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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. 9-11 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® is a registered trademark of the American Medical Association.


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 Touchpoints Support Services, 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

Touchpoints Support Services Can Assist Providers and Patients With:

- Submission of VIVITROL prescriptions to Specialty Pharmacies
- Prior authorization support (Please note: Prior Authorization Form submission may be required)
- Co-pay assistance for eligible patients*
- Reimbursement coverage verification
- Claims review following enrollment through Touchpoints Support Services
- Patient transition services

We recommend that you work directly with Touchpoints Support Services for assistance and to discuss options for acquiring VIVITROL. Reimbursement analysts dedicated to VIVITROL are available to assist your office with patient-specific benefits verification, prior authorization requirements, and pharmacy triage.

*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
Acquiring VIVITROL®

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.
- 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 Touchpoints 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/sha 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.

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

**Option 1**

*Utilize Touchpoints Support Services*

- FULLY complete the Touchpoints Enrollment Form
- Fax ALL of the following documents to Touchpoints Support Services at 1-877-329-8484:
  - Touchpoints Support Services Enrollment Form
  - Photocopy of the front and back of the patient’s insurance card (enlarged to ensure legibility)
  - Copy of VIVITROL Copay Savings Program card for eligible patients who have elected co-pay assistance
  - 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.

**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 Copay Savings Program card for eligible patients who have elected co-pay assistance
  - 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.
Touchpoints Support Services Patient Enrollment Form

The enrollment form represents the initial steps in utilizing Touchpoints Support Services.

Will your office be injecting VIVITROL®?
Please indicate if you require Touchpoints Support Services 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

Enrollment form templates can be accessed at: www.vivitrolsupport.com

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.

Quick Tip
Always submit the Prior Authorization Form to the payer and either to Touchpoints Support Services or the Specialty Pharmacy, whichever applies.

Prior Authorization Form

Certain payers may require prior authorization for VIVITROL 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. Touchpoints Support Services 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.

Be sure to document the medical necessity for prescribing VIVITROL

Ensure the correct ICD-10-CM code is listed (See page 16 for more coding information)

Detailed information about the patient and physician will be required

Check if patient has Alcohol Dependence or Opioid Dependence

Quick Tip

PLEASE SEE IMPORTANT SAFETY INFORMATION ON BACK COVER. PLEASE SEE ACCOMPANYING PRESCRIBING INFORMATION AND MEDICATION GUIDE. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.
Reducing the Financial Barriers to VIVITROL® Therapy

The VIVITROL Co-pay Savings Program

- 91%[1] of insured patients using the Co-pay Savings Program[4] had no out-of-pocket expenses for VIVITROL.

The VIVITROL Co-pay Savings Program Assists With VIVITROL Treatment Costs

Income: There are no income requirements to be eligible for the VIVITROL Co-pay Savings Program.

Co-pays and Deductibles: Covers up to $500/month of co-pay or deductible expenses related to VIVITROL therapy for eligible patients[1] with no duration limits.

Self-pay: Eligible patients without prescription drug coverage and those who choose not to use their prescription drug coverage may utilize the VIVITROL Co-pay Savings Program to receive up to $500 towards the purchase price of VIVITROL.

How the VIVITROL Co-pay Savings Program Works

- Provide the specialty pharmacy with a copy of the patient’s co-pay 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 Touchpoints Support Services at 1-800-VIVITROL (1-800-848-4876).

Quick Tip

Instruct your eligible patients[1] who have elected co-pay assistance to give the VIVITROL Co-pay Card information to the Specialty Pharmacy when they call to collect the co-payment.

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

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[2]; 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]
**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®. 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 (eg, 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 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 Touchpoints 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. Physicians 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.

**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.*
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 reimbursement.

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®, 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 Touchpoints Support Services at 1-800-VIVITROL (1-800-848-4876).

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. 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.

For more information on payer-specific coverage for VIVITROL, contact your payer or Touchpoints Support Services at 1-800-VIVITROL (1-800-848-4876).

Quick Tip
If necessary, as part of discharge planning, contact Touchpoints Support Services at 1-800-VIVITROL (1-800-848-4876) to locate follow-on providers for VIVITROL therapy. Select Option 3 to speak with a Touchpoints Transitions Coordinator.

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®.

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

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

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

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.

Field 4: HCPCS Code
Enter the appropriate HCPCS code (J2315) and CPT® code (96372).

Field 64: Service Units
Enter the appropriate number of units.
Note: Important to submit for 380 units (1 mg = 1 unit).

