Vivitrol®
(naltrexone for extended-release injectable suspension) 380 mg/vial

Billing and Coding Resource:

Coding at a glance

This Billing and Coding Resource is for illustrative purposes only and is not intended to provide reimbursement or legal advice. All billing codes and coding information included in this document are gathered from third party sources, provided for informational purposes only, and represent no statement, promise, or guarantee by Alkermes, Inc. that coverage will be available, that the codes or forms will be appropriate, or that reimbursement will be made. Payer coverage and reimbursement requirements vary by plan, patient, and setting of care, and are complex and subject to change. Providers must understand and comply with each payer's rules and should always consult with the applicable local payer regarding coverage and coding requirements prior to submitting claims. It is the provider's sole responsibility to determine medical necessity and to in turn identify which codes to report and to submit accurate claims. Under no circumstances shall Alkermes, Inc., or its employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages that may arise from or be incurred in connection with this information or any use thereof.

INDICATIONS

VIVITROL® is indicated for:

- The treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration.
- The prevention of relapse to opioid dependence, following opioid detoxification.

VIVITROL should be part of a comprehensive management program that includes psychosocial support.

IMPORTANT SAFETY INFORMATION

VIVITROL is contraindicated in patients:

- Receiving opioid analgesics
- With current physiologic opioid dependence or in acute opioid withdrawal
- Who have failed the naloxone challenge test or have a positive urine screen for opioids
- Who have exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent

Please see Important Safety Information on pages 6-8. Please see full Prescribing Information.

Coding at a glance

This information is intended to provide general background and is not to be used as billing or coding advice or as coding recommendations for any specific claim. The information is gathered from third party sources and Alkermes makes no representation that coverage will be available, that the codes are accurate or appropriate, or that reimbursement will be paid, for the medication or medical services provided to a patient.

Payer coverage and reimbursement requirements vary by plan, patient and setting of care, and are subject to change. It is important to check with each payer about the payer's specific rules and requirements prior to submitting claims. The healthcare provider is responsible for determining the appropriate codes to accurately reflect their patient's condition, the medication and services provided to the patient, and for the representations made in the claims for reimbursement submitted on behalf of the patient.

Product, Administration, and Related Codes

Coding decisions should be made by the physician based on an independent review of the patient's condition.

Please refer to the indications for VIVITROL® on the front cover.

VIVITROL (naltrexone for extended-release injectable suspension) Coding	**NDC for VIVITROL[1]**	**65757-300-01**	Naltrexone for extended-release injectable suspension
	HCPCS[2]	**J2315**	Injection, naltrexone, depot form, 1 mg
Professional Services	**CPT®*[3]**	**96372**	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
	ICD-10-PCS Procedure[4]	**3E023GC**	Introduction of other therapeutic substance into muscle, percutaneous approach
Professional Claims	**Place of Service Codes[5]**	**02**	Telehealth Provided Other Than in Patient's Home
		11	Office
		19	Off Campus - Outpatient Hospital
		21	Inpatient Hospital
		22	On Campus - Outpatient Hospital
		49	Independent Clinic
		53	Community Mental Health Center
		55	Residential Substance Abuse Treatment Facility
		57	Non-residential Substance Abuse Treatment Facility
		58	Non-residential Opioid Treatment Facility
Ambulatory Payment Classification	**APC for VIVITROL[6]**	**0759**	Naltrexone, depot form
Medicare Severity-Diagnosis Related Groups (MS-DRGs)	**Inpatient Groups[7]**	**894**	Alcohol, drug abuse or dependence, left AMA
		895	Alcohol, drug abuse or dependence with rehabilitation therapy
		896	Alcohol, drug abuse or dependence without rehabilitation therapy with MCC
		897	Alcohol, drug abuse or dependence without rehabilitation therapy without MCC

AMA=against medical advice; MCC=major complication or comorbidity.
Additional coding may be found at www.cms.gov.

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Coding at a glance

Product, Administration, and Related Codes (cont'd)

All-Patient Refined-Diagnosis Related Groups (APR-DRGs)	Inpatient Groups[8]		
		770	Drug & alcohol abuse or dependence, left against medical advice
		772	Alcohol & drug dependence with rehab or rehab/detox therapy
		773	Opioid abuse & dependence

Additional coding may be found at www.cms.gov.

