VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

SUBLOCADE (Buprenorphine Extended Release)

Effective Date: 8/2/21

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

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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.

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

Buprenorphine extended-release injection (e.g., Sublocade) is proven and/or medically necessary for the treatment of moderate to severe opioid use disorder in patients who meet all of the following criteria:

For initial therapy, all of the following:

- Patient is currently maintained on a 8mg to 24mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection;

  and

- Patient has not, nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine;

  And

- Member is part of a complete treatment program that includes counseling and psychosocial support

  and

- Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling;

  and

- Initial authorization will be for no more than 6 months.

For continuation therapy, all of 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.

*Note: Patients screening positive for opioid use outside of an opioid dependence treatment regimen is evidence that the patient has not achieved or is no longer in sustained, prolonged, clinical stability with their treatment program.

Use of Buprenorphine extended-release injection is unproven and not medically necessary for:

- Pain management
- Patients who have not achieved and sustained prolonged clinical stability and tolerance to opioids for at least six months
- Patients who are recently tapered to a lower dose of sublingual or transmucosal buprenorphine for the sole purpose of transitioning to Probuphine
- Patients who are new entrants to opioid dependence treatment
- Patients who have an opioid-positive urine drug screen within the previous ninety days.

References

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3. Rosenthal RN, Lofwall MR, Kim S, Chen M, Effect of Buprenorphine Implants on Illicit Opioid Use Among Abstinent Adults With Opioid Dependence Treated With Sublingual Buprenorphine: A Randomized Clinical Trial. JAMA. 2016 Jul 19;316(3):282-90.

4. Buprenorphine Treatment Physician Locator. (n.d.). Retrieved July 22, 2019, from http://www.samhsa.gov/medicationassisted-treatment/physician-program-data/treatment-physician-locator.

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6. Sublocade [package insert]. Burlington, MA: Indivior Inc., February 2020.

7. Haight BR, Learned SM, Laffont CM, et al. Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2019 Feb 23;393(10173):778- 790.

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