

# BILLING & CODING RESOURCE

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**Vivitrol**<sup>®</sup>  
(naltrexone for extended-release  
injectable suspension)

Vivitrol2gether is a customized patient support services program to help you and your patients in their recovery journey throughout product consideration, fulfillment, and transition of care.

→ **Our Vivitrol2gether team is ready to provide patient support services to you and your patients.** Call 1-800-VIVITROL (1-800-848-4876), 9 am–8 pm (EST) and visit [VIVITROL.com](https://www.vivitrol.com) to access a variety of helpful resources.

Please see **Important Safety Information** beginning on page 20.  
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# Introduction

VIVITROL® (naltrexone for extended-release injectable suspension) 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. VIVITROL is also indicated for the prevention of relapse to opioid dependence, following opioid detoxification. Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support. Opioid-dependent patients, including those being treated for alcohol dependence, must be opioid-free at the time of VIVITROL administration.

## Overview

This resource includes a general discussion of government (Medicare and Medicaid) and private payer reimbursement concepts specific to physician-administered injectables. An important first step to initiating VIVITROL therapy is identifying the patient's coverage benefits. An initial benefits verification will identify the following:

- ✓ Coverage for VIVITROL
- ✓ Utilization requirements such as prior authorization
- ✓ General coding information
- ✓ Access through the medical and/or pharmacy benefit
- ✓ Utilization of a Specialty Pharmacy

# Coverage and Reimbursement

Coverage for VIVITROL varies by site of service. It is recommended that each specific place of service is verified prior to VIVITROL treatment.

## Physician Office

### Commercial Payer

Most third-party payers, including managed care organizations, will provide coverage for VIVITROL. However, specific coverage requirements and utilization management depend on a patient's benefits and will vary based on plan type. Some commercial insurers may apply coverage and utilization restrictions such as prior authorization or step therapy. Commercial payers may cover VIVITROL as a medical benefit, pharmacy benefit, or both. Specialty pharmacies typically ship VIVITROL directly to the physician's office in the patient's name.<sup>1</sup> The specialty pharmacy may bill the pharmacy benefit directly or bill the medical benefit using assignment of benefits.<sup>2</sup> In either case, the office will not be required to purchase VIVITROL because the specialty pharmacy will bill the patient's insurance for the drug.<sup>1</sup> Payment for drugs varies according to the contracted rate between the office and the specific payer, and the patient's cost share will depend on their plan.<sup>2</sup> Contact the payer for more details.

### Medicaid\*

In general, state Medicaid programs and managed Medicaid plans cover VIVITROL.<sup>3</sup> Each state agency and/or managed Medicaid plan determines its own coverage guidelines such as whether the drug is available as a medical or pharmacy benefit, any utilization management requirements (eg, prior authorization, step therapy, quantity limits), and other management controls.<sup>3</sup> When Medicaid covers VIVITROL under a patient's **pharmacy benefit**, a local pharmacy typically supplies it. Due to special packaging requirements, the pharmacy may deliver VIVITROL to the provider for administration. The pharmacy, not the prescribing physician, bills Medicaid for the cost of the medication. When Medicaid covers VIVITROL under a patient's **medical benefit**, physicians will order VIVITROL from distributors, maintain their own inventory, administer the injection, and bill Medicaid for the drug. Medicaid may pay for drugs such as VIVITROL based on a percentage of average sales price (ASP), average wholesale price (AWP), wholesale acquisition cost (WAC), or other state-specific calculation.<sup>4,5</sup> Patients may have a nominal cost share for drugs and services. To determine accurate reimbursement for services, including how VIVITROL is reimbursed by Medicaid, contact the Provider Relations Representative for the specific managed Medicaid organization or state Medicaid office.

\*Coverage within a Medicaid plan type may vary by site of service. It is recommended that each specific place of service is verified prior to VIVITROL treatment. Managed Medicaid plans may also have specific criteria for coverage and should be verified prior to VIVITROL treatment.

