Buy-and-Bill Guide

This guide provides information and resources to acquire BRIXADI® (buprenorphine) extended-release injection for subcutaneous use (CIII) from a specialty distributor and request reimbursement. It includes:

- Information on purchasing BRIXADI from specialty distributors
- Possible billing codes for BRIXADI and associated services
- An example of a claim form with helpful information

INDICATIONS AND USAGE

BRIXADI is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

BRIXADI should be used as part of a complete treatment plan that includes counseling and psychosocial support.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; BRIXADI RISK EVALUATION AND MITIGATION STRATEGY

- **Serious harm or death could result if administered intravenously. BRIXADI forms a liquid crystalline gel upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life-threatening pulmonary emboli, if administered intravenously.**
- **Because of the risk of serious harm or death that could result from intravenous self-administration, BRIXADI is only available through a restricted program called the BRIXADI REMS. Healthcare settings and pharmacies that order and dispense BRIXADI must be certified in this program and comply with the REMS requirements.**

BRIXADI (buprenorphine) extended-release injection (weekly, 50 mg/mL buprenorphine) and BRIXADI (monthly, 356 mg/mL buprenorphine) are different formulations. Doses of BRIXADI (weekly) cannot be combined to yield an equivalent monthly dose.

BRIXADI is contraindicated in patients with hypersensitivity (e.g. anaphylactic shock) to buprenorphine or any other ingredients in the solution for injection.

Please see the full Important Safety Information on pages 6 to 7 and the BRIXADI Full Prescribing Information, including Boxed Warning, at BRIXADIhcp.com or accompanying this document.

Brixadi®
(buprenorphine) extended-release injection for subcutaneous use (III)
Weekly 8 • 16 • 24 • 32 mg Monthly 64 • 96 • 128 mg

BRIXADI Buy-and-Bill Fulfillment Process

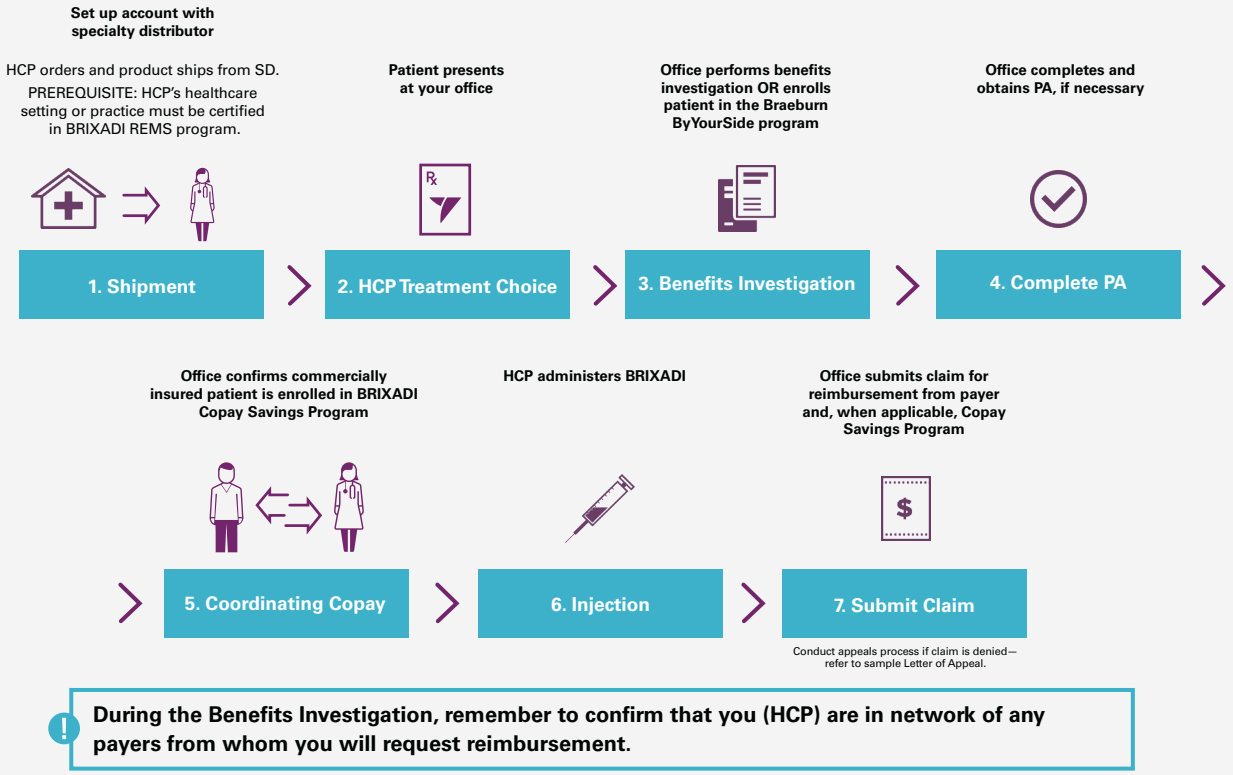
Acquiring BRIXADI can be done directly through a specialty distributor (SD) in Braeburn's limited distribution network

