GUIDE TO FULFILLING VIVITROL®
PRESCRIPTIONS AND PATIENT SUPPORT SERVICES

Please see Important Safety Information on pages 6 and 7.
Please see full Prescribing Information.

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

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

You have the option to use Vivitrol2gether® dedicated case manager services

Vivitrol2gether Patient Support Services is designed to help with:

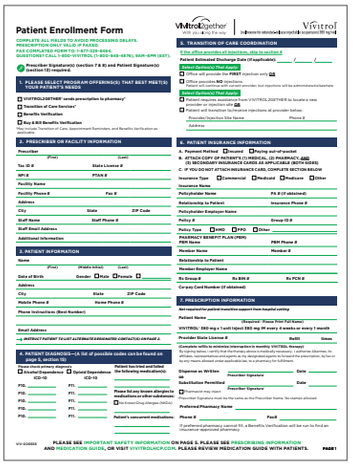
- Reimbursement coverage verification
- Submission of VIVITROL prescriptions to a pharmacy (specialty or other)
- Submission of VIVITROL Co-pay Savings Program application for eligible patients*
- Providing patient support services throughout fulfillment, transition of care, and during treatment with VIVITROL

Vivitrol2gether®
With you along the way

To help your patients get started on medication with Vivitrol2gether, your office can submit required documents to Vivitrol2gether Patient Support Services via fax at 1-877-329-8484 or electronically at iAssist.com

Be sure to include the following documents when submitting via fax or electronically:

- Vivitrol2gether enrollment form
- Clear image/photo of patient's insurance card (front and back)


Patient Enrollment Form

Sample Vivitrol2gether Enrollment Form

Our team is ready to support you and your patients. Call 1-800-VIVITROL (1-800-848-4876) Monday-Friday 9AM-8PM ET and visit vivitrolhcp.com/support to access helpful resources.

CRITICAL!

- Fax the PA form (if required) and an enlarged photocopy of patient's pharmacy and health insurance cards to the health insurer's toll-free fax number on the PA form. Pharmacies and health insurers typically prefer that these come directly from your office
- Follow up within 24 hours to ensure the prescription is being processed. Remember to identify date of scheduled injection. If the pharmacy cannot process the VIVITROL prescription, consider enrolling your patient into Vivitrol2gether to receive assistance with pharmacy routing

***Terms and Conditions**

Eligible patients who have commercial insurance or no insurance may pay as little as $0 per prescription of VIVITROL. Maximum savings per prescription is $500 up to 12 prescriptions per calendar year, with maximum savings up to $6,000 per calendar year. Patients' out-of-pocket expenses may vary. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Additional terms and conditions apply. **Please see www.vivitrolcopayterms.com for full VIVITROL Co-pay Program Terms and Conditions.**

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Work directly with a specialty pharmacy (SP)

1 FIRST VIVITROL® PRESCRIPTION	2 SP VERIFICATION
TO DO	
▪ Determine available SP options with your fulfillment representative ▪ Fax identified medical and pharmacy insurance cards and enrollment form to the SP ▪ Give the patient a copy of the enrollment form and keep one for their chart ▪ Work with the SP to complete the PA if the plan requires one	▪ SP verifies benefits; confirms prescription* ▪ Confirm status of PA if submitted, or start PA process with provider if not yet submitted ▪ SP applies co-pay savings for eligible patients
CHECKLIST	
✓ Photocopies of the front and back of the medical and pharmacy insurance cards are enlarged to ensure legibility ✓ Enrollment form is legible ✓ All patient and provider signatures are provided ✓ Injection provider section is complete ✓ Contact and alternate contact information is provided	✓ To help avoid delays, provider must return SP calls if additional information is required ✓ If eligible, be sure co-pay savings is applied
TIPS	
▪ Be sure all forms are complete and legible. Enlarge photocopies to ensure readability ▪ Be sure health plan and SP have a copy of completed PA form (if required)	▪ Follow up regularly with SP via phone, email, or fax ▪ Provide contact information to the SP, including primary/secondary phone and email addresses ▪ The patient should have a copy of their co-pay savings card so they can remind the SP they are eligible for the co-pay savings program ▪ Remind the patient that the SP will contact them

*If SP is not contracted to fill prescriptions for a specific insurer, the prescription is transferred to another pharmacy.