ICD-10-CM Diagnosis Codes

Claims submitted for VIVITROL® should include at least one (1) ICD-10-CM diagnosis code to indicate the patient's condition. Specific diagnosis codes should represent the condition as supported by the patient's medical record. The diagnosis codes listed below may apply for patients for whom VIVITROL may be appropriate.

Please refer to the indications for VIVITROL on the front cover.

Patient Diagnosis ICD-10-CM Diagnosis[9]		
Alcohol Dependence		
	F10.20	Alcohol dependence, uncomplicated
	F10.21	Alcohol dependence, in remission
	F10.22*	Alcohol dependence with intoxication
	F10.23*	Alcohol dependence with withdrawal
	F10.24	Alcohol dependence with alcohol-induced mood disorder
	F10.25*	Alcohol dependence with alcohol-induced psychotic disorder
	F10.26	Alcohol dependence with alcohol-induced persisting amnestic disorder
	F10.27	Alcohol dependence with alcohol-induced persisting dementia
	F10.28*	Alcohol dependence with alcohol-induced disorder
	F10.29	Alcohol dependence with unspecified alcohol-induced disorder
Opioid Dependence		
	F11.20	Opioid dependence, uncomplicated
	F11.21	Opioid dependence, in remission
	F11.22*	Opioid dependence with intoxication
	F11.23	Opioid dependence with withdrawal
	F11.24	Opioid dependence with opioid-induced mood disorder
	F11.25*	Opioid dependence with opioid-induced psychotic disorder
	F11.28*	Opioid dependence with opioid-induced disorder
	F11.29	Opioid dependence with unspecified opioid-induced disorder

*Selection of a subcategory is required.

Please see Important Safety Information on pages 6-8.
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Coding at a glance

Other Services

In connection with a patient's treatment with VIVITROL®, you may determine that other services are necessary as part of a patient's treatment, such as a comprehensive management program, psychosocial support, and opioid detoxification for induction onto VIVITROL. Providers are solely responsible for determining treatment plans and services they provide to their patients based on a patient's medical needs and the provider's medical knowledge and experience. It is also the provider's sole responsibility to identify which codes to report for those services and to submit accurate claims.

Below is a nonexhaustive list of examples of other services and codes. This list is provided for illustrative purposes only and is neither a directive nor a recommendation on the appropriateness of any particular service or billing code included in the list.

Please refer to the indications for VIVITROL on the front cover.

Alcohol and Drug Abuse Treatment[2]	
H0001	Alcohol and/or drug assessment
H0012	Alcohol and/or drug services; sub-acute detoxification (residential addiction program outpatient)
H0013	Alcohol and/or drug services; acute detoxification (residential addiction program outpatient)
H0014	Alcohol and/or drug services; ambulatory detoxification
H0015	Alcohol and/or drug services; intensive outpatient (treatment program that operates at least 3 hours/day and at least 3 days/week and is based on an individualized treatment plan), including assessment, counseling; crisis intervention, and activity therapies or education
S9475	Ambulatory setting substance abuse treatment or detoxification services, per diem
Evaluation and Management[2,3]	
99202	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making
99203	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making
99204	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making
99205	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making
99211	Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making
G0463	Hospital outpatient clinic visit for assessment and management of a patient

Coding at a glance

Other Services (cont'd)

Pathology and Laboratory[2,3]	
H0003	Alcohol and/or screening; laboratory analysis of specimens for presence of alcohol and/or drugs
80354	Fentanyl
80356	Heroin metabolite
80361	Opiates, 1 or more
80362	Opioids and opiate analogs; 1 or 2
80363	3 or 4
80364	5 or more
Behavioral Health/Psychosocial[2]	
H0005	Alcohol and/or drug services; group counseling by a clinician
H0006	Alcohol and/or drug services; case management
H2017	Psychosocial rehabilitation services, per 15 minutes
H2018	Psychosocial rehabilitation services, per diem
Health and Behavior Assessment/Intervention[2,3]	
G0396	Alcohol and/or substance (other than tobacco) misuse structured assessment (eg, AUDIT, DAST), and brief intervention 15 to 30 minutes
G0397	Alcohol and/or substance (other than tobacco) misuse structured assessment (eg, AUDIT, DAST), and intervention, greater than 30 minutes
99408	Alcohol and/or substance (other than tobacco) abuse structured screening (eg, AUDIT, DAST), and brief intervention (SBI) services; 15 to 30 minutes
99409	Greater than 30 minutes