In order to keep a supply of BRIXADI in stock, you must be certified in the BRIXADI REMS prior to purchasing/dispensing BRIXADI. To become certified in the BRIXADI REMS, visit www.brixadirems.com.

Scan here to learn more about the BRIXADI REMS program.

Braeburn ByYourSide Support

- Investigate patient insurance benefits
- Understand PA and appeal process
- General access inquiries



During the Benefits Investigation, remember to confirm that you (HCP) are in network of any payers from whom you will request reimbursement.

BRAEBURN ByYourSide

Dedicated Braeburn ByYourSide team provides support with your patient's access to BRIXADI.

Braeburn ByYourSide provides:

- Investigation of patient insurance coverage and potential out-of-pocket costs for BRIXADI
- Assistance in understanding PA and appeal process
- Answers to other questions related to patient access

Please see the full Important Safety Information on pages 6 to 7 and the BRIXADI Full Prescribing Information, including Boxed Warning, at BRIXADIhcp.com or accompanying this document.

BRIXADI Buy-and-Bill Fulfillment Process (continued)

Scan here for a list of specialty distributors.

Specialty distributors in Braeburn's limited distribution network (as of April 1, 2024)

For a full, up-to-date list of the specialty distributors in Braeburn's limited distribution network, visit BRIXADIhcp.com/access-and-support or scan the QR code.

Specialty Distributor	Phone	Fax	Website
Besse Medical Supply	1-800-543-2111	1-800-543-8695	besse.com
CuraScript SD Specialty Distribution	1-877-900-9223	1-866-628-8942	curascriptsd.com

BRIXADI NDC Codes and Billing Codes

BRIXADI National Drug Codes (NDCs)

Code #	Explanation
NDCs[1]	
58284-0208-01	BRIXADI 8 mg (buprenorphine for weekly subcutaneous injection)
58284-0216-01	BRIXADI 16 mg (buprenorphine for weekly subcutaneous injection)
58284-0224-01	BRIXADI 24 mg (buprenorphine for weekly subcutaneous injection)
58284-0232-01	BRIXADI 32 mg (buprenorphine for weekly subcutaneous injection)
58284-0264-01	BRIXADI 64 mg (buprenorphine for monthly subcutaneous injection)
58284-0296-01	BRIXADI 96 mg (buprenorphine for monthly subcutaneous injection)
58284-0228-01	BRIXADI 128 mg (buprenorphine for monthly subcutaneous injection)

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Current billing codes (as of April 1, 2024)

The table below lists the possible codes used for injections as well as OUD services and procedures. The following codes are offered as a resource to help complete claim forms. The prescribing HCP will determine which codes best represent the individual patient's diagnosis and treatment. Individual codes used for BRIXADI and its administration may vary by payer and site of care. Check with the individual payers to confirm their specific billing, coding, and documentation requirements.

