



TITAN ACCESS PROGRAM FOR PROBUPHINE FAQ'S

These FAQs contain general coding and billing information compiled from public sources and is provided to help you understand the availability of reimbursement related to PROBUPHINE[®] (buprenorphine) implant. These FAQs are provided as general information only and are not intended as coverage or coding advice. Titan cannot and will not provide specific reimbursement rates, and does not guarantee any level of reimbursement. Titan makes no other representations or warranties regarding the selection of codes for procedures or compliance of the information in these FAQs with any other billing protocols or requirements.

Similarly, all CPT, HCPCS and ICD-10-CM codes are supplied for information purposes only and represent no statement, promise or guarantee by Titan that these codes will be appropriate or that reimbursement will be made. As with all claims, individual hospitals and physicians are responsible for exercising independent clinical judgement in selecting the codes that most accurately reflect a patient's condition and the procedures performed. Laws, regulations and policies concerning coding and payment are complex and subject to change. Physicians and hospitals should refer to current, complete, and authoritative publications, such as AMA CPT[®] lists, Medicare transmittals, and third-party payor policies as the basis for selecting codes that describe care rendered to an individual patient, and may wish to contact individual Medicare contractors or other third-party insurers as needed.

1. How can physicians obtain PROBUPHINE for administration to patients?

PROBUPHINE is not available through the local retail pharmacy because PROBUPHINE must be administered directly by a clinician who has been REMS trained and certified in the insertion and removal procedure specific to PROBUPHINE.

The physician has a choice in how he or she would like to obtain PROBUPHINE. The physician can purchase the product directly from Titan through the Titan Access Program and subsequently bill the patient or their insurance company, Medicare, or Medicaid after the patient is treated with PROBUPHINE. This is known as Buy and Bill. Another option is for the physician to write a prescription and to have the product shipped directly to their office by our Pharmacies at no cost to the physician.

2. How does the Pharmacy Program work?

The physician's office submits a completed Patient enrollment form to the Titan Access Program. The Titan Access Program will certify the prescriber is REMS-certified and that the address listed is the "DEA Ship To" address. The Titan Access Program will then refer the valid prescription to our REMS Certified Pharmacies, who will review the form to obtain all required information. The Pharmacy bills the insurance company for payment of the product only. You must purchase the insertion and extraction kits on your own at a nominal fee.

For additional questions, please call the Titan Access Program directly at (844) 859-6341 or visit www.titanaccessprogram.com.

3. How does the Buy & Bill program work?

Titan offers credit terms up to 60 days for Buy & Bill of PROBUPHINE. Under a restricted distribution model, PROBUPHINE is made available to REMS certified prescribers. PROBUPHINE is available through a physician purchasing program system, which requires the prescribing physician to *purchase PROBUPHINE, take ownership and then collect reimbursement* through insurance companies or the patient in a self-pay scenario. As a prescriber, you would order the product from the Titan Access Program by checking the Buy & Bill box on the Patient Enrollment Form, by submitting a Physician Order Form or by calling the Titan Access Program directly at (844) 859-6341.

The Titan Access Program is available to provide reimbursement support information, including patient benefit verification and prior authorization, prior to ordering PROBUPHINE.

It is *recommended that your patients enroll in* the Titan Access Program to verify benefits and obtain information on prior authorization requirements prior to implantation or extraction of PROBUPHINE.

4. What are the benefits of the Titan Access Program HUB?

By submitting a Patient Enrollment Form to the HUB, the Titan Access Program may complete a benefit investigation and assist physicians with the prior authorization process prior to scheduling the patient for the implant to determine benefit eligibility and payer medication and procedural coverage.

It is *recommended that your patients enroll in* the Titan Access Program to verify benefits and obtain information on prior authorization requirements prior to implantation or extraction of PROBUPHINE.

5. Will PROBUPHINE be covered by private or employer-based insurance?

Major payers such as Anthem BCBS, Cigna, UnitedHealthcare, Aetna, CareSource, Highmark BCBS, Wellcare Health Plan and several other large regional payers have been contacted on behalf of PROBUPHINE. Approximately 90%+ is covered on the medical benefit, however coverage and payment of benefits are subject to all terms, conditions, limitations, and exclusions of the member's contract at time of service

Many health plans have either approved prior authorizations or have confirmed coverage and reimbursement. In addition, the Titan Access Program can provide information on payer coverage for PROBUPHINE, verify patients benefits and provide information to your office regarding prior authorizations and/or medical pre- determinations.