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# Coverage and Reimbursement

## Physician Office (cont'd)

### Medicare\*

Medicare may cover VIVITROL through Part B that covers physician services<sup>6</sup> or the prescription drug benefit (Part D).<sup>7</sup> If the patient has a managed Medicare/Medicare Advantage (Part C) plan, the plan may allow access to VIVITROL through either the medical or pharmacy benefit, or both.<sup>8</sup> Medicare Part B may create coverage criteria, such as diagnosis requirements for drugs, but does not use prior authorization. Medicare Parts C and D may apply coverage restrictions such as prior authorization, step therapy/fail-first, quantity limits, or other management controls.<sup>9</sup> Medicare Part B reimburses VIVITROL based on ASP + 6%.<sup>10</sup> Medicare Part C plans may use a variety of methodologies to reimburse physician offices for drugs. If VIVITROL is available through the patient's Part D plan, the specialty pharmacy typically ships VIVITROL directly to the physician's office in the patient's name, and the office will not be required to purchase or bill for VIVITROL. For Part B, patients have a 20% cost share for drugs<sup>10</sup> that may be covered by supplemental insurance if the patient has a policy.<sup>11</sup> For Parts C and D, the patient's cost share will vary according to their plan. Contact the plan for more details.

### Injection Services

Most payers provide coverage of injection services separately from the drug. Coverage and payment of injection services for commercial payers, Medicare, and Medicaid vary widely by commercial plan, Medicare type (Parts B, C, and D), and state, respectively. Most payers use a fee schedule to reimburse physician offices for injection services. The patient cost share is 20% for Medicare Part B but varies for commercial, Medicaid, and Medicare Part C plans. Providers should contact Vivitrol2gether<sup>SM</sup> at **1-800-VIVITROL (1-800-848-4876)** or contact the plan directly to identify reimbursement for administration of VIVITROL.

\*Coverage within a plan type may vary by site of service. It is recommended that each specific place of service is verified initially.

# Coverage and Reimbursement

## Hospital Outpatient

### Commercial Payer

Most third-party payers, including managed care organizations, will provide coverage for VIVITROL. However, specific coverage requirements and utilization management depend on a patient's benefits and will vary based on plan type. Some commercial insurers may apply coverage and utilization restrictions such as prior authorization or step therapy. Commercial payers typically cover VIVITROL when administered in a hospital outpatient setting as a medical benefit. Hospitals usually acquire VIVITROL from distributors. Payment for drugs varies according to the contracted rate between the facility and the specific payer, and the patient's cost share will depend on their plan. Contact the payer for more details.

### Medicaid\*

In general, state Medicaid programs and managed Medicaid plans cover VIVITROL. Each state agency and/or managed Medicaid plan determines its own coverage guidelines such as prior authorization, step therapy, quantity limits, and other management controls. When administered in a hospital outpatient setting, Medicaid typically covers VIVITROL under a patient's medical benefit. Hospitals will order VIVITROL from distributors, maintain their own inventory, administer the injection, and bill Medicaid for the cost of VIVITROL. Medicaid may pay for drugs such as VIVITROL based on a percentage of ASP, AWP, WAC, or other state-specific calculation. Patients may have a nominal cost share. To determine accurate reimbursement for services, including how VIVITROL is reimbursed by Medicaid, contact the Provider Relations Representative for the specific managed Medicaid organization or state Medicaid office.

### Medicare†

Medicare typically covers VIVITROL when administered in a hospital outpatient setting through Part B. If the patient has a managed Medicare/Medicare Advantage (Part C) plan, the plan usually covers VIVITROL as a medical benefit. Medicare Part B may create coverage criteria, such as diagnosis requirements for drugs, but does not use prior authorization. Medicare Part C may apply coverage restrictions such as prior authorization, step therapy/fail-first, quantity limits, or other management controls. Medicare Part B reimburses VIVITROL based on ASP + 6%. Medicare Part C plans may use a variety of methodologies to reimburse physician offices for drugs and services. For Part B, patients have a 20% cost share for drugs and services that may be covered by supplemental insurance if the patient has a policy. For Part C, the patient's cost share will vary according to their plan. Contact the plan for more details.

### Injection Services

Most payers provide coverage of injection services separately from the drug. Coverage and payment of injection services for commercial, Medicare, and Medicaid vary widely by commercial plan, Medicare type (Parts B or C), and state, respectively. Medicare Part B assigns Current Procedural Terminology (CPT®) codes to Ambulatory Payment Classifications (APCs) to reimburse hospital outpatient facilities for injection services. The patient cost share is 20% for Medicare Part B but varies for commercial, Medicaid, and Medicare Part C plans. Providers should contact Vivitrol2gether<sup>SM</sup> at **1-800-VIVITROL (1-800-848-4876)** or contact the plan directly to identify reimbursement for administration of VIVITROL.

\*Coverage within a Medicaid plan type may vary by site of service. It is recommended that each specific place of service is verified prior to VIVITROL treatment. Managed Medicaid plans may also have specific criteria for coverage and should be verified prior to VIVITROL treatment.

