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Policy Number: C4199-A

Belbuca (buprenorphine buccal film) & Butrans (buprenorphine transdermal)

PRODUCTS AFFECTED

Belbuca (buprenorphine buccal film), Butrans (buprenorphine transdermal system)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Severe chronic pain

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case- by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. CHRONIC, SEVERE NON-CANCER PAIN:
   1. Member has a diagnosis of severe pain AND the same source of pain is chronic (> 6 months) in nature
      AND
   2. Documentation member is opioid-tolerant and requires around-the clock-long-term opioid treatment.
      AND
   3. The member does NOT have any of the following or any other FDA labeled contraindications: acute or severe bronchial asthma OR known or suspected gastrointestinal obstruction, includingparalytic ileus

AND

4. Prescriber attestation that non-pharmacologic therapy (e.g., physical therapy, exercise, Cognitive Behavioral Therapy, weight loss) and non-opioid therapy [e.g., topical diclofenac, nonsteroidal anti-inflammatory drugs (NSAIDs), tricyclic antidepressants (TCAs), and serotonin and norepinephrine reuptake inhibitors (SNRIs), or anticonvulsants] were maximized prior to prescribing opioids or as concurrent therapy
   AND
5. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion
   AND
6. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member)
   AND
7. Prescriber attestation that the member can safely take the requested dose of the requested drug based on their current opioid use history.
   AND
8. Prescriber attestation that member has a signed Patient-Provider agreement or equivalent for controlled substance therapy
   AND
9. Prescriber attests that member has a treatment plan or other measures to provide a baseline status for stabilization/improvement in the patient. A treatment plan may include: Pain intensity (scales or ratings), Functional status (physical and psychosocial), Patient's goal of therapy (level of pain acceptable and/or functional status), and current non- pharmacological treatment
   AND
10. Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented intolerance to ONE preferred formulary ORAL immediate acting products AND ONE preferred formulary LONG-ACTING PRODUCT
    AND
11. BELBUCA ONLY: Documentation that member has tried, failed, or has contraindication to Butrans (buprenorphine)
    AND
12. FOR DOSING REQUESTS GREATER THAN MED LIMIT (PER STATE/LOB): Documentation that prescriber has discussed the high dose with the patient, provides a therapeutic clinical rational for a dose higher than the maximum allowed MED, an appropriate titration schedule tothe current dose and plan for maintenance dosing once goals are reached.

B. ACTIVE TREATMENT OF CANCER RELATEDPAIN:
   1. Documentation of cancer diagnosis and need for pain therapy
      AND
   2. Documentation that the member had an adequate trial and therapeutic failure or documented intolerance to preferred formulary ORAL long-acting narcotic analgesic
      AND
   3. BELBUCA ONLY: Documentation that member has tried, failed or has contraindication to Butrans (buprenorphine)

CONTINUATION OF THERAPY:

A. CHRONIC, SEVERE NON-CANCER PAIN:
   1. Documentation of updated treatment plan within the last 6 months
      AND

2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion
   AND
3. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member)
   AND
4. Documentation of positive clinical response as demonstrated by improvement or stabilization in pain symptoms and/or pain control.
   AND
5. FOR DOSING REQUESTS GREATER THAN MED LIMIT (PER STATE/LOB):
   i. Dose requested is titrated down from initial authorization. If not, the prescriber has explained medical necessity for continued dosing above maximum state/line of business MME: (i) A treatment plan that includes a proposed regimen for reducing the dose of opioid or a reason is given why a dose decrease is not recommended for the member. (ii)Documentation of member's response to the requested medication (ex. decreased pain, improved level of functioning or quality of life.)
      AND
   ii. Provider has submitted an attestation that the following risk assessment was performed the WITHIN THE LAST 2 WEEKS: Checked the state's Prescription Monitoring Program/ Prescription Drug Monitoring Program (PMP/PDMP) for opioid over dosages or dangerous combinations, Reviewed a urine drug screen (UDS), offered a prescription for naloxone to patients or patient's household if member has risk factors of prior overdose, substance use disorder, doses in excess of 90 Morphine Equivalent Dosing (MED)/ day or concomitant benzodiazepines use, For evidence of Substance use Disorder, prescriber will offer or arrange for evidence based treatment where needed
      AND
   iii. Documentation of sustained improvement in Pain or Function (e.g., PEG scale with a 30% response from baseline); if no response, an alteration in the treatment plan has been initiated to discontinue treatment

B. ACTIVE TREATMENT OF CANCER RELATEDPAIN:
   1. Documentation of positive clinical response as demonstrated by improvement or stabilization in pain symptoms and/or pain control.

