MEDICATION POLICY

Generic Name: Fentanyl sublingual spray

Therapeutic Class or Brand Name: Subsys®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 10/19/15 **Date Last Reviewed/Revised:** 10/9/16

GPI Code: 651000250009

Prior Authorization Criteria (may be considered medically necessary when criteria I through V are met):

I. Documented diagnosis of breakthrough cancer pain.

II. Documentation that patient is already receiving and is tolerant to around-the-clock opioid therapy for their cancer pain (i.e. patient has been taking one of the following medications around-the-clock for a minimum of one week: at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily).

III. Documented trial and failure of, intolerance to, or contraindication to, at least two generic short-acting narcotics for breakthrough pain (i.e. concentrated morphine oral solution, hydromorphone, oxycodone, etc.).

IV. Minimum age requirement: 18 years old.

V. Prescriber is an oncologist or pain specialist.

Exclusion Criteria:

- N/A

Other Criteria:

- Subsys® is not bioequivalent with other fentanyl products. The initial dose of Subsys® is always 100 mcg with the ONLY exception of patients already using Actiq®.
- The initial dose for patients already using Actiq® is outlined in the table below:

Current Actiq® Dose	Initial Subsys® Dose
≤ 400 mcg	100 mcg spray
600 mcg to 800 mcg	200 mcg spray
≥ 1200 mcg	400 mcg spray

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Quantity/Days Supply Restrictions:

- The quantity is limited to a maximum of 120 doses per 30 days.

Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is providing satisfactory pain control for the patient's breakthrough cancer pain.

Appendix:

N/A

References:

1. http://subsysspray.com/assets/subsys/client_files/files/PrescribingInfo.pdf.
2. Medi-Span.
3. http://blue.regence.com/trgmedpol/drugs/dru073.pdf.
4. http://www.caremark.com/portal/asset/Specialty_Assurant_Actiq.pdf.
5. http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0CDAQFjACahUKEwjox86k7M_IAhXJm4gKHRFTArc&url=http%3A%2F%2Fwww.fchp.org%2Fproviders%2Fpharmacy%2F~%2Fmedia%2FFiles%2FFCHP%2FImported%2FSubsys_sublingualspray.pdf.ashx&usg=AFQjCNFnrOjz5xo4cRveSqZqJ_WWt1P6ew&sig2=TU8c56lg0-1Dai7-rFwVRg.

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Historical Tracking Of Changes Made To Policy	
10/9/2016	1. Policy reviewed: no changes made.