



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: 1/10/18

GPI Code: 651000250009

Prior Authorization Criteria (may be considered medically necessary when criteria I through VI 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. Patient is enrolled in the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program.
- VI. Prescriber is an oncologist or pain specialist enrolled in the TIRF REMS ACCESS program.

Exclusion Criteria:

- N/A

Other Criteria:

- Subsys® is only available through a restricted program called the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access program. Outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program. Further information is available at www.TIRFREMSaccess.com or by calling 1-866-822-1483.
- 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®.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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- 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

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:

- http://subsyspray.com/assets/subsys/client_files/files/PrescribingInfo.pdf.
- [Medi-Span.](#)
- <http://blue.regence.com/trgmedpol/drugs/dru073.pdf>.
- [http://www.caremark.com/portal/asset/Specialty Assurant Actiq.pdf](http://www.caremark.com/portal/asset/Specialty_Assurant_Actiq.pdf).
- 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&usq=AFQjCNFnroJz5xo4cRveSqZqJ_WWt1P6ew&sig2=TU8c56lg0-1Dai7-rFwVRg.

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<i>Historical Tracking Of Changes Made To Policy</i>	
<i>1/10/2018</i>	<ol style="list-style-type: none">Added “V. Patient is enrolled in the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program” under Prior Authorization Criteria.Changed “VI. Prescriber is an oncologist or pain specialist” to “VI. Prescriber is an oncologist or pain specialist enrolled in the TIRF REMS ACCESS program” under Prior Authorization Criteria.Added “Subsys® is only available through a restricted program called the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access program. Outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program. Further information is available at www.TIRFREMSaccess.com or by calling 1-866-822-1483” under Other Criteria.
<i>10/9/2016</i>	<ol style="list-style-type: none">Policy reviewed: no changes made.

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