</u>: NSAIDs, including ANJESO, can cause serious skin reactions, including exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal and can occur without warning. Discontinue ANJESO at first appearance of skin rash or other signs of hypersensitivity.

<u>Hematologic Toxicity</u>: Anemia has occurred in NSAID-treated patients. Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia. NSAIDs, including ANJESO, may increase the risk of bleeding events. Monitor patients for signs of bleeding.





^{*}See Important Coding Notes in the Coding section of this guide.



PHYSICIAN OFFICE: ANJESO USE FOR NON-SURGICAL PAIN MANAGEMENT (CONT.)

Reimbursement Highlights

Medicare

For non-surgical pain management, Medicare Fee for Service (FFS) is likely to cover ANJESO under Part B for medically necessary use consistent with drug labeling.¹¹

- The Medicare FFS payment amount for ANJESO is based on the WAC + 3% until an ASP is available. Once an ASP is available, the payment amount is based on ASP + 6%
- Medicare FFS in the physician office reimburses providers 80% of the Medicare allowable¹¹
- The patient or the patient's supplemental/secondary insurance is responsible for the remaining 20%
- Medicare's share of payment may be reduced by sequestration if applicable on the date of service

Medicare Advantage*

For Medicare Advantage (Part C) claims, ANJESO reimbursement and patient co-pay may vary from traditional Medicare Part B plans.

- Medicare Advantage plans may or may not follow traditional CMS reimbursement guidelines
- Contact local Medicare Advantage payers in advance to determine coverage and reimbursement for ANJESO

Commercial and Medicaid*

• Contact Commercial and Medicaid payers to verify payment for non-surgical ANJESO use in the physician office

IMPORTANT SAFETY INFORMATION (CONT'D) DRUG INTERACTIONS

<u>Drugs That Interfere With Hemostasis (e.g. warfarin, aspirin, SSRIs/SNRIs)</u>: Monitor patients for bleeding who are concomitantly taking ANJESO with drugs that interfere with hemostasis. Concomitant use of ANJESO and analgesic doses of aspirin is not generally recommended.

Angiotensin Converting Enzyme (ACE) Inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers: Concomitant use with ANJESO may diminish the antihypertensive effect of these drugs. Monitor blood pressure.

Please scroll down to see Important Safety Information.
Please see full Prescribing Information, including Boxed Warning, at www.anjeso.com.



^{*}Prior authorizations and/or predeterminations may be required. Prior to administering, verify individual contracted rates by reviewing the facility's contracts or contacting the payer's provider relations representative.

HOPD



SAMPLE CMS-1500 CLAIM FORM FOR USE IN THE PHYSICIAN OFFICE

INTRODUCTION

- As noninstitutional providers, physician offices use the ANSI 837P electronic claim form or the CMS-1500 paper claim form. A CMS-1500 claim form with relevant excerpts is shown below for ANJESO non-surgical pain management use¹⁴
- In this example, the provider administered 30 mg of ANJESO by IV push as per the approved dose for use in adults. No other IV drugs were administered. No surgical procedure was performed
- A Item 21: Diagnosis Code(s)

 Enter the appropriate ICD-10-CM diagnosis code(s)
- B Item 24A: Date of Service
 Enter the date of drug administration

NOTE: When a line item NDC is required by payers, for example dual-eligible Medicare and Medicaid beneficiaries, enter in the shaded area of Item 24A:

 Qualifier "N4" before the 11-digit ANJESO NDC (71518-0001-01), followed by 3 spaces, the unit of measure (UN for units), and ANJESO units administered

24. A.	. DA	ATE(S) C	F SER	VICE	
	From			To	
MM	DD	YY	MM	DD	YY
N47′	N471518000101			30	
01	01	21	01	01	21

- Item 24B: Place of Service Code
 Enter 11 for Physician Office setting of care
- Enter the appropriate infusion CPT code (96374 or 96375) for ANJESO administration depending on other drugs infused the same day. In this example, no other IV drugs were administered, so 96374 is shown on the claim form

On a separate line, enter J1738 for ANJESO (Injection, meloxicam, 1 mg)

- Enter the diagnosis code reference letter from Item 21. Enter only one diagnosis pointer
- F Item 24F: Charges
 Enter the amount of your charge for ANJESO and CPT codes
- G Item 24G: Units
 Enter the units of ANJESO administered. In this example, Enter 30 to describe 30 mg of ANJESO administered

