Clinical Policy: Opioid Analgesics

Reference Number: HIM.PA.139
Effective Date: 08.01.18
Last Review Date: 11.18
Line of Business: HIM* Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Requests for transmucosal immediate-release fentanyl products (TIRFs) should be evaluated using the Fentanyl IR (Abstral, Actiq, Fentora, Lazanda, Subsys) policy – CP.PMN.127.

Description
Opioid analgesics exert their analgesic effect through opiate receptors distributed in tissues throughout the body.

This policy applies to all formulary long and short acting opioids requiring prior authorization or any non-formulary drug request that has met the formulary exception criteria – HIM.PA.103.

FDA Approved Indication(s)
Opioid analgesics are indicated for the management and treatment of moderate to severe pain.

Policy/Criteria
Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Cancer or Palliative Care (must meet all)**:**

1. Prescribed for pain associated with cancer or for palliative care (hospice or any terminal condition);
2. If request is for a formulary long-acting or short acting agent requiring prior authorization: member has failed an adequate trial of two other short-acting opioids analgesics dosed around the clock, unless contraindicated or clinically significant adverse effects are experienced;
3. For OHIO request ONLY: If total dose of opioid exceeds 80 MME/day, member is stable (history of > 7 days of therapy) on current dose or documentation supports gradual upward titration of dose.

Approval duration: 12 months

B. Nucynta ER for Diabetic Peripheral Neuropathy (must meet all)**:**

1. Request is for Nucynta ER;
2. Diagnosis of diabetic peripheral neuropathy;
3. Age ≥ 18 years;
4. Failure of gabapentin at ≥ 1800 mg/day unless contraindicated or clinically significant adverse effects are experienced;

5. Failure of a formulary TCA (e.g., amitriptyline, nortriptyline, imipramine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of a formulary SNRI (e.g., duloxetine, venlafaxine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 500 mg/day.

Approval duration: Duration of request or 180 days (whichever is less)

C. Agents Requiring Formulary Prior Authorization (PA) less than a 14 day Supply (must meet all):

1. Prescribed for the treatment of pain unrelated to cancer or palliative care;
2. Member meets either of the following (a or b):
   a. If request is for a short-acting opioid: Failure of an adequate trial of two other short-acting opioids analgesics on the formulary dosed around the clock, unless contraindicated or clinically significant adverse effects are experienced;
   b. If request is for a long-acting opioid: Failure of an adequate trial of two other long-acting opioids analgesics on the formulary dosed around the clock unless contraindicated or clinically significant adverse effects are experience and must meet criteria for long acting agent use in section I D (see below);
3. For OHIO requests ONLY: Total opioid dose does not exceed 80 MME/day or for members who are stable (history of > 7 days of therapy) on doses higher than 80 MME/day, one of the following is met (a or b):
   a. Provider will initiate a dose taper;
      **Future approval will require decrease from current dose*
   b. Documentation that a dose taper has been attempted within the past 6 months, with the reasons for taper failure;
4. For OHIO requests ONLY: If opioid is being prescribed concomitantly with a benzodiazepine, member meets both of the following (a and b):
   a. Documentation that the provider has acknowledged combined use of opioid medication and benzodiazepine;
   b. Prescribed for short term (< 3 months) use or provider will discontinue concurrent use of benzodiazepine and opioid therapy within a 3-month period.
      **Re-authorization request for concurrent use of opioid and benzodiazepine will not be approved*

Approval Duration: 7 days

D. Long-Acting Agents <u>OR</u> Requests Exceeding a 14-day Supply Within 28 Days <u>OR</u> 28-day Supply Within 90 Days (must meet all)**:**

**If member is new to Centene benefit and has received 90 days of the opioid in the last 120 days, <u>approve request for 6 months</u> and advise provider to attempt opioid taper.*

1. Prescribed for the treatment of pain unrelated to cancer or palliative care;
2. Member meets one of the following (a or b):
   a. Prescribed agent is a short acting agent that is covered without formulary PA requirement or member has failed an adequate trial of two other short-acting opioids analgesics on the formulary, dosed around the clock, unless contraindicated or clinically significant adverse effects are experienced;

b. Failure of an adequate trial of two short-acting opioids analgesics dosed around the clock; additionally if formulary PA is required, failure of an adequate trial of 2 formulary long acting agents, unless contraindicated or clinically significant adverse effects are experienced;

3. Failure of at least 2 non-opioid ancillary treatments (such as non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, anticonvulsants, antidepressants, etc.) unless contraindicated or clinically significant adverse effect are experienced;
4. For OHIO requests ONLY: Total opioid dose does not exceed 80 MME/day or for members who are stable (history of > 7 days of therapy) on doses higher than 80 MME/day, one of the following is met (a or b):
   c. Provider will initiate a dose taper;
      **Future approval will require decrease from current dose*
   d. Documentation that a dose taper has been attempted within the past 6 months, with the reasons for taper failure;
5. For OHIO requests ONLY: If opioid is being prescribed concomitantly with a benzodiazepine, member meets both of the following (a and b):
   a. Documentation that the provider has acknowledged combined use of opioid medication and benzodiazepine;
   b. Prescribed for short term (< 3 months) use or provider will discontinue concurrent use of benzodiazepine and opioid therapy within a 3-month period.

Approval duration: Duration of request or 30 days (whichever is less)

E. Other diagnoses/indications – Not applicable

II. Continued Therapy

A. Cancer or Palliative Care (must meet all)**:**

1. Currently receiving prescribed agent via Centene benefit for cancer and palliative care or have previously met initial approval criteria;
2. For OHIO requests ONLY: If total dose of opioid exceeds 80 MME/day, member is stable (history of > 7 days of therapy) on current dose or documentation supports gradual upward titration of dose.

