BlueCross BlueShield of Alabama

Transmucosal Immediate Release Fentanyl Prior Authorization (Through Generic) and Quantity Limit Criteria Program Summary

This program applies to Commercial, GenPlus, NetResults A series, NetResults F series and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Transmucosal Immediate Release Fentanyl (TIRF) Authorization (PA) (Through Generic) and Quantity Limit (QL) program is to ensure appropriate selection of patients for treatment of chronic cancer pain in appropriate quantities according to product labeling and/or clinical guidelines and/or clinical studies, and to help promote the use of lower cost generic agents. For chronic cancer pain, criteria encourage the optimum use of long-acting opioids and appropriate quantities of TIRF agents. PA criteria will approve only one agent in only one strength at a time. The program will allow continuation of therapy with one of the brand agents when a patient is currently receiving one of the brand agents. Brand agents will be allowed for members who have a documented intolerance, FDA labeled contraindication, or hypersensitivity to a generic. Requests for TIRF, including increased quantities, will be reviewed when patient-specific documentation is provided.

TARGET DRUGS

Abstral® (fentanyl sublingual tablet)
Actiq® (fentanyl lozenge)[a]
Fentora® (fentanyl buccal tablet)
Lazanda® (fentanyl nasal spray)
Subsys™ (fentanyl sublingual spray)
a – generic fentanyl citrate lozenge included in program

PROGRAM QUANTITY LIMITS

Brand (generic)	GPI	Multisource Code	Quantity per Day Limit
Abstral® (fentanyl sublingual tablet)			
100 mcg tablet	65100025100710	M, N, O, or Y	4 tablets
200 mcg tablet	65100025100720	M, N, O, or Y	4 tablets
300 mcg tablet	65100025100725	M, N, O, or Y	4 tablets
400 mcg tablet	65100025100730	M, N, O, or Y	4 tablets
600 mcg tablet	65100025100740	M, N, O, or Y	4 tablets
800 mcg tablet	65100025100750	M, N, O, or Y	4 tablets
Actiq® (fentanyl lozenge)[a]			
200 mcg lozenge	65100025108450	M, N, O, or Y	4 lozenges
400 mcg lozenge	65100025108455	M, N, O, or Y	4 lozenges
600 mcg lozenge	65100025108460	M, N, O, or Y	4 lozenges
800 mcg lozenge	65100025108465	M, N, O, or Y	4 lozenges
1200 mcg lozenge	65100025108475	M, N, O, or Y	4 lozenges
1600 mcg lozenge	65100025108485	M, N, O, or Y	4 lozenges
Fentora® (fentanyl buccal tablet)			
100 mcg tablet	65100025100310	M, N, O, or Y	4 tablets
200 mcg tablet	65100025100320	M, N, O, or Y	4 tablets
400 mcg tablet	65100025100330	M, N, O, or Y	4 tablets
600 mcg tablet	65100025100340	M, N, O, or Y	4 tablets
800 mcg tablet	65100025100350	M, N, O, or Y	4 tablets

Brand (generic)	GPI	Multisource Code	Quantity per Day Limit
Lazanda® (fentanyl nasal spray)			
100 mcg/spray	65100025102050	M, N, O, or Y	1 bottle
300 mcg/spray	65100025102057	M, N, O, or Y	1 bottle
400 mcg/spray	65100025102060	M, N, O, or Y	1 bottle
Subsys™ (fentanyl sublingual spray)			
100 mcg spray	65100025000910	M, N, O, or Y	4 sprays
200 mcg spray	65100025000920	M, N, O, or Y	4 sprays
400 mcg spray	65100025000930	M, N, O, or Y	4 sprays
600 mcg spray	65100025000940	M, N, O, or Y	4 sprays
800 mcg spray	65100025000950	M, N, O, or Y	4 sprays
1200 mcg spray	65100025000960	M, N, O, or Y	8 sprays (4 dose packages of 2 x 600 mcg sprays)
1600 mcg spray	65100025000970	M, N, O, or Y	8 sprays (4 dose packages of 2 x 800 mcg sprays)

a – generic fentanyl citrate lozenge included in program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

TIRF will be approved when ALL of the following are met:

