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DRUG POLICY

Topical Nonsteroidal Anti-Inflammatory Drugs (NSAID)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Topical Nonsteroidal Anti-Inflammatory Drug (NSAID) policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The criteria will encourage the use of the more cost-effective generic and over the counter oral and topical NSAIDS prior to the use of a brand or more costly generic when clinically appropriate while maintaining optimal therapeutic outcomes.

FDA-Approved Indications:

Pennsaid 2% solution is indicated for the treatment of the pain of osteoarthritis of the knee(s).

Flector patch is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.

POLICY

Criteria for Initial Approval

- I. Pennsaid (diclofenac sodium) 2% solution may be considered **medically necessary** when ALL of the following criteria are met:
 - Member has been diagnosed with osteoarthritis of the knee
 - Member has a contraindication to or has tried and failed generic oral diclofenac and at least one other oral, traditional NSAID; OR has one of the following risk factors:
 - The member is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids)

- The member has a history of gastroduodenal ulcer, gastrointestinal bleeding, or gastroduodenal perforation
- The member has a documented swallowing disorder
- The member is 75 years of age or older
- Member has tried and failed over the counter (OTC) diclofenac 1% gel*
- Member has tried and failed generic diclofenac 1.5% topical solution

Approval will be for 12 months

- II. Flector (diclofenac epolamine) patch may be considered **medically necessary** when ALL of the following criteria are met:
- Member has a diagnosis of acute, localized pain due to minor strains, sprains, or contusions
 - Member has a contraindication to or has tried and failed generic oral diclofenac and at least one other oral, traditional NSAID; OR has one of the following risk factors:
 - The member is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids)
 - The member has a history of gastroduodenal ulcer, gastrointestinal bleeding, or gastroduodenal perforation
 - The member has a documented swallowing disorder
 - The member is 75 years of age or older
 - Member has tried and failed over the counter (OTC) diclofenac 1% gel*
 - Member has tried and failed generic diclofenac 1.5% topical solution

Approval will be for 1 month.

*Note: The trial and failure of prescription diclofenac 1% gel would also apply if the trial occurred prior to the OTC product being available

Continuation of Therapy

- I. The continuation of treatment with Pennsaid (diclofenac sodium) 2% solution may be considered **medically necessary** when ALL of the following criteria are met:
- The member meets all initial authorization criteria
 - The member is experiencing a positive response to therapy with the requested drug (e.g., improvement in pain symptoms of osteoarthritis)

Approval will be for 12 months

- II. For the continuation requests for Flector (diclofenac epolamine) patch, all members must meet initial authorization criteria.

Pennsaid and Flector are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Pennsaid 2% solution – 2 bottles (224 grams) per 30 days

Flector – 60 patches per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

- Pennsaid [prescribing information]. Horizon Therapeutics USA Inc., Lake Forest, IL. January 2022.
- Flector [prescribing information]. Pfizer Inc., New York, NY. April 2021.
- Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis Rheumatol.* 2020 Feb;72(2):220-233. doi:10.1002/art.41142. Epub 2020 Jan 6. Accessed June 17, 2022.
- Rannou F, Pelletier JP, Martel-Pelletier J. Efficacy and safety of topical NSAIDs in the management of osteoarthritis: evidence from real-life setting trials and surveys. *Semin Arthritis Rheum* 2016;45 Suppl: S18–21. Accessed June 23, 2022.
- Lanza FL, Chan FKI, Quigley EMM, Practice Parameters Committee of the American College of Gastroenterology. Guidelines for Prevention of NSAID-Related Ulcer Complications. *Am J Gastroenterol.* 2009; 104:728 – 738.doi: Accessed June 22, 2022.
- Atkinson TJ, Fudin J, Pandula A, Mirza M. Medication pain management in the elderly: unique and underutilized analgesic treatment options. *Clin Ther.* 2013;35(11):1669-1689. Accessed June 23, 2022.
- Brophy RH, Fillingham YA. AAOS Clinical Practice Guideline Summary: Management of Osteoarthritis of the Knee (Nonarthroplasty), Third Edition. *J Am Acad Orthop Surg.* 2022 May 1;30(9):e721-e729.

POLICY HISTORY

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