



AmeriHealth.

Policy Title Buprenorphine and Naloxone (Suboxone®) and Buprenorphine (Subutex®)

Policy Number FS.CLIN.90

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification and age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy Buprenorphine and Naloxone (**Suboxone**) and Buprenorphine (**Subutex**) are indicated for the treatment of opioid dependence.

The use of Buprenorphine and Naloxone (Suboxone) and Buprenorphine (Subutex) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy description **Suboxone** is a combination product containing buprenorphine and naloxone. **Subutex** is a single agent product containing buprenorphine. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Naloxone is an antagonist at the mu-opioid receptor.

Policy guideline inclusion **Buprenorphine and Naloxone (Suboxone)**
Buprenorphine and Naloxone (Suboxone) is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of opioid dependence in patients 16 years of age or older
- Documentation prescriber has received a Drug Addiction Treatment Act (DATA) 2000 waiver (prescribers special identification number must be provided) or documentation prescriber has applied for the DATA 2000 waiver

Authorization Length

Buprenorphine and Naloxone (Suboxone) authorizations will be granted for a period of 6 months.

Re-authorization Criteria

Buprenorphine and Naloxone (Suboxone) is re-approved when all of the following inclusion criteria are met:

- Documentation of comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self help programs, behavioral therapy, or other psychosocial services and documentation of urine toxicology screen)

Buprenorphine (Subutex)

Buprenorphine (Subutex) is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of opioid dependence in patients 16 years of age or older
- Documentation prescriber has received a Drug Addiction Treatment Act (DATA) 2000 waiver (prescribers special identification number must be provided) or documentation prescriber has applied for the DATA 2000 waiver
- Documentation of one of the following:
 - Documentation of use for induction phase of treatment
 - Documentation of use in a phase other than induction in patients who have a contraindication/intolerance to Suboxone
 - Documentation patient is pregnant

Authorization Length

Buprenorphine (Subutex) authorizations will be granted for a period of 10 days for the induction phase

Buprenorphine (Subutex) authorizations will be granted for a period of 1 year for pregnant patients. At the conclusion of 1 year patients who will continue on the medication will be required to meet the original criteria

Buprenorphine (Subutex) authorizations will be granted for a period of 6 months for patients who have a contraindication or intolerance to Suboxone.

Buprenorphine (Subutex) Re-authorization Criteria for patients who have a contraindication or intolerance to Suboxone

Buprenorphine (Subutex) is re-approved when all of the following inclusion criteria are met:

Documentation of comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self help programs, behavioral therapy, or other psychosocial services and documentation of urine toxicology screen)

Quantity Limit

Buprenorphine and Naloxone (Suboxone) and Buprenorphine (Subutex) quantities will be limited to 120 units per 30 days.

Buprenorphine and Naloxone (Suboxone) and Buprenorphine (Subutex) is approved in quantities greater than 120 per 30 days when all of the following inclusion criteria are met:

- Documentation of comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self help programs, behavioral therapy, or other psychosocial services)
- Documentation of a trial and failure with lower doses

- Documentation of a randomized, double blind, active or placebo controlled trial demonstrating the safety and efficacy of the requested dose for the condition submitted, where the results are published in a national peer-reviewed journal.

Duplicate therapy

Buprenorphine and Naloxone (Suboxone) and Buprenorphine (Subutex) will be subject to duplicate therapy limits. Patients receiving Buprenorphine and Naloxone (Suboxone) and Buprenorphine (Subutex) will have claims deny for additional opioid medications.

Opioids are approved in patients that have received Buprenorphine and Naloxone (Suboxone) or Buprenorphine (Subutex) when the following inclusion criteria is met:

Documentation of treatment plan showing discontinuation of Buprenorphine and Naloxone (Suboxone) or Buprenorphine (Subutex)

Policy guideline exclusion

Buprenorphine and Naloxone (Suboxone)

Buprenorphine and Naloxone (Suboxone) is denied when any of the following exclusion criteria are present:

- No documentation of a diagnosis of opioid dependence in patients 16 years of age or older
- No documentation prescriber has received a Drug Addiction Treatment Act (DATA) 2000 waiver (prescribers special identification number must be provided) or documentation prescriber has applied for the DATA 2000 waiver

Authorization Length

Buprenorphine and Naloxone (Suboxone) authorizations will be granted for a period of 6 months.

