UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3008-12
Program	Step Therapy
Medication	Butrans® (buprenorphine patch)
P&T Approval Date	02/2013, 11/2013, 10/2014, 10/2015, 8/2016, 11/2016, 2/2017, 7/2017, 11/2017, 11/2018, 11/2019, 11/2020
Effective Date	2/1/2021; Oxford only: N/A

1. Background:

Butrans and Belbuca are indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock analgesic for an extended period of time.

Members with Butrans documented in claims history will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the below criteria.

2. Coverage Criteria[a]:

A. Butrans* will be approved based on **ONE** of the following criteria:[b]

1. **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 provided.

   -OR-

2. **BOTH** of the following:

   a. The patient has a history of failure after a 30 day trial, contraindication, or intolerance to **BOTH** of the following [c]:

(1) Belbuca
(2) tramadol (e.g. Ultram ER)

-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 provided.

Authorization for cancer or end-of-life pain will be issued for 24 months
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.

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

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 Medical Necessity may be in place.

4. References:

1. Butrans [Package Insert]. Stamford, CT: Purdue Pharma L.P.; October 2019.
2. Belbuca [Package Insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; July 2020

Program	Step Therapy – Butrans, Belbuca
Change Control	
Date	Change
11/2013	Review. Updated Butrans reference. Updated additional clinical rules section.
10/2014	Noted it does not apply to CT lines of business and also revised to note Duragesic is typically excluded from coverage.
10/2015	Changed Ultram ER to generic tramadol ER as an alternative in the step criteria. Updated references. Added Maryland

	Continuation of Care.
7/2016	Added Indiana and West Virginia coverage information.
8/2016	Added Belbuca to step criteria. Changed preferred products from tramadol ER and fentanyl to tramadol ER and morphine sulfate CR (generic MS Contin). Updated references.
11/2016	Added criteria for cancer diagnosis to align with Medical Necessity criteria. Added California coverage information.
2/2017	Separated criteria for Butrans and Belbuca to require trial and failure of Belbuca prior to approval of Butrans.
7/2017	State mandate reference language updated. Added requirement for trial and failure of Belbuca for Butrans coverage in cancer and end of life pain. Updated references.
11/2017	Modified step one options. Removed Belbuca from step. Updated Connecticut regulatory information. Added provider attestation.
11/2018	Annual review. Revised documentation for date of use.
11/2019	Added a note for stage four advanced metastatic cancer and state mandates. Modified language for cancer diagnosis/end of life pain to align with other opioid programs. Updated references.
11/2020	Added duration of trial requirements. Updated references.