1. The patient has a diagnosis of chronic cancer pain due to active malignancy
   AND
2. The patient is currently opioid tolerant (taking at least 60 mg 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)
   AND
3. The patient is taking a long-acting opioid concurrently with the TIRF
   AND
4. The patient is receiving only one TIRF agent in one strength
   AND
5. ONE of the following:
   6. The request is for a generic product
      OR
   7. The request is for a brand product AND ONE of the following:
      8. The patient's medication history includes use of one or more of the generic agents
         OR
      9. There is documentation that the patient is currently using the requested agent
         OR
      10. The prescriber states the patient is using the requested agent
         OR
      11. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one of the generic agents

   AND
12. ONE of the following:
    a. The requested dose is within the program quantity limit
       OR
    b. The requested dose is above the program quantity limit AND ONE of the following:
       i. ALL of the following:
          1. The requested dose is at or below the FDA labeled maximum dose
             AND

2. The requested dose cannot be achieved using a lesser quantity of a higher strength
   AND
3. Episodes of breakthrough pain cannot be controlled by modifying the long-acting opioid dosage
   AND
4. The prescriber has submitted documentation in support of therapy with a higher dose (quantity) for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

OR

ii. ALL of the following:
   1. The requested dose is above the FDA labeled maximum dose
      AND
   2. Episodes of breakthrough pain cannot be controlled by modifying the long-acting opioid dosage
      AND
   3. The prescriber has submitted documentation in support of therapy with a higher dose (quantity) for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: 1 month for increased dose requests during a dose titration period
Up to 6 months for all other requests

FDA APPROVED INDICATIONS AND DOSAGE[1-5]

Drug	Indication	Dosage
Abstral (fentanyl sublingual tablet) 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg	Management of breakthrough cancer pain in patients 18 years and older who are already receiving or tolerant to opioid therapy	Dose titration should be used to determine effective and tolerable maintenance dose. Initial dose should be 100 mcg. No more than 2 doses should be used per pain episode, doses separated by at least 30 minutes. After an episode, patients must wait at least 2 hours prior to treating the next episode.
Actiq (fentanyl lozenge)[a] 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg	Management of breakthrough cancer pain in patients 16 years and older who are already receiving and who are tolerant to around-the-clock opioid therapy	No more than 2 doses should be used per pain episode. After an episode, patients must wait at least 4 hours prior to treating the next episode. Limit to four or fewer units daily
Fentora (fentanyl buccal tablet) 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg	Management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy	Doses should be separated by at least 30 minutes with no more than 2 doses per episode. After treatment of one episode, patients must wait at least 4 hours prior to treating the next episode.
Lazanda (fentanyl nasal spray) 100 mcg, 300 mcg, 400 mcg	Management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain	Dose titration should be used to determine an effective dose, from 100 mcg to 200 mcg to 400 mcg, and up to a maximum of 800 mcg. Maximum dose is a single spray into one nostril or single spray into each nostril per episode with no more than 4 doses per day.
Subsys (fentanyl sublingual spray) 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg	Management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain	Initial dose should always be 100 mcg. Dose titration should be used to determine an effective dose; Patients should use no more than 4 doses per day. Subsys is not equivalent on a mcg per mcg basis with any other fentanyl product.

a – Generic product available

CLINICAL RATIONALE

Transmucosal immediate release fentanyl (TIRF) products are indicated only in patients who are already receiving opioid therapy and who are tolerant to opioid therapy. Patients considered opioid tolerant are those who are taking at least 60 mg 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. Fentanyl products **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates. For this reason, fentanyl containing agents are contraindicated in the management of acute or postoperative pain.[1-5] Inappropriate use of fentanyl has resulted in life-threatening reactions and patient deaths, prompting FDA warnings on both transdermal and oral formulations.[6]

REFERENCES

1. Fentora prescribing information. Cephalon. December 2016.
2. Actiq prescribing information. Cephalon. December 2016.
3. Abstral prescribing information. Novartis Consumer Health/ProStrakan Inc. December 2016.
4. Lazanda prescribing information. Archimedes Pharma Us Inc. December 2016.
5. Subsys prescribing information. Insys Therapeutics, Inc. December 2016.
6. FDA. Serious side effects with cancer pain drug. 9/28/2007. Available at: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048473.htm. Accessed February 2010.