

Transmucosal Immediate Release Fentanyl (TIRF) Products

Covered Medications	
Oral transmucosal fentanyl citrate lozenges (Actiq®) Fentanyl buccal tablets (Fentora®) Fentanyl sublingual tablets (Abstral®)	Fentanyl buccal soluble film (Onsolis®) Fentanyl nasal spray (Lazanda®) Fentanyl sublingual spray (Subsys™)

What they do and how they are used
<ul style="list-style-type: none"> ➤ Transmucosal and nasal fentanyl are indicated for the management of breakthrough pain in patients with cancer receiving longer acting narcotics. Episodes of pain that occur in patients with stable or persistent chronic pain despite around-the-clock narcotic medication are considered breakthrough pain. ➤ These fentanyl citrate products are FDA-labeled for breakthrough cancer pain. ➤ In order to avoid potential life-threatening side-effects, such as a reduced rate of breathing, only patients who are tolerant to (and used to) the effects of narcotics should use fentanyl. In addition, these products are not to be used for acute or postoperative pain. ➤ Less-costly narcotics (available as generics) that can alternatively be used for the control of breakthrough pain include immediate-release morphine- or oxycodone-containing drugs (Percocet®, Percodan®), hydromorphone (Dilaudid®), and hydrocodone-containing drugs (Vicodin®, Lortab®). ➤ Actiq® comes in the form of a lozenge on a stick, Fentora® is a buccal tablet, Abstral® is a sublingual tablet and Onsolis® is a buccal soluble film. These medications are slowly dissolved in the mouth, between the cheek and the upper or lower gum, or under the tongue. Actiq® and Fentora® should be sucked, not chewed. Abstral® is applied to the floor of the mouth and allowed to dissolve. Onsolis® should be applied to the side of the cheek until it dissolves, not chewed or swallowed. ➤ Lazanda® is a nasal spray that is administered as a single spray in the nostril. ➤ Subsys™ is a sublingual spray that is administered under the tongue. ➤ The FDA has approved a single shared Risk Evaluation and Mitigation Strategy (REMS) for the transmucosal immediate-release fentanyl (TIRF) products. The new shared system will replace the individual REMS in place for TIRF products. TIRF products include Abstral®, Actiq®, Fentora®, Lazanda®, Subsys™ and Onsolis®. ➤ These REMS programs are required to ensure that the appropriate patients receive the product in accordance with labeling (e.g., patients with cancer, who are already receiving and who are tolerant to regular opioid therapy). ➤ The REMS programs require registration and successful completion of a knowledge assessment in order for physicians to prescribe and pharmacist to dispense these products. Patients and distributors must also register in order to receive or distribute these products respectively. ➤ The doses of the transmucosal and nasal fentanyl products vary depending upon the individual being treated and strengths of the medications are not interchangeable. For example, due to its greater bioavailability, lower doses of Fentora® may achieve the same results as higher doses of Actiq®. ➤ When and if patients are changed from one product to another, the doses cannot be converted on a mcg basis from any other oral fentanyl transmucosal or nasal product. Treatment must begin with titration from the 100 mcg or 200 mcg dose; differences in the products extent of absorption may result in fatal overdose. ➤ Once a successful dose is established, up to 4 doses may be consumed per day. If more than 4 doses per day are required, the dose of the long-acting narcotic used for maintaining relief of chronic pain should be reconsidered. ➤ In the event that a patient needs to use more than one transmucosal unit for a single breakthrough pain episode, he/she may take another unit 30 minutes after the start of the first unit. However, single doses should be separated by at least 2 hours (four hours for Subsys™). ➤ The maximum dose of the nasal spray per breakthrough pain episode is one spray per nostril. If adequate pain relief is not achieved after 30 minutes another rescue medication may be used. ➤

Rationale for coverage authorization
<ul style="list-style-type: none"> ➤ To provide coverage for transmucosal immediate-release fentanyl products for the management of chronic breakthrough cancer pain in situations where the patient is currently receiving a long-acting opioid and where the use of other less-costly immediate-release narcotics is not an option. <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> ➤ To provide coverage for a quantity of transmucosal immediate-release fentanyl product sufficient for the management of chronic breakthrough cancer pain.