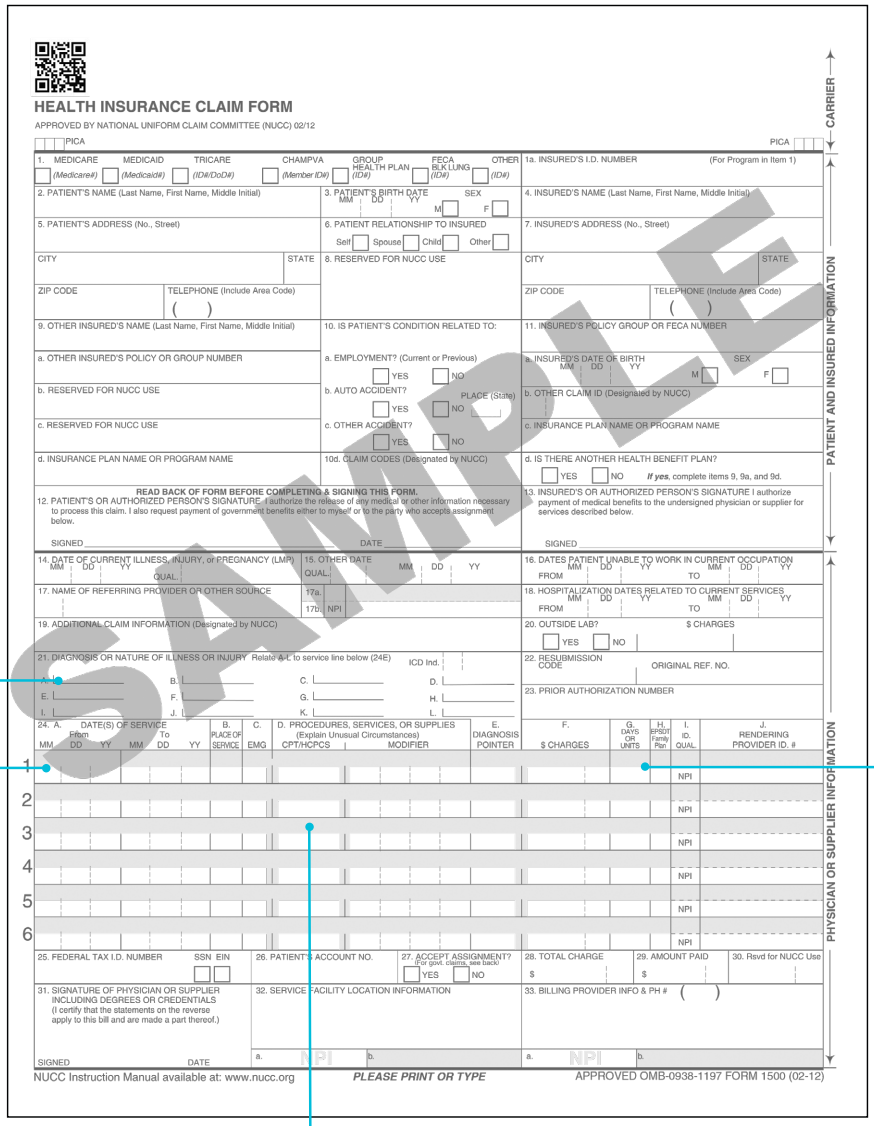
Code #	Explanation
International Classification of Diseases, 10th ed., Clinical Modification (ICD-10-CM)[2]	
F11.2	Opioid dependence
F11.20	Uncomplicated
F11.220	Opioid dependence with intoxication, uncomplicated
F11.221	Opioid dependence with intoxication, delirium
F11.222	Opioid dependence with intoxication, with perceptual disturbance
F11.229	Opioid dependence with intoxication, unspecified
F11.250	Opioid dependence with opioid-induced psychotic disorder, with delusions
F11.251	Opioid dependence with opioid-induced psychotic disorder, with hallucinations
F11.259	Opioid dependence with opioid-induced psychotic disorder, unspecified
F11.281	Opioid dependence with other opioid-induced sexual dysfunction
F11.282	Opioid dependence with other opioid-induced sleep disorder
F11.288	Opioid dependence with other opioid-induced disorder

This is not an exhaustive list of codes.

