



Billing and Coding Guide for SUBLOCADE® (buprenorphine extended-release)

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.
- Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.

Please see accompanying full Prescribing Information, including BOXED WARNING, and Medication Guide, or for more information about SUBLOCADE, visit www.SUBLOCADEHCP.com. For REMS information visit www.SUBLOCADEREMS.com.



(buprenorphine extended-release) injection for subcutaneous use **(** 100mg•300mg

INSUPPORT[®] was created by Indivior[®] to provide information on the access and reimbursement processes on behalf of patients seeking treatment with SUBLOCADE[®] (buprenorphine extended-release). INSUPPORT provides information for healthcare providers (HCPs) and their offices in support of these patients, including:

BENEFIT COVERAGE INFORMATION

- Conduct a benefit investigation of the patient's insurance coverage for SUBLOCADE for the patient's current site of care
- Provide information on the prior authorization and appeals process and confirm product acquisition requirements from the patient's health insurance provider
- If applicable, determine eligibility and enroll an eligible patient for the Copay Assistance Program for SUBLOCADE, or provide alternate funding information



COPAY ASSISTANCE PROGRAM

- Designed to help eligible^a patients with the out-of-pocket costs for SUBLOCADE
- Eligible^a patients may pay as little as \$0 per injection of SUBLOCADE for the first 2 injections. Restrictions apply



PATIENT ACCESS SPECIALIST

• A local specialist that can provide in-person information about INSUPPORT, including patient insurance benefits and requirements



TRANSITION OF CARE

 Assistance in the transition process for patients who are receiving treatment with SUBLOCADE and transitioning to a new healthcare setting to continue SUBLOCADE treatment

INSUPPORT ONLINE Fnroll patients electronically by electronically by electronically by electronically by electronically by electronical electronicac electronical electronical electronical ele



- Enroll patients electronically by emailing the SUBLOCADE patient enrollment form to enroll@insupport.com
- Find information about the steps in the patient access program, utilize tools, and access other resources on <u>www.INSUPPORT.com</u>

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^a The INSUPPORT Copay Assistance Program is valid ONLY for patients with private insurance who are prescribed SUBLOCADE for on-label use. Patients with government insurance are not eligible for the Copay Assistance Program, including, but not limited to, Medicare, Medicaid, Medigap, VA, DoD, TRICARE, CHAMPVA, or any other federally or state-funded government-assisted program. Other restrictions apply. See insert or visit <u>www.INSUPPORT.com</u> to view complete Terms & Conditions.

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INTERNATIONAL CLASSIFICATION OF DISEASES, 10TH REVISION, CLINICAL MODIFICATION (ICD-10-CM) CODES FOR OPIOID DEPENDENCE¹

SUBLOCADE[®] (buprenorphine extended-release) 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.²

SUBLOCADE should be used as part of a complete treatment program that includes counseling and psychosocial support.

ICD-10-CM CODES ^a		
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 intoxication 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	

*Social determinants of health, ICD-10-CM Z-codes describe social problems, conditions, or risk factors that may influence a patient's health and may be reported when documented in the medical record.

The individual or entity submitting a claim using INSUPPORT[®] reimbursement and coding information must ensure that all information submitted on or with the claim is accurate, complete, and applicable to the claim being filed.

The above-listed codes are provided for informational, nonpromotional purposes only. Third-party coverage and reimbursement are complex and may change frequently. Providers are responsible for determining and submitting appropriate codes and charges and appropriate medical services and products in accordance with providers' independent professional judgment.

Indivior makes no representations or warranties or guarantees of any kind relating to access, coverage, or reimbursement.

The appropriateness of filing any particular claim is and remains the responsibility of that claim's submitter based on the submitter's own judgment.

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BILLING CODES

NATIONAL DRUG CODES (NDCs)² FOR SUBLOCADE[®] (buprenorphine extended-release) AND FORMATTING ON MEDICAL CLAIMS

10-DIGIT NDC	MILLI- GRAMS	11-DIGIT NDC FORMAT FOR CLAIMS ³	NDC LOCATION ON CLAIM FORMS ^{4,5}
12496-0100-01	100 mg	N412496010001	CMS-1500: Item Number 24A
12496-0300-01	300 mg	N412496030001	(shaded area) CMS-1450: Form Locator 43

Please note that some payers, including state Medicaid programs, require HCPs to report the 11-digit version of the NDC compliant with the Health Insurance Portability and Accountability Act (HIPAA) (5-4-2 format) for a physician-administered drug along with the unit of measure, quantity, and its Healthcare Common Procedure Coding System (HCPCS) code on paper claim forms and their electronic equivalents.³

CURRENT PROCEDURAL TERMINOLOGY (CPT) CODE⁶

CPT CODE ^a	DESCRIPTION
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

^a CPT Copyright 2023 American Medical Association. All rights reserved. CPT[®] is a registered trademark of the American Medical Association.