HEALTH INSURANCE CLAIM FORM YES NO



ASC MEDICARE PASS-THROUGH PAYMENT INDICATOR AND RATE

INTRODUCTION

How to Find the Latest Medicare Pass-Through Quarterly Payment Rate on the CMS Website^{20,21}

- The Medicare payment rate for J1738 is updated quarterly by CMS
- Download the latest quarterly file at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11 Addenda Updates
- For J1738 Medicare payment rate and payment status:
 - Navigate to the workbook or section 508 compliant version file entitled Addendum BB ASC Covered Ancillary Services Integral to Covered Surgical **Procedures**
- The HCPCS code for ANJESO is J1738, which has a payment indicator of K2 in the ASC payment System
 - The K2 payment indicator is defined as "drugs and biologicals paid separately when provided integral to a surgical procedure on the ASC list; based on the OPPS rate"

HOPD MEDICARE PASS-THROUGH PAYMENT INDICATOR AND RATE

How to Find the Latest Medicare Pass-Through Quarterly Payment Rate on the CMS Website^{15,22}

- The Medicare payment rate for J1738 is updated quarterly by CMS
- Download the latest quarterly file at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-Aand-Addendum-B-Updates
- For J1738 Medicare payment rate and payment status:
 - Navigate and download the latest Addendum B file Open either the workbook or section 508 compliant version entitled Addendum B-Final OPPS Payment by HCPCS Code
- The HCPCS code used for ANJESO is J1738, which has a status indicator of G in the Hospital OPPS
 - The G status indicator is defined as "pass-through drugs and biologicals paid under OPPS; separate APC payment includes pass-through amount"





(meloxicam) injection

ANSI	American National Standards Institute
APC	Ambulatory Payment Classification
ASC	Ambulatory Surgical Center
ASP	Average Sales Price
CCI	Correct Coding Initiative
CMS	Centers for Medicare and Medicaid Services
COX	Cyclooxygenase
СРТ	Current Procedural Terminology
ED	Emergency Department
FFS	Fee for Service
FL	Form Locator
HCPCS	Healthcare Common Procedure Coding System
HOPD	Hospital Outpatient Department
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
IV	Intravenous
N4	Qualifier Indicating NDC Code
NDC	National Drug Code
NSAID	Non-steroidal Anti-inflammatory Drug
OPPS	Outpatient Prospective Payment System
WAC	Wholesale Acquisition Cost
UB-04	Universal Billing Form (Used by Institutional Providers)
UN	Qualifier Indicating Drug Units