Code #	Explanation
Place of Service (POS) Codes[3]	
9	Prison/Correctional Facility
11	Office
21	Inpatient Hospital
22	Outpatient Hospital
23	Emergency Room – Hospital
55	Residential Substance Abuse Treatment Facility
Healthcare Common Procedure Coding System (HCPCS)[2]	
J0577	Injection, buprenorphine extended-release (BRIXADI), less than or equal to 7 days of therapy
J0578	Injection, buprenorphine extended-release (BRIXADI), greater than 7 days and up to 28 days of therapy
Current Procedural Terminology (CPT) Code[2]	
96372	Therapeutic, prophylactic, and diagnostic injections and infusions *(excludes chemotherapy and other highly complex drug or highly complex biologic agent administration)*
Screening, Brief Intervention (SBI); Medicaid Screening[2]	
H0049	Alcohol and drug screening
H0050	Brief intervention (per 15 minutes)

Sample CMS-1500 Claim Form

The CMS-1500 Claim Form is used by HCPs to submit claims for medical products and services. It provides information about the patient's diagnosis, treatment, and insurance policy. The below sample is provided for guidance when billing for BRIXADI.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE MM DD YY QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1									NPI	
2									NPI	
3									NPI	
4									NPI	
5									NPI	
6									NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

Box 21: Diagnosis or nature of illness or injury

Note: Enter the appropriate diagnosis code as reflected in the patient's medical record.

See page 4 of this guide for examples of possible ICD codes.

NDC number

See page 3 of this guide for BRIXADI NDCs.

Box 24G: Days or units

Enter the appropriate number of units in syringes.

Box 24D: Procedures, services, or supplies

If your office has purchased BRIXADI:

- Enter the appropriate CPT code and HCPCS code if physician office elected "buy-and-bill" method for patients with medical benefit
- Note: Some payers may require an entered HCPCS code with a charge of $0. The physician office is responsible for determining what each individual payer requires prior to submitting claim

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; BRIXADI RISK EVALUATION AND MITIGATION STRATEGY

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BRIXADI is contraindicated in patients with hypersensitivity (e.g. anaphylactic shock) to buprenorphine or any other ingredients in the solution for injection.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse: BRIXADI contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Monitor all patients for progression of opioid dependence and addictive behaviors.

Respiratory and CNS Depression: Buprenorphine has been associated with life-threatening respiratory depression and death. Use BRIXADI with caution in patients with compromised respiratory function. Due to its extended-release characteristics, if BRIXADI is discontinued as a result of compromised respiratory function, monitor patients for ongoing buprenorphine effects for approximately 1 month for BRIXADI (weekly) and for approximately 4 months for BRIXADI (monthly). Educate patients and caregivers on how to recognize respiratory depression and emphasize the importance of calling 911 or getting emergency medical help right away in the event of a known or suspected overdose.

Patient Access to Naloxone for the Emergency Treatment of Opioid Overdose: Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver. Because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose, strongly consider prescribing naloxone for the emergency treatment of opioid overdose, both when initiating and renewing treatment with BRIXADI. If naloxone is prescribed, educate patients and caregivers on how to treat with naloxone, and emphasize the importance of calling 911 or getting emergency medical help, even if naloxone is administered.

Concomitant Use of Benzodiazepines or other CNS Depressants: Concomitant use of buprenorphine and benzodiazepines or other CNS depressants increase the risk of adverse reactions including respiratory depression, overdose and death. Ensure that other healthcare providers prescribing benzodiazepines or other CNS depressants are aware of the patient's buprenorphine treatment and coordinate care to minimize the risk associated with concomitant use. Inform patients and caregivers that potentially fatal additive effects may occur if BRIXADI is used with benzodiazepines or other CNS depressants, including alcohol, and not to use these concomitantly unless supervised by a healthcare provider.

Neonatal Opioid Withdrawal Syndrome, Pregnancy, and Lactation: Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy. NOWS may be life-threatening if not recognized and treated in the neonate. Healthcare providers should observe newborns for signs of NOWS and manage accordingly. Advise pregnant women receiving opioid addiction treatment with BRIXADI of the risk of neonatal opioid withdrawal syndrome. Warn patients that buprenorphine passes into breast milk. Advise the nursing mother taking buprenorphine to monitor the infant for increased drowsiness and breathing difficulties.

Adrenal Insufficiency: If adrenal insufficiency is diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Risk of Opioid Withdrawal with Abrupt Discontinuation: Patients who elect to discontinue BRIXADI treatment should be monitored for withdrawal signs and symptoms with consideration given to the product's extended-release characteristics.

