Flurbiprofen Powder

Description

Flurbiprofen Powder

Background
Flurbiprofen is a non-steroidal anti-inflammatory (NSAID) medication that decreases inflammation, pain and fever by inhibiting COX-1 and 2 enzymes, which then inhibits the production of prostaglandins and leukotrienes (1).

Flurbiprofen is commercially available as a 50mg or 100mg oral tablet and as an ophthalmic 0.03% sterile solution (2).

Regulatory Status
Flurbiprofen is FDA approved in an oral formulation for the relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis (1). Flurbiprofen ophthalmic solution is indicated for the inhibition of intraoperative miosis (2).

Flurbiprofen carries a boxed warning for cardiovascular risk. Non-steroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction and stroke. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

The boxed warning also includes GI risk. NSAIDs cause an increased risk of serious GI adverse reactions including bleeding, ulceration and perforation of the stomach or intestines. These reactions can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious GI reactions (1).

Flurbiprofen is contraindicated for treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery (1).
Safety and efficacy in children have not been established (1).

**Off-Label Uses**
Off-label (non-FDA approved) compounded topical preparations of flurbiprofen have not been shown to be superior to commercially available topical diclofenac preparations.

**Related Policies**
Celebrex, Ketoprofen

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

Flurbiprofen powder may be considered **medically necessary** in an oral formulation for patients 18 years of age or older for the treatment of the FDA-approved indications of osteoarthritis, rheumatoid arthritis and intraoperative miosis (ophthalmic solution only).

Flurbiprofen powder may be considered **investigational** for patients under the age of 18 years, in patients without a diagnosis of osteoarthritis, rheumatoid arthritis, or intraoperative miosis, or as a topical dosage formulation.

**Prior-Approval Requirements**

**Age**
18 years and older

**Diagnoses**
Patient must have **ONE** of the following:

1. Osteoarthritis  
2. Rheumatoid arthritis  
3. Intraoperative miosis (ophthalmic dosage form)

**AND**

1. The requested dosage form is for oral use or ophthalmic use  
2. The requested dose does not exceed the FDA approved limit of 100 mg/unit for an oral preparation or 0.03% for an ophthalmic preparation  
3. The requested dose is not commercially available
Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Flurbiprofen is FDA-approved in an oral formulation for adults in the treatment of osteoarthritis, rheumatoid arthritis and in an ophthalmic solution for the treatment of intraoperative miosis (1,2). There are no clinical studies to support the safety and effectiveness of flurbiprofen in a topical delivery system (excluding ophthalmic).

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

References
**Section:** Prescription Drugs  
**Effective Date:** July 1, 2013  
**Subsection:** Analgesic  
**Original Policy Date:** July 1, 2013  
**Subject:** Flurbiprofen Powder  
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**Keywords**

This policy was approved by the FEP Pharmacy and Medical Policy Committee on June 6, 2013 and is effective July 1, 2013.

**Signature on file**

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