†Coverage within a plan type may vary by site of service. It is recommended that each specific place of service is verified initially.

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# Coverage and Reimbursement

## Hospital Inpatient

### Commercial Payer

Medically necessary services, including VIVITROL® (naltrexone for extended-release injectable suspension), are covered but are generally not paid separately. Most commercial insurers negotiate annual contracts and may use All-Patient Refined-Diagnosis Related Groups (APR- DRGs), case rates, and per diems. Reimbursement will vary based on a patient's specific plan and the hospital's contract with the payer.

### Medicaid

Medically necessary services, including VIVITROL, are covered but are generally not paid separately. Medicaid state programs may base reimbursement on APR-DRGs, Medicare Severity-Diagnosis Related Groups (MS-DRGs), and per diem rates, and provide a single payment to the hospital. In certain circumstances, VIVITROL may be covered separately.

### Medicare

Medicare Part A covers drugs and services provided in the hospital inpatient setting. Coverage for VIVITROL is generally included in the payment made based on the entire stay, not on individual items or services. Medicare pays for hospital inpatient admissions under the Hospital Inpatient Prospective Payment System (IPPS), commonly referred to as the MS-DRG system. Each MS-DRG is associated with a fixed, hospital-specific payment that is intended to cover all facility costs during the hospital inpatient stay.

For more information on payer-specific coverage for VIVITROL, contact your payer or Vivitrol2gether<sup>SM</sup> at **1-800-VIVITROL (1-800-848-4876)**.

→ **Enroll your patients in Vivitrol2gether for assistance in fulfilling VIVITROL prescriptions.** Our team is ready to support you and your patients. Call 1-800-VIVITROL (1-800-848-4876), 9am–8pm (EST) and visit [VIVITROL.com](https://www.vivitrol.com) to access a variety of helpful resources.



If necessary, as part of discharge planning, contact Vivitrol2gether at **1-800-VIVITROL (1-800-848-4876)** to locate follow-on providers for VIVITROL therapy. You may also use the Provider Locator tool online at [VIVITROL.com/find-a-treatment-provider](https://www.vivitrol.com/find-a-treatment-provider)



# Coverage and Reimbursement

## Residential Substance Abuse Facility

### Commercial Payer

Reimbursement for VIVITROL and the associated administration will vary, based on the contract established between the Residential Substance Abuse Facility and health plan. Commercial payers generally cover but may not pay for injectable medications separately. Commercial payers may base reimbursement on MS-DRGs, per diem rates, or other all-inclusive rates that account for all costs of care provided in the Residential Substance Abuse Facility. However, in certain circumstances, depending on the clinical needs of the patient, or a contracted arrangement with the payer, VIVITROL may be reimbursable outside of these capitated rates. Contact the payer for more details.

### Medicaid

The Medicaid reimbursement methodology for Residential Substance Abuse Facilities varies greatly state by state. These facilities can be paid a standard per diem by facility bed size, substance abuse services paid fee-for-service or negotiated rate, prospective cost-based rate per service, or fee-for-service using hourly rates.

To determine accurate reimbursement for services, including how VIVITROL is reimbursed by Medicaid in this setting of care, contact your Provider Relations Representative for the specific Managed Medicaid Organization or state Medicaid office.

### Medicare

CMS has determined that Medicare coverage of physician services treating patients in Residential Substance Abuse Facilities (POS code 55) fall under the Medicare Physician Fee Schedule non-facility payment rates. Reimbursement is based on Average Sales Price (ASP)+6% and based on the allowable amount. Physician offices are reimbursed for 80% of the allowable amount, and the patient is generally responsible for the remaining 20% co-payment. Some patients may have a supplemental insurance policy that assists with the 20% co-payment.

Upon discharge from Residential to the outpatient setting, subsequent injections of VIVITROL may be reimbursed under Medicare Part B, C, or D.

### Injection Services

Injection services for Commercial payers, Medicare, and Medicaid vary widely by commercial plan, Medicare type (Part B, C [Medicare Advantage], and D), and state, respectively. Providers should contact Vivitrol2gether<sup>SM</sup> at **1-800-VIVITROL (1-800-848-4876)** or contact the plan directly to identify reimbursement for administration of VIVITROL.

#### Quick Tip

Reimbursement varies widely by payment type. Providers are strongly encouraged to contact their payer for more information about reimbursement in this setting of care.

