**Butrans (transdermal buprenorphine) and Belbuca (buccal buprenorphine)**

Prior Authorization Criteria

Butrans and Belbuca are indicated for the management of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate.

**Mechanism of Action:**

Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa opioid receptor.

All of the following criteria must be met for coverage of Butrans or Belbuca:

1. Member must be at least 18 years of age.
2. Documentation of the presence of moderate to severe chronic pain with requires a continuous around-the-clock opioid analgesic for an extended period of time.
3. Review of the member’s prescription claims history documents the use of 1 or more NSAID (non-steroidal anti-inflammatory drug) as well as the use of 1 or more oral opioid analgesic, within the past 90 days.
4. The use of all other around-the-clock opioid drugs must be discontinued when Butrans or Belbuca therapy is initiated.
5. Neither Butrans transdermal patch nor Belbuca buccal films are intended for the treatment of opioid dependence and will not be approved for such.

**Butrans transdermal patches** are available in 5 mcg/hour, 7.5 mcg/hour, 10 mcg/hour, 15 mcg/hour and 20 mcg/hour strengths. Each transdermal system is intended to be worn for 7 days. 20 mcg/hour is the maximum approved dose; doses exceeding this limit may risk QTc interval prolongation. Upon approval, coverage will be limited to 4 units of Butrans every 28 days. Exceptions to the quantity limit may be approved to accommodate dose titration, but will not be approved to accommodate doses greater than 20mcg/hour or the application of multiple transdermal systems.

**Belbuca buccal films** are available as 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg strengths. The 600 mcg, 750 mcg and 900 mcg strengths are only for use following titration from lower doses.
Belbuca is dosed either daily (initiation of treatment in opioid naïve patients) or twice daily. Quantity limits of 60 films of one strength per 30 days are in place. The maximum Belbuca dose is 900 mcg every 12 hours. This dosage should not be exceeded due to the potential for QTc interval prolongation.

Butrans and Belbuca prescribing information have a boxed warning for the following:
- Addiction, abuse, and misuse potential
- Life-threatening Respiratory Depression
- Accidental Exposure
- Neonatal Opioid Withdrawal Syndrome

References:
2. Belbuca [prescribing information]. Malvern, PA. Endo Pharmaceuticals Inc; October 2015.