

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.

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:



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



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



INSUPPORT ONLINE

- Enroll patients electronically by submitting 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 www.INSUPPORT.com

^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 www.INSUPPORT.com 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.

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

ICD-10-CM CODES	
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
F11.24	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

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

NDC	MILLIGRAMS	NDC FORMAT FOR CLAIMS ³	NDC LOCATION ON CLAIM FORMS ^{4,5}
12496-0100-01	100 mg	N412496010001	• CMS-1500: Box 24A (shaded area) • CMS-1450: Field 43
12496-0300-01	300 mg	N412496030001	

CURRENT PROCEDURAL TERMINOLOGY (CPT) CODE⁶

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

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

^a CPT Copyright 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

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. 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.

PRODUCT-SPECIFIC HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODES FOR SUBLOCADE⁷

HCPCS CODE	DESCRIPTION	NUMBER OF 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

Q-codes are primarily applicable to the physician office or hospital outpatient clinic settings.

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 its HCPCS code on paper claim forms and their electronic equivalents.³

HCPCS MODIFIERS FOR SUBLOCADE^{7,8,9}

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 in the physician office or hospital outpatient department
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 in the hospital outpatient department
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

Modifier -JZ is effective January 1, 2023 and is required on Medicare claims with dates of service (DOS) on/after July 1, 2023. Medicare will start rejecting Part B claims for single-use packaged drugs without modifier -JZ when applicable effective DOS on/after October 1, 2023.⁸

Reporting informational modifier JG is required on Medicare claims for 340B-covered entities that are paid under the Outpatient Prospective Payment System (OPPS) starting January 1, 2023. No later than January 1, 2024, 340B modifier JG is required on Medicare claims for separately payable Part B-covered drugs and biologicals for all 340B-covered entities, including hospital-based and non-hospital-based entities. "JG" applies for products that do not have temporary pass-through status.⁹

Other modifiers may apply; check with individual payers to confirm the latest guidance.

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BILLING SUBLOCADE® (buprenorphine extended-release)

BILLING IN MEDICARE VS OTHER PAYERS

The table below highlights the codes and associated descriptions.

	Claim Form	OPIOID TREATMENT PROGRAM	PHYSICIAN OFFICE	HOSPITAL OUTPATIENT
		CMS-1500	CMS-1500	CMS-1450
MEDICARE ¹⁰	Professional Services	G2069	G2086 and G2087	96372
	SUBLOCADE		Q9991 or Q9992	Q9991 or Q9992
ALL OTHER PAYERS	Professional Services	96372	96372	96372
	SUBLOCADE	Q9991 or Q9992	Q9991 or Q9992	Q9991 or Q9992

G-CODE DESCRIPTIONS IN OPIOID TREATMENT PROGRAM (OTP) AND PHYSICIAN OFFICE SETTINGS¹⁰

The table below notes the relevant G-codes for an episode of care in the OTP or physician office setting. Please note the G-codes are for weekly episodes of care.

G-CODE	DESCRIPTION
Weekly Codes in OTP Setting	
G2069	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)
G2074	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)
Monthly Codes in Physician Office Setting	
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
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

Medicare reimburses 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.”¹⁰ The Substance Abuse and Mental Health Services Administration (SAMHSA) certifies and requires that OTPs must¹¹:

- 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

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ADDITIONAL RESOURCES



INSUPPORT®
Patient Enrollment Form

<https://www.insupport.com/enrollment>



INSUPPORT
Resources & Tools for HCPs

<https://www.insupport.com/resources>

For more information on the INSUPPORT program, call INSUPPORT at 844-INSPPRT (844-467-7778) or visit www.INSUPPORT.com.

REFERENCES

1. Centers for Medicare & Medicaid Services (CMS). ICD-10-CM tabular list of diseases and injuries. 2023. Accessed May 3, 2023. <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm> 2. 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 May 3, 2023. <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 May 2023. <https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00004769> 5. ASC 837I version 5010A2 institutional health care claim to the CMS-1450 Claim Form crosswalk. Palmetto GBA. Accessed May 2023. [https://www.palmettogba.com/palmetto/providers.nsf/files/EDL_837I_v5010A2_crosswalk.pdf/\\$FILE/EDL_837I_v5010A2_crosswalk.pdf#:~:text=The%20implementation%20of%20the%20ASC%20837I%20v5010A2%20presents,submission%20during%20and%20after%20the%20transition%20to%20the](https://www.palmettogba.com/palmetto/providers.nsf/files/EDL_837I_v5010A2_crosswalk.pdf/$FILE/EDL_837I_v5010A2_crosswalk.pdf#:~:text=The%20implementation%20of%20the%20ASC%20837I%20v5010A2%20presents,submission%20during%20and%20after%20the%20transition%20to%20the) 6. 2023 Professional Edition, Current Procedural Terminology (CPT). Copyright 2022. American Medical Association; 2022. All rights reserved. 7. CMS. July 2023 alpha-numeric HCPCS file. Accessed May 3, 2023. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update> 8. CMS. Medicare Program. Discarded drugs and biologicals – JW modifier and JZ modifier policy: frequently asked questions. Accessed March 13, 2023. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf> 9. CMS. Medicare-FFS Program Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS). Updated March 2023. Accessed March 13, 2023. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf> 10. CMS. Revisions to payment policies under the Medicare Physician Fee Schedule, Quality Payment Program and other revisions to Part B for CY 2020. Accessed May 3, 2023. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F> 11. The Joint Commission. Opioid treatment program (OTP) accreditation. Accessed May 3, 2023. <https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-opioid-treatment-program-accreditation/>

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Sublocade[®]
(buprenorphine extended-release)
injection for subcutaneous use ©
100mg-300mg