# Sample CMS-1500 Claim Form

The CMS-1500 Claim Form is used by healthcare professionals and suppliers to bill for products and services administered by a healthcare provider. Below is a sample CMS-1500 Claim Form with important instructions in order to correctly bill for VIVITROL® (naltrexone for extended-release injectable suspension).

This document is provided for your guidance only. Please contact the payer or Vivitrol2gether<sup>SM</sup> to verify coding and claim information.

## Box 21: Diagnosis or nature of illness or injury

**Note:** Enter the appropriate diagnosis code as reflected in the patient's medical record.

## Box 24A: Date(s) of service

Enter additional information as required by the payer, in the shaded portion.

**Note:** Information may include, but is not limited to, NDC, unit of measure, and method of delivery.

## Box 24G: Days or Units

Enter the appropriate number of units.

**Note:** Important to submit for 380 units (1 mg = 1 unit).

## Box 24D: Procedures, Services, or Supplies

**If provider office has purchased VIVITROL:** Enter the appropriate HCPCS code (J2315) if physician office elected "buy and bill" method for patient and CPT\*\* code (96372). Payers may also require the NDC number on the claim form.

**If VIVITROL has been delivered in the patient's name from a Specialty Pharmacy:** Enter only the appropriate CPT\*\* code (96372).

**Note:** Some payers may require an entered HCPCS code (J2315) with a charge of \$0. It is advisable to determine what each individual payer requires prior to submitting claim.

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# Sample CMS-1450 (UB-04) Claim Form

The CMS-1450 (UB-04) Claim Form is used for submitting institutional claims for inpatient and outpatient services. Below is a sample CMS-1450 (UB-04) Claim Form with important instructions in order to correctly bill for VIVITROL® (naltrexone for extended-release injectable suspension).

This document is provided for your guidance only. Please contact the payer or Vivitrol2gether<sup>SM</sup> to verify coding and claim information.

## Fields 42-43: Revenue Code, Description

Enter the appropriate revenue code and description corresponding to the HCPCS code.

**Example:** 0636 for VIVITROL, 0510 for clinic visit.

## Field 66: Diagnosis Code

Enter appropriate ICD-10-CM diagnosis code as reflected in the patient's medical record.

**Note:** Other diagnosis codes may be applicable.

## Field 44: HCPCS Code

Enter the appropriate HCPCS code (J2315) and CPT\*\* code (96372).

## Field 46: Service Units

Enter the appropriate number of units.

**Note:** Important to submit for 380 units (1 mg = 1 unit).

A sample CMS-1450 (UB-04) Claim Form is shown with several fields highlighted by callouts. The form includes sections for Patient Information, Payer Information, Billing Information, and a table for Services. The Services table has columns for Revenue Code, Description, HCPCS Code, and Service Units. A large 'SAMPLE' watermark is overlaid on the form.

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# 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.

<b>VIVITROL®</b> (naltrexone for extended-release injectable suspension) Coding	<b>NDC for VIVITROL<sup>12</sup></b>	<b>65757-0300-01</b>	Naltrexone for extended-release injectable suspension
	<b>HCPCS<sup>13</sup></b>	<b>J2315</b>	Injection, naltrexone, depot form, 1 mg
<b>Professional Services</b>	<b>CPT®*14</b>	<b>96372</b>	Therapeutic, prophylactic, or diagnostic injection (specify material injected); subcutaneous or intramuscular
	<b>ICD-10-CM Procedure<sup>15</sup></b>	<b>3E023GC</b>	Introduction of other therapeutic substance into muscle, percutaneous approach
<b>Professional Claims</b>	<b>Place of Service Codes<sup>16</sup></b>	<b>11</b>	Office
		<b>21</b>	Inpatient hospital
		<b>22</b>	Outpatient hospital
		<b>55</b>	Residential substance abuse treatment facility
<b>Ambulatory Payment Classification</b>	<b>APC for VIVITROL<sup>17</sup></b>	<b>0759</b>	Naltrexone, depot form
<b>Medicare Severity-Diagnosis Related Groups (MS-DRGs)</b>	<b>Inpatient Groups<sup>18</sup></b>	<b>894</b>	Alcohol/drug abuse or dependence, left AMA
		<b>895</b>	Alcohol/drug abuse or dependence with rehabilitation therapy
		<b>896</b>	Alcohol/drug abuse or dependence without rehabilitation therapy with MCC
		<b>897</b>	Alcohol/drug abuse or dependence without rehabilitation therapy without MCC

Abbreviations: AMA, against medical advice; MCC; major complication or comorbidity. Additional coding may be found at [www.cms.gov](http://www.cms.gov).