(meloxicam) injection

- 1. ANJESO [package insert]. Malvern, PA: Baudax Bio Inc; 2020.
- 2. Pollak RA, Gottlieb IJ, Hakakian F, et al. Efficacy and safety of intravenous meloxicam in patients with moderate-to-severe pain following bunionectomy: a randomized, double-blind, placebo-controlled trial. *Clin J Pain*. 2018;34(10):918-926.
- 3. Singla N, Bindewald M, Singla S, et al. Efficacy and safety of intravenous meloxicam in subjects with moderate-to-severe pain following abdominoplasty. *Plast Reconstr Surg Glob Open*. 2018;6:e1846.
- 4. Centers for Medicare & Medicaid Services. CMS website. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions, Second Quarter, 2020 Coding Cycle for Drug and Biological Products. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf. Accessed February 1, 2021.
- 5. U.S. Department of Health and Human Services. U.S. Food & Drug Administration. National Drug Code Directory. https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm. Accessed February 1, 2021.
- 6. Centers for Medicare & Medicaid Services. CMS website. MLN Matters MM11814 Revised. July 2020. Update of the Hospital Outpatient Prospective Payment System (OPPS) https://www.cms.gov/files/document/mm11814.pdf. Accessed February 1, 2021.
- 7. Centers for Medicare & Medicaid Services. CMS website. MLN Matters MM11842 Revised. July 2020. Update of the Ambulatory Surgical Center Prospective Payment System (ASC). https://www.cms.gov/files/document/mm11842.pdf. Accessed February 1, 2021.
- 8. Department of Health and Human Services. Rules and Regulations. Federal Register. 2019;84(218):61142-61492.
- 9. Social Security Administration. SSA website. Payment of Benefits. https://www.ssa.gov/OP Home/ssact/title18/1833.htm. Accessed February 1, 2021.
- 10. Centers for Medicare & Medicaid Services. CMS website. Medicare Claims Processing Manual. Chapter 4. Part B Hospital (Including Inpatient Hospital Part B and OPPS). https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c04.pdf. Accessed February 1, 2021.
- 11. Centers for Medicare & Medicaid Services. CMS website. Medicare Claims Processing Manual. Chapter 17. Drugs and Biologicals. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf. Accessed February 1, 2021.
- 12. Centers for Medicare & Medicaid Services. CMS website. MLN Matters MM11963. September 2020. October 2020 Update of the Ambulatory Surgical Center (ASC) Payment System. https://www.cms.gov/files/document/mm11963.pdf. Accessed February 1, 2021.
- 13. Centers for Medicare & Medicaid Services. CMS website. MLN Matters MM11960. September 2020. October 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS). https://www.cms.gov/files/document/mm11960.pdf. Accessed February 1, 2021.
- 14. Centers for Medicare & Medicaid Services. CMS website. Medicare Claims Processing Manual. Chapter 26. Completing and Processing the Form CMS-1500 Data Set. https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104c26pdf.pdf. Accessed February 1, 2021.
- 15. Centers for Medicare & Medicaid Services. CMS website. OPPS Addendum A and Addendum B. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates. Accessed February 1, 2021.
- 16. Centers for Medicare & Medicaid Services. CMS website. Medicare Claims Processing Manual. Chapter 25. Completing and Processing the Form CMS-1450 Data Set. https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104c25.pdf. Accessed February 1, 2021.
- 17. Centers for Medicare & Medicaid Services. CMS website. MLN Matters ICN 907166. September 2018. Global Surgery Booklet. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GloballSurgery-ICN907166.pdf. Accessed February 1, 2021.
- 18. Centers for Medicare & Medicaid Services. CMS website. Medicare Claims Processing Manual. Chapter 12 Physicians/Nonphysician Practitioners. 40.1. A. Components of a Global Surgical Package. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf. Accessed February 1, 2021.
- 19. Centers for Medicare & Medicaid Services. CMS website. National Correct Coding Initiative Policy Manual For Medicare Services. Chapter XIII. Category III Codes. 1.1.2021. https://www.cms.gov/files/document/chapter13cptcodes0001t-0999tfinal112021.pdf. Accessed February 1, 2021.
- 20. Centers for Medicare & Medicaid Services. CMS website. ASC Addendum BB. https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1736-fc. Accessed February 1, 2021.
- 21. Centers for Medicare & Medicaid Services. CMS website. ASC Addendum DD1. https://www.cms.gov/medicaremedicare-fee-service-paymentasc-regulations-and-notices/cms-1736-fc. Accessed February 1, 2021.
- 22. Centers for Medicaid & Medicaid Services. CMS website. OPPS Addendum D1. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS1392FC_Addendum_D1.pdf. Accessed February 1, 2021.





IMPORTANT SAFETY INFORMATION (CONT'D) DRUG INTERACTIONS (CONT'D)

INTRODUCTION

ACE Inhibitors and ARBs: Concomitant use with ANJESO in elderly, volume depleted, or those with renal impairment may result in deterioration of renal function. In such high-risk patients, monitor for signs of worsening renal function.

<u>Diuretics</u>: NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to ensure diuretic efficacy including antihypertensive effects.

ADVERSE REACTIONS

The most common adverse reactions in controlled clinical trials occurring in ≥ 2% of patients treated with ANJESO and at a greater frequency than placebo include: constipation, gamma-glutamyl transferase increased, and anemia.

USE IN SPECIFIC POPULATIONS

Pregnancy: Use of NSAIDs during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs in pregnant women starting at 30 weeks gestation.

Infertility: NSAIDs are associated with reversible infertility. Consider withdrawal of ANJESO in women who have trouble conceiving.





Baudax Reimbursement HUB

For help with specific coverage and reimbursement related needs, the Baudax Reimbursement HUB is staffed by a specialized team with acute care reimbursement experience who can assist with the following:



INTRODUCTION

General product and service questions*



Payer policy and Medicare Local Coverage Determination (LCD) information questions



Coding and reimbursement support



Prior authorization and predetermination support for patients who provided consent



Patient-specific insurance verifications for patients who provided consent



Identifying and tracking pending or denied claims for patients who provided consent



Direct: 1-855-405-9983



Visit: www.baudaxreimbursementhub.com



Fax: 1-844-910-3276

Monday through Friday between 9 AM and 7 PM ET

