Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

SUBLOCADE® (buprenorphine extended-release) PA CRITERIA:

SUBLOCADE® (buprenorphine extended-release) is a partial opioid agonist indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

Prior authorization is required for SUBLOCADE® (buprenorphine extended-release). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 12 Months

1. The patient must meet the minimum age requirements recommended by the package insert for the FDA approved indication; **AND**

2. The patient has a diagnosis of moderate to severe opioid use disorder (OUD); **AND**

3. The patient has a documented clinical reason provided by the prescriber on why oral agents could not be utilized (e.g., history of abuse or diversion to oral agent, history of relapse due to non-adherence to oral agent or high risk of non-adherence, homelessness, or other inability to use oral agents safely, etc.); **AND**

4. Prescriber attests that the patient meets one of the following scenarios:
    a. For a patient not currently taking buprenorphine, the patient has or will receive an initial dose of transmucosal buprenorphine before administration of the first SUBLOCADE® injection; **or**
    b. Patient is currently maintained on 8 to 24 mg of transmucosal buprenorphine daily prior to transitioning to SUBLOCADE® injection; **AND**

5. Prescriber attests that no other buprenorphine dosage forms will be used concurrently once the patient transitions to SUBLOCADE®; **AND**

6. The patient is prescribed naloxone for the emergency treatment of opioid overdose and consulted on its use; **AND**

7. Prescribed SUBLOCADE® dose does not exceed 300mg (1.5mL) for the first two initial doses and 100mg (0.5mL) monthly for maintenance afterwards. If the patient requires a monthly maintenance dose of 300mg (1.5mL), documentation of an inadequate response to the 100mg maintenance dose must be provided.

Re-Authorization: 12 Months

1. Patient continues to meet initial authorization criteria; **AND**

2. Prescribed dose does not exceed a maintenance dose of 100mg monthly. If the patient requires a maintenance dose of 300mg monthly, documentation of an inadequate response to the 100mg maintenance dose must be provided; **AND**

3. The patient has positive response to SUBLOCADE® therapy, as defined as:
    a. The patient has not received an opioid analgesic or oral buprenorphine agent since last approval; **OR**
    b. The patient has an all-negative drug screen to opioids since the last authorization; **OR**
    c. Documentation from the prescriber evaluation of the patient's progress of OUD if relapse occurred.

SUBLOCADE® (buprenorphine) Dosing and Administration:

- The recommended dose of SUBLOCADE® following induction and dose adjustment with transmucosal buprenorphine is 300mg for the first two initial doses followed by a maintenance dose of 100mg monthly.

- The maintenance dose may be increased to 300mg monthly for patients who tolerate the 100mg dose, but do not demonstrate a satisfactory clinical response.

- SUBLOCADE® is administered subcutaneously. It is for healthcare provider preparation and administration only.

Formulation:

- SUBLOCADE® is available as 100mg/0.5mL or 300mg/1.5mL subcutaneous injection provided in a prefilled single-dose syringe.