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

<b>All-Patient Refined-Diagnosis Related Groups (APR-DRGs)</b>	<b>Inpatient Groups<sup>19</sup></b>	<b>770 (1-4)</b>	DRUG & ALCOHOL ABUSE OR DEPENDENCE, LEFT AGAINST MEDICAL ADVICE
		<b>772 (1-4)</b>	ALCOHOL & DRUG DEPENDENCE W REHAB OR REHAB/DETOX THERAPY
		<b>773 (1-4)</b>	OPIOID ABUSE & DEPENDENCE
		<b>775 (1-4)</b>	ALCOHOL ABUSE & DEPENDENCE

Abbreviations: AMA, against medical advice; MCC; major complication or comorbidity. Additional coding may be found at [www.cms.gov](http://www.cms.gov).

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# Coding at a Glance

## ICD-10-CM Diagnosis Codes

Claims submitted for VIVITROL® (naltrexone for extended-release injectable suspension) 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.

Patient Diagnosis	ICD-10-CM Diagnosis <sup>15</sup>	Alcohol Dependence
		<p><b>F10.20</b> Alcohol dependence, uncomplicated</p> <p><b>F10.21</b> Alcohol dependence, in remission</p> <p><b>F10.22*</b> Alcohol dependence with intoxication</p> <p><b>F10.23*</b> Alcohol dependence with withdrawal</p> <p><b>F10.24</b> Alcohol dependence with alcohol-induced mood disorder</p> <p><b>F10.25*</b> Alcohol dependence with alcohol-induced psychotic disorder</p> <p><b>F10.26</b> Alcohol dependence with alcohol-induced persisting amnesic disorder</p> <p><b>F10.27</b> Alcohol dependence with alcohol-induced persisting dementia</p> <p><b>F10.28*</b> Alcohol dependence with other alcohol-induced disorders</p> <p><b>F10.29</b> Alcohol dependence with unspecified alcohol-induced disorder</p>

\*Selection of a subcategory may be required.

# Coding at a Glance

## Other Services<sup>13,20</sup>

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 non-exhaustive 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.

Alcohol and Drug Abuse Treatment	
H0001	Alcohol and/or drug assessment
H0012-H0015	Alcohol and/or drug services; detoxification
S9475	Ambulatory setting substance abuse treatment or detoxification services, per diem
Evaluation and Management	
99201-99205	Office or other outpatient services; new patient
99211-99215	Office or other outpatient services; established patient
G0463	Hospital outpatient clinic visit for assessment and management of a patient
Pathology and Laboratory	
H0003	Alcohol and/or drug screening; laboratory analysis of specimens for presence of alcohol and/or drugs
80354	Fentanyl
80356	Heroin metabolite
80361-80364	Opiates, opioids and opiate analogs

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# Coding at a Glance

## Other Services (cont'd)<sup>13,20</sup>

Behavioral Health/Psychosocial	
H0005	Alcohol and/or drug services; group counseling by a clinician
H0006	Alcohol and/or drug services; case management
H2017-H2018	Psychosocial rehabilitation services
G0396-G0397	Alcohol and/or substance (other than tobacco) abuse structured assessment (eg, AUDIT, DAST), and intervention
Health and Behavior Assessment/Intervention	
96150-96155	Health and behavior assessment, re-assessment, or intervention

Providers should consult applicable payers and relevant coding resources (e.g., 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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# Appendix A: Prior Authorization Form

Certain payers may require prior authorization for VIVITROL® (naltrexone for extended-release injectable suspension) treatment. Prior authorization allows the payer to review the reason for the requested therapy to determine medical appropriateness. Some payers allow the provider to call and request the prior authorization. However, others may require a written request for treatment. Payers may have specific forms and criteria for use for VIVITROL. Please refer to the individual payer for their specific requirements.

For assistance in acquiring the appropriate Prior Authorization Form, please contact your payer. Vivitrol2gether<sup>SM</sup> may be able to assist in determining the proper Prior Authorization Form as well.

If a prior authorization is required, a form similar to the one below may be required in order to obtain VIVITROL.

Detailed information about the patient and physician will be required.

Ensure the correct ICD-10-CM code is listed (see page 12 for more coding information).

