BlueCross BlueShield of Alabama

Flector® Prior Authorization with Quantity Limit Program Summary

This prior authorization applies to Commercial, NetResults A series, SourceRx and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Flector Prior Authorization (PA) is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical guidelines. The PA defines appropriate use as therapy for a Food and Drug Administration (FDA) approved indication of acute pain due to minor strains, sprains, and/or contusions. The PA criteria also require that the patient has tried at least two oral prescription NSAIDs when not contraindicated. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests for Flector will be reviewed when patient specific documentation is provided.

TARGET AGENT

Flector® (diclofenac epolamine)

Brand (generic)	GPI	Quantity Limit per 30 Days
Flector (diclofenac epolamine)		
180 gram topical patch (1.3% in aqueous base)	90210030205920	60 patches

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Flector will be approved when ALL of the following are met:

1. Patient must have diagnosis of ACUTE pain due to minor strains, sprains, and/or contusions
   AND
2. ONE of the following:
   A. The patient has failed therapy with at least two (2) oral prescription NSAIDs, one within the past 6 months
      OR
   B. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to oral NSAIDs (i.e., renal failure, history of gastrointestinal bleed, etc.)
   AND
3. The patient does NOT have any FDA labeled contraindication(s) to the requested agent
   AND
4. ONE of the following:
   A. The requested quantity (dose) is NOT greater than the program quantity limit
      OR
   B. ALL of the following
      i. The requested quantity (dose) is greater than the program quantity limit
         AND

ii. The requested quantity (dose) is less than or equal to the FDA labeled dose
AND
iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

OR

C. ALL of the following:
i. The requested quantity (dose) is greater than the program quantity limit
AND
ii. The requested quantity (dose) is greater than the FDA labeled dose
AND
iii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of approval: 3 months

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

FDA APPROVED INDICATIONS AND DOSAGE[1]

Drug	Indication	Dosage and Administration
Flector (diclofenac epolamine) 180 mg topical patch (1.3% in aqueous base)	Topical treatment of acute pain due to minor strains, sprains, and contusions.	One patch to the most painful area twice a day.^

^Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.

CLINICAL RATIONALE:

Acute Injuries

A review (U.S., 2011) on treatment of acute musculoskeletal injuries (e.g., strains, sprains, contusions) suggests therapy usually begins with nonpharmacological interventions (RICE: rest, ice, compression, elevation). Oral nonsteroidal agents (e.g., diclofenac, ibuprofen, others) reduce swelling and can lead to a more rapid return of activity vs. RICE alone in patients with ankle sprains. Acetaminophen can also provide relief. For patients who cannot take oral non-steroidal anti-inflammatory drugs (NSAIDs), topical NSAIDs may provide relief with less systemic adverse effects. Patients should not use both topical and oral NSAIDs simultaneously.[12]

A 2016 review suggests topical NSAIDs are good options for acute musculoskeletal pain in patients at risk of adverse effects from oral NSAIDs who present with a focal area pain. Topical agents are only effective for treating more superficial structures.[3]

A Cochrane Review (2015) evaluating topical NSAIDs for acute pain due to strains, sprains, or sports/overuse type injuries found there were insufficient data to reliably compare individual topical NSAIDs with each other or the same oral NSAID.[4]

Efficacy

Efficacy of Flector was demonstrated in two of four studies of patients with minor sprains, strains, and contusions. Patients were randomly assigned to treatment with Flector or a placebo patch. In the first of the two studies patients with ankle sprains were treated once daily for a week. In the second study, patients with sprains, strains, and contusions were treated twice daily for up to two weeks. Pain was assessed over the period of treatment. Patients treated with Flector experienced a greater reduction in pain compared to patients randomized to the placebo patch. The safety and effectiveness of Flector patch in pediatric patients have not been established.[1]

Safety

Flector contains the following black box warning:[1]

- Cardiovascular Thrombotic Events
  - 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 easly in treatment and may increase with duration of use.
  - Flector Patch is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
- Gastrointestinal Bleeding, Ulceration, and Perforation
  - 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.

REFERENCES

1. Flector prescribing information. Pfizer, Inc. May 2016.
2. Cochrane Data System Review 2015;6: CD007402.
3. Medical Clinics of North America 2016;100:869-890.
4. Rogers N, Rowland K, Hickner J. An alternative to oral NSAIDs for acute musculoskeletal in*juries. J Fam Practic*e. March 2011;60(3):147-148.