Clinical Policy: Buprenorphine-Naloxone (Bunavail, Cassipa, Suboxone)

Reference Number: HIM.PA.35
Effective Date: 02.01.17
Last Review Date: 02.20
Line of Business: HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Buprenorphine-naloxone (Bunavail®, Cassipa®, Suboxone®) is a partial-opioid agonist.

FDA Approved Indication(s)

Bunavail, Cassipa, and Suboxone are indicated for the treatment of opioid dependence.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Bunavail, Cassipa, and Suboxone are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Opioid Dependence (must meet all)**:**

1. Diagnosis of opioid dependence;
2. If request is for buprenorphine/naloxone (Suboxone) sublingual film, documented clinically significant adverse effects or contraindications to Suboxone sublingual tablets;
3. Dose does not exceed:
   a. Bunavail: 12.6 mg/2.1 mg per day;
   b. Cassipa: 16 mg/4 mg per day;
   c. Suboxone 24 mg/6 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Opioid Dependence (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. One of the following conditions is met (a or b):
   a. Member has NOT received an opioid analgesic since last approval;

b. Prescriber submits documentation acknowledging that the use of opioid during the last approval period was due to legitimate diagnosis of pain;

4. If request is for a dose increase, new dose does not exceed:
   a. Bunavail: 12.6 mg/2.1 mg per day;
   b. Cassipa: 16 mg/4 mg per day;
   c. Suboxone 24 mg/6 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Pain management;

B. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to buprenorphine or naloxone
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Buprenorphine-naloxone (Suboxone) sublingual (SL) or buccal dissolving film	Induction: Titrate to 8 mg/2 mg SL on Day 1 and 16 mg/4 mg SL on Day 2; then start maintenance treatment Maintenance: Target dose: buprenorphine 16 mg/naloxone 4 mg once daily; dosage should be adjusted in increments or decrements of 2 mg/ 0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	24 mg/6 mg per day

Indication	Dosing Regimen	Maximum Dose
Buprenorphine-naloxone (Bunavail) buccal film	Maintenance: Target dose: buprenorphine 8.4 mg/naloxone 1.4 mg once daily; dosage should be adjusted in increments or decrements of 2.1 mg/ 0.3 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.1 mg/0.3 mg to 12.6 mg/2.1 mg per day	12.6 mg/2.1 mg per day
Buprenorphine-naloxone (Cassipa) SL film	Maintenance: Target dose: buprenorphine 16 mg/naloxone 4 mg SL once daily; dosage should be titrated to target dose using another marketed product (Cassipa comes in a single dose and cannot be adjusted)	16 mg/4 mg per day
Buprenorphine-naloxone SL tablet	Maintenance: Target dose: buprenorphine 16 mg/naloxone 4 mg SL once daily; dosage should be adjusted in increments or decrements of 2 mg/ 0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	24 mg/6 mg per day

VI. Product Availability

Drug Name	Availability
Buprenorphine-naloxone (Suboxone)	Sublingual film: buprenorphine/naloxone 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, 12 mg/3 mg
Buprenorphine-naloxone (Bunavail)	Buccal film: buprenorphine/naloxone 2.1 mg/0.3 mg; 4.2 mg/0.7 mg, 6.3 mg/1 mg
Buprenorphine-naloxone	Sublingual tablet: buprenorphine/naloxone 2 mg/0.5 mg, 8 mg/2 mg
Buprenorphine-naloxone (Cassipa)	Sublingual film: buprenorphine/naloxone 16 mg/4 mg

VII. References

1. Suboxone Sublingual Film Prescribing Information. North Chesterfield, VA: Indivior Inc.; October 2019. Available at: https://www.suboxone.com/. Accessed November 26, 2019.
2. Bunavail Prescribing Information. Raleigh, NC: BioDelivery Sciences International, Inc.; October 2019. Available at: https://bdsi.com/bunavail/. Accessed November 26, 2019.
3. Cassipa Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208042s000lbl.pdf. Accessed November 26, 2019.
4. Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2004. (Treatment Improvement Protocol (TIP) Series, No.

40.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK64245/. Accessed October 23, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Clinical changes made to criteria: Initial: added a requirement for diagnosis of opioid dependence; removed age requirement; modified generalized FDA approved limit to specific max dose; Continued: modified to allow use of opioid since last approval if prescriber submits documentation acknowledging that the use of opioid during the last approval was due to legitimate diagnosis of pain; added max dose requirement. Updated references.	12.16	02.17
1Q18 annual review Removed XDEA number (DATA2000 waiver) as a requirement since prescription use of this product is limited under the Drug Addiction Treatment Act. Removed criteria related to participation in drug abuse counseling and urine drugs screens (e.g., submission of at least 2 negative random urine drug screens) to shift the responsibility of appropriate monitoring and use to the prescriber. Added Bunavail as an option for MHS Indiana members only since it is a MHS Indiana formulary agent that requires a PA. Removed requirement related to adherence to therapy on re-auth and added requirement for positive response to therapy References reviewed and updated	11.08.17	02.18
1Q 2019 annual review: preferencing changed to tablet formulation; no significant change from previously approved policy; references reviewed and updated.	12.11.18	02.19
1Q 2020 annual review: no significant changes; RT4: added new dosage form Cassipa to the policy; references reviewed and updated.	11.26.19	02.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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