6. Will PROBUPHINE (buprenorphine) be covered by Medicaid and/or Medicare?

Titan Pharmaceuticals has signed a CMS National Rebate Agreement, under which state FFS Medicaid programs generally will be required to make coverage available if medically necessary. Currently Titan is working with the Medicare Administrative Contractors with the goal of developing appropriate Medical Coverage Policies under Medicare Part B. Medicare does cover all medically necessary medications under Part B. The physician or clinic is required to purchase the medication and then bill Medicare for both the drug and the services provided using the CMS 1500 claim form.

Payer coverage policies can vary from plan to plan locally. Titan will work with all major payers locally

representing Managed Medicaid to support the development of medical coverage policies for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine- containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet equivalent or generic equivalent).

7. Is a Prior Authorization required from payers before scheduling a patient for a PROBUPHINE implant?

Insurers require prior authorizations on most outpatient procedures and drugs to determine coverage and reimbursement. Titan has partnered with the Titan Access Program to assist patients with verification of insurance coverage, as well as to provide information about the prior authorization process or medical pre-determination.

8. Are there copay programs for patients?

Titan offers eligible commercial patients co-pay and co-insurance support to assist with out-of-pocket costs associated with PROBUPHINE.

Patients with Commercial Insurance may receive up to \$1500 per dispense (6-month implant) for their copay based on documented patient health insurance Out Of Pocket (OOP), related to Probuphine only. Patients with Commercial Insurance that also meet the FPL requirement (<400% FPL) may receive up to \$2500 per dispense (6-month implant) for their copay based on documented patient health insurance Out Of Pocket (OOP), related to Probuphine only.

Patients enrolled in insurance plans paid in part or full by any state or federally funded programs, including Medicare (also including Medicare Advantage or Part D plans), VA, DOD or TriCare are not eligible for this program.

9. What if I can't afford PROBUPHINE? Or what if my insurance company doesn't cover it?

Titan offers a Patient Assistance Program that provides free PROBUPHINE for financially disadvantaged patients who meet eligibility requirements. Contact the Titan Access Program for more information.

10. Does PROBUPHINE have a permanent J code?

PROBUPHINE has a permanent J code of J0570. Please remember that Reimbursement levels are at the discretion of the Payer and not Titan Pharmaceuticals. Also please keep in mind that payer processing and payment timing of claims varies by health plan and, as always, the billing physician is responsible for determining the appropriate code for each claim.

11. What procedure coding information is available?

The codes listed below are available as of January 2018 and may be appropriate for use in claims related to use of PROBUPHINE. This coding information is subject to change on an annual basis and it is the responsibility of the physician submitting the claims to ensure that the material is still accurate and applicable to the claim at the time it is filed.

Please also note that the choice of codes used is the sole responsibility and judgment of the prescribing physician.

- HCPCS code G0516: insertion, non- biodegradable drug delivery implants, 4 or more
- HCPCS code G0517: removal, non- biodegradable drug delivery implants, 4 or more
- HCPCS code G0518: removal with reinsertion, non-biodegradable drug delivery implants, 4 or more
- *CPT codes 11981, 11982, 11983 - insertion, removal, and removal followed by insertion of drug implant
- *CPT code 17999 - unlisted procedure, skin, mucous membrane and subcutaneous. This code could be used for both the implantation and extraction of the PROBUPHINE implants. In addition, health plans may use of these codes along with an AMA modifier.

The 2018 National Medicare Physician Fee Schedule average allowables for a single non-biodegradable implant are as follows:

- G0516 – Insert drug implant device, >4 \$239.40
- G0517 – Remove drug implant device \$263.16
- G0518 – Remove/insert drug implant \$454.31

The 2018 Medicare Physician Fee Schedule can be found at the following link:
<https://www.cms.gov/apps/physician-fee-schedule/license-agreement.aspx>

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12. How does a Federally Qualified Health Center (“FQHC”) bill for PROBUPHINE?

FQHC’s typically have a pharmacy on-site or a community pharmacy that can service PHS or 340B pricing entities such as FQHC’s. As for billing the procedure, FQHC’s have rate structures or episodes of care fees established with the payers such as Medicaid or Medicare. Please note that drug payment rates can change quarterly.

13. In the summer, we sometimes work half days. What if it's delivered and we're gone?

Please coordinate delivery of PROBUPHINE with the Titan Access Program or one of the REMS Certified Pharmacies and be sure to communicate hours of operation. The delivery will require a signature to receive, therefore if the office is closed FedEx will retain the product until the next business day.

