Attention: Nurse Practitioners, Physicians Assistants and Physicians

Billing Guidelines: Buprenorphine extended-release injection, for subcutaneous use (Sublocade) HCPCS code J3490: Billing Guidelines

Effective with date of service March 1, 2018, North Carolina Medicaid and NC Health Choice (NCHC) programs cover buprenorphine extended-release injection (Sublocade), for subcutaneous use in the Physician’s Drug Program (PDP) when billed with HCPCS code J3490 - Unclassified drugs.

Sublocade will be available as an injection of 100 mg/0.5 mL and 300 mg/1.5 mL provided in a prefilled syringe. It is indicated for the treatment of moderate to severe opioid-use disorder in adult patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of seven days.

The recommended dose for Sublocade is two once monthly initial doses of 300 mg followed by 100 mg once monthly maintenance doses. Increasing the maintenance dose to 300 mg once monthly may be considered for patients in which the benefits outweigh the risks. See full prescribing information for further detail.

Under the Drug Addiction Treatment Act (DATA), use of Sublocade in the treatment of opioid dependence is limited to healthcare providers who meet Drug Enforcement Administration (DEA) waiver requirements and who have notified the Secretary of Health and Human Services of their intent to prescribe this product for the treatment of opioid dependence.

To mitigate the risk of serious harm or death that could result from intravenous self-administration of Sublocade, healthcare facilities are required to register for the FDA approved Sublocade Risk Evaluation and Mitigation Strategy (REMS) program. In addition, waived providers who choose to utilize Sublocade must meet NC controlled substances regulations and C-3 handling and storage requirements.

For Medicaid and NCHC Billing

- The ICD-10-CM diagnosis code required for billing are:
  - F11.10 - Opioid abuse, uncomplicated;
  - F11.11 - Opioid abuse, in remission;
  - F11.120 - Opioid abuse with intoxication, uncomplicated;
  - F11.121 - Opioid abuse with intoxication delirium;
  - F11.122 - Opioid abuse with intoxication with perceptual disturbance;
  - F11.129 - Opioid abuse with intoxication, unspecified;
  - F11.14 - Opioid abuse with opioid-induced mood disorder;
  - F11.150 - Opioid abuse with opioid-induced psychotic disorder with delusions;
  - F11.151 - Opioid abuse with opioid-induced psychotic disorder with hallucinations;
  - F11.159 - Opioid abuse with opioid-induced psychotic disorder, unspecified;
  - F11.181 - Opioid abuse with opioid-induced sexual dysfunction;
  - F11.182 - Opioid abuse with opioid-induced sleep disorder;
  - F11.188 - Opioid abuse with other opioid-induced disorder;
  - F11.19 - Opioid abuse with unspecified opioid-induced disorder;
  - F11.20 - Opioid dependence, uncomplicated;
- F11.21 - Opioid dependence, in remission;
- F11.220 - Opioid dependence with intoxication, uncomplicated;
- F11.221 - Opioid dependence with intoxication delirium;
- F11.222 - Opioid dependence with intoxication with perceptual disturbance;
- F11.229 - Opioid dependence with intoxication, unspecified;
- F11.23 - Opioid dependence with withdrawal;
- F11.24 - Opioid dependence with opioid-induced mood disorder;
- F11.250 - Opioid dependence with opioid-induced psychotic disorder with delusions;
- F11.251 - Opioid dependence with opioid-induced psychotic disorder with hallucinations;
- F11.259 - Opioid dependence with opioid-induced psychotic disorder, unspecified;
- F11.281 - Opioid dependence with opioid-induced sexual dysfunction;
- F11.282 - Opioid dependence with opioid-induced sleep disorder;
- F11.288 - Opioid dependence with other opioid-induced disorder;
- F11.29 - Opioid dependence with unspecified opioid-induced disorder;
- F11.90 - Opioid use, unspecified, uncomplicated;
- F11.920 - Opioid use, unspecified with intoxication, uncomplicated;
- F11.921 - Opioid use, unspecified with intoxication delirium;
- F11.922 - Opioid use, unspecified with intoxication with perceptual disturbance;
- F11.929 - Opioid use, unspecified with intoxication, unspecified;
- F11.93 - Opioid use, unspecified with withdrawal;
- F11.94 - Opioid use, unspecified with opioid-induced mood disorder;
- F11.950 - Opioid use, unspecified with opioid-induced psychotic disorder with delusions;
- F11.951 - Opioid use, unspecified with opioid-induced psychotic disorder with hallucinations;
- F11.959 - Opioid use, unspecified with opioid-induced psychotic disorder, unspecified;
- F11.981 - Opioid use, unspecified with opioid-induced sexual dysfunction;
- F11.982 - Opioid use, unspecified with opioid-induced sleep disorder;
- F11.988 - Opioid use, unspecified with other opioid-induced disorder;
- F11.99 - Opioid use, unspecified with unspecified opioid-induced disorder

- Providers must bill with HCPCS code J3490 - Unclassified drugs.
- One Medicaid unit of coverage is one syringe. NCHC bills according to Medicaid units.
- The maximum reimbursement rate per unit is $1706.40.
- Providers must bill 11-digit National Drug Codes (NDCs) and appropriate NDC units. The NDCs are 12496-0100-01 and 12496-0300-01.
- The NDC units should be reported as “UN1.”
- For additional information, refer to the January 2012, Special Bulletin, National Drug Code Implementation Update.
- For additional information regarding NDC claim requirements related to the PDP, refer to the PDP Clinical Coverage Policy No. 1B, Attachment A, H.7 on Medicaid's website.
- Providers shall bill their usual and customary charge for non-340-B drugs.
- PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have registered with the Office of Pharmacy Affairs (OPA). Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the UD modifier on the drug detail.
- The fee schedule for the PDP is available on Medicaid's PDP web page.

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