Fentanyl Mucosal Agents Prior Authorization Fax Form  
New York State Medicaid Clinical Drug Review Program

# Instructions

## Program Information

* Drugs included in the Clinical Drug Review Program require prior authorization.
* A list of CDRP drugs is available at [www.nyhealth.gov](http://www.nyhealth.gov) and at [http://newyork.fhsc.com](http://newyork.fhsc.com/).
* Fax requests are NOT permitted for some CDRP drugs.

## Prescriber Procedure

* To initiate the prior authorization process, please fax the completed form(s) to 1-800-268-2990.
* Following review of all of the required information, you will be contacted by the Clinical Support Center regarding prior authorization for the requested fentanyl mucosal agent.

Please fax this form and all supporting documentation to 1-800-268-2990.

| Enrollee Information | |
| --- | --- |
| Enrollee Name: | Date of Birth: |
| enrollee medicaid id number (2 letters, 5 numbers, 1 letter): | |

| Prescriber Information | | |
| --- | --- | --- |
| prescriber Name: | contact person: | |
| prescriber 10-digit national provider identifier (NPI): | office Phone Number: | office Fax number: |

| Drug Information | | |
| --- | --- | --- |
| Which drug are you requesting? (Document name, strength, direction, and quantity.) | | |
| Name: | Abstral® (fentanyl sublingual tablet) | Lazanda® (fentanyl nasal spray) |
| Actiq® (fentanyl lozenge) | Onsolis® (fentanyl buccal soluble film) |
| Fentora® (fentanyl buccal tablet) | Subsys® (fentanyl sublingual spray) |
| strength: |  | |
| direction: |  | |
| quantity: |  | |

| Clinical Criteria |
| --- |
| Is this medication being prescribed to manage breakthrough cancer pain? |
| Yes  No |
| If No, please list diagnosis: |
|  |

| Are you or have you consulted with an Oncologist or Pain Management Specialist? |
| --- |
| Yes  No |

| Is the patient already receiving long-acting opioid therapy for underlying persistent pain? |
| --- |
| Yes  No |
| If No, please provide clinical reason: |
|  |

| Is the patient tolerant[[1]](#footnote-1) (please see definition of tolerance below) to the opioid therapy currently being used for his/her underlying persistent pain? |
| --- |
| Yes  No |
| If No, please provide clinical reason: |
|  |

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| --- | --- | --- | --- |
| *Clinical Criteria (Prescription Fill/Refill Limit)* | | | |
| Patients are limited to a total of four opioid prescription fills per rolling 30 days. What is the clinical rationale for exceeding four fills of any opioid prescription per month? | | | |
|  | | | |
| Please provide current long-acting and short-acting opioid therapy: | | | |
| Medication | Start Date | Strength | Frequency |
|  |  |  |  |
|  |  |  |  |
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| Frequency/Quantity/Duration (F/Q/D) |
| --- |
| ABSTRAL, ACTIQ, FENTORA, ONSOLIS, and SUBSYS:  For patients who have a diagnosis other than cancer or sickle cell, does the quantity prescribed exceed four (4) units per day, 120 units per 30 days? (Please refer to the PDL at [newyork.fhsc.com](http://teams2-icore/sites/FHSCDocMgmt/Client%20Documentation/NYPDP/CDRP%20Forms/newyork.fhsc.com).)  Yes  No  **lazanda:**  For patients who have a diagnosis other than cancer or sickle cell, does the quantity prescribed exceed 5 mL (1 bottle) per day, 150 mL (30 bottles) per 30 days? (Please refer to the PDL at [newyork.fhsc.com](http://teams2-icore/sites/FHSCDocMgmt/Client%20Documentation/NYPDP/CDRP%20Forms/newyork.fhsc.com).)  Yes  No |
| If Yes, please provide clinical reason: |

| Opioid/Benzodiazepine Therapeutic Duplication |
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| **If the patient currently requires concurrent use of a benzodiazepine and an opioid, please provide clinical rationale.** |
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| ***Opioid/Buprenorphine Therapeutic Duplication*** |
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| **If the patient is currently taking a Buprenorphine product, please answer the following questions:** |
| **Are you willing to prescribe a non-opiate analgesic (i.e. NSAID, etc.)?** |
| Yes  No |
| **Is the patient having surgery or had an acute event requiring narcotic pain medication?** |
| Yes  No |
| ***If yes to the above question, only a 15 day’s supply of Fentanyl Mucosal product will be authorized.*** |
| **If no, what is the clinical rationale for the patient requiring concurrent use of an opioid and a buprenorphine product?** |
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## WARNINGS: IMPORTANCE OF PROPER PATIENT SELECTION and POTENTIAL FOR ABUSE for ABSTRAL®, ACTIQ®, FENTORA®, LAZANDA®, ONSOLIS™, and SUBSYS™

These products (Abstral®, Actiq®, Fentora®, Lazanda®, Onsolis®, and Subsys®) contain fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. They can be abused in a manner similar to other opioid agonists, legal or illicit. Consider the potential for abuse when prescribing these products in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances have the highest potential for abuse and risk of fatal overdose due to respiratory depression.

Serious adverse events, including deaths, in patients treated with oral transmucosal fentanyl products have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of these products for any other fentanyl product may result in fatal overdose.

These products are indicated only for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine/daily, or at least 25 mcg transdermal fentanyl/hour, or at least 30 mg of oral oxycodone daily, or at least 8 mg oral hydromorphone daily, or at least 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer.

These products are contraindicated in opioid non-tolerant patients and in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients treated with other fentanyl products.

When prescribing, do not convert patients on a mcg-per-mcg basis from another fentanyl product. Patients beginning treatment with one of these products must begin with titration from the lowest available dose. Special care must be used when dosing these products. The concomitant use of these products with cytochrome P450 3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression.

These products are intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain. Patients and their caregivers must be instructed that these products contain a medicine in an amount which can be fatal in children, in individuals for whom it is not prescribed, and in those who are not opioid tolerant. All medication must be kept out of the reach of children.

I attest that this medication is medically necessary for this patient and that all of the information on this form is accurate to the best of my knowledge. I attest that documentation of the above diagnosis and medical necessity is available for review if requested by New York Medicaid.

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| --- | --- | --- |
|  |  |  |
| prescriber Signature |  | date |

1. Patients are considered to be opioid-tolerant if they are taking **around-the-clock** medicine for **one week** consisting of **at least**:

   60 mg of morphine or

   25 mcg transdermal fentanyl/hour or

   30 mg of oxycodone or

   8 mg of oral hydromorphone or

   Equianalgesic dose of another opioid daily for a week or longer [↑](#footnote-ref-1)