This Billing and Coding Resource is for illustrative purposes only and is not intended to provide reimbursement or legal advice. All billing codes and coding information included in this document are gathered from third party sources, provided for informational purposes only, and represent no statement, promise, or guarantee by Alkermes, Inc. that coverage will be available, that the codes or forms will be appropriate, or that reimbursement will be made. Payer coverage and reimbursement requirements vary by plan, patient, and setting of care, and are complex and subject to change. Providers must understand and comply with each payer’s rules and should always consult with the applicable local payer regarding coverage and coding requirements prior to submitting claims. It is the provider’s sole responsibility to determine medical necessity and to in turn identify which codes to report and to submit accurate claims. Under no circumstances shall Alkermes, Inc., or its employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages that may arise from or be incurred in connection with this information or any use thereof.
Vivitrol2gether is a customized patient support services program to help you and your patients in their recovery journey throughout product consideration, fulfillment, and transition of care.

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

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

VIVITROL® (naltrexone for extended-release injectable suspension) is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration. VIVITROL is also indicated for the prevention of relapse to opioid dependence, following opioid detoxification. Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support. Opioid-dependent patients, including those being treated for alcohol dependence, must be opioid-free at the time of initial VIVITROL administration.

Overview

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

- Coverage for VIVITROL
- Utilization requirements such as prior authorization
- General coding information
- Medical versus pharmacy benefit
- Utilization of a Specialty Pharmacy
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 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. Vivitrol2gether℠ 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.

Please see Important Safety Information beginning on page 19.

Also, please click for Prescribing Information and Medication Guide. Review Medication Guide with your patients.
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 Vivitrol2gether℠ 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.

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.
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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 Vivitrol2gether℠ at 1-800-VIVITROL (1-800-848-4876).

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

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

Please see Important Safety Information beginning on page 19.
Also, please click for Prescribing Information and Medication Guide.
Review Medication Guide with your patients.
Coverage and Reimbursement
Residential Substance Abuse Facility

Commercial Payer

Reimbursement for VIVITROL and the associated administration will vary, based on the contract established between the Residential Substance Abuse Facility and health plan. 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 Vivitrol2gether℠ at 1-800-VIVITROL (1-800-848-4876) or contact the plan directly to identify reimbursement for administration of VIVITROL.

Quick Tip

Reimbursement varies widely by payment type. Providers are strongly encouraged to contact their payer for more information about reimbursement in this setting of care.
Sample CMS-1500 Claim Form

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

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

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

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.

Please see Important Safety Information beginning on page 19. 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).

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

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

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.

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

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Coding at a Glance

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Product, Administration, and Related Codes

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

<table>
<thead>
<tr>
<th>NDC for VIVITROL®</th>
<th>NDC for VIVITROL® 65757-0300-01</th>
<th>Naltrexone for extended-release injectable suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td>J2315</td>
<td>Injection, naltrexone, depot form, 1 mg</td>
</tr>
<tr>
<td>CPT</td>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify material injected); subcutaneous or intramuscular</td>
</tr>
<tr>
<td>Procedure ICD-10-CM</td>
<td>3E023GC</td>
<td>Introduction of other therapeutic substance into muscle, percutaneous approach</td>
</tr>
<tr>
<td>Place of Service Codes</td>
<td>11, 21, 22, 55</td>
<td>Office, Inpatient hospital, Outpatient hospital, Residential substance abuse treatment facility</td>
</tr>
<tr>
<td>APC for VIVITROL®</td>
<td>0759</td>
<td>Naltrexone, depot form</td>
</tr>
<tr>
<td>Diagnosis-Related Groups</td>
<td>894, 895, 896, 897</td>
<td>Alcohol/drug abuse or dependence, left AMA, Alcohol/drug abuse or dependence with rehabilitation therapy, Alcohol/drug abuse or dependence without rehabilitation therapy with MCC, Alcohol/drug abuse or dependence without rehabilitation therapy without MCC</td>
</tr>
</tbody>
</table>

