

Anjeso[®]

(meloxicam) injection



Important Reimbursement Information for ANJESO

PASS-THROUGH STATUS AND UNIQUE J-CODE

ANJESO Important Safety Information (ISI)

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.

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.

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 October 1, 2020. 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.

Please scroll down to see Important Safety Information.

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

MEDICARE PASS-THROUGH STATUS FOR PROCEDURES IN ASCs AND HOPDs





CMS allows pass-through status for ANJESO when used in Medicare-certified ASCs and HOPDs

– *Pass-through status enables ANJESO to be reimbursed separately from the payment for the procedure in those settings*



PASS-THROUGH PAYMENT

Payment is based on the wholesale acquisition cost (WAC) + 3% until an average sales price (ASP) is established.

For ASC providers:

-  Facility reimbursement: 80% of Medicare payment*
-  Patient responsibility: remaining 20%†

For HOPD providers:

-  Facility reimbursement: 100% of Medicare payment
-  Patient responsibility: \$0

Medicare's share of payment may be reduced by sequestration.

Medicare Advantage (Part C): 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. Separate payment for ANJESO will be dependent on the provider's contract/plan arrangement. Contact local Medicare Advantage payers in advance to determine coverage and reimbursement for ANJESO.

*Medicare-certified ASCs.

†Patient or supplemental/secondary insurance policy. The deductible applies if it has not been met.
CMS, Centers for Medicare & Medicaid Services.

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.

WARNINGS AND PRECAUTIONS

Hepatotoxicity: 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.

Hypertension: 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..

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UNIQUE J-CODE



Effective October 1, 2020

– J1738 is for 1 mg of ANJESO (not 1 vial). Indicate the number of units used: for example, 30 units of J1738 for 30 mg meloxicam injection administered

Vial not shown at actual size.

HCPCS CODE	DESCRIPTION	UNITS IN VIAL*
J1738	Injection, meloxicam, 1 mg	30

J1738 replaces all prior codes that may have been used for ANJESO, including J3490, C9399, and C9059.

*The approved dose for adults is 30 mg.

ANJESO NDC CODES AND WAC

10-DIGIT NDC	71518-001-01
11-DIGIT NDC	71518-0001-01
WAC	\$94

HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Heart Failure and Edema: 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.

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.

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.

Anaphylactic Reactions: 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.

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

Serious Skin Reactions: 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.

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



Up to 24 hours
pain relief^{1,*}



Demonstrated safety
and tolerability¹



COX-2 preferential
IV NSAID^{2,3,†}



Once-daily
IV push¹

* 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.¹

† 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.¹

COX-1, cyclooxygenase 1; COX-2, cyclooxygenase 2.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Inform patients to stop taking ANJESO immediately if they develop any type of rash or fever and to contact their healthcare provider as soon as possible.

Hematologic Toxicity: 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.

Fetal Toxicity: Limit use of NSAIDs, including ANJESO, between about 20 to 30 weeks in pregnancy due to the risk of oligohydramnios/fetal renal dysfunction. Avoid use of NSAIDs in women at about 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/fetal renal dysfunction and premature closure of the fetal ductus arteriosus.

DRUG INTERACTIONS

Drugs That Interfere With Hemostasis (eg, warfarin, aspirin, SSRIs/SNRIs): 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.

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

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.

Diuretics: 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 $\geq 2\%$ 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, including ANJESO, can cause premature closure of the fetal ductus arteriosus and fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, limit dose and duration of ANJESO use between about 20 and 30 weeks of gestation and avoid ANJESO use at about 30 weeks of gestation and later in pregnancy.

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

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References: 1. ANJESO [package insert]. Malvern, PA: Baudax Bio Inc; 2021. 2. Pollak RA, Gottlieb JJ, 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; doi:10.1097/GOX.0000000000001846.