

Prior Authorization DRUG Guidelines

SUBLOCADE (Buprenorphine Extended Release)

Effective Date: 8/2/21

Date Developed: 7/21/22 by Dr. Howard Taekman

Last Approval Date: 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Sublocade (buprenorphine-extended release) is a sterile solution for subcutaneous injection only. It is designed to deliver buprenorphine at a controlled rate over a one-month period. The ER Sublocade formulation is injected SUBQ as a liquid; subsequent precipitation following injection results in a solid depot which will gradually release buprenorphine via diffusion and biodegradation of the depot.

Buprenorphine hydrochloride is an opioid partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor, thus it exhibits a ceiling to its effects. The danger of overdose, abuse liability, and toxicity may be less than with full opioid agonists.

Preauthorization Criteria

Maintenance treatment of moderate to severe opioid use disorder in patients who have initiated treatment with 8 to 24 mg of a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

- **NOTE:** Member must be a part of a complete treatment program that includes counseling and psychosocial support
- **NOTE:** Initial authorization will be for no more than 6 months.
- **NOTE:** Continuation of therapy requires the following:
 - Physician documentation that the patient has experienced a positive clinical response to buprenorphine extended release therapy, as defined by the provider;
and
 - Patient has not, nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine;
and
 - Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling;
and

- Continuation authorization will be for no more than 12 months.

Adverse Effects: accidental overdose, hyperalgesia, hypotension, QT prolongation, respiratory depression, constipation

US Boxed Warnings: addiction, abuse, respiratory depression, withdrawal syndromes (see product literature for complete listing)

References

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8/3/21	No	Howard Taekman, MD; Robert Sterling, MD	NEW
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
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			background of Sublocade. Modified the preauthorization criteria and added “Maintenance treatment of moderate to severe opioid use disorder in patients who have initiated treatment with 8 to 24 mg of a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.” Added Adverse effects and U.S Boxed Warning sections. References updated.
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