Abbreviations: AMA, against medical advice; MCC; major complication or comorbidity.
Additional coding may be found at www.cms.gov.
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Please see Important Safety Information beginning on page 19. Also, please click for Prescribing Information and Medication Guide. Review Medication Guide with your patients.
## Coding at a Glance

### ICD-10-CM Diagnosis Codes

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

<table>
<thead>
<tr>
<th>Patient Diagnosis</th>
<th>ICD-10-CM Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alcohol Dependence</strong></td>
<td></td>
</tr>
<tr>
<td>F10.20</td>
<td>Alcohol dependence, uncomplicated</td>
</tr>
<tr>
<td>F10.21</td>
<td>Alcohol dependence, in remission</td>
</tr>
<tr>
<td>F10.22</td>
<td>Alcohol dependence with intoxication</td>
</tr>
<tr>
<td>F10.23</td>
<td>Alcohol dependence with withdrawal</td>
</tr>
<tr>
<td>F10.24</td>
<td>Alcohol dependence with alcohol-induced mood disorder</td>
</tr>
<tr>
<td>F10.25</td>
<td>Alcohol dependence with alcohol-induced psychotic disorder</td>
</tr>
<tr>
<td>F10.26</td>
<td>Alcohol dependence with alcohol-induced persisting amnestic disorder</td>
</tr>
<tr>
<td>F10.27</td>
<td>Alcohol dependence with alcohol-induced persisting dementia</td>
</tr>
<tr>
<td>F10.28</td>
<td>Alcohol dependence with other alcohol-induced disorders</td>
</tr>
<tr>
<td>F10.29</td>
<td>Alcohol dependence with unspecified alcohol-induced disorder</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Opioid Dependence</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>F11.20</td>
<td>Opioid dependence, uncomplicated</td>
</tr>
<tr>
<td>F11.21</td>
<td>Opioid dependence, in remission</td>
</tr>
<tr>
<td>F11.22</td>
<td>Opioid dependence with intoxication</td>
</tr>
<tr>
<td>F11.23</td>
<td>Opioid dependence with withdrawal</td>
</tr>
<tr>
<td>F11.24</td>
<td>Opioid dependence with opioid-induced mood disorder</td>
</tr>
<tr>
<td>F11.25</td>
<td>Opioid dependence with opioid-induced psychotic disorder</td>
</tr>
<tr>
<td>F11.28</td>
<td>Opioid dependence with other opioid-induced disorder</td>
</tr>
<tr>
<td>F11.29</td>
<td>Opioid dependence with unspecified opioid-induced disorder</td>
</tr>
</tbody>
</table>
Coding at a Glance
Other Services

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

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

<table>
<thead>
<tr>
<th>Alcohol and Drug Abuse Treatment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>H0001</td>
<td>Alcohol and/or drug assessment</td>
</tr>
<tr>
<td>H0012-H0015</td>
<td>Alcohol and/or drug services; detoxification</td>
</tr>
<tr>
<td>GO463</td>
<td>Hospital outpatient clinic visit for assessment and management of a patient</td>
</tr>
<tr>
<td>S9475</td>
<td>Ambulatory setting substance abuse treatment or detoxification services, per diem</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation and Management</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>99201-99205</td>
<td>Office or other outpatient services; new patient</td>
</tr>
<tr>
<td>99211-99215</td>
<td>Office or other outpatient services; established patient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pathology and Laboratory</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>H0003</td>
<td>Alcohol and/or drug screening; laboratory analysis of specimens for presence of alcohol and/or drugs</td>
</tr>
<tr>
<td>80354</td>
<td>Fentanyl</td>
</tr>
<tr>
<td>80356</td>
<td>Heroin metabolite</td>
</tr>
<tr>
<td>80361-80364</td>
<td>Opiates, opioids and opiate analogs</td>
</tr>
</tbody>
</table>
Coding at a Glance
Other Services (cont’d)\textsuperscript{8,9}