Benefit design

Actiq® , Fentora®

Coverage is provided without a coverage authorization process when a prescription for a ≥ 60-day supply of a long-acting narcotic analgesic exists in claim history during the previous 90 days **AND** a prescription for a ≥ 60-day supply of fentanyl citrate exists in claim history during the previous 90 days **AND** a prescription for a short acting narcotic analgesic exists in claim history during the previous 720 days.

1. In situations where there is no prescription for a short acting and a long-acting narcotic analgesic as well as fentanyl in claim history to indicate that the product is not being used first-line and the patient has chronic pain/opioid tolerance, coverage for fentanyl transmucosal products will be determined through prior authorization.

Abstral® , Onsolis® , Lazanda®

Coverage is provided without a coverage authorization process when a prescription for cancer drug markers **AND** a ≥ 60-day supply of a long-acting narcotic analgesic exists in claim history during the previous 90 days **AND** a prescription for a short acting narcotic analgesic exists in claim history during the previous 720 days.

1. In situations where there is no prescription for a short acting and a long-acting narcotic analgesic in claim history to indicate breakthrough cancer pain, that the product is not being used first-line, and the patient has chronic pain/opioid tolerance, coverage will be determined through prior authorization.

AND

Coverage is provided for a quantity sufficient for titration to effective dose using lower strengths, and for up to 4 units per day for management of chronic breakthrough pain.

Subsys™ :

Coverage is determined through prior authorization for every claim.

AND

Coverage is provided for a quantity sufficient for the treatment of up to 4 units per day for the management of chronic breakthrough cancer pain

What they cost (in dollars) – generic pricing in parenthesis where available

AWP per unit: Patients typically use up to 4 doses daily.

Strength (mcg)	Actiq® (fentanyl citrate)			Fentora® (fentanyl citrate)		
	AWP/ unit	AWP/ month	AWP/ Year	AWP/ unit	AWP/ month	AWP/ Year
100	-	-	-	28.59	3,431	41,170
200	54.48 (18.80)	6,538 (2,256)	78,451(27,072)	36.13	4,336	50,027
400	69 (23.82)	8,280 (2,858)	99,360 (34,301)	52.45	6,294	75,528
600	84.48 (29.18)	10,138 (3,502)	121,651 (42,019)	68.10	8,172	98,064
800	100.04 (34.57)	12,005 (4,148)	144,058 (49,781)	83.87	10,064	120,773
1200	130.04	15,605	187,258	-	-	-
1600	160.40	19,248	230,976	-	-	-

What they cost (in dollars) – generic pricing in parenthesis where available AWP per unit: Patients typically use up to 4 doses daily for Abstral and Onsolis, up to 1 daily for Lazanda									
	Lazanda® (4-8 doses per bottle)			Abstral®			Onsolis®		
Strength (mcg)	AWP/ unit	AWP/ month	AWP/ Year	AWP/ unit	AWP/ month	AWP/ Year	AWP/ unit	AWP/ month	AWP/ Year
100	336	10,080	120,960	16.80	2,016	24,192	-	-	-
200	-	-	-	19.20	2,304	27,648	25.72	3,086	37,036
300	-	-	-	22.80	2,736	32,832	-	-	-
400	480	14,400	172,800	28.80	3,456	41,472	37.76	4,531	54,374
600	-	-	-	38.40	4,608	55,296	49.84	5,980	71,769
800	-	-	-	48.00	5,760	69,120	61.87	7,424	89,093
1200	-	-	-	-	-	-	73.96	8,875	106,502
1600	-	-	-	-	-	-	-	-	-

What they cost (in dollars) – generic pricing in parenthesis where available AWP per unit: Patients typically use up to 4 doses daily.			
	Subsys® (fentanyl)		
Strength (mcg)	AWP/ dose	AWP/ month	AWP/ Year
100	25.72	3086	37,037
200	32.51	3901	46,815
400	47.21	5665	67,982
600	61.29	7355	88,258
800	75.48	9058	108,691
1200*	104.28	12,514	150,163
1600**	133.08	15,970	191,635