14. Can I order only 3 implants instead of 4?

No, the FDA-Approved PROBUPHINE kit only comes as a four-implant delivery system. In addition, the approved dosage for administration is a single dose (four implants).

15. I am concerned patients will be unable to afford PROBUPHINE?

The majority of insurance companies are currently covering PROBUPHINE and we have a patient co-pay program set up through the Titan Access Program that will assist eligible commercially-insured patients with their out of pocket costs for PROBUPHINE.

16. Does Titan offer a payment plan?

Titan offers 60-day payment terms under the Buy & Bill system, meaning no payment would be due until 60 days post product delivery. Typically, most claims are paid within 45-60 days once filed. Titan does not offer a payment plan.

17. If I ordered PROBUPHINE and the patient changes their mind, can it be returned?

Yes, provided that the implant and kits have not been opened. The kit must be returned in 30 days if it is not used.

18. How does a cash-only physician process a patient through the Titan Access Program?

The patient must complete the Patient Enrollment Form and submit it to the Titan Access Program to verify benefits for PROBUPHINE and the procedures.

19. Do I pay full price if I just need one replacement rod?

Contact the Titan Access Program if a rod is required for replacement due to contamination or damage. Generally, the rod will be replaced at no charge through the Titan Access Program.

20. Do I get reimbursed for implant and removal procedural kits?

The implant and removal procedural kits are considered a practice expense as part of the procedure and is typically included in the CPT procedure code reimbursement. Reimbursement will vary from payer to payer so it is important to reach out to your payer provider relations representative to determine reimbursement for services.

21. When the Patient Enrollment Form is sent in to the HUB does the office also send the Physician Order Form?

It is not necessary to send in both a Patient Enrollment Form and a physician order form. The product order (optional insertion and removal kits) is facilitated through either the Buy & Bill Patient Enrollment Form or the Specialty Provider Patient Enrollment Form.

22. Does the Titan Access Program HUB file with the insurance company for reimbursement or does the doctor's office file?

The Titan Access Program can assist with benefit investigation and provide information regarding prior authorization requirements; only the physician office can file a claim for actual reimbursement with insurance companies.

23. How can a HCP working within the Veterans Administration order PROBUPHINE, since they are required to order all prescriptions through the VA pharmacy?

Currently Titan has an agreement with the VA National PBM in place. A coverage policy has not been established for PROBUPHINE so the physician would need to speak with the medical center pharmacy. The individual VA Medical Center Pharmacy Department can either call the VA PBM at Hines, IL or go to the Titan Access Programs to secure the VA Approved Order Form.

24. If the kit and PROBUPHINE are going to the prescriber who is not doing the insertion, how will the implanter get the kit at his/her office?

The order or the prescription for PROBUPHINE must come through a REMS-certified prescriber. The

REMS-certified prescriber can either perform the insertion in his/her office if they have been certified to perform the procedure or refer to a REMS-certified implanter for insertion in their office, if the prescriber is certified as prescriber only. An alternative is for the physician to designate the implanter's office as one of their secondary DEA registered locations. The Prescriber Only can then oversee the procedure in the secondary DEA address/Implanters office.

25. Will there ever be a standardized reimbursement rate for PROBUPHINE for individual insurance companies?

No; all insurance companies set their various fee schedules independently. The only standardized reimbursement is through the Medicare Physician Fee Schedule established annually.

26. How are physicians reimbursed by the insurer?

Upon implanting PROBUPHINE, the physician must file a claim with the patient's insurance company or can bill the patient directly and ask the patient to file their claim with the insurer in order to be reimbursed. The Titan Access Program Hub will investigate benefits and apply for prior authorization for the patients enrolled in the program. However, the final step of obtaining reimbursement rests with the physician filing a claim for both the procedure and the medication.

It is important for the patient and physician to determine in advance if the insurer allows for the patient to file a claim directly rather than the physician's office. In some states and/or with some payers, this is not permitted.

27. How do Physicians find information on out of network HCP reimbursement?

An out-of-network physician may still enroll patients in the Titan Access Program to verify benefits and secure a PA or medical pre-cert. The physician would contact the payer provider relations representative to confirm reimbursement for fees and services. If the insurer does not credential the physician or the physician elects not to join as a network provider, the physician may bill the patient directly and the patient would submit the claim based on the pre-authorization.

28. As the HUB completes a new task with payers, or there's new developments in reimbursement how does the HUB communicate this change?

The HUB communicates directly with the office related to benefit investigation and prior authorization issues.

Please see [INDICATION AND IMPORTANT SAFETY INFORMATION, including BOXED WARNING.](#)