

BILLING & CODING GUIDE



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Vivitrol[®]
(naltrexone for extended-release
injectable suspension)

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DISCLAIMER

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT** and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Alkermes, Inc., that these codes will be appropriate or that reimbursement will be made. The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.† It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

*CPT®=Current Procedural Terminology. Copyright of the American Medical Association, 2017.

†Centers for Medicare & Medicaid Services. CMS Manual System, Pub 100-04 Medicare Claims Processing.

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2386CP.pdf>.

Accessed July 13, 2017.

‡2011 HCPCS Level II Professional Edition. Elsevier Saunders, 2010. (pg. 84).

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Vivitrol[®]
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Introduction

Alkermes has developed this Billing & Coding Guide for VIVITROL® (naltrexone for extended-release injectable suspension) to assist physicians and other providers in understanding payer coverage, coding, and reimbursement for VIVITROL. In addition, it provides information on Vivitrol2getherSM, including assistance with VIVITROL acquisition. Lastly, this guide provides sample claim forms, a sample Letter of Appeal, and a sample Letter of Medical Necessity.

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. 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 initial VIVITROL administration.

The information provided represents no statement, promise, or guarantee by Alkermes, Inc. concerning coverage, levels of reimbursement, payment, or charge. It is not intended to assist providers in obtaining reimbursement for any specific claim. Individual payer organizations should be contacted for coverage and reimbursement policies and processes, including prior authorization, if necessary.

Overview

This guide 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
- ✓ Medical versus pharmacy benefit
- ✓ Utilization of a Specialty Pharmacy

Beyond the Billing & Coding Guide

Vivitrol2getherSM Program Overview

Along with VIVITROL, we offer Vivitrol2gether—a customized support program to help you and your patients in their recovery journey from opioid or alcohol dependence throughout fulfillment and transition of care.

With Vivitrol2gether, you choose the VIVITROL[®] (naltrexone for extended-release injectable suspension) fulfillment features that work best to support your patients. If you prefer to work directly with pharmacies, we provide the resources you need, with VIVITROL team members available to answer your questions quickly. You can also choose to sign up to work with a dedicated case manager to help assist you in the fulfillment process, as well as use an online tracking portal to find VIVITROL fulfillment details and patient services.

Whichever option you choose, Vivitrol2gether provides the resources to support patient access:

- ✓ Specialty or other pharmacy selection options based on a patient's health plan coverage
- ✓ Education about health plan and pharmacy requirements, including prior authorizations and coverage requirements
- ✓ Easy access to resources to help facilitate VIVITROL delivery



➔ **Work directly with 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** to access a variety of helpful resources.

Acquiring VIVITROL® (naltrexone for extended-release injectable suspension)

There are multiple ways to acquire VIVITROL. The acquisition method will be determined by site of service and the patient's insurance coverage. VIVITROL may be covered as a medical or pharmacy benefit. Coverage determines how VIVITROL can be obtained. Typically, health insurance providers require you to acquire VIVITROL through a Specialty Pharmacy or purchase VIVITROL direct from a wholesaler or specialty distributor.

VIVITROL Coverage and Shipment

Specialty Pharmacy

- Specialty Pharmacies require a physician to submit an order or enrollment form to begin the acquisition process for VIVITROL.
- VIVITROL is typically shipped by a Specialty Pharmacy to a provider's office in the patient's name. In this case, the patient's insurance covers VIVITROL either through a pharmacy or medical benefit. A medical benefit may require Assignment of Benefits (AOB). Since the Specialty Pharmacy will bill the patient's insurance directly, your office will not be required to purchase VIVITROL even though you will receive it at your office and hold it for the patient.
- Most Specialty Pharmacies require that the patient authorize the initial shipment over the phone before shipping. Once this authorization has taken place, the Specialty Pharmacy will work with your office to schedule deliveries.
 - If your patient does not hear from the Specialty Pharmacy at least 5 days before his/her next scheduled injection, have your patient call his/her healthcare provider or Vivitrol2getherSM at **1-800-VIVITROL (1-800-848-4876)** for help.
- If your patient misses the Specialty Pharmacy's call, make sure he/she calls the Specialty Pharmacy back or he/she may not be able to receive his/her VIVITROL injection.
 - To protect your patient's privacy, the Specialty Pharmacy will not be very specific when leaving a message.
 - Normally, the Specialty Pharmacy will ask that your patient contact them about his/her prescription.
- If the Specialty Pharmacy is unable to reach your patient, they may alert your patient's healthcare provider and close your patient's file without fulfilling his/her VIVITROL prescription.