*packaged as 2x600mcg
 **packaged as 2x800mcg

Coverage authorization criteria
<p>Actiq®, Fentora®</p> <p>For patients new to treatment:</p> <ul style="list-style-type: none"> Coverage is provided for Actiq® and Fentora® for use in the management of breakthrough cancer pain that cannot be managed successfully with other oral immediate-release narcotics (other than fentanyl containing products) in patients who have chronic persistent pain who are already receiving and who are tolerant to long-acting narcotic analgesics. <p>For existing patients already using the product*:</p> <ul style="list-style-type: none"> Coverage is provided for Actiq® and Fentora® for use in the management of breakthrough non-cancer related pain that cannot be managed successfully with other oral immediate-release narcotics (other than fentanyl containing products) in patients who are currently on treatment with Actiq® or Fentora® and have chronic persistent pain and who are already receiving and who are tolerant to long-acting narcotic analgesics. <p>*prior to April 2012, Medco's Standard criteria provided coverage for non-cancer related breakthrough pain due efficacy data for this drug in refractory breakthrough pain and lack of a REMS program that limited the indication to its labeled use.</p> <p><u>Coverage duration: 6 months</u></p>

Abstral[®], Onsolis[®], Lazanda[®], Subsys[™]

1. Coverage is provided for Abstral[®], Subsys[™], Onsolis[®] and Lazanda[®] for use in patients age 18 years and older for the management of breakthrough cancer pain that cannot be managed successfully with other oral immediate-release narcotics (other than fentanyl containing products) in patients who have chronic persistent pain who are already receiving and who are tolerant to long-acting narcotic analgesics.
2. Additionally, for Subsys[™]: Coverage is provided if the patient is only receiving one transmucosal immediate-release fentanyl product at a time.

Coverage duration: 6 months

Quantity Duration Limit:

Actiq[®]: 120 units per 30-days (any strength)

- Coverage review process is available to determine coverage for a greater quantity (up to 180 units per 30-days) for patients experiencing more frequent episodes of breakthrough pain.

Fentora[®] & Abstral[®]: 100 mcg and 200 mcg tablet strengths = 240 tablets per 30 days (No coverage review) or 300 mcg, 400 mcg, 600 mcg, and 800 mcg tablet strengths = 120 units per 30-days

- Coverage review process is available to determine coverage for a greater quantity of 300 mcg, 400 mcg, 600 mcg, and 800 mcg tablet strengths only (up to 180 units per 30-days), for patients experiencing more frequent episodes of breakthrough pain.

Onsolis[®]: 200 mcg strength = 240 units per 30 days (No coverage review) or 400 mcg, 600 mcg, 800 mcg, and 1200 mcg unit strengths = 120 units per 30-days

- Coverage review process is available to determine coverage for a greater quantity of 400 mcg, 600 mcg, 800 mcg and 1200 mcg unit strengths only (up to 180 units per 30-days) , for patients experiencing more frequent episodes of breakthrough pain.

Lazanda[®]: Coverage is provided for up to 30 bottles of Lazanda 100 mcg or 400 mcg nasal sprays per month.

Coverage for an additional quantity is not available.

Subsys[™]: 120 units per 30-days (any strength)

- Coverage review process is available to determine coverage for a greater quantity in accord with the following:
 - Coverage is provided for up to 180 sprays per 30 days to provide additional doses for patients experiencing more frequent episodes of breakthrough pain, or
 - Coverage is provided for up to 240 sprays per 30 days of the 600 mcg or 800 mcg strengths to provide additional doses for patients requiring non-commercially available dosages (1200 mcg or 1600 mcg per dose, respectively).

References

- Abstral[®] (fentanyl sublingual tablet). Prescribing information. Bedminster NJ: ProStrakan, December 2011.
- Actiq[®] (oral transmucosal fentanyl citrate). Prescribing information. Salt Lake City, UT: Cephalon, December 2011.
- Chou, Roger, Gilbert Fanciullo, and Perry G. Fine. "Opioid Treatment Guidelines." *The Journal of Pain* 10 (2009): 113-30. Print.
- Fentora[®] (fentanyl buccal tablet). Prescribing information. Salt Lake City, UT: Cephalon, December 2011.
- Lazanda[®] (fentanyl nasal spray). Prescribing information. Bedminster, NJ: Archimedes, December 2011.
- NCCN Guidelines Version 2.2011. Adult Cancer Pain. Available at URL: http://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed 11/11/11.
- Onsolis[®] (fentanyl buccal soluble film). Prescribing information. Somerset, NJ: Meda Pharmaceuticals Inc, December 2011.
- Subsys[™] (fentanyl sublingual spray). Prescribing information. Phoenix, AZ: INSYS Therapeutics, April 2012
- The TIRF REMS Access program. Available at URL: www.TIRFREMSaccess.com. Accessed 2/17/12.