SUBLOCADE should be administered by an HCP by subcutaneous injection only. Do not administer SUBLOCADE intravenously, intradermally, or intramuscularly.²

The individual or entity submitting a claim using INSUPPORT[®] reimbursement and coding information must ensure that all information submitted on or with the claim is accurate, complete, and applicable to the claim being filed. The abovelisted codes are provided for informational, nonpromotional purposes only. The information provided is accurate on the publication date, but it should be independently verified. The appropriateness of filing any particular claim is and remains the responsibility of the HCP based on their own judgment.

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BILLING CODES

PRODUCT-SPECIFIC HCPCS CODES FOR SUBLOCADE® (buprenorphine extended-release)⁷

HCPCS CODE	DESCRIPTION	NUMBER OF BILLING UNITS
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	1
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	1

HCPCS MODIFIERS FOR SUBLOCADE®7,8

MODIFIER	DESCRIPTION	APPROPRIATE USE WITH SUBLOCADE	
JZ	Zero drug amount discarded/not administered to any patient	Append modifier -JZ to Q9991 or Q9992 to identify that no amount of drug was discarded from a single-dose pre-filled syringe. The policy applies to all providers and suppliers who buy and bill separately payable drugs under Medicare Part B	
JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	Append modifier -JG to Q9991 or Q9992 to identify the drug was acquired under the 340B Drug Discount Program by a 340B-covered entity	
RE	Furnished in full compliance with FDA-mandated risk evaluation and mitigation strategy (REMS)	Append modifier -RE to Q9991 or Q9992 to identify the drug was administered in full compliance with the REMS policy	

340B-covered entities may report modifier JG or TB through December 31, 2024. 340B-covered entities must report modifier TB starting with services on January 1, 2025.⁹

Other modifiers may apply; check with individual payers to confirm modifier reporting requirements.

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BILLING CODES

PLACE OF SERVICE (POS) CODES¹⁰

POS codes identify the location where services are rendered by an HCP. The following POS codes may be appropriate for an HCP to report on a CMS-1500 claim form for professional services:

POS CODE	POS NAME	DESCRIPTION
9	Prison/ Correctional Facility	A prison, jail, reformatory, work farm, detention center, or any other similar facility maintained by either Federal, State or local authorities for the purpose of confinement or rehabilitation of adult or juvenile criminal offenders.
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
50	Federally Qualified Health Center	A facility located in a medically underserved area that provides Medicare beneficiaries preventive primary medical care under the general direction of a physician.
53	Community Mental Health Center	A facility that provides the following services: outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically ill, and residents of the CMHC's mental health services area who have been discharged from inpatient treatment at a mental health facility; 24 hour a day emergency care services; day treatment, other partial hospitalization services, or psychosocial rehabilitation services; screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission; and consultation and education services.
55	Residential Substance Abuse Treatment Facility	A facility which provides treatment for substance (alcohol and drug) abuse to live-in residents who do not require acute medical care. Services include individual and group therapy and counseling, family counseling, laboratory tests, drugs and supplies, psychological testing, and room and board.
57	Non-residential Substance Abuse Treatment Facility	A location which provides treatment for substance (alcohol and drug) abuse on an ambulatory basis. Services include individual and group therapy and counseling, family counseling, laboratory tests, drugs and supplies, and psychological testing.
58	Non-residential Opioid Treatment Facility	A location that provides treatment for opioid use disorder on an ambulatory basis. Services include methadone and other forms of Medication Assisted Treatment (MAT)

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MEDICARE FEE-FOR-SERVICE SUBLOCADE® (buprenorphine extended-release) INJECTION BILLING⁷

The table below lists the relevant codes used to report MAT, Principal Illness Navigation (PIN) and other services associated with SUBLOCADE for opioid use disorder. Please note the G-codes are for weekly or monthly episodes of care. Check each payer policy as other payers may recognize the Medicare-specific codes.

G-CODE	DESCRIPTION	APPROPRIATE USE	
G2069ª	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled opioid treatment program)	May be billed weekly and represents a bundled buprenorphine and episode of care payment, including the medication, for opioid use disorder services performed in an OTP .	
G2074ª	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled opioid treatment program)	Billed weekly for OTP services furnished during an episode of care when a medication is not administered, but other services in the bundle are furnished.	
G2086	Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month	May be used for the first calendar month and represents a bundled episode of care payment for substance use disorder services performed in an office.	
G2087	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month	May be used for a subsequent calendar month and represents a bundled episode of care payment for substance use disorder services performed in an office.	
G0023⁵	Principal illness navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator, 60 minutes per calendar month The full code description is available at <u>https://www.cms.gov/files/zip/july-2024- alpha-numeric-hcpcs-file.zip</u>		
G0024⁵	Principal illness navigation services, additional 30 minutes per calendar month (list separately in addition to G0023)	PIN services are provided to Medicare patients with high-risk conditions, such as substance-use disorders, who receive a patient-centered assessment to better identify their needs and connect them to clinical and support resources.	
G0140 ⁶	Principal illness navigation-peer support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist, 60 minutes per calendar month The full code description is available at <u>https://www.cms.gov/files/zip/july-2024- alpha-numeric-hcpcs-file.zip</u>		
G0146 ^b	Principal illness navigation-peer support, additional 30 minutes per calendar month (list separately in addition to G0140)		

