



TENNCARE POLICY MANUAL

Policy No:	BEN 11-001 (rev. 3)	
Subject:	TennCare Coverage of Buprenorphine for Opioid Addiction	
Approval:	<i>James R Harley</i>	Date: <i>7/25/14</i>

PURPOSE AND SCOPE:

The purpose of this policy is to clarify the circumstances under which TennCare covers certain formulations of the drug buprenorphine for treatment of opioid addiction. This policy applies solely to those formulations of buprenorphine approved by the FDA for office-based opioid addiction treatment.

BACKGROUND:

The Drug Addiction Treatment Act (DATA) of 2000 allows qualified physicians who obtain a waiver from the federal government to prescribe and dispense Schedule III, IV, and V narcotic drugs to treat opioid addiction.¹ Since such forms of treatment were previously available only in a clinic setting, DATA 2000 includes an array of measures to prevent the abuse and diversion of these narcotics. Safeguards include:

- Restriction on the number of patients an individual physician may treat in this manner²
- Requirement that a physician applying for a waiver be certified to treat addiction³
- Assignment of a unique identification number to each physician who obtains a waiver⁴

Since the enactment of DATA 2000, the Food and Drug Administration (FDA) has approved multiple formulations of the drug buprenorphine, a Schedule III narcotic, for office-based opioid addiction treatment. Although TennCare began covering certain formulations of buprenorphine following the FDA's approval, the number of prescriptions for TennCare enrollees has grown substantially over time. This significant growth demonstrates the need for explicit control on use of the drug.

¹ This provision of DATA 2000 is codified at 21 U.S.C. § 823(g).

² See 21 U.S.C. § 823(g)(2)(B)(iii) and 21 C.F.R. § 1301.28(b)(1)(iii). The maximum number of patients a physician may treat in this manner for the first year following registration is 30. After a year, a physician who has obtained permission may treat up to 100 patients.

³ 21 U.S.C. § 823(g)(2)(G)(ii).

⁴ 21 U.S.C. § 823(g)(2)(D)(ii). This identification number, assigned by the Drug Enforcement Administration (DEA), begins with an "X". See the National Technical Information Service's DEA Registration Record Layout.

POLICY:

TennCare’s coverage of buprenorphine is subject to strict limitations on recipients qualified to receive the drug, rules regarding prior authorization, and clearly defined maximum daily dosages. The goal of this policy is not to maintain TennCare recipients on buprenorphine indefinitely, but to taper recipients’ use of the drug until they are successfully detoxified.

Qualified Recipients

TennCare covers buprenorphine only for an enrollee who:

- Has a diagnosis of opioid addiction
- Is prescribed the medication by a physician who has:
 - Completed a certification program (evidenced by a unique identification number—assigned by the Drug Enforcement Administration (DEA)—beginning with “X”); **AND**
 - Reviewed the Controlled Substances Database on the date of the prior authorization request to verify that no concomitant narcotic use by the enrollee is occurring; **AND**
 - Submitted an anticipated treatment plan (including planned dosing for the induction and maintenance phases of treatment, projected frequency of office visits, and proposed psychosocial counseling⁵); **AND**
 - Obtained a TennCare/Medicaid ID number.

TennCare covers the buprenorphine hydrochloride formulation only for enrollees who are unable to take the buprenorphine hydrochloride and naloxone hydrochloride formulation, either because of pregnancy⁶ or because of an allergy to naloxone. Documentation of an allergy must be faxed to TennCare’s pharmacy benefits manager.

Prior Authorization

To ensure that physicians are closely monitoring their patients’ use of buprenorphine over time, TennCare imposes the following requirements regarding prior authorization of the drug:

- All prescriptions require prior authorization and will be approved for no more than six months at a time.
- Prior authorizations are assigned to the prescribing physician, thereby ensuring that only prescriptions from that physician will be covered by TennCare.
- Prescriptions issued by a physician other than the previous prescribing physician require a new prior authorization and documentation that the previous prescribing physician has communicated transfer of care.
- Every prior authorization must contain a physician’s original signature.

⁵ Counseling provided by a drug manufacturer (e.g., Reckitt Benckiser’s “Here to Help” program or Orexo’s “RISE” program) may not be the sole source of such treatment.

⁶ Buprenorphine hydrochloride is preferable to buprenorphine hydrochloride and naloxone hydrochloride in treating pregnant women because naloxone poses the risk of inducing withdrawal symptoms in mother and fetus alike. See p. 70 of *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*.

TennCare’s prior authorization form for buprenorphine is located online at https://tenncare.magellanhealth.com/static/docs/Prior_Authorization_Forms/TennCare_Buprenorphine_Products.pdf.