Risk of Hepatitis, Hepatic Events, and Use in Patients with Impaired Hepatic Function: Liver function tests should be performed on all patients prior to initiation, during treatment, and if a hepatic event is suspected. Because buprenorphine levels cannot be rapidly decreased, patients with pre-existing moderate to severe hepatic impairment are not candidates for treatment with BRIXADI. Patients who develop moderate to severe hepatic impairment while being treated with BRIXADI should be monitored for signs and symptoms of toxicity or overdose of buprenorphine and may require a dose adjustment.

Hypersensitivity Reactions: Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have been reported in patients receiving buprenorphine-containing products. The most common signs and symptoms include rashes, hives, and pruritus. The BRIXADI needle cap is synthetically derived from natural rubber latex which may cause allergic reactions in latex-sensitive individuals.

Precipitation of Opioid Withdrawal in Patients Dependent on Full Opioid Agonists: BRIXADI injection may precipitate opioid withdrawal signs and symptoms in individuals physically dependent on full opioid agonists. In patients who are new entrants to treatment, to avoid precipitating an opioid withdrawal syndrome, administer a 4 mg test dose of transmucosal buprenorphine when objective signs of mild to moderate withdrawal appear and monitor for precipitated withdrawal before injecting BRIXADI.

Risks Associated with Treatment of Emergent Acute Pain: While on BRIXADI, situations may arise where patients need acute pain management, or may require anesthesia. Treat patients receiving BRIXADI with non-opioid analgesic whenever possible. Patients requiring opioid therapy for analgesia may be treated with a high-affinity full opioid analgesic under the supervision of a healthcare provider, with particular attention to respiratory function. Higher doses may be required for analgesic effect. Therefore, a higher potential for toxicity exists with opioid administration. Advise patients of the importance of instructing their family members, in the event of emergency, to inform the treating healthcare provider or emergency room staff that the patient is being treated with BRIXADI.

Use in Opioid Naïve Patients: There have been reported deaths of opioid naïve individuals who received a 2 mg dose of buprenorphine as a sublingual tablet. BRIXADI is not appropriate for use in opioid naïve patients.

Patients at Risk for Arrhythmia: Thorough QT studies with buprenorphine products have demonstrated QT prolongation ≤ 15 msec. This QTc prolongation effect does not appear to be mediated by hERG channels. Based on these two findings, buprenorphine is unlikely to be pro-arrhythmic when used alone in patients without risk factors. The risk of combining buprenorphine with other QT- prolonging agents is not known.

Impairment of Ability to Drive and Operate Machinery: BRIXADI may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery. Caution patients about driving or operating hazardous machinery until they are reasonably certain that BRIXADI does not adversely affect their ability to engage in such activities.

Orthostatic Hypotension: Buprenorphine may produce orthostatic hypotension in ambulatory patients.

Elevation of Cerebrospinal Fluid Pressure: Buprenorphine may elevate cerebrospinal fluid pressure and should be used with caution in patients with head injury, intracranial lesions, and other circumstances when cerebrospinal pressure may be increased.

Elevation of Intracholedochal Pressure: Buprenorphine has been shown to increase intracholedochal pressure, as do other opioids, and thus should be administered with caution to patients with dysfunction of the biliary tract.

Effects in Acute Abdominal Conditions: Buprenorphine may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Unintentional Pediatric Exposure: Buprenorphine can cause severe, possibly fatal, respiratory depression in children who are accidentally exposed to it.

ADVERSE REACTIONS

Adverse reactions commonly associated with BRIXADI administration (in ≥5% of patients) were injection site pain, headache, constipation, nausea, injection site erythema, injection site pruritus, insomnia, and urinary tract infection.

To report SUSPECTED ADVERSE REACTIONS, contact Braeburn at 1-833-274-9234 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the BRIXADI Full Prescribing Information, including Boxed Warning, at BRIXADIhcp.com or accompanying this document.

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References: 1. BRIXADI. Prescribing information. Braeburn Inc; 2023. **2.** American Academy of Professional Coders. Medical Coding & Billing Tools - CPT®, ICD-10, HCPCS Codes, & Modifiers. https://www.aapc.com/codes. Accessed March 18, 2024. **3.** Centers for Medicare & Medicaid Services. Place of Service Code Set. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set. Accessed March 18, 2024.

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BRX-1102/March 2024

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