Please Refer to Appendix A for Specialty Distributors or Wholesalers.

➔ **Work directly with 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** to access a variety of helpful resources.

If you are using a Specialty Pharmacy, the following process flow will be helpful:

Option 1

Utilize a Dedicated Case Manager

- **FULLY** complete the Vivitrol2getherSM Form.
- Fax **ALL** of the following documents to Vivitrol2gether at 1-877-329-8484:
 - Vivitrol2gether Enrollment Form,
 - Photocopy of the front and back of the patient's insurance card (enlarged to ensure legibility),
 - Copy of VIVITROL[®] Co-pay Savings Program card for eligible patients who have elected co-pay assistance, and
 - Prior Authorization Form (**ONLY** if one is required by the patient's insurance).

IMPORTANT: Also fax the Prior Authorization Form (if required) and a photocopy of the insurance card to the payer's fax number listed on the Prior Authorization Form, as they typically prefer that it come directly from your office.

The image shows a 'Patient Enrollment' form for Vivitrol2gether. It is divided into several sections:

- 1. PRESCRIBER OR FACILITY INFORMATION:** Includes fields for Prescriber Name, DEA #, Prescriber Phone #, Facility Name, Address, City, State, ZIP Code, Staff Contact Name, Staff Contact Phone #, and Staff Contact E-mail.
- 2. PATIENT INFORMATION:** Includes Name (Print), Date of Birth, Gender (Male/Female), Race, Ethnicity, and Insurance information (Medicare/Medicaid/Other).
- 3. PATIENT DIAGNOSIS:** A section for listing medical conditions.
- 4. PRESCRIPTION INFORMATION AND ATTESTATION:** Includes fields for Prescriber Name, Date, and Signature.

 The form also contains checkboxes for 'I am a patient' and 'I am a prescriber' and various attestation statements regarding the accuracy of the information provided.

Sample Vivitrol2gether Enrollment Form

(See page 6 for more information)

Option 2

Direct to Specialty Pharmacy

- **FULLY** complete the Specialty Pharmacy Form.
- Fax **ALL** of the following documents to the number listed on the form:
 - Specialty Pharmacy Form,
 - Photocopy of the front and back of the patient's insurance card (enlarged to ensure legibility),
 - Copy of VIVITROL[®] Co-pay Savings Program card for eligible patients who have elected co-pay assistance, and
 - Prior Authorization Form (**ONLY** if one is required by the patient's insurance).

IMPORTANT: Also fax the Prior Authorization Form (if required) and a photocopy of the insurance card to the payer's fax number listed on the Prior Authorization Form, as they typically prefer that it come directly from your office.

The image shows a 'Pharmacy Authorization and Formulary Exceptions Request' form. It is divided into several sections:

- PATIENT INFORMATION:** Includes fields for Name, Date of Birth, Telephone, and Address.
- PHARMACY INFORMATION:** Includes fields for Pharmacy Name, Address, and Telephone.
- DRUG INFORMATION:** Includes fields for Drug Name, Strength, and Route.
- REASON FOR REQUEST:** A section for providing a supporting statement.
- PRESCRIBING PROVIDER'S SIGNATURE:** Includes fields for Name, Title, and Signature.

 The form also contains checkboxes for 'APPROVED', 'DENIED', and 'PENDING'.

Sample Specialty Pharmacy Form

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Dedicated Case Manager Patient Enrollment Form

The enrollment form represents the initial step in utilizing Vivitrol2getherSM.

Helpful Hint:

To enroll, 4 signatures are required on this form

- ✓ 1 from you (bottom of front page)
- ✓ 3 from your patient


Will your office be injecting VIVITROL?

Please indicate if you require Vivitrol2getherSM to locate an Injection Provider.


Check the appropriate diagnosis code box.

Include an enlarged copy of the patient's insurance card or complete this section.

Complete all fields in order to avoid delays.



With you along the way



(naltrexone for extended-release injectable suspension)

Patient Enrollment

COMPLETE ALL FIELDS TO AVOID PROCESSING DELAYS. PRESCRIPTION ONLY VALID IF FAXED. FAX COMPLETED FORM TO: 1-877-329-8484. V2G ID# (Vivitrol2gether Use Only): _____

QUESTIONS? CALL 1-800-VIVITROL (1-800-848-4876), 9AM-8PM (EST).

