

5.70.79

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Subsection:	Analgesics and Anesthetics	Original Policy Date:	March 27, 2020
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Last Review Date: March 12, 2021

Anjeso

Description

Anjeso (meloxicam) injection

Background

Anjeso (meloxicam) is a non-steroidal anti-inflammatory drug (NSAID) that blocks cyclooxygenase (COX), an enzyme responsible for initiating the inflammation pathway. Anjeso selectively inhibits COX-2, a subset of the COX enzymes that triggers inflammation through conversion of arachidonic acid into prostaglandin H₂. By decreasing COX enzymatic activity, localized pyrexia, inflammation and pain generated from the cyclooxygenase pathway are effectively reduced (1).

Regulatory Status

FDA-approved indication: Anjeso is an NSAID indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics (1).

Limitations of use: Because of delayed onset of analgesia, Anjeso alone is not recommended for use when rapid onset of analgesia is required (1).

Anjeso has boxed warnings for increased risks of the following cardiovascular (CV) and gastrointestinal (GI) adverse events: myocardial infarction, stroke, bleeding, ulceration, and intestinal or gastric perforation. The risks of these events increase with duration of use, elderly age, and prior history of peptic ulcer disease or GI bleeding. Patients with a history of Coronary Artery Bypass Graft Surgery (CABG) should not use Anjeso (1).

Anjeso is contraindicated in patients with the following: (1)

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- History of asthma, urticarial or allergic-type reaction after taking aspirin or other NSAID medications.
- 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.

NSAIDs should be prescribed with extreme caution in patients with a prior history of ulcer disease or gastrointestinal bleeding. To minimize the potential risk for an adverse GI event, the lowest effective dose should be used for the shortest duration consistent with individual patient treatment goals. Physicians and patients should remain alert for signs and symptoms of GI ulceration and bleeding during Anjeso therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. For high-risk patients, alternate therapies that do not involve NSAIDs should be considered (1).

To minimize the potential risk for an adverse CV event in NSAID-treated patients, the lowest effective dose should be used for the shortest duration possible (1).

Anjeso intravenous injections may cause exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), and other serious adverse skin reactions that are potentially fatal. Anjeso should be discontinued at the first appearance of any dermal rash or sign of hypersensitivity (1).

The safety and effectiveness of Anjeso in pediatric patients less than 18 years of age have not been established (1).

Related policies

Anti-Inflammatory Pain Powders, Celebrex

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Anjeso may be considered **medically necessary** in patients 18 years of age or older for the treatment of moderate to severe pain and if the conditions indicated below are met.

Anjeso may be considered **investigational** for patients less than 18 years of age and for all other indications.

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Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Moderate to severe pain

AND ALL of the following:

- Not being used concomitantly with another NSAID
- Patient is not a candidate for oral NSAID therapy
- NO** coronary artery bypass graft (CABG) surgery within the last 14 days

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 1 month

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Anjeso (meloxicam) is a non-steroidal anti-inflammatory drug (NSAID) that blocks cyclooxygenase (COX), an enzyme responsible for initiating the inflammation pathway. Anjeso selectively inhibits COX-2, a subset of the COX enzymes that triggers inflammation through conversion of arachidonic acid into prostaglandin H₂. By decreasing COX enzymatic activity, localized pyrexia, inflammation and pain generated from the cyclooxygenase pathway are effectively reduced. The safety and effectiveness of Anjeso in pediatric patients less than 18 years of age have not been established (1).

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Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Anjeso while maintaining optimal therapeutic outcomes.

References

1. Anjeso [package insert]. Malvern, PA: Baudax Bio, Inc.; February 2020.

Policy History

Date	Action	Reason
March 2020	Addition to PA	
June 2020	Annual review	
March 2021	Annual review	

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.