Providers should consult applicable payers and relevant coding resources (eg, the CPT® Manual published by the AMA) in selecting appropriate codes for the services they render, in accordance with payer rules. Healthcare providers are solely responsible for the accuracy of all claims and related documentation submitted to payers for reimbursement. Payer rules regarding coverage, coding, and payment for services vary by payer and plan (and often include rules that govern coding for services provided in the same visit and limitations on billing separately for services), are complex, and updated frequently. Additional modifiers and other information may be needed in submitting claims associated with services provided. Providers are solely responsible for complying with all applicable payer requirements and for selecting codes that accurately reflect a patient's condition and the services rendered.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Vulnerability to Opioid Overdose

- After opioid detoxification, patients are likely to have a reduced tolerance to opioids. VIVITROL® blocks the effects of exogenous opioids for approximately 28 days after administration. As the blockade wanes and eventually dissipates completely, use of previously tolerated doses of opioids could result in potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc). Cases of opioid overdose with fatal outcomes have been reported in patients who used opioids at the end of a dosing interval, after missing a scheduled dose, or after discontinuing treatment.
- Patients and caregivers should be told of this increased sensitivity to opioids and the risk of overdose.
- Although VIVITROL is a potent antagonist with a prolonged pharmacological effect, the blockade produced by VIVITROL is surmountable. The plasma concentration of exogenous opioids attained immediately following their acute administration may be sufficient to overcome the competitive receptor blockade. This poses a potential risk to individuals who attempt, on their own, to overcome the blockade by administering large amounts of exogenous opioids.
- Any attempt by a patient to overcome the VIVITROL blockade by taking opioids may lead to fatal overdose. Patients should be told of the serious consequences of trying to overcome the opioid blockade.
- Patient Access to an Opioid Overdose Reversal Agent for the Emergency Treatment of Opioid Overdose: At the initial VIVITROL injection and with each subsequent injection, inform patients and caregivers about opioid overdose reversal agents (e.g., naloxone and nalmefene) and discuss the importance of having access to an opioid overdose reversal agent. Strongly consider recommending or prescribing an opioid overdose reversal agent for the emergency treatment of an opioid overdose.

Injection Site Reactions

- VIVITROL must be prepared and administered by a healthcare provider and must ONLY be administered as a deep intramuscular gluteal injection.
- Inadvertent subcutaneous/adipose layer injection of VIVITROL may increase the likelihood of severe injection site reactions. Select proper needle size for patient body habitus and use only the needles provided in the carton.
- VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising, or pruritus; however, in some cases injection site reactions may be very severe.
- Injection site reactions not improving may require prompt medical attention, including, in some cases, surgical intervention.
- In the clinical trials, one patient developed an area of induration that continued to enlarge after 4 weeks, with subsequent development of necrotic tissue that required surgical excision.
- Patients should be informed that any concerning injection site reactions should be brought to the attention of their healthcare provider.

Precipitation of Opioid Withdrawal

- When withdrawal is precipitated abruptly by administration of an opioid antagonist to a patient with opioid dependence, the resulting withdrawal syndrome can be severe. Some cases have been severe enough to require hospitalization and/or management in the ICU.
- To prevent occurrence of precipitated withdrawal, patients with opioid dependence, including those being treated for alcohol dependence, should be opioid-free (including tramadol) before starting VIVITROL treatment:
  - An opioid-free interval of a minimum of 7–10 days is recommended for patients previously dependent on short-acting opioids.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Precipitation of Opioid Withdrawal (cont'd)

- Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as 2 weeks.