Admittance Date: _____ Estimated Discharge Date: _____

1. PRESCRIBER OR FACILITY INFORMATION

Prescriber Name* _____

State License # _____ DEA # _____

Prescriber Phone # _____ NPI # _____

Facility Name _____ Fax # _____

Address _____

City _____ State _____ ZIP Code _____

Staff Contact Name _____

Staff Contact Phone # _____

Staff Contact E-mail _____

2. PATIENT INFORMATION

Name (First) _____ (Last) _____

Date of Birth _____ Gender Male Female

Address _____

City _____ State _____ ZIP Code _____

Home Phone # _____ Mobile Phone # _____

Best Number to Call Home Mobile

Best Day to Call M T W TH F

Best Time to Call Morning Afternoon Evening

E-mail Address _____

→ INSTRUCT PATIENT TO LIST ALTERNATE CONTACTS ON PAGE 2.

3. PATIENT DIAGNOSIS—Please complete the diagnosis code(s) you would like to use by filling in the additional digits.

(A list of codes can be found on page 3, section 12)

Alcohol Dependence ICD-10 _____	Opioid Dependence ICD-10 _____	Patient has tried and failed the following medication(s): F10. _____ F10. _____ F10. _____ F10. _____ F10. _____
		Please list any known allergies to medications or other substances: _____ _____ _____ Other _____

Check if patient has concurrent medications

4. INJECTION PROVIDER/SPECIALTY PHARMACY INFORMATION

Will your patient receive ongoing injections at your location?
 Yes, patient will receive all injections at this location. Complete step B of this section.
 No, patient will transition to a new provider after the first dose. Complete steps A and B of this section.

A. Injecting provider
 A new provider is unknown; need assistance from Vivitrol2gether to locate one.
 Vivitrol2gether should contact provider below to coordinate ongoing care for this patient

Provider Name _____ Phone # _____

Provider Address _____

B. Shipping details
 Patient needs VIVITROL delivered by (date) ____/____/____
 Preferred pharmacy (if applicable) _____
 Special shipping instructions/restrictions _____

5. PATIENT INSURANCE INFORMATION

A. Payment Method Insured Paying out-of-pocket

B. ATTACH A COPY OF BOTH SIDES OF THE PATIENT'S INSURANCE CARD(S).

C. IF YOU ELECT NOT TO ATTACH AN INSURANCE CARD, COMPLETE SECTION BELOW.

PRIMARY INSURANCE / MEDICAL INSURANCE

Insurance Type Commercial Medicaid Medicare QHP

Carrier Name _____

Policyholder Name _____ PA # (if obtained) _____

Relationship to Patient _____ Carrier Phone # _____

Policyholder Employer Name _____

Policy # _____ Group ID # _____

Policy Type HMO PPO Other

PHARMACY BENEFIT PLAN (PBM)

PBM Name _____ PBM Phone # _____

Policyholder Name _____ Policy # _____

Relationship to Patient _____

Policyholder Employer Name _____

Rx Grp _____ Rx BIN # _____ Rx PCN _____

Co-pay Card Number (if already obtained) _____

6. PRESCRIPTION INFORMATION AND ATTESTATION *PRESCRIBER SIGNATURE MUST BE THE SAME AS THE PRESCRIBER NAME ABOVE

Patient Name _____

VIVITROL 380 mg x 1 unit Inject 380 mg IM every 4 weeks or every 1 month _____ Provider State License # _____

Refill _____ times (Complete refills to minimize interruption in monthly VIVITROL therapy)

By signing below, I verify that the information provided in this Vivitrol2gether enrollment form is complete and accurate to the best of my knowledge. I understand that Alkermes, Inc., reserves the right at any time and for any reason, without notice, to modify this Vivitrol2gether enrollment form or to modify or discontinue any services or assistance provided through Vivitrol2gether. Finally, I authorize Alkermes, its affiliates, representatives and agents as my designated agents to use and disclose my patient's health information as necessary to verify the accuracy of any information provided, to provide reimbursement services through Vivitrol2gether, to forward the above prescription, by fax or other mode of delivery, to a pharmacy for fulfillment, and (as applicable) to assess my patient's eligibility for co-pay assistance.

Prescriber's Signature _____ (if applicable) Dispense as Written _____ Date of Signature _____
(no stamps allowed) Substitution Permitted _____

PLEASE SEE IMPORTANT SAFETY INFORMATION ON PAGE 4. PLEASE SEE PRESCRIBING INFORMATION AND MEDICATION GUIDE, OR VISIT VIVITROL.COM. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.

PAGE 1

Editable PDF templates can be downloaded at [VIVITROL.com/EnrollmentForm].

