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DRUG POLICY

Oral and Nasal Fentanyl Products

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 oral and nasal fentanyl products drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. There are currently four (4) oral fentanyl products and one nasal product included in this policy: Abstral® (fentanyl sublingual), Actiq® (fentanyl transmucosal lozenge), Fentora® (fentanyl buccal tablet), Subsys® (fentanyl sublingual spray) and Lazanda® (fentanyl nasal solution). This policy includes both brand and generic versions if available for the drug. These fentanyl products are opioids agonists approved by the Food and Drug Administration (FDA) for the management of breakthrough pain in cancer patients 18 years and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Actiq is approved for use in patients that are 16 years of age and older.

POLICY

- I. Sublingual fentanyl, transmucosal fentanyl lozenges, buccal fentanyl tablets, sublingual fentanyl spray and fentanyl nasal spray may be considered **medically necessary** for the treatment of breakthrough pain in cancer patients when all of the following criteria are met:
 - The patient is 18 years or older (**16 years or older for transmucosal fentanyl lozenges**)
 - The patient is already receiving and is tolerant to opioid therapy for underlying persistent cancer pain.

Approval will be 12 months.

- II. **Approval for quantity limits** greater than 4 dosage units (oral formulations) or one bottle (nasal formulations) will be allowed when the following criteria are met:

- Requested dose cannot be achieved using a lesser quantity of a higher strength and is still within the FDA labeled maximum dosing recommendations
- If the breakthrough pain cannot be controlled by modifying the long-acting opioid dosage; **OR** the requested dosage/strength is needed for titration purposes only

Approval will be **12 months** (1 month when needed for titration purposes).

III. Sublingual fentanyl, transmucosal fentanyl lozenges, buccal fentanyl tablets, sublingual fentanyl spray and fentanyl nasal spray is considered **not medically necessary** in patients who do not meet the criteria set forth above.

CLINICAL RATIONALE

Breakthrough pain (BTP) is a transitory pain that occurs despite the use of around-the-clock analgesia to control chronic pain. Prevalence of BTP in patients with chronic cancer pain ranges from 33-65%. Historically, short-acting opioids have been used for management of BTP. However the pharmacokinetic profile of these agents does not correlate with sudden onset and severity of BTP. Presently, fentanyl is the only rapid-onset analgesic that is indicated in BTP associated with chronic cancer pain in patients already receiving and tolerant to around-the-clock opioid therapy. Use of these agents in non-cancer pain is not indicated as it is not supported by current literature.

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.

- No applicable codes.

REFERENCES

- Abstral package insert. Galena Biopharma. Lake Oswego, OR. JNovember 2014.
- Actiq package insert. Cephalon: Fraser, PA. October 2019.
- Fentora package insert. Cephalon: Salt Lake City, UT. October 2019.
- Lazanda package insert. Depomed, Inc. Newark, CA. March 2015.
- Subsys package insert. Insys Therapeutics: Phoenix, AZ. February 2020.
- Smith H. Considerations in selecting rapid-onset opioids for the management of breakthrough pain. J Pain Research 2013;6:189-200.

POLICY HISTORY

Policy #: 05.01.43

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