<table>
<thead>
<tr>
<th>Behavioral Health/Psychosocial</th>
</tr>
</thead>
<tbody>
<tr>
<td>H0005</td>
</tr>
<tr>
<td>Alcohol and/or drug services; group counseling by a clinician</td>
</tr>
<tr>
<td>H0006</td>
</tr>
<tr>
<td>Alcohol and/or drug services; case management</td>
</tr>
<tr>
<td>H2017-H2018</td>
</tr>
<tr>
<td>Psychosocial rehabilitation services</td>
</tr>
<tr>
<td>GO396-GO397</td>
</tr>
<tr>
<td>Alcohol and/or substance (other than tobacco) abuse structured assessment (eg, AUDIT, DAST), and intervention</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health and Behavior Assessment/Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>96150-96155</td>
</tr>
<tr>
<td>Health and behavior assessment, re-assessment, or intervention</td>
</tr>
</tbody>
</table>

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

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

For assistance in acquiring the appropriate Prior Authorization Form, please contact your payer. Vivitrol2gether℠ 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.

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


Please see Important Safety Information beginning on page 19. Also, please click for Prescribing Information and Medication Guide. Review Medication Guide with your patients.
Appendix B: Sample Letters

Sample Letter of Medical Necessity

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

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

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

Patient History, Diagnosis, and Treatment

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

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

Thank you for your immediate attention to this request.

Sincerely,
[Physician Name]
[Practice Name]

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 Vivitrol2gether℠ on the Portal at www.vivitrol.com or by contacting a Vivitrol2gether Representative at 1-800-VIVITROL (1-800-848-4876).

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

<table>
<thead>
<tr>
<th>[Date]</th>
<th>[Contact]</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Title]</td>
<td>[Name of Health Insurance Company]</td>
</tr>
<tr>
<td>[Address]</td>
<td></td>
</tr>
<tr>
<td>[City, State, Zip Code]</td>
<td></td>
</tr>
<tr>
<td>Insured: [Patient Name]</td>
<td></td>
</tr>
<tr>
<td>Policy Number: [Number]</td>
<td></td>
</tr>
<tr>
<td>Group Number: [Number]</td>
<td></td>
</tr>
<tr>
<td>Diagnosis: [Diagnosis and ICD-10 code]</td>
<td></td>
</tr>
</tbody>
</table>

Dear [Contact Name]:

This letter serves as a request for reconsideration of reimbursement of costs incurred for VIVITROL® (naltrexone for extended release injectable suspension) treatment administered for [Patient Name] on [date of service]. [Patient Name] has been under my treatment for [his/her] diagnosis of [diagnosis].

You have indicated VIVITROL is not covered by [Insurance Name] for this patient because [reason for denial].

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

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

Thank you for your immediate attention to this request.

Sincerely,

[Physician Name]  
[Physician Practice Name]

Attachments [original claim form, denial/EOB, additional supporting documents]
Appendix C: Tips for Submitting Claims

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

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

Common Reasons for Denials of Claims

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

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

Different payers will often have different requirements for appeals. It is important to determine the process on a patient-specific basis. For more information, please contact Vivitrol2gether℠ 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 sold by the manufacturer in that quarter.

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

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

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

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

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

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

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

**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.

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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

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.
IMPORTANT SAFETY INFORMATION
for VIVITROL® (naltrexone for extended-release injectable suspension)

Precipitation of Opioid Withdrawal (cont’d):
• 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 intramuscular injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder.

Alcohol Withdrawal:
• Use of VIVITROL does not eliminate nor diminish alcohol withdrawal symptoms.

ADVERSE REACTIONS
• The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence (ie, those occurring in ≥5% and at least twice as frequently with VIVITROL than placebo) include nausea, vomiting, injection site reactions (including induration, pruritus, nodules, and swelling), arthralgia, arthritis, or joint stiffness, muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders.
• The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients (ie, those occurring in ≥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 click for accompanying Prescribing Information and Medication Guide.

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