Quick Tip

Include a scanned copy of the front and back of the insurance card to ensure proper processing. Ensure eligible patients complete the co-pay information on page 3 of the enrollment form.

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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. Vivitrol2getherSM 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 16](#) 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 PRESCRIBING PROVIDER					
PATIENT INFORMATION			PRESCRIBING PROVIDER		
NAME			NAME		
<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE					
ID #	DATE OF BIRTH	AGE	TELEPHONE	FAX	
TELEPHONE	PCP		IPA 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-10 CM CODE)			NEW OR INITIAL THERAPY?	DURATION OF TREATMENT	
			<input type="checkbox"/> YES <input type="checkbox"/> NO		
SUPPORTING STATEMENT					
REASON FOR REQUEST					
PREVIOUS TREATMENTS TRIED			EXPLANATION OF MEDICAL NECESSITY		
PRESCRIBING PROVIDER'S SIGNATURE					

PLAN USE ONLY					
<input type="checkbox"/> APPROVED <input type="checkbox"/> MODIFIED <input type="checkbox"/> DENIED <input type="checkbox"/> DEFERRED		REVIEWER'S NOTES			
MEDICAL DIRECTOR OR DESIGNEE'S SIGNATURE				DATE	

REVISED September 18, 2008

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.

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Reducing Financial Barriers for Eligible Patients*

The VIVITROL® Co-pay Savings Program is part of the comprehensive patient support services designed to help your eligible patients* with out-of-pocket expenses associated with their VIVITROL® (naltrexone for extended-release injectable suspension) prescriptions.

- 90%¹ of insured patients using the VIVITROL® Co-pay Savings Program had no out-of-pocket expenses for VIVITROL.†

The VIVITROL® Co-pay Savings Program:

- Covers up to \$500/month of VIVITROL co-pay or deductible expenses for eligible patients.* This may mean \$0 co-pay or deductible expenses for your patients.
- Has no income eligibility requirements.
- Has no preset duration limits or expiration. The VIVITROL® Co-pay Savings Program card can be used multiple times.
- Allows eligible patients to print co-pay cards directly from www.VIVITROLCopay.com. Patients can cut out the card and keep it in their wallet, so that they always have their ID number handy to give to a healthcare provider or pharmacy.

How the VIVITROL® Co-pay Savings Program Works:

- Provide the Specialty Pharmacy with a copy of the patient's co-pay savings card.
- The VIVITROL® Co-pay Savings Program will reimburse the Specialty Pharmacy directly, allowing the patient to incur limited or no out-of-pocket expenses.

For more information about the VIVITROL® Co-pay Savings Program, please contact Vivitrol2getherSM at **1-800-VIVITROL (1-800-848-4876)**, or visit **VIVITROL.com** for information or to download a co-pay savings card.

Quick Tip

Instruct your eligible patients* who will be using the co-pay savings program to give the VIVITROL® Co-pay Savings Card information to the Specialty Pharmacy when they call to collect the co-payment.

***Eligibility for Alkermes-Sponsored Co-pay Assistance:** Offer valid only for prescriptions for FDA-approved indications. Patients must be at least 18 years old. If patients are purchasing their VIVITROL prescriptions with benefits from Medicare, including Medicare Part D or Medicare Advantage plans; Medicaid, including Medicaid Managed Care or Alternative Benefit Plans (“ABPs”) under the Affordable Care Act; Medigap; Veterans Administration (“VA”); Department of Defense (“DoD”); TRICARE®; or any similar state-funded programs such as medical or pharmaceutical assistance programs, they are not eligible for this offer. Void where prohibited by law, taxed, or restricted. Alkermes, Inc. reserves the right to rescind, revoke, or amend these offers without notice.¹

†Data derived from insured patients enrolled in the program from March 2014 through February 2015.

Coverage and Reimbursement

Physician Office and Hospital Outpatient

Commercial payers, Medicaid, and Medicare typically provide reimbursement to physicians, clinics, and hospital outpatient centers for injectable drugs. Often, a separate payment is made for the drug and for the administration service. Benefit verification should be conducted on a patient-specific basis.

The information below and on the following pages summarizes payment in the physician office and hospital outpatient setting by payer type.

Commercial Insurance

Coverage

VIVITROL® (naltrexone for extended-release injectable suspension) may be covered as a medical benefit, pharmacy benefit, or both. VIVITROL is typically shipped by a Specialty Pharmacy to a provider's office in the patient's name. In this case, the patient's insurance covers VIVITROL either through the pharmacy or the medical benefit. A medical benefit may require Assignment of Benefits (AOB). Since the Specialty Pharmacy will ship VIVITROL from their inventory and bill the patient's insurance directly, your office will not be required to purchase VIVITROL even though you will receive it at your office and hold it for the patient.

