ORAL FENTANYL FOR CANCER-RELATED PAIN

Description: Oral fentanyl, an opioid analgesic, is indicated for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. This product is available in three forms:

- an oral transmucosal lozenge (Actiq®, Abstral®);
- a buccal tablet (Fentora™, Onsolis™, and Fentanyl Buccal tablets [generic form of Fentora™]); and
- a sublingual spray (Subsys®).

Serious adverse events, including deaths, have occurred in patients treated with an oral fentanyl. In many cases, these deaths have occurred as a result of improper patient selection, improper dosing, and/or improper product substitution. Prescribing information for the oral fentanyls state that they must not be used in opioid non-tolerant patients and that life-threatening hypoventilation could occur at any dosage in patients not taking chronic opiates. For this reason, these products are contraindicated in the management of acute or postoperative pain.

Addition of oral fentanyl to a long-acting opioid regimen involves titration of the dose until one unit gives adequate pain relief with acceptable side effects. Product labeling for the oral fentanyls recommends limiting consumption to four or fewer units per day once titration to an effective dose has been accomplished. If patients consistently use more than four units per day, adjustment of the around-the-clock opioid is indicated.

Policy: The use of oral fentanyl (i.e., Actiq®, Fentora™, Onsolis™, Abstral®, Fentanyl Buccal tablets, Subsys® sublingual spray) may be considered MEDICALLY NECESSARY for the FDA-approved indication:
Management of breakthrough cancer pain in patients who are already receiving and who are tolerant to opioid therapy* for their underlying persistent cancer pain.

* Patients considered opioid tolerant are those taking at least 60 mg oral morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

The use of an oral fentanyl for any indication other than the FDA-approved indication is considered NOT MEDICALLY NECESSARY; appropriate alternative medications are available for treatment of non-cancer-related pain.

Coverage: Coverage will be limited to 4 units per day, except when the following criteria are met:

- The episodes of breakthrough pain cannot be controlled by modifying the dose of the long-acting opioid and
- The requested dose cannot be achieved using a lesser quantity of a higher strength (e.g., FentoraTM 8 x 100mcg could be achieved with 4 x 200mcg)

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member’s summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.
HCPCS:
J3490 Unclassified drugs
J8499 Prescription drug, oral, nonchemotherapeutic, NOS
S5000 Prescription drug, generic
S5001 Prescription drug, brand name

Policy History:

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Most recent history:
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Revised February 8, 2012
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Reviewed February 12, 2014

Cross Reference:

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