DURATION OF APPROVAL:
Initial authorization: Cancer, End-of-Life, Palliative Care: 12 months, Chronic Pain: 6 months Continuation of Therapy: Chronic Pain:12 months, Cancer, End-of-Life, Palliative Care: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with surgeon, pain management specialist, oncologist or palliative care specialist [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Butrans- maximum quantity is 20mcg/hr. transdermally worn for 7 days, Belbuca- maximum is900mcg transmucosal every 12 hours
NOTE*Medications with a Morphine Equivalent Dosing (MED) > 200 for those patients without a diagnosis of cancer, end-of-life or palliative care, will require a medical director Review

PLACE OF ADMINISTRATION:
The recommendation is that transdermal and oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Transdermal and oral

DRUG CLASS:
Opioid Partial Agonists

FDA-APPROVED USES:
BUTRANS (buprenorphine) transdermal system is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate

BELBUCA (buprenorphine buccal film) is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Belbuca (buprenorphine) buccal film is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. They should be reserved for use in patients for whom alternative treatment options (such as, non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Belbuca (buprenorphine) buccal film is not indicated as an as-needed (prn) analgesic. There are many other long-acting generically available opioid analgesics, including Morphine ER, Hydromorphone ER, Oxycodone ER, Oxymorphone ER, Methadone, and Fentanyl transdermal patches. All opioids are similarly effective for pain relief as determined by years of clinical experience, systematic reviews, and clinical practice guidelines. There is no evidence that supports superiority of one product (brand or generic) over another product (brand or generic). There is also no evidence to support superiority of a long-acting opioid agent over a short acting opioid agent. There is no evidence in of a difference in efficacy between scheduled dosing of a sustained release opioid over as needed dosing of an immediate release opioid. There is no reliable evidence that anyone opioid is safer than another, including abuse-deterrent formulations, long-acting opioids compared to

short-acting opioids, Schedule 3

Controlled Substances (Belbuca) compared to Schedule 2 Controlled Substances (Fentanyl, Morphine, others), or use of partial- verses pure opioid agonists. Clinical guidelines recognize the use of long-actingopioids for management of chronic pain in specific circumstances but do not recommend one medicationor dosage form.

Evidence on long-term opioid therapy for chronic pain is very limited but suggests an increased risk of serious harms that are dose dependent. Long-term opioids for chronic pain are associated with increased risk of abuse, overdose, fracture, and myocardial infarction versus not currently being prescribed opioids. All long-acting opioid analgesics have a boxed warning for addiction, abuse, misuse, life-threatening respiratory depression, accidental exposure, and neonatal opioid withdrawal syndrome. Belbuca is a buccal dissolving film tablet that provides transmucosal delivery of buprenorphine

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Belbuca (buprenorphine buccal film) & Butrans (buprenorphine transdermal system) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy

OTHER SPECIAL CONSIDERATIONS:

CDC Recommendations for Opioid Prescribing for Chronic Pain:

A. Determining when to initiate or continue opioids for chronic pain

1. Opioids are not first-line or routine therapy for chronic pain
2. Establish and measure goals for pain and function
3. Discuss benefits and risks and availability of non-opioid therapies with patient

B. Opioid selection, dosage, duration, follow-up, and discontinuation

1. Use immediate-release opioids when starting
2. Start low and go slow-Use caution at any dose and avoid increasing to high dosages
3. When opioids are needed for acute pain, prescribe no more than needed, do NOT prescribe ER/LA opioids for acute pain
4. Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if opioids cause harm or are not helping

C. Assessing risk and addressing harms of opioid use

1. Evaluate risk factors for opioid-related harms
2. Check CSPMP for high dosages and prescriptions from other providers at the beginning of the treatment and at least quarterly while on the opioid treatment
3. Use urine drug testing to identify prescribed substances and undisclosed use
4. Avoid concurrent benzodiazepine and opioid prescribing
5. Arrange treatment for opioid use disorder if needed

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Butrans PTWK 5MCG/HR, Butrans PTWK 7.5MCG/HR, Butrans PTWK 10MCG/HR, Butrans PTWK 15MCG/HR, Butrans PTWK 20MCG/HR, Belbuca FILM 75MCG, Belbuca FILM 75MCG, Belbuca FILM 150MCG, Belbuca FILM 150MCG, Belbuca FILM 300MCG, Belbuca FILM 300MCG, Belbuca FILM 450MCG, Belbuca FILM 450MCG, Belbuca FILM 600MCG, Belbuca FILM 600MCG, Belbuca FILM 750MCG, Belbuca FILM 750MCG, Belbuca FILM 900MCG, Belbuca FILM 900MCG

REFERENCES

1. Butrans Prescribing Information. Stamford, CT. Purdue Pharma L.P. September 2018.
2. Belbuca Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. October 2019.
3. Kurt Kroenke, Daniel P Alford, Charles Argoff, Bernard Canlas, Edward Covington, Joseph W Frank, Karl J Haake, Steven Hanling, W Michael Hooten, Stefan G Kertesz, Richard L Kravitz, Erin E Krebs, Steven P Stanos, Mark Sullivan; Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report, Pain Medicine, , pny307, https://doi.org/10.1093/pm/pny307
4. Cdc.gov. (2019). CDC Guideline for Prescribing Opioids for Chronic Pain | Drug Overdose | CDC Injury Center. [online] Available at: https://www.cdc.gov/drugoverdose/prescribing/guideline.html [Accessed 20 Feb. 2019].
5. Aacc.org. (2019). [online] Available at: https://www.aacc.org/-/media/Files/Science-and-Practice/Practice-Guidelines/Pain-Management/LMPGPain-Management20171220.pdf [Accessed 20 Feb. 2019].
6. Centers for Disease Control and Prevention. 2018 Annual Surveillance Report of Drug- Related Risks and Outcomes — United States. Surveillance Special Report 2. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Published August 31, 2018.