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IN BRIEF

New Labeling for Once-Monthly Subcutaneous Buprenorphine *(Sublocade)*

The FDA has approved changes to the labeling of *Sublocade* (Indivior), an extended-release formulation of the partial opioid agonist buprenorphine, to permit faster initiation and use of alternative injection sites. *Sublocade* is indicated for once-monthly subcutaneous treatment of moderate to severe opioid use disorder.[1]

Buprenorphine is the maintenance treatment of choice for most patients with opioid use disorder. To prevent severe opioid withdrawal, patients must already be receiving treatment with buprenorphine or undergo a trial with a short-acting transmucosal product before a long-acting formulation can be initiated.[2] The labeling changes allow for a first subcutaneous dose of *Sublocade* to be given after a single transmucosal test dose of buprenorphine; previously, use of transmucosal buprenorphine for at least 7 days had been required. The new labeling also allows for *Sublocade* to be administered into the abdomen, thigh, buttock, or back of the upper arm; previously, it could only be injected into the abdomen.

Brixadi, another subcutaneous, extended-release formulation of buprenorphine, is already indicated for use following only a single test dose of transmucosal buprenorphine (see Table 1).[3]

Approval of the new *Sublocade* dosage regimen was based on the results of an open-label trial (available only as an abstract) in which 140 patients were randomized 2:1 to receive *Sublocade* after either a single dose of transmucosal buprenorphine (rapid induction) or 7-14 days of transmucosal treatment (standard induction). The rate of treatment retention at the time of the second injection (1 week after the initial injection), the primary endpoint, was noninferior with rapid induction compared to standard induction (67.1% vs 59.6%). Rates of precipitated opioid withdrawal were similar in the rapid and standard induction groups (16.9% vs 14.6%).[4]

How *Sublocade* and *Brixadi* compare to one another in efficacy is unknown. Use of a long-acting subcutaneous formulation of buprenorphine should reduce the risks of treatment nonadherence and drug diversion, but it is considerably more expensive than sublingual formulations.[2] ■

Table 1. *Sublocade* vs *Brixadi*

	Sublocade (Indivior)	*Brixadi* (Braeburn)
Initial dosage in patients not taking buprenorphine	300 mg SC after transmucosal test dose, then 300 mg 1 week to 1 month later	16 mg SC after transmucosal test dose, then 8 mg up to 3 days later[1]
Target maintenance dosage	100 or 300 mg SC once/month[2]	24 or 32 mg SC once/week, or 96 or 128 mg SC q28 days
Administration sites	Abdomen, thigh, buttock, or upper arm	Abdomen, thigh, buttock, or upper arm[3]
Storage	Room temperature for up to 12 weeks, or refrigerated	Room temperature
Cost[4]	$2117	$1708

1. If needed during the first week of treatment, an additional 8-mg dose can be given at least 24 hours after the first 8-mg dose.
2. The 300-mg monthly maintenance dose is recommended if patients do not have a satisfactory clinical response to the 100-mg dose.
3. In patients who were not previously receiving buprenorphine, weekly *Brixadi* should not be injected into the upper arm until steady state has been reached (4 consecutive doses); injection in the upper arm is associated with plasma buprenorphine levels ~10% lower than injection in other sites.
4. Approximate WAC for 1 month's treatment with *Sublocade* or 4 weeks' treatment with *Brixadi*. WAC = wholesaler acquisition cost, or manufacturer's published price to wholesalers; WAC represents published catalogue or list prices and may not represent an actual transactional price. Source: AnalySource® Monthly. March 5, 2025. Reprinted with permission by First Databank, Inc. All rights reserved. ©2025. www.fdbhealth.com/policies/drug-pricing-policy.

1. Once-monthly subcutaneous buprenorphine (Sublocade) for opioid use disorder. Med Lett Drugs Ther 2018; 60:35.
2. Drugs for opioid use disorder. Med Lett Drugs Ther 2023; 65:137.
3. Once-weekly or once-monthly subcutaneous buprenorphine (Brixadi) for opioid use disorder. Med Lett Drugs Ther 2023; 65:133.
4. R Shiwach et al. A randomized open-label study comparing rapid and standard inductions to injectable buprenorphine extended-release (BUP-XR) treatment. Canadian Society of Addiction Medicine Scientific Congress; Victoria, British Columbia, Canada; October 19-21, 2023. Available at: http://bit.ly/43Gd3hv. Accessed March 13, 2025.

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