HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

FENTANYL TRANSMUCOSAL AGENTS

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL CITRATE	ABSTRAL ACTIQ FENTORA	01747		ROUTE=BUCCAL, SUBLINGUAL
FENTANYL CITRATE	LAZANDA	01747		ROUTE=NASAL
FENTANYL	SUBSYS	06438		ROUTE=SUBLINGUAL

GUIDELINES FOR USE

1. Is the patient 18 years of age or older, or 16 years of age and older if the request is for fentanyl buccal/lozenge (Actiq or generic equivalent)?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Fentanyl Transmucosal Agents guideline, this medication is only covered for use in members **[18 years of age and older, or 16 years of age and older for Actiq or its generic equivalent]**. Your provider did not indicate that you meet this condition and therefore your request was not approved.

2. Does the patient have a diagnosis of breakthrough pain due to cancer?

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Fentanyl Transmucosal Agents guideline, this medication is only covered for patients with breakthrough pain due to cancer. Your provider did not indicate that you have this condition and therefore your request was not approved.

3. Is the patient currently receiving and is tolerant to at least one or more long-acting opioid analgesics with an average daily dose of at least 30mg of oxycodone per day, or at least 8mg of hydromorphone per day, or at least 60mg of morphine per day, or at least 25mg of oxymorphone per day, or an equianalgesic daily dose of another opioid?

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Fentanyl Transmucosal Agents guideline, this medication is only covered for patients who are currently receiving and tolerant to another long-acting opioid pain reliever. Your provider did not indicate that you are currently receiving and tolerant to another long-acting opioid reliever and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

4. Is the request for a MSB (e.g. Actiq)?

   If yes, continue to #5.
   If no, **approve for 12 months by HICL.** Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for _____ has been approved with a quantity limit of _____ per 30 days for a 12-month period.

   PAC NOTE: Do not enter any values for MDD in the authorization. The quantity limits are hard-coded in the system. Please reference the quantity limit listed below for the requested product when completing the free text of the approval letter.
   - **Abstral: 120 tablets per 30 days**
   - **Actiq: 120 tablets per 30 days**
   - **Fentora: 120 tablets per 30 days**
   - **Lazanda: 15 bottles per 30 days**
   - **Subsys: 120 sprays per 30 days**

5. Has the patient tried and failed therapy with the generic equivalent of the requested drug or did the provider submit clinical rationale for not using the generic at this time?

   If yes, **approve for 12 months by HICL.**
   Requests for products on formulary with a restriction, please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for _____ has been approved with a quantity limit of _____ per 30 days for a 12-month period.
   Requests for products not on formulary, please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for _____ has been approved with a quantity limit of _____ per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

   PAC NOTE: The quantity limits are hard-coded in the system. Please reference the quantity limit listed below for the requested product when completing the free text of the approval letter.
   - **Abstral:** 120 tablets per 30 days
   - **Actiq:** 120 tablets per 30 days
   - **Fentora:** 120 tablets per 30 days
   - **Lazanda:** 15 bottles per 30 days
   - **Subsys:** 120 sprays per 30 days

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Fentanyl Transmucosal Agents guideline, this medication is only covered for patients who have first tried and failed therapy with the generic equivalent of the requested medication. Your provider did not indicate that you previously tried **[generic]** and therefore your request was not approved.

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RATIONALE

To ensure that pain management with transmucosal or nasally-administered fentanyl agents is being used appropriately in adult patients with breakthrough pain secondary to cancer that are already on and are tolerant to another long-acting opioid medication.

FDA APPROVED INDICATIONS

Abstral, Actiq, Fentora, Lazanda, Subsys, and oral fentanyl citrate are indicated for breakthrough pain, secondary to cancer.

REFERENCES

- Abstral Product Information. ProStrakan, Inc. Bedminster, NJ. January 2014.
- Actiq Product Information. Cephalon, Inc. Frazer, PA. December 2011.
- Fentora Product Information. Cephalon, Inc. Frazer, PA. February 2013.
- Lazanda Product Information. Archimedes Pharma US. Bedminster, NJ. March 2015.
- Subsys Product Information. Insys Therapeutics. Phoenix, AZ. December 2014.

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