Payer Reimbursement

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 and provider site of service. Some commercial insurers may apply coverage and utilization restrictions such as prior authorization or step therapy.

Injection Services

Physician Office – Commercial payer payment for drug administration (intramuscular injection) varies by health plan, with payment normally based on a plan's common fee schedule, similar to the Medicare reimbursement methodology for physician services or other contracted rates.

Hospital Outpatient – Similar to a physician's office, reimbursement for injections may be based on a common fee schedule similar to the Medicare reimbursement methodology for physician services, facility-specific cost-to-charge ratios, per diem methodologies, or other contracted rates.

Community Pharmacy Injector Network – In many areas where allowed community pharmacists provide VIVITROL injection services. Vivitrol2getherSM may be able to assist locating a local Injection Provider.

Coverage and Reimbursement

Physician Office and Hospital Outpatient - Medicaid*

Coverage

In general, state Medicaid programs cover physician-administered injectables, with each agency determining its own coverage and reimbursement policies for drugs and other healthcare services. It is important for providers to know and understand how each agency develops medication coverage and payment policies, including coverage criteria for VIVITROL® (naltrexone for extended-release injectable suspension). Providers should check their Medicaid program for specific VIVITROL coverage information.

Medicaid coverage may vary by patient, provider type, place of service, and benefit type (e.g., fee-for-service [FFS] vs managed care). VIVITROL may be covered as a medical or pharmacy benefit, or both. Coverage policies can range from no restrictions on usage to highly restrictive. VIVITROL restrictions may include prior authorization, step therapy/fail-first, quantity limits, and other similar management controls.

Coverage for medications may also be available for Medicaid beneficiaries enrolled in managed care programs. Typically, Medicaid Managed Care Organizations (MCOs) have the authority to operate their drug benefit independent of coverage policies and reimbursement under the FFS program. VIVITROL coverage by these MCOs may again be subject to prior authorization, step therapy/fail-first, and other management controls. Reimbursement for VIVITROL, which may be based on a percentage of the Average Wholesale Price (AWP)/Average Sales Price (ASP), will vary by state and by state-MCO contract.

Payer Reimbursement

When Medicaid covers VIVITROL under a patient's **pharmacy benefit**, VIVITROL is typically supplied by local pharmacies. Due to special packaging requirements, the pharmacy may deliver VIVITROL to the provider for administration. The pharmacy then bills Medicaid for both VIVITROL (using the National Drug Code [NDC]) and a dispensing fee (a nominal patient co-payment may sometimes be required). The pharmacy, not the prescribing physician, bills Medicaid for the cost of the medication.

When VIVITROL is covered under a patient's **medical benefit**, physicians will order VIVITROL from distributors, maintain their own inventory, administer the injection, and bill Medicaid for the cost of VIVITROL and the injection fee. Reimbursement is based on the state Medicaid fee schedule (amount based on a percentage of ASP, AWP, Wholesale Acquisition Cost [WAC], or other state-specific calculation). VIVITROL is billed using both the HCPCS code (J2315) and NDC number (65757-0300-01).

Injection Services

Medicaid reimbursement for VIVITROL drug injection services provided in the physician office setting varies by state Medicaid program. Many states base reimbursement on a statewide fee schedule that may be updated on a quarterly or annual basis.

*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 and Hospital Outpatient - Medicare†

Coverage

VIVITROL® (naltrexone for extended-release injectable suspension) is generally covered under Medicare Part B, Medicare Part C, or Medicare Part D. Medicare Part B offers VIVITROL coverage through buy-and-bill, Medicare Part C offers coverage under private MCOs approved by Medicare, and Medicare Part D offers coverage through a pharmacy benefit (typically shipped by a Specialty or Retail Pharmacy). To confirm patient-specific coverage, please submit a Vivitrol2getherSM Patient Enrollment Form so that specific benefit types can be determined.

Medicare Part B

Physician Office – Reimbursement is based on Average Sales Price (ASP)+6% and is 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.