**Pharmacy Authorization and Formulary Exceptions Request**

DATE \_\_\_\_\_ LEVEL OF SERVICE  
 ROUTINE (72 HRS)  
 EXPEDITED (24 HRS. PRESCRIBING PROVIDER MUST ALSO CALL PLAN)

TO BE COMPLETED BY PATIENT INFORMATION			PRESCRIBING PROVIDER	
NAME _____			NAME _____	
<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE				
ID # _____	DATE OF BIRTH _____	AGE _____	TELEPHONE _____	FAX _____
TELEPHONE _____	POB _____		PIA OR GROUP _____	SPECIALTY _____
ADDRESS _____			ADDRESS _____	
PHARMACY INFORMATION				
NAME _____		PHARMACIST OR TECHNICIAN _____		
TELEPHONE _____	FAX _____	ADDRESS _____		
REQUESTED PRESCRIPTION				
DRUG NAME _____		STRENGTH OR CONCENTRATION _____		
ROUTE AND DIRECTIONS _____		QUANTITY _____	REFILLS _____	
DIAGNOSIS (ICD-9 CM CODE) _____	NEW OR INITIAL THERAPY? <input type="checkbox"/> YES <input type="checkbox"/> NO		DURATION OF TREATMENT _____	
SUPPORTING STATEMENT				
REASON FOR REQUEST _____				
PREVIOUS TREATMENTS TRIED _____		EXPLANATION OF MEDICAL NECESSITY _____		
DIAGNOSIS (ICD-10 CM CODE) _____				
PRESCRIBING PROVIDER'S SIGNATURE _____				
PLAN USE ONLY				
<input type="checkbox"/> APPROVED	REVIEWER'S NOTES _____			
<input type="checkbox"/> MODIFIED				
<input type="checkbox"/> DENIED				
<input type="checkbox"/> DEFERRED				
MEDICAL DIRECTOR OR DESIGNEE'S SIGNATURE _____				DATE _____

Be sure to document the medical necessity for prescribing VIVITROL.

**Quick Tip** Always submit the Prior Authorization Form to the payer and to either Vivitrol2gether or the Specialty Pharmacy, whichever applies.

# Appendix B: Sample Letters

## Sample Letter of Medical Necessity

Payers may require providers to submit a Letter of Medical Necessity with the claim form to support coverage of VIVITROL® (naltrexone for extended-release injectable suspension). The Letter of Medical Necessity explains why the drug or procedure is being requested. Manually submitted claims for VIVITROL may include medical necessity documentation, along with other supporting documentation (e.g., medical records, peer-reviewed literature, etc).

[Date]

[Contact]  
[Title]  
[Payer Name]  
[Address]  
[City, State, Zip Code]  
Re: [Patient Name], ID Number: [Policy ID Number]

Dear [Contact Name]:  
I am writing on behalf of my patient, [Patient Name], to request that [Payer Name] approve coverage and payment regarding [his/her] treatment with VIVITROL® (naltrexone for extended-release injectable suspension) for [Patient Diagnosis].

Patient History, Diagnosis, and Treatment

Because of [insert relevant patient information-history, diagnosis, etc.], I have administered VIVITROL as a medically necessary part of this patient's treatment and request your reconsideration of the [date of service] claim for [Patient Name]. Please contact me at [Physician phone number, including area code] if you require additional information.

For complete information and a copy of the VIVITROL Prescribing Information and Medication Guide, please visit VIVITROL.com.

Thank you for your immediate attention to this request.

Sincerely,  
[Physician Name]  
[Physician]  
[Practice Name]

VIV-002070-v5

Please note, payers may have a published medical policy on VIVITROL. Providers may want to refer to this policy in preparing a Letter of Medical Necessity.



A sample of the Letter of Medical Necessity is available through Vivitol2gether<sup>SM</sup> on the Portal at [www.vivitrol.com](http://www.vivitrol.com) or by contacting a Vivitol2gether Representative at **1-800-VIVITROL (1-800-848-4876)**.

# Appendix B: Sample Letters

## Sample Letter of Appeal

In some cases, payers may allow an appeal to be submitted by phone, however, some payers may require a formal Letter of Appeal. The following is a sample Letter of Appeal for VIVITROL.

[Date]  
[Contact]  
[Title]  
[Name of Health Insurance Company]  
[Address]  
[City, State, Zip Code]  
Insured: [Patient Name]  
Policy Number: [Number]  
Group Number: [Number]  
Diagnosis: [Diagnosis and ICD-10 code]

Dear [Contact Name]:

This letter serves as a request for reconsideration of reimbursement of costs incurred for VIVITROL® (naltrexone for extended release injectable suspension) treatment administered for [Patient Name] on [date of service]. [Patient Name] has been under my treatment for [his/her] diagnosis of [diagnosis]. You have indicated VIVITROL is not covered by [Insurance Name] for this patient because [reason for denial].