Please see important safety information on back cover. Please see accompanying prescribing information and medication guide. Please review medication guide with 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® Coding

<table>
<thead>
<tr>
<th>NDC for VIVITROL®</th>
<th>Naltrexone for extended-release injectable suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>65757-0300-01</td>
<td></td>
</tr>
<tr>
<td>HCPCS</td>
<td>J2315</td>
</tr>
</tbody>
</table>

### Professional Services

<table>
<thead>
<tr>
<th>CPT/ICD-10-CM Procedure</th>
<th>Procedure Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify material injected); subcutaneous or intramuscular</td>
</tr>
</tbody>
</table>

### Professional Claims

<table>
<thead>
<tr>
<th>Place of Service Codes</th>
<th>Place of Service Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Office</td>
</tr>
<tr>
<td>21</td>
<td>Inpatient hospital</td>
</tr>
<tr>
<td>22</td>
<td>Outpatient hospital</td>
</tr>
<tr>
<td>55</td>
<td>Residential substance abuse treatment facility</td>
</tr>
</tbody>
</table>

### Ambulatory Payment Classification

<table>
<thead>
<tr>
<th>APC for VIVITROL®</th>
<th>Place of Service Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>0759</td>
<td>Naltrexone, depot form</td>
</tr>
</tbody>
</table>

### Diagnosis-Related Groups

<table>
<thead>
<tr>
<th>Inpatient/Outpatient Groups</th>
<th>Diagnosis-related Group Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>894</td>
<td>Alcohol/drug abuse or dependence, left AMA</td>
</tr>
<tr>
<td>895</td>
<td>Alcohol/drug abuse or dependence w rehabilitation therapy w MCC</td>
</tr>
<tr>
<td>896</td>
<td>Alcohol/drug abuse or dependence w/ rehabilitation therapy w/ MCC</td>
</tr>
<tr>
<td>897</td>
<td>Alcohol/drug abuse and dependence, left AMA</td>
</tr>
<tr>
<td></td>
<td>Alcohol/drug abuse or dependence w rehabilitation therapy w MCC</td>
</tr>
<tr>
<td></td>
<td>Alcohol/drug abuse or dependence w/ rehabilitation therapy w/ MCC</td>
</tr>
</tbody>
</table>

Additional coding may be found at http://www.cms.gov.

### ICD-10-CM Diagnosis Codes

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

#### Alcohol Dependence

- F10.20 Alcohol dependence, uncomplicated
- F10.21 Alcohol dependence, in remission
- F10.22 Alcohol dependence with intoxication
- F10.23 Alcohol dependence with withdrawal
- F10.24 Alcohol dependence with alcohol-induced mood disorder
- F10.25 Alcohol dependence with alcohol-induced psychotic disorder
- F10.26 Alcohol dependence with alcohol-induced persisting amnestic disorder
- F10.27 Alcohol dependence with alcohol-induced persisting anorectic disorder
- F10.28 Alcohol dependence with alcohol-induced dystonic disorder
- F10.29 Alcohol dependence with unspecified alcohol-induced disorder

#### Opioid Dependence

- F11.20 Opioid dependence, uncomplicated
- F11.21 Opioid dependence, in remission
- F11.22 Opioid dependence with intoxication
- F11.23 Opioid dependence with withdrawal
- F11.24 Opioid dependence with opioid-induced mood disorder
- F11.25 Opioid dependence with opioid-induced psychotic disorder
- F11.26 Opioid dependence with opioid-induced persisting anorectic disorder
- F11.27 Opioid dependence with opioid-induced persisting amnestic disorder
- F11.28 Opioid dependence with opioid-induced dystonic disorder
- F11.29 Opioid dependence with unspecified opioid-induced disorder

### Appendix A: Alternate Options to Acquire VIVITROL

**Specialty Distributor for Buy-and-Bill Coverage**

You may decide to purchase VIVITROL 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) • 1-800-543-8955 (fax) • Besse.com

**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 Company, McKesson or H.D. Smith.

**References:**

2. VIVITROL [prescribing information]. Waltham, MA: Alkermes, Inc; 2015.
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®. 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 (eg, medical records, peer-reviewed literature, etc).

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.

Quick Tip

A sample of the Letter of Medical Necessity is available through Touchpoints Support Services on the Portal at www.vivitrol.com or by contacting a Touchpoints Support Services Representative at 1-800-VIVITROL (1-800-848-4876).

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.
Appendix C: Tips for Submitting Claims

The following tips will assist you with verifying benefits, navigating prior authorization, and successfully submitting claims for VIVITROL®:

- 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

Tips for Resubmitting or Appealing Denied Claims

The most 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 Touchpoints Support Services 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 pricing compendia, such as First Databank or Red Book.

Besse Medical: This specialty distribution option is available to distribute VIVITROL.

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


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 health care.

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.
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. 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, poly(ethylene glycol) 2000 (PEG), carboxymethylcellulose, or any other components of the diluent

WARNINGS/PRECAUTIONS
Vulnerability to Opioid Overdose
• Because VIVITROL blocks the effects of exogenous opioids for approximately 28 days after administration, patients are likely to have a reduced tolerance to opioids after opioid detoxification. As the blockade dissipates, 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.
• 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
• Withdrawal precipitated by administration of VIVITROL may be severe.
• Some cases of withdrawal symptoms have been severe enough to require hospitalization and management in the ICU.

Precipitation of Opioid Withdrawal (cont’d)
• To prevent precipitated withdrawal, patients, including those being treated for alcohol dependence:
  – Should be opioid-free (including tramadol) for a minimum of 7–10 days before starting VIVITROL.
  – Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as two weeks.
• 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 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 also include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

PLEASE SEE ACCOMPANYING PRESCRIBING INFORMATION AND MEDICATION GUIDE.