Hospital Outpatient – Services paid under the Medicare Hospital Outpatient Prospective Payment System (OPPS) are assigned to an Ambulatory Payment Classification (APC) code. VIVITROL has been assigned APC code 0759 (naltrexone, depot form), with Status Indicator K (nonpass-through drugs paid under OPPS, with separate APC payment). Payment rates are adjusted annually. The patient is generally responsible for the remaining 20% co-payment.¹

Medicare Part C

Medicare Advantage (MA) plans typically include the Part D Medicare prescription drug coverage option. VIVITROL coverage will be based on a plan's formulary. Some plans with tiered formularies may call for step therapy or prior authorization. Sometimes a MA plan may exclude coverage for VIVITROL. If so, a provider may be able to ask the MA plan to make an exception (show proof that no drug on the formulary will work for the patient). Under MA plans, VIVITROL is often shipped by a Specialty Pharmacy to a provider's office.

Medicare Part D

For Medicare Part D coverage, VIVITROL is typically shipped by a Specialty Pharmacy to a provider's office in the patient's name. Since the Specialty Pharmacy will bill the patient's insurance directly, your office will not be required to purchase VIVITROL even though you will receive it at your office and hold it for the patient.

Injection Services

Physician Office – Physician offices are reimbursed for 80% of the allowable amount, and the patient is responsible for the remaining 20% co-payment (based on the national fee schedule).

Hospital Outpatient – Drug administration Current Procedural Terminology (CPT^{®†}) codes are assigned to APCs according to their clinical and resource requirements.

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

‡CPT[®]=Current Procedural Terminology. Copyright of the American Medical Association, 2017.

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Coverage and Reimbursement

Hospital Inpatient

Commercial payers, Medicaid, and Medicare generally reimburse for care in the Hospital Inpatient setting under one of two methods. Usually, care is reimbursed as a bundled payment made to the facility for the patient's stay. However, under certain circumstances, payers may allow separate coverage.

Payers have varying benefit designs and coverage restrictions. Be sure to verify the patient's coverage by site of service. The information below summarizes payment in the inpatient setting by payer.

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 predominantly use 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. Most Medicaid state programs base reimbursement on 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

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 Vivitrol2getherSM at **1-800-VIVITROL (1-800-848-4876)**.

→ **Work directly with 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** 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. Select Option 3 to speak with a Vivitrol2gether Nurse Coordinator.

Coverage and Reimbursement

Residential Substance Abuse Facility

Commercial Payer

Reimbursement for VIVITROL® (naltrexone for extended-release injectable suspension) and the associated administration will vary, based on the contract established between the Residential Substance Abuse Facility and health plan. Normally, Residential Substance Abuse Facilities are capitated for all costs of care including injectable medications based on a MS-DRG, per diem rate, or all-inclusive rate. 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 your 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 will be reimbursed under Medicare Part B, C, or D.

Injection Services

Injection services for Commercial, Medicare, and Medicaid vary widely by commercial plan, Medicare type (Part B, C [Medicare Advantage], and D), and state, respectively. Providers should contact Vivitrol2getherSM 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 Vivitrol2getherSM to verify coding and claim information.

1500
HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05

1. MEDICARE MEDICAID TRICARE CHAMPVA OTHER
Medicare # Medicare # TRICARE # Member ID# HEALTH PLAN (SON or OP) BUCKLE (ID) OTHER

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE SEX
4. INSUREE'S I.D. NUMBER (For Program in Item 1)

5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED 7. INSUREE'S ADDRESS (No., Street)
8. PATIENT STATUS 9. INSUREE'S NAME (Last Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO: 11. INSUREE'S POLICY GROUP OR FECA NUMBER
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who assigns assignment)

13. NAME OF REFERRING PROVIDER OR OTHER SOURCE 14. DATE OF CURRENT ILLNESS (If symptoms or injury) FROM TO
15. IF PATIENT HAS HAD NAME OR SIMILAR ILLNESS GIVE FIRST DATE. MM DD YY

16. RESERVED FOR LOCAL USE 17. RESERVED FOR LOCAL USE 18. RESERVED FOR LOCAL USE

19. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Please Items 1, 2, 3 or 4 to Item 5 by Line)
20. OUTSIDE LAB? \$ CHARGES
21. X XX XX 380 NPI
22. PRIOR AUTHORIZATION NUMBER

23. PROCEDURES, SERVICES, OR SUPPLIES (Single Inpatient Outpatient) CPT/HCPCS ICD-9-CM ICD-10-CM
NDC 65757-0300-01, VIVITROL INJ, 380mg J2315 1 XXX XX 380 NPI
01 01 12 01 09 12 96372 - XXX XX 1 NPI

24. A. DATES OF SERVICE FROM TO B. PLACE C. D. PROCEDURES, SERVICES, OR SUPPLIES E. DIAGNOSIS PORTER F. G. H. I. J.
01 01 12 01 09 12 96372 - XXX XX 1 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? 28. TOTAL CHARGE 29. AMOUNT PAID 30. BALANCE DUE
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE OR CREDENTIALS (I certify that the statements on this invoice apply to this bill and are made a part thereof.) 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH #

SIGNED DATE PLEASE PRINT OR TYPE APPROVED OMB-0938-0999 FORM CMS-1500 (08-05)

Box 21: Diagnosis or nature of illness or injury
Note: Enter the appropriate diagnosis code as reflected in the patient's medical record.