Because of [insert relevant patient information-history, diagnosis, etc.], I have administered VIVITROL as a medically necessary part of this patient's treatment and request your reconsideration of the [date of service] claim for [Patient Name]. Please contact me at [Physician phone number, including area code] if you require additional information.

For complete information and a copy of the VIVITROL Prescribing Information and Medication Guide, please visit [VIVITROL.com](http://VIVITROL.com).

Thank you for your immediate attention to this request.

Sincerely,  
[Physician Name]  
[Physician Practice Name]

Attachments [original claim form, denial/EOB, additional supporting documents]

VIV-002857-v2

## Appendix C: Tips for Submitting Claims

The following tips will assist you with verifying benefits, navigating prior authorization, and submitting claims for VIVITROL® (naltrexone for extended-release injectable suspension):

- ✓ Determine if VIVITROL is covered as a medical or pharmacy benefit and if there are any applicable prior authorization requirements
- ✓ Accurately complete and submit Prior Authorization Form (if required)
- ✓ Ensure medical records include full and proper documentation of patient's history, prior therapy, and rationale for treatment
- ✓ Determine any special distribution requirements (e.g., mandatory use of a specific Specialty Pharmacy or requirements to buy and bill)
- ✓ Specify the proper number of units in Item 24G on the CMS-1500 Claim Form or in Locator Box 46 on the CMS-1450 (UB-04) Claim Form
- ✓ If required, include a Letter of Medical Necessity that outlines the patient's medical history and the rationale for therapy
- ✓ Consider attaching a copy of the Package Insert and any other supporting documentation
- ✓ Verify that all identification numbers and names are entered correctly
- ✓ Use correct ICD-10-CM codes, including fourth or fifth digits
- ✓ Verify the use of proper HCPCS and CPT®\* codes
- ✓ Confirm that the correct revenue code is used with the appropriate supporting HCPCS code J2315
- ✓ File the claim in a timely fashion

## Common Reasons for Denials of Claims

Common reasons for denials or underpayment of claims for therapy with VIVITROL include:

- ✓ Incorrect submission of payer-specific requirements including Prior Authorization Form
- ✓ Omission of any additional information that clarifies J2315 or other codes
- ✓ Utilization of incorrect CPT®\* or HCPCS codes (e.g., diagnosis code)
- ✓ Incorrect or incomplete documentation in the patient's medical record
- ✓ Failure to indicate the proper number of units of HCPCS code J2315 Item 24G of the CMS-1500 Claim Form

**Different payers will often have different requirements for appeals. It is important to determine the process on a patient-specific basis. For more information, please contact Vivitrol2gether<sup>SM</sup> at 1-800-VIVITROL (1-800-848-4876).**

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# Glossary of Terms

**All Patient Refined Diagnosis Related Group (APR-DRG):** A classification system that organizes hospital inpatients based on their reason for admission, severity of illness, and risk of mortality.

**Average Sales Price (ASP):** A reference point defined by statute for pricing drugs and biologics. The manufacturer's total sales—excluding sales that are exempt from the Medicaid best price calculation and sales to an entity that are nominal in amount, and including prompt pay discounts, cash discounts, free goods, and rebates—to all purchasers in the U.S. for the NDC for a quarter divided by the total number of units of that NDC sold by the manufacturer in that quarter.

**Average Wholesale Price (AWP):** A price point often used to facilitate electronic processing of reimbursement claims. The AWP for a drug is typically published in drug pricing compendia, such as First Databank or *Red Book*.

**Centers for Medicare & Medicaid Services (CMS):** Federal agency within the United States that administers Medicare and Medicaid programs.

**Current Procedural Terminology (CPT®\*):** Uniform listing of descriptive terms and codes used throughout the industry for reporting professional medical services.

**Fee Schedule:** Listing of the maximum fees that an insurer will pay for certain services; physician fee schedules are usually based on CPT®\* codes.

**Healthcare Common Procedure Coding System (HCPCS):** Describes drugs and biologics, some supplies and devices, and certain services/procedures not described by CPT®\* codes; used in the physician office and hospital outpatient settings.

**International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM):** Statistical classification system consisting of a listing of diagnosis and identifying codes for reporting diagnosis of health plan enrollees identified by physicians; coding and terminology to accurately describe primary and secondary diagnosis and provide for consistent documentation for claims.