Dosage

Buprenorphine is effective in treating opioid addiction because it produces some of the same effects as opioids—pain relief, respiratory depression, and euphoria, for example—while also possessing a “ceiling effect,” a point at which increased use of the drug does not heighten its effects. Based on the available data regarding the dosage effectiveness of buprenorphine, TennCare enforces the following limits:

- The buprenorphine quantity limit is 16 mg per day, regardless of preexisting prescriptions for a larger amount.⁷
 - In accordance with clinical trials and clinical guidelines issued by the Substance Abuse and Mental Health Services Administration (SAMHSA), the maintenance dosing range and target dose should be between 4 and 16 mg per day.
 - Clinical trials have established that 85 to 92 percent of a patient’s mu-opioid receptors are blocked by a 16 mg daily dose of buprenorphine. Furthermore, in terms of mean mu-opioid receptor binding potential values, a 32 mg daily dose of buprenorphine differs little from a 16 mg daily dose.⁸
- Buprenorphine is to be administered as a single daily dose (or two doses if clinically necessary, i.e., if the side effects of a single daily dose cannot be tolerated).⁹
- The 16 mg quantity limit will be authorized for no more than 6 months, after which a quantity limit of 8 mg per day will be imposed. For pregnant enrollees, the 6-month period begins immediately after the conclusion of the pregnancy.
- Quantity limit exceptions exceeding 16 mg per day will not be granted.
- Physicians who consistently prescribe higher doses of buprenorphine than their peers could be reported to the appropriate State Agency or to the DEA.

Restrictions

Under no circumstances does TennCare cover a prescription for buprenorphine when written—

- By a mid-level practitioner; **OR**
- For treatment of pain; **OR**

⁷ The quantity limit applies only to adult enrollees. Children may obtain higher doses if medical necessity is established through the prior authorization process. See TennCare Rules 1200-13-13-.04(1)(c)9(i), 1200-13-13-.10(3)(a)20(vii), 1200-13-14-.04(1)(c)9(i), and 1200-13-14-.10(3)(a)20(vii).

⁸ See the studies conducted by Greenwald et al., Correia et al., and Bickel et al. (full citations for which appear in the “References” section of this policy).

⁹ The package inserts for buprenorphine sublingual tablets and sublingual film recommend a single daily dose of 16 mg. Buprenorphine’s elimination half-life is 24 to 42 hours, meaning that the human body retains the drug—and feels its effects—for an extended period of time. Given these long-lasting properties, multiple doses of the drug are generally unnecessary.

- For treatment of depression.

OFFICES OF PRIMARY RESPONSIBILITY:

Pharmacy Division

Office of the Chief Medical Officer

REFERENCES:

Federal	<p><i>United States Code</i></p> <ul style="list-style-type: none"> • 21 U.S.C. § 823, located online at http://www.gpo.gov/fdsys/pkg/USCODE-2012-title21/pdf/USCODE-2012-title21-chap13-subchapl-partC-sec823.pdf <p><i>Code of Federal Regulations</i></p> <ul style="list-style-type: none"> • 21 C.F.R. § 1301.28, located online at http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=af9868808cae0337e885d1f607addaa8&rgn=div8&view=text&node=21:9.0.1.1.2.0.3.20&idno=21 <p><i>Government Publications</i></p> <ul style="list-style-type: none"> • “DEA Registration Record Layout,” National Technical Information Service, revised June 17, 2009 and located online at http://www.ntis.gov/pdf/dea-rec-lay-jun-2009.pdf • “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction,” Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004, located online at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf
State	<p><i>TennCare Rules</i></p> <ul style="list-style-type: none"> • 1200-13-13-.04 and 1200-13-14-.04, “Covered Services,” located online at http://www.state.tn.us/sos/rules/1200/1200-13/1200-13.htm • 1200-13-13-.10 and 1200-13-14-.10, “Exclusions,” located online at http://www.state.tn.us/sos/rules/1200/1200-13/1200-13.htm <p><i>Government Publications</i></p> <ul style="list-style-type: none"> • TennCare Prior Authorization Form for buprenorphine products, located online at https://tenncare.magellanhealth.com/static/docs/Prior_Authorization_Forms/Tenn_Care_Buprenorphine_Products.pdf <p><i>Additional Resources</i></p> <ul style="list-style-type: none"> • TennCare Preferred Drug List (PDL), located online at https://tenncare.magellanhealth.com/static/docs/Preferred_Drug_List_and_Drug_Criteria/TennCare_PDL.pdf

Other	<p>Package Insert for buprenorphine sublingual tablets, published by Reckitt Benckiser Pharmaceuticals Inc. and located online at http://www.naabt.org/documents/packageinsert.pdf</p> <p>Package Insert for buprenorphine sublingual film, published by Reckitt Benckiser Pharmaceuticals Inc. and located online at http://www.suboxone.com/pdfs/SuboxonePI.pdf</p> <p>Greenwald, M. K., Johanson, C. E., Moody, D. E., Woods, J. H., Kilbourn, M. R., Koeppe, R. A. et al. (2003). Effects of buprenorphine maintenance dose on mu-opioid receptor availability, plasma concentrations, and antagonist blockade in heroin-dependent volunteers. <i>Neuropsychopharmacology</i>, 28, 2000-2009.</p> <p>Correia, C. J., Walsh, S. L., Bigelow, G. E., & Strain, E. C. (2006). Effects associated with double-blind omission of buprenorphine/naloxone over a 98-h period. <i>Psychopharmacology</i>, 189, 297-306.</p> <p>Bickel, W. K., Amass, L., Crean, J. P., & Badger, G. J. (1999). Buprenorphine dosing every 1, 2, or 3 days in opioid-dependent patients. <i>Psychopharmacology</i>, 146, 111-118.</p>
--------------	---

Original: 03/22/11: JTR
Revision 1: 09/26/11: JTR
Revision 2: 04/08/13: JTR
Revision 3: 07/25/14: JTR