Re-authorization Criteria

Buprenorphine and Naloxone (Suboxone) is denied when the following exclusion criteria is present:

No documentation of comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self help programs, behavioral therapy, or other psychosocial services and documentation of urine toxicology screen)

Buprenorphine (Subutex)

Buprenorphine (Subutex) is denied when any of the following exclusion criteria are present:

- No documentation of a diagnosis of opioid dependence in patients 16 years of age or older
- No documentation prescriber has received a Drug Addiction Treatment Act (DATA) 2000 waiver (prescribers special identification number must be provided) or documentation prescriber has applied for the DATA 2000 waiver
- No documentation of one of the following:
 - Documentation of use for induction phase of treatment
 - Documentation of use in a phase other than induction in patients who have a contraindication/intolerance to Suboxone
 - Patient is pregnant

Authorization Length

Buprenorphine (Subutex) authorizations will be granted for a period of 10 days for the induction phase

Buprenorphine (Subutex) authorizations will be granted for a period of 1 year for pregnant patients. At the conclusion of 1 year patients who will continue on the medication will be required to meet the original criteria

Buprenorphine (Subutex) authorizations will be granted for a period of 6 months for patients who have a contraindication or intolerance to Suboxone.

Buprenorphine (Subutex) Re-authorization Criteria for patients who have a contraindication or intolerance to Suboxone

Buprenorphine (Subutex) is denied when the following exclusion criteria is present:

No documentation of comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self help programs, behavioral therapy, or other psychosocial services and documentation of urine toxicology screen)

Quantity Limit

Buprenorphine and Naloxone (Suboxone) and Buprenorphine (Subutex) quantities will be limited to 120 units per 30 days.

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- No documentation of comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self help programs, behavioral therapy, or other psychosocial services)
- No documentation of a trial and failure with lower doses
- No documentation of a randomized, double blind, active or placebo controlled trial demonstrating the safety and efficacy of the requested dose for the condition submitted, where the results are published in a national peer-reviewed journal.

Duplicate therapy

Buprenorphine and Naloxone (Suboxone) and Buprenorphine (Subutex) will be subject to duplicate therapy limits. Patients receiving Buprenorphine and Naloxone (Suboxone) and Buprenorphine (Subutex) will have claims deny for additional opioid medications.

Opioids are denied in patients that have received Buprenorphine and Naloxone (Suboxone) or Buprenorphine (Subutex) when the following exclusion criteria is present:

No documentation of treatment plan showing discontinuation of Buprenorphine and Naloxone (Suboxone) or Buprenorphine (Subutex)

Policy List of Applicable Drugs

Suboxone	Buprenorphine and Naloxone
Subutex	Buprenorphine

Dosing and administration	Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.
Policy references	<p>Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. A treatment Improvement Protocol. US Department of Health and Human Services. 2004.</p> <p>Drugs, Brains, and Behavior, the Science of Addiction. National Institute on Drug Abuse. National Institutes of Health. US Department of Health and Human Services. 2008.</p> <p>Facts and Comparisons Website [Suboxone/Subutex]. Available at www.factsandcomparisons.com. Accessed April 11, 2011.</p> <p>Micromedex website [Suboxone/Subutex] Available at www.micromedex.com. Accessed April 11, 2011.</p> <p>Suboxone [package insert] Reckitt Benckiser Pharmaceuticals. Richmond VA; 2006.</p> <p>Subutex [package insert] Reckitt Benckiser Pharmaceuticals. Richmond VA; 2006.</p>
Policy link to related policies	
Version effective date	October 1, 2011

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