UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2099-10
Program	Prior Authorization/Medical Necessity – Buprenorphine Products (Pain Indications)
Medication	Belbuca (buprenorphine hydrochloride film) and Butrans^ (buprenorphine patch, extended-release)
P&T Approval Date	8/2016, 2/2017, 7/2017, 11/2017, 11/2018, 3/2019, 11/2019, 11/2020, 11/2021
Effective Date	2/1/2022; Oxford only: 2/1/2022

1. Background:

Belbuca and **Butrans**^ are buprenorphine products indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate. Similar to other long-acting opioids, the use of **Belbuca** and **Butrans**^ should be reserved for use in patients for whom alternative treatment options (e.g. non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or inadequate to provide sufficient management of pain. **Belbuca** and **Butrans**^ are not indicated for as-needed (prn) analgesics.

The CDC and the American Academy of Neurology recommend the following best practices in the prescription of long-acting opioids:

- Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.
- Before starting opioid therapy, treatment goals should be established with patients that include realistic goals for pain and function and should consider how therapy will be discontinued if benefits do not outweigh risks. Track pain and function at every visit (at least every 3 months) using a brief, validated instrument. Continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids.
- Document the daily morphine milligram equivalents (MME) in mg/day from all sources of opioids. Access the state prescription drug monitoring program (PDMP) data at treatment initiation and periodically during treatment. Currently all states except for Missouri have a PDMP.
- To avoid increased risk of respiratory depression, long-acting opioids should not be prescribed concurrently with benzodiazepines.
- Screen for past and current substance abuse and for severe depression, anxiety, and PTSD prior to initiation.

- Use random urine drug screening prior to initiation and periodically during treatment with a frequency according to risk.
- Use a patient treatment agreement, signed by both the patient and prescriber, that addresses risks of use and responsibilities of the patient.
- Methadone should not be the first choice for a long-acting opioid. Only clinicians who are familiar with methadone's unique risk profile and who are prepared to educate and closely monitor their patients should consider prescribing methadone for pain.
- Avoid escalating doses above 50-90 mg/day MME unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist.
- Clinicians should evaluate benefits and harms of continued therapy at least every 3 months. If benefits do not outweigh harms, opioids should be tapered and discontinued. Evaluation should include assessment of substance use disorder/opioid dependence. Validated scales (such as the DAST-10) are available at www.drugabuse.gov.

Table 1. Maximum Recommended Dose Per Product Label

Brand	Active Ingredient	Max Dose*
Belbuca	Buprenorphine (buccal film)	1800 mcg (900 mcg every 12 hours)
Butrans^	Buprenorphine (patch)	20 mcg/hour patch every 7 days

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

2. Coverage Criteria [a]

A. Cancer or End of Life (defined as a < 2 year life expectancy) related pain[b]

1. **Belbuca** will be approved based on **BOTH** of the following:

   a. Patient is being treated for pain due to active cancer diagnosis or end of life related pain (document cancer diagnosis for end of life, expectancy of <2 years)

   -AND-

   b. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information

Authorization will be issued for 24 months

2. **Butrans^** will be approved based on **ALL** of the following:

a. Patient is being treated for pain due to active cancer diagnosis or end of life related pain (document cancer diagnosis for end of life, expectancy of <2 years)

-AND-

b. The patient has a history of failure after a 30 day trial, contraindication or intolerance to Belbuca[c].

-AND-

c. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information.

Authorization will be issued for 24 months.

B. Non-cancer pain

1. Initial Authorization

a. **Belbuca** will be approved based on **ALL** of the following criteria:

(1) The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment.

-AND-

(2) **Prescriber attests to all of the following**:
(a) The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
(b) Pain is moderate to severe and expected to persist for an extended period of time
(c) Pain is chronic
(d) Medication is not being used for opioid dependence
(e) Dose does not exceed the maximum recommended dose per product label. (See Table 1)

-AND-

(3) The patient is not receiving other long-acting opioids concurrently.

b. **Butrans**^ will be approved based on **ALL** of the following criteria:

(1) The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment.

-AND-

(2) **Prescriber attests to all of the following:**
(a) The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
(b) Pain is moderate to severe and expected to persist for an extended period of time
(c) Pain is chronic
(d) Medication is not being used for opioid dependence
(e) Dose does not exceed the maximum recommended dose per product label. (See Table 1)

-AND-

(3) The patient is not receiving other long-acting opioids concurrently.

-AND-

(4) The patient has a history of failure after a 30 day trial, contraindication or intolerance to a trial **BOTH** of the following [c]:
(a) Belbuca
(b) tramadol (e.g. Ultram ER)

Authorization for non-cancer pain will be issued for 6 months.

2. Reauthorization

a. **Belbuca or Butrans**^ will be reauthorized based on **ALL** of the following:

(1) Prescriber attests to **ALL** of the following:
- Treatment goals are defined, including estimated duration of treatment.

- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression.
- The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)

-AND-

(a) Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

-AND-

(b) Identify rationale for not tapering and discontinuing opioid. (Document rationale).

-AND-

(2) Dose does not exceed maximum dose recommended by product label (see Table 1). (Document total daily dose).

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] Coverage of medications used to treat stage four advanced metastatic cancer or associated conditions (e.g., cancer pain) may be approved based on state mandates.
[c] In Connecticut, trial must be a generic product.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Step may be in place.

[^] Butrans is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

4. References:

1. Belbuca [Package Insert]. Malvern, PA: Endo Pharmaceuticals Inc.; July 2020.
2. Butrans [Package Insert]. Stamford, CT: Purdue Pharma L.P.; October 2019.
3. Franklin GM. Opioids for chronic noncancer pain. A position paper of the American Academy of Neurology. Neurology. 2014;83:1277-1284.
4. Rosenquist EWK. Overview of the treatment of chronic non-cancer pain in adults. Tauben, D. UptoDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed October 5, 2020).
5. Argoff CE, Silvershein DI. A Comparison of Long- and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet Patient Needs. Mayo Clin Proc. 2009;84(7):602-612.
6. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 15, 2016.

Program	Prior Authorization/Medical Necessity – Buprenorphine Products (Pain Indications)
Change Control	
Date	Change
8/2016	New program
11/2016	Administrative change. Added California coverage information.
2/2017	Separated criteria for Butrans and Belbuca to require trial and failure of Belbuca prior to approval of Butrans. Updated references.
7/2017	State mandate reference language updated. Updated dose limit to allow for doses up to maximum recommended by the FDA Removed allowance for higher doses for pain management specialists. Removed need to provide specific assessment scores for reauthorization criteria.
11/2017	Modified step one options for Butrans and removed for Belbuca. Updated Connecticut regulatory information. Updated authorization timeframe for cancer pain.
11/2018	Annual review. Revised requirements to allow provider attestation on initial authorization and reauthorization.
3/2019	Added criteria for exceeding maximum dose to Butrans initial authorization.
11/2019	Added a note for stage four advanced metastatic cancer and state mandates. Revised cancer and end-of-life criterion.
11/2020	Added duration of trial requirement. Updated references.
11/2021	Annual review. No changes.