NDC Number: 65757-0300-01, VIVITROL INJ, 380 mg.

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 with medical benefit 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.

14 Please see Important Safety Information on back of this guide. Also, please click for Prescribing Information and Medication Guide. Review Medication Guide with your patients.



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 Vivitrol2getherSM to verify coding and claim information.

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498										499		500	

Field 44: HCPCS Code
Enter the appropriate HCPCS code (J2315) and CPT®* code (96372).

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 46: Service Units
Enter the appropriate number of units.
Note: Important to submit for 380 units (1 mg = 1 unit).

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.

*CPT®=Current Procedural Terminology. Copyright of the American Medical Association, 2017.

15 Please see Important Safety Information on back of this guide. Also, please click for Prescribing Information and Medication Guide. Review Medication Guide with your patients.



Coding at a Glance

Coding decisions should be made by the physician based on an independent review of the patient's condition. Below is a list of codes you may find helpful.

VIVITROL® (naltrexone for extended-release injectable suspension) Coding	NDC for VIVITROL²	65757-0300-01	Naltrexone for extended-release injectable suspension
	HCPCS³	J2315	Injection, naltrexone, depot form, 1 mg
Professional Services	CPT^{3,4}	96372	Therapeutic, prophylactic, or diagnostic injection (specify material injected); subcutaneous or intramuscular
	ICD-10-CM Procedure⁵	3E023GC	Introduction of other therapeutic substance into muscle, percutaneous approach
Professional Claims	Place of Service Codes⁶	11	Office
		21	Inpatient hospital
		22	Outpatient hospital
		55	Residential substance abuse treatment facility
Ambulatory Payment Classification	APC for VIVITROL⁷	0759	Naltrexone, depot form
Diagnosis- Related Groups	Inpatient/ Outpatient Groups⁸	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

Abbreviations: AMA, against medical advice; MCC; major complication or comorbidity.

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

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 Diagnosis⁵	Alcohol Dependence
		<p>F10.20 Alcohol dependence, uncomplicated</p> <p>F10.21 Alcohol dependence, in remission</p> <p>F10.22 Alcohol dependence with intoxication</p> <p>F10.23 Alcohol dependence with withdrawal</p> <p>F10.24 Alcohol dependence with alcohol-induced mood disorder</p> <p>F10.25 Alcohol dependence with alcohol-induced psychotic disorder</p> <p>F10.26 Alcohol dependence with alcohol-induced persisting amnesic disorder</p> <p>F10.27 Alcohol dependence with alcohol-induced persisting dementia</p> <p>F10.28 Alcohol dependence with other alcohol-induced disorders</p> <p>F10.29 Alcohol dependence with unspecified alcohol-induced disorder</p>
		Opioid Dependence
		<p>F11.20 Opioid dependence, uncomplicated</p> <p>F11.21 Opioid dependence, in remission</p> <p>F11.22 Opioid dependence with intoxication</p> <p>F11.23 Opioid dependence with withdrawal</p> <p>F11.24 Opioid dependence with opioid-induced mood disorder</p> <p>F11.25 Opioid dependence with opioid-induced psychotic disorder</p> <p>F11.28 Opioid dependence with other opioid-induced disorder</p> <p>F11.29 Opioid dependence with unspecified opioid-induced disorder</p>

16 Please see **Important Safety Information** on back of this guide. Also, please click for **Prescribing Information** and **Medication Guide**. Review Medication Guide with your patients.

Vivitrol®
(naltrexone for extended-release injectable suspension)

Appendix A: Alternate Options to Acquire VIVITROL Specialty Distributor for Buy-and-Bill Coverage.

You may decide to purchase VIVITROL® (naltrexone for extended-release injectable suspension) or a patient's insurance may require you to buy VIVITROL and bill the insurance company directly following each VIVITROL injection. Please confirm with the payer for the most appropriate route of acquisition prior to initiation of VIVITROL.

Providers who have not previously worked with a distributor of medication are required to establish an account to place an order for VIVITROL.