**Medicare Part A:** Hospital insurance that helps cover inpatient care in hospitals, skilled nursing facilities, hospice, and home healthcare.

**Medicare Part B:** Helps cover medically necessary services like doctors' services, outpatient care, durable medical equipment, home health services, and other medical services. Part B also covers some preventive services.

**Medicare Part C:** Medicare Advantage plans, sometimes called "Part C" or "MA Plans," are offered by private companies approved by Medicare. The plan will provide all of your Part A (Hospital Insurance) and Part B (Medical Insurance) coverage. Medicare Advantage plans may offer extra coverage, such as vision, hearing, dental, and/or health and wellness programs. Most include Medicare Prescription Drug Coverage (Part D).

**Medicare Part D:** Medicare Prescription Drug Coverage.

**Medicare Severity-Diagnosis Related Group (MS-DRG):** A classification system that is used to calculate inpatient hospital stay costs based on patient attributes.

**Revenue Code:** Four-digit codes required on all hospital claims that allow facilities to attribute supplies and services to specific cost centers within the hospital; maintained by the National Uniform Billing Committee.

**Separate Payment:** Drugs and biologics that are eligible for separate payment are reimbursed by the payer individually rather than as a bundled payment with other healthcare services.

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**19** Please see **Important Safety Information** beginning on page 20.  
Also, please click for **Prescribing Information** and **Medication Guide**.  
Review **Medication Guide** with your patients.

**Vivitrol**<sup>®</sup>  
(naltrexone for extended-release  
injectable suspension)

# IMPORTANT SAFETY INFORMATION

for VIVITROL<sup>®</sup> (naltrexone for extended-release injectable suspension)

## INDICATIONS

### VIVITROL is indicated for:

- 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.
- Prevention of relapse to opioid dependence, following opioid detoxification.
- VIVITROL should be part of a comprehensive management program that includes psychosocial support.

## CONTRAINDICATIONS

### VIVITROL is contraindicated in patients:

- Receiving opioid analgesics
- With current physiologic opioid dependence
- 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

## WARNINGS AND PRECAUTIONS

### 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. Discuss the availability of naloxone for the emergency treatment of opioid overdose

with the patient and caregiver, at the initial VIVITROL injection and with each subsequent injection. Strongly consider prescribing naloxone for the emergency treatment of opioid 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.

### Injection Site Reactions:

- VIVITROL must be prepared and administered by a healthcare provider.
- 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.
- 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.
- Injection site reactions not improving may require prompt medical attention, including, in some cases, surgical intervention.
- 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.
- Patients should be informed that any concerning injection site reactions should be brought to the attention of their healthcare provider.

# IMPORTANT SAFETY INFORMATION

for VIVITROL<sup>®</sup> (naltrexone for extended-release injectable suspension)

## Precipitation of Opioid Withdrawal:

- When withdrawal is precipitated abruptly by administration of an opioid antagonist to an opioid-dependent patient, the resulting withdrawal syndrome can be severe. Some cases of withdrawal symptoms have been severe enough to require hospitalization, and in some cases, management in the ICU.
- To prevent occurrence of precipitated withdrawal, opioid-dependent patients, 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.
  - Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as two 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.
- Precipitated opioid withdrawal has been observed in alcohol-dependent patients 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; advise them to seek help if experiencing symptoms of acute hepatitis. Discontinue use of VIVITROL in patients who exhibit acute hepatitis symptoms.

## Depression and Suicidality:

- Alcohol- and opioid-dependent patients 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:

- Cases of urticaria, angioedema, and anaphylaxis have been observed with the use of VIVITROL.
- Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.
- In the event of a hypersensitivity reaction, patients should be advised to seek immediate medical attention in a healthcare setting prepared to treat anaphylaxis. 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.

**21** Please see **Important Safety Information** beginning on page 20. Also, please click for **Prescribing Information** and **Medication Guide**. Review **Medication Guide** with your patients.

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# IMPORTANT SAFETY INFORMATION

for VIVITROL<sup>®</sup> (naltrexone for extended-release injectable suspension)

## ADVERSE REACTIONS

- The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence (ie, those occurring in  $\geq 5\%$  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 opioid-dependent patients (ie, those occurring in  $\geq 2\%$  and at least twice as frequently with VIVITROL than placebo) were hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.  
**You are encouraged to report side effects to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**  
**Please click for accompanying [Prescribing Information](#) and [Medication Guide](#).**

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