Belbuca (buprenorphine buccal film) & Butrans (buprenorphine transdermal system) Policy Number: C4199-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
4/1/2012	2/1/2019	2/1/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
	RxPA	Q2 2019

PRODUCTS AFFECTED:
Belbuca (buprenorphine buccal film), Butrans (buprenorphine transdermal system)

DRUG CLASS:
Opioid Partial Agonists

ROUTE OF ADMINISTRATION:
Transdermal and Oral

PLACE OF SERVICE:
Retail Pharmacy

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

FDA-APPROVED USES: 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.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: severe chronic pain

REQUIRED MEDICAL INFORMATION:
A. CHRONIC, SEVERE NON-CANCER PAIN:
1. Documentation of a diagnosis of severe pain lasting 3 months or greater, severe enough to require daily, around-the-clock, long-term opioid treatment
AND
2. The patient does NOT have any of the following contraindications to Belbuca: Acute or severe bronchial asthma OR known or suspected gastrointestinal obstruction, including paralytic ileus
AND
3. The patient has been evaluated and will be monitored regularly for the development of addiction, abuse, or misuse of the requested drug.

AND

4. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request to ensure the member is not concurrently utilizing opioids, benzodiazepines or sedative/hypnotic agents. NOTE: PDMP check is required on date of request and completed within the last 48 hours.
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber agrees to review member's records AND/OR perform drug screens on a periodic basis or as necessary to ensure no abuse or diversion
   AND
5. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member) EXCEPTION: If drug screen is POSITIVE for ANY non-prescribed drug of abuse, prescriber must submit an acknowledgement and rationale for requesting continued therapy despite a positive drug screen. Continuation of therapy will not be authorized unless written documentation is submitted for Molina Pharmacy/Medical Director Review
   AND
6. The patient can safely take the requested dose of the requested drug based on their current opioid use history.
   AND
7. Member has a signed Patient-Provider agreement (see template example in Appendix)
   AND
8. Member has a treatment plan including: 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
9. Documentation that the patient had an adequate trial and therapeutic failure or documented intolerance to three formulary ORAL long-acting narcotic analgesic AND to the preferred topical narcotic analgesic
   AND
10. There is NO concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. OR treatment plan to taper use and coordinate care
    AND
11. BELBUCA ONLY: Tried, failed or has contraindication to Butrans (buprenorphine) transdermal system

B. ACTIVE TREATMENT OF CANCER RELATED PAIN:
   1. Documentation of cancer diagnosis currently being treated
      AND
   2. Documentation that the patient had an adequate trial and therapeutic failure or documented intolerance to three formulary ORAL long-acting narcotic analgesic AND to the preferred topical narcotic analgesic
      AND
   3. BELBUCA ONLY: Tried, failed or has contraindication to Butrans (buprenorphine) transdermal system

DURATION OF APPROVAL: Initial authorization: 6 months, Continuation of therapy: 6 months

QUANTITY: Butrans- maximum quantity is 20mcg/hr worn for 7 days,
Belbuca- maximum is 900mcg transmucosal

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with surgeon, pain management specialist, oncologist or palliative care specialist

AGE RESTRICTIONS: BELBUCA: 16 years of age and older

GENDER: Male and female

CONTINUATION OF THERAPY:

A. CHRONIC, SEVERE NON-CANCER PAIN:
   1. Documentation of updated treatment plan within the last 12 months
      AND
   2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request to ensure the member is not concurrently utilizing opioids, benzodiazepines or sedative/hypnotic agents. NOTE: PDMP check is required on date of request and completed within the last 48 hours.
      OR
      (b) FOR STATES WITHOUT PDMPs: Prescriber agrees to review member's records AND/OR perform drug screens on a periodic basis or as necessary to ensure no abuse or diversion
      AND
   3. Documentation of updated random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member) EXCEPTION: If drug screen is POSITIVE for ANY non-prescribed drug of abuse, prescriber must submit an acknowledgement and rationale for requesting continued therapy despite a positive drug screen. Continuation of therapy will not be authorized unless written documentation is submitted for Molina Pharmacy/Medical Director Review
      AND
   4. There is NO concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. OR treatment plan to taper use and coordinate care

B. ACTIVE TREATMENT OF CANCER RELATED PAIN:
   1. Documentation of stable to improvement with pain management therapy

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

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 efficacy between scheduled dosing of a sustained release opioid over as needed dosing of an immediate release opioid. There is no reliable evidence that any one 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 longacting opioids for management of chronic pain in specific circumstances but do not recommend one medication or 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.

APPENDIX: None

REFERENCES:

1. Butrans Prescribing Information. Stamford, CT. Purdue Pharma L.P. September 2018.
2. Belbuca Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. December 2016.
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.
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