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Work directly with a specialty pharmacy (SP)

3 SHIPMENT OF VIVITROL®

TO DO

- SP must contact patient (or financially responsible designee) to authorize billing and shipment
- Instruct patient to take or return SP call in order to authorize shipment
- Provide patient with SP name and phone numbers
- Once authorized, SP contacts the office to schedule shipment

CHECKLIST

- ✓ Patient has authorized shipment or been provided with the SP number to call
- ✓ Alternate patient contacts provided
- ✓ Shipment is coordinated with the timing of the injection

TIPS

- Educate designees, if used, on VIVITROL
- Communicate scheduled VIVITROL injection date for each patient

4 DELIVERY AND INJECTION OF VIVITROL

TO DO

- Confirm receipt of VIVITROL
- Patient receives injection of VIVITROL from HCP
- Schedule next injection
- Notify SP of next VIVITROL injection date
- Make sure the patient knows the next injection date and the SP name/phone number to authorize shipment

CHECKLIST

- ✓ Create a discharge plan for the patient as needed, including follow-on injection and care. For assistance, call 1-800-VIVITROL or consult vivitrolhcp.com/support to locate an injection provider
- ✓ Communicate to patient that the SP will contact them every month to authorize shipment

TIPS

- Follow up with the patient to ensure the documentation is signed and returned
- Confirm patient contact information and notify SP of any changes

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Purchase directly through buy and bill programs

1 **Contact payer to confirm HCPCS code J2315 is covered by patient's policy**

2 **Register with IQVIA (formerly Opus Health). Call 1-877-838-3836 for assistance. You'll receive a practice-populated form for enrollment.** After receiving the EOB, send the form and co-pay card to IQVIA at https://vivitrolbuyandbillcopay.opushealth.com

3 **Ask a VIVITROL® representative for information on how to open an account with an Alkermes distribution partner**

4 **Order VIVITROL and schedule the injection appointment**

5 **Fill out and send the appropriate form, as shown below:**

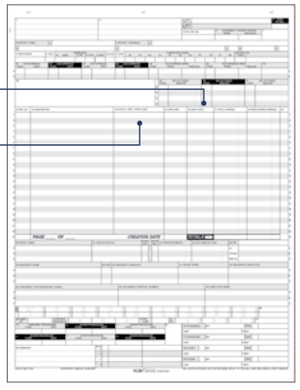
Sample CMS-1500 Claim Form

Specify **380 mg**

Enter HCPCS code **J2315**

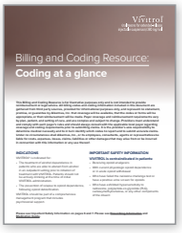
Enter CPT®* code **96372**

Sample CMS-1450 (UB-04) Claim Form



These documents are provided for your guidance only. Please contact the payer or Vivitrol2gether® for questions about coding and claim information.

For more information, download the Billing & Coding Resource at vivitrolhcp.com/support



*CPT Copyright 2024 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

CMS=Centers for Medicare & Medicaid Services; CPT®=Current Procedural Terminology; EOB=explanation of benefits; HCPCS=Healthcare Common Procedure Coding System.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

VIVITROL® is indicated for:

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

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

IMPORTANT SAFETY INFORMATION

VIVITROL is contraindicated in patients:

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

Vulnerability to Opioid Overdose

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

Injection Site Reactions

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

Precipitation of Opioid Withdrawal

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

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IMPORTANT SAFETY INFORMATION (cont'd)

Precipitation of Opioid Withdrawal (cont'd)

- 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 2 weeks.

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

Hepatotoxicity

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

Depression and Suicidality

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

When Reversal of VIVITROL Blockade Is Required for Pain Management

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

Eosinophilic Pneumonia

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

Hypersensitivity Reactions including Anaphylaxis

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

Intramuscular Injections

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

Alcohol Withdrawal

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

Interference With Laboratory Tests

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

Adverse Reactions

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

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KEY CONSIDERATIONS
WHEN ORDERING VIVITROL® (naltrexone for extended-release injectable suspension)

It is important that patients and caregivers understand and plan for VIVITROL treatment.

Make sure that:

- ☐ If VIVITROL is determined to be appropriate treatment, planning starts as soon as possible
- ☐ All forms are completed and front/back photocopies of insurance cards are legible
- ☐ All patient and provider signatures are provided
- ☐ The health plan and SP have copies of the completed PA form, if required
- ☐ The SP has all relevant contact information, including the patient's contact/alternate contact information
- ☐ The patient has been given the SP contact information and instructed **to take or return the SP call** in order to authorize shipment of VIVITROL
- ☐ The next VIVITROL injection date is scheduled with the patient and is communicated to the SP
- ☐ For buy and bill, the payer-confirmed code J2315 is covered by patient's policy and CPT® code 96372 and 380 mg are entered correctly on the form

Suggestions to help improve fill time

- Learn which pharmacies work with your patients' health plans
- Follow up regularly with SP contact person via phone, email, or fax
- Communicate scheduled VIVITROL injection date for each patient

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