^a Medicare reimburses opioid treatment programs (OTPs) with a bundled payment for opioid use disorder treatment services. An OTP is defined as "a program or practitioner engaged in opioid treatment of individuals with an opioid agonist medication." The Substance Abuse and Mental Health Services Administration (SAMHSA) certifies and requires that OTPs must:

Be accredited by a federally deemed accrediting body

• Be accredited under the Behavioral Health Care Accreditation Program (if the OTP "is part of an organization accredited under a different program by The Joint Commission")

• Have an active patient eligible for survey¹¹ ^bPIN services are performed by certified or trained auxiliary personnel incidental to the professional services of a physician or other practitioner. A healthcare practitioner initiates PIN services during an initiating visit where they identify the medical necessity of PIN services and establish an appropriate treatment plan. The same practitioner bills for the subsequent PIN services that auxiliary personnel provide. The billing practitioner personally performs initiating visits. Auxiliary personnel may perform the subsequent PIN services. Certain evaluation/management [E/M] visits, such as inpatient and observation visits, emergency department visits, and SNF visits would not serve as PIN initiating visits because the practitioner providing the E/M visit would not typically provide continuing care to the patient. This includes providing necessary PIN services in subsequent months.¹²

PROFESSIONAL CMS-1500 (837P) AND INSTITUTIONAL CMS-1450 (UB-04) (837I) CLAIM FORMS

Both claim forms and their electronic equivalents are used to submit healthcare claims to payers. The type of provider submitting a claim determines the appropriate claim form to use. The CMS-1500 (or electronic format 837P) is used by a healthcare provider to report professional services such as those commonly provided in a physician office or independent treatment clinic. The CMS-1450 (or electronic format 837I) is used by institutional providers to report services such as those commonly provided in a hospital outpatient department or a hospital-affiliated treatment facility.

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ADDITIONAL RESOURCES



For more information on the INSUPPORT[®] program, call INSUPPORT at 844-INSPPRT (844-467-7778) or visit <u>www.INSUPPORT.com</u>.



INSUPPORT Patient Enrollment Form https://www.insupport.com/enrollment



INSUPPORT Resources & Tools for HCPs https://www.insupport.com/resources



SUBLOCADE® (buprenorphine extended-release) Network Specialty Distributors List https://www.insupport.com/resources



Network Specialty Pharmacy Locator https://www.insupport.com/specialtyproduct/specialty-pharmacy-locator

REFERENCES

L. Centers for Medicare & Medicaid Services (CMS). 2024 ICD-10-CM tabular list of diseases and injuries. Accessed April 16, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm SUBLOCADE. Prescribing information. Indivior Inc. **3.** CMS. Medicare Learning Network. MLN Matters Number: SE1234. Important information concerning the Medicare crossover process and state Medicaid agency requirements for National Drug Codes (NDCs) associated with physician-administered Part B drugs. September 5, 2012. Accessed April 16, 2024. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/SE1234.pdf 4. Novitas. Paper to electronic claim crosswalk (5010). Updated March 7, 2022. Accessed April 16, 2024. https://www.novitas-solutions.com/webcenter/portal/Medicare.pdf 4. Novitas. Paper to electronic claim crosswalk (5010). Updated March 7, 2022. Accessed April 16, 2024. https://www.novitas-solutions.com/webcenter/portal/Medicare.pdf 4. Novitas. Paper to electronic claim crosswalk (5010). Updated March 7, 2022. Accessed April 16, 2024. https://www.novitas-solutions.com/webcenter/portal/Medicare.pdf 4. Novitas. Paper to electronic claim crosswalk (5010). Updated March 7, 2022. Accessed April 16, 2024. https://www.novitas-solutions.com/webcenter/portal/Medicare.pdf 4. Novitas. Paper to electronic claim crosswalk (5010). Updated March 7, 2022. Accessed April 16, 2024. https://www.cms.gov/medicare.pdf 4. 2011. Updated December 14, 2016. Accessed April 16, 2024. <a href="https://www.cms.gov/medicare.com/pdf/asc"8

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