- If a more rapid transition from agonist to antagonist therapy is deemed necessary and appropriate by the healthcare provider, monitor the patient closely in an appropriate medical setting where precipitated withdrawal can be managed.
- Patients should be made aware of the risk associated with precipitated withdrawal and be encouraged to give an accurate account of last opioid use, as precipitated opioid withdrawal has been observed in patients with alcohol dependence in circumstances where the prescriber had been unaware of the additional use of opioids or co-dependence on opioids.

Hepatotoxicity

- Cases of hepatitis and clinically significant liver dysfunction have been observed in association with VIVITROL®. Warn patients of the risk of hepatic injury and advise them to seek help if experiencing symptoms of acute hepatitis. Discontinue VIVITROL in patients who exhibit signs and symptoms of acute hepatitis.

Depression and Suicidality

- Patients with alcohol dependence or opioid dependence taking VIVITROL should be monitored for depression or suicidal thoughts. Alert families and caregivers to monitor and report the emergence of symptoms of depression or suicidality.

When Reversal of VIVITROL Blockade Is Required for Pain Management

- For VIVITROL patients in emergency situations, suggestions for pain management include regional analgesia or use of non-opioid analgesics. If opioid therapy is required to reverse the VIVITROL blockade, patients should be closely monitored by trained personnel in a setting staffed and equipped for CPR.

Eosinophilic Pneumonia

- Patients who develop dyspnea and hypoxemia should seek medical attention immediately. Consider the possibility of eosinophilic pneumonia in patients who do not respond to antibiotics.

Hypersensitivity Reactions including Anaphylaxis

- Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis, and should be advised to seek immediate medical attention in a healthcare setting prepared to treat anaphylaxis should a hypersensitivity reaction occur. The patient should not receive any further treatment with VIVITROL.

Intramuscular Injections

- As with any intramuscular injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder.

Alcohol Withdrawal

- Use of VIVITROL does not eliminate nor diminish alcohol withdrawal symptoms.

Interference With Laboratory Tests

- VIVITROL may be cross-reactive with certain immunoassay methods for the detection of drugs of abuse (specifically opioids) in urine. For further information, reference to the specific immunoassay instructions is recommended.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Adverse Reactions

- The adverse events seen most frequently in association with VIVITROL® therapy for alcohol dependence (occurring in ≥5% and at least twice as frequently with VIVITROL than placebo) include nausea, vomiting, injection site reactions (including induration, pruritus, nodules, and swelling), arthralgia, arthritis, or joint stiffness, muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders.
- The adverse events seen most frequently in association with VIVITROL in patients with opioid dependence (occurring in ≥2% and at least twice as frequently with VIVITROL than placebo) include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

Click for full Prescribing Information.

References: 1. VIVITROL [prescribing information]. Waltham, MA: Alkermes, Inc. **2.** July 2023 alpha-numeric HCPCS file. Centers for Medicare & Medicaid Services. Accessed February 11, 2026. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update **3.** American Medical Association. *2023 CPT Professional.* Chicago, IL: American Medical Association; 2022. **4.** 2023 ICD-10-PCS procedure code 3E023GC. ICD10data.com. Accessed February 11, 2026. https://www.icd10data.com/ICD10PCS/Codes/3/E/0/2/3E023GC **5.** Place of service code set. Centers for Medicare & Medicaid Services. Accessed February 11, 2026. https://www.cms.gov/medicare/coding/place-of-service-codes/place_of_service_code_set **6.** Ambulatory payment classifications. Find-a-Code. Accessed February 11, 2026. http://www.findacode.com/apc/0759-naltrexone-depot-form-apc-code.html **7.** FY 2023 final rule and correcting amendment tables. Centers for Medicare & Medicaid Services. Accessed February 11, 2026. https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page#Tables **8.** Relative value, average length of stay, high- and low-cost outlier threshold and percentage table for APR-DRG grouper version 37. Pennsylvania Department of Human Services. Accessed February 11, 2026. https://www.dhs.pa.gov/docs/For-Providers/Documents/Regulations%20Handbooks%20Guides%20Manuals/PA%20V37%20Relative%20Weights%20to%20DHS%2001.17.20.pdf **9.** ICD code lists: valid ICD-10 list. Centers for Medicare & Medicaid Services. Accessed February 11, 2026. https://www.cms.gov/medicare/coordination-benefits-recovery-overview/icd-code-lists

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