Besse Medical

Alkermes has contracted with a specialty distributor for VIVITROL, Besse Medical, who has extended payment terms of 75 days after purchase, for eligible providers. This typically allows time for third-party payer claims to be processed and for payment to be received before providers are required to remit payment to the distributor for the medication purchased.

Besse Medical Contact Information:

1-800-543-2111 (phone) • 1-800-543-8695 (fax) • www.besse.com

Smith Medical Partners

Smith Medical Partners is another option for acquiring VIVITROL under Buy-and-Bill.

Smith Medical Partners Contact Information:

1-800-292-9653 (phone) • 1-630-227-9220 (fax) • www.smpspecialty.com and click "Get Started."

Wholesaler

If your site of service is an institution such as a hospital, you may utilize your current wholesaler such as ABC - AmerisourceBergen, Cardinal Health, McKesson, or H.D. Smith.

*CPT®=Current Procedural Terminology. Copyright of the American Medical Association, 2017.

References: **1.** Data on File as of July 2017. Alkermes, Inc. **2.** VIVITROL [prescribing information]. Waltham, MA: Alkermes, Inc; 2015. **3.** Drugs administered other than oral method (J0120-J8999). American Academy of Professional Coders website. <http://coder.aapc.com/hcpcs-codes-range/9/270>. Accessed July 13, 2017. **4.** American Medical Association. *2015 Current Procedural Terminology*. Chicago, IL: American Medical Association; 2015. **5.** ICD10Data.com website. Accessed July 13, 2017. **6.** Place of service codes for professional claims. CMS website. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf>. Accessed July 13, 2017. **7.** Ambulatory payment classifications. Find-a-Code website. <http://www.findacode.com/apc/0759-naltrexone-depot-form-apc-code.html>. Accessed July 13, 2017. **8.** List of diagnosis related groups (DRGs), FY2008. CMS website. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareFeeforSvcPartsAB/downloads/DRGdesc08.pdf>. Accessed July 13, 2017.

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].

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

Please see Important Safety Information about VIVITROL on page 2.

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.

Thank you for your immediate attention to this request.

Sincerely,
[Physician Name]
[Physician Practice Name]

PLEASE SEE [IMPORTANT SAFETY INFORMATION](#) ON PAGE 2. PLEASE SEE [PRESCRIBING INFORMATION AND MEDICATION GUIDE](#), OR VISIT [VIVITROL.COM](#). PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.

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 Vivitrol2getherSM on the Portal at www.vivitrol.com or by contacting a Vivitrol2gether 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® (naltrexone for extended-release injectable suspension).

[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].

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

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

Please see additional Important Safety Information about VIVITROL on page 2.

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, please visit VIVITROL.com for a copy of the VIVITROL Prescribing Information and Medication Guide.

Thank you for your immediate attention to this request.
Sincerely,

[Physician Name]
[Physician Practice Name]

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

PLEASE SEE [IMPORTANT SAFETY INFORMATION](#) ON PAGE 2. PLEASE SEE [PRESCRIBING INFORMATION AND MEDICATION GUIDE](#), OR VISIT VIVITROL.COM. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.

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 Vivitrol2getherSM at 1-800-VIVITROL (1-800-848-4876).

Glossary of Terms

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*.

Besse Medical: This specialty distribution option is available to distribute VIVITROL® (naltrexone for extended-release injectable suspension).

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.

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.

*CPT®=Current Procedural Terminology. Copyright of the American Medical Association, 2017.

21 Please see Important Safety Information on back of this guide. Also, please click for Prescribing Information and Medication Guide. Review Medication Guide with your patients.

Vivitrol®
(naltrexone for extended-release
injectable suspension)

IMPORTANT SAFETY INFORMATION

for VIVITROL[®] (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.
- 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 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.
- 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.

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.

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:

- Cases of eosinophilic pneumonia requiring hospitalization have been reported. Warn patients of the risk of eosinophilic pneumonia and to seek medical attention if they develop symptoms of pneumonia.

Hypersensitivity Reactions:

- Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.

Intramuscular Injections:

- As with any IM 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.

ADVERSE REACTIONS

- Serious adverse reactions that may be associated with VIVITROL therapy in clinical use include severe injection site reactions, eosinophilic pneumonia, serious allergic reactions, unintended precipitation of opioid withdrawal, accidental opioid overdose, and depression and suicidality.
- 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), 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 or call 1-800-FDA-1088.

Please see accompanying [Prescribing Information](#) and [Medication Guide](#).



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