Department:	Pharmacy	**Original Approval:**	08/10/2018
Policy #:	PM151	**Last Approval:**	08/10/2018
Title:	Buprenorphine for subcutaneous use (Sublocade and Probuphine)		
Approved By:	UM Pharmacy Subcommittee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Buprenorphine for subcutaneous use (Sublocade) and Buprenorphine implant (Probuphine): History and/or physical examination notes and relevant notes that address the problem and need for the service: -Diagnosis -Age -Labs/diagnostics – Housing status- Medication list (current and past) to include start and end dates of previous trials for opioid use disorder.

BACKGROUND

Sublocade is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days. Sublocade should be used as part of a complete treatment plan that includes counseling and psychosocial support.[1]

Probuphine is an implant that contains the medicine buprenorphine. Probuphine is used to treat certain adults who are addicted to (dependent on) opioid drugs (either prescription or illegal). Probuphine is part of a complete treatment program that also includes counseling and behavioral therapy. Probuphine implants contain the opioid buprenorphine, which may cause physical dependence.[2]

DEFINITIONS

Suboxone failure:

1. Presence of endocarditis
2. Severe mental illness preventing compliance with medication
3. Homelessness that may jeopardize compliance (or risk of theft/diversion)
4. Incarcerated short term (e.g. has a 30 day or less jail sentence)
5. Recent hospitalization due to overdose

INDICATIONS/CRITERIA

Medicaid Members	***Sublocade and Probuphine are not considered for approval for opioid dependence maintenance treatment unless member has tried and failed buprenorphine/naloxone (Suboxone).*** ***Sublocade and Probuphine are included in the WA HCA Single Preferred Drug List. Continue to criteria for approval below.***
Medicare Members	**Follow the criteria below.** Medicare does not have a National Coverage Determination (NCD) for Sublocade™ (buprenorphine extended-release) and/or Probuphine®

	(buprenorphine). Local Coverage Determinations (LCDs) do not exist at this time. ***Step-utilization of Part D drugs not required.***

FDA-Approved Indications

1. Opioid dependence, Maintenance treatment

Criteria. *The patient must meet the following criteria* (A, B, C, D, E, & F AND G OR H)

A. The patient must be 18 years of age or older
B. Trial and failure of Suboxone therapy per definition above.
C. It must be for maintenance treatment of opioid dependence.
D. It must be prescribed by a physician qualified by HHS (Health and Human Services) and registered with SAMHSA (Substance Abuse and Mental Health Services Administration). (SAMHSA Provider Locator)[3]
E. Patient will receive counseling and psychosocial support
F. Patient will not be receiving other opioids
G. Sublocade only: Patient has achieved clinical stability on a buprenorphine product
   - **i.** Patient must have a minimum of 7 days prior treatment with a transmucosal buprenorphine-containing product for induction and dose-adjustment
   - **ii.** Prescriber must be certified in the Sublocade REMS program.

H. Probuphine only: Patient has achieved and sustained prolonged clinical stability (6 months or longer) on a transmucosal buprenorphine product for induction and dose-adjustment
   - **i.** Patient is not on more than 8mg per day
   - **ii.** Patient will be monitored for implant migration, expulsion, and nerve damage
   - **iii.** Prescriber must be certified in the Probuphine REMS program

Initial Approval/Extended Approval.

A) *Initial Approval:* Approve 6 months of therapy.
B) *Extended Approval:* Approve at additional 6-month intervals if the patient has shown no signs of opioid dependence relapse.

Dosing

Sublocade: 300mg subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100 mg monthly. Dosing may be increased to 300mg monthly
Probuphine: 74.2mg implants- 4 implants per 180 days

Duration of Therapy

1 year for Probuphine- After one insertion in each arm, most patients should be transitioned back to a transmucosal buprenorphine-containing product for continued treatment.[2]

Labs/Diagnostics. Urine drug screening results negative for illicit drugs indicate efficacy; monitor at least weekly for the first month, depending on the patient's level of stability, and once-monthly thereafter for patients on a stable regimen

Waste Management for All Indications. Entire syringe should be used in its entirety.

Conditions Not Recommended for Approval

1. **Pain control**

SPECIAL CONSIDERATIONS

Patients who do not qualify for Sublocade should be referred to treatment through a hub & spoke treatment center for coordination with a nurse case manager to address compliance and social issues. https://www.hca.wa.gov/about-hca/behavioral-health-recovery/washington-state-hub-and-spoke-project

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References	1. Sublocade [prescribing information]. North Chesterfield, VA: Indivior UK Limited; 8/2018 2. Probuphine [prescribing information]. Princeton, NJ: Braeburn Pharmaceuticals, Inc; 2/2018 3. Buprenorphine Treatment Physician Locator. (n.d.). Retrieved 8/6/18, from http://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator.

CFR		
WAC	WAC 284-43-2050	
RCW		
Contract Citation	☒ WAH	
	☒ IMC	
	☒ MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
08/06/2018	New policy	Jennifer Farley, PharmD
08/10/2018	Approval	UM Pharmacy Subcommittee