Approval duration: 12 months

B. Nucynta ER for Diabetic Peripheral Neuropathy (must meet all)**:**

1. Currently receiving Nucynta ER for the diagnosis of diabetic peripheral neuropathy or member has met initial approval criteria;
2. Provider submits medical justification supporting continued need of Nucynta ER;
3. If request is for a dose increase, new dose does not exceed 500mg/day.

Approval duration: Duration of request or 30 days (whichever is less)

C. Agents Requiring Formulary Prior Authorization (PA) less than a 14 day Supply

1. Previously received medication via Centene benefit or has previously met the initial approval criteria;
2. For OHIO requests ONLY: Total opioid dose should NOT exceed 80 MME/day or if the current dose is higher than 80 MME/day, one of the following is met (a, b or c):

a. Dose reduction has occurred since previous approval;
b. A dose taper has been attempted within the past 6 months and was not successful;
**Reason(s) for taper failure must be provided*
c. Prescribed by or consultation with a pain management specialist;

3. For OHIO requests ONLY: If the requested dose is for > 80 MME/day, an increase in dose has not occurred since previous approval;
4. For OHIO requests ONLY: If opioid is being prescribed concomitantly with a benzodiazepine, member meets all of the following (a, b, and c):
   a. Currently receiving concurrent opioid and benzodiazepine therapy via Centene benefit or member has previously met the initial approval criteria;
   b. Documentation supports that discontinuation of combination opioid and benzodiazepine therapy has been attempted in the last 3 months without success;
   c. Prescribed by or in consultation with a pain management specialist.

Approval Duration: 7 days

D. Long-Acting Agents <u>OR</u> Requests Exceeding a 14-day Supply Within 28 Days <u>OR</u> 28-day Supply Within 90 Days (must meet all)**:** (must meet all):
**If member is new to Centene benefit and has received 90 days of the opioid in the last 120 days, <u>approve request for 6 months</u> and advise provider to attempt opioid taper.*

1. Previously received medication via Centene benefit or member has previously met initial approval criteria;
2. Has received more than a 7-day supply of opioid in the last 90 days;
   If member does not meet this requirement, please use the initial approval criteria to review this request
3. Provider submits medical justification supporting continued need of opioid analgesics, including all of the following (a through i):
   a. Diagnosis or conditions that are contributing to the pain;
   b. Pain intensity (scales or ratings);
   c. Functional status (physical and psychosocial);
   d. Patient's goal of therapy (level of pain acceptable and/or functional status);
   e. Current analgesic (opioid and adjuvant) regimen;
   f. Current non-pharmacological treatment;
   g. Opioid-related side effects;
   h. Indications of medical misuse;
   i. Action plan if analgesic failure occurs;
4. For OHIO requests ONLY: Total opioid dose should NOT exceed 80 MME/day or if the current dose is higher than 80 MME/day, one of the following is met (a, b or c):
   a. Dose reduction has occurred since previous approval;
   b. A dose taper has been attempted within the past 6 months and was not successful;
   **Reason(s) for taper failure must be provided*
   c. Prescribed by or consultation with a pain management specialist;
5. For OHIO requests ONLY: If the requested dose is for > 80 MME/day, an increase in dose has not occurred since previous approval;
6. For OHIO requests ONLY: If opioid is being prescribed concomitantly with a benzodiazepine, member meets all of the following (a, b, and c):
   a. Currently receiving concurrent opioid and benzodiazepine therapy via Centene benefit or member has previously met the initial approval criteria;

b. Documentation supports that discontinuation of combination opioid and benzodiazepine therapy has been attempted in the last 3 months without success;
c. Prescribed by or in consultation with a pain management specialist.

Approval duration: Duration of request or 90 days (whichever is less)

E. Other diagnoses/indications – Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized – Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
NSAID: non-steroidal anti-inflammatory drug

Appendix B: General Information

Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors	
Type of Opioid (strength units)	**MME Conversion Factor**
Codeine (mg)	0.15
Dihydrocodeine (mg)	0.25
Fentanyl buccal or SL tablets, or lozenge/troche (mcg)	0.13
Fentanyl film or oral spray (mcg)	0.18
Fentanyl nasal spray (mcg)	0.16
Fentanyl patch (mcg)	7.2
Hydrocodone (mg)	1
Hydromorphone (mg)	4
Levorphanol tartrate (mg)	11
Meperidine hydrochloride (mg)	0.1
Methadone (mg)	
>0, ≤ 20	4
>20, ≤ 40	8
>40, ≤ 60	10
>60	12
Morphine (mg)	1
Opium (mg)	1
Oxycodone (mg)	1.5
Oxymorphone (mg)	3
Pentazocine (mg)	0.37
Tapentadol (mg)	0.4
Tramadol (mg)	0.1

V. Dosage and Administration

There are numerous narcotic analgesics, please refer to the package insert of your drug of interest for information on appropriate dosage and administration.

VI. Product Availability

There are numerous narcotic analgesics, please refer to the package insert of your drug of interest for product availability information.

VII. References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. JAMA. 2016 Apr 19; 315(15):1624-45.
2. Initial and Continued Approval follow-up periods based on the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain – 2016. http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf
3. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. J Addict Med. 2015 Sep-Oct;9(5):358-67.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created	06.09.18	06.18
No significant changes: modified the day supply requirement for PA override to align with programming; request exceeding 7 day supply/90 days changed to requests exceeding a 14-day supply within 28 Days OR 28-day supply within 90 Days	07.17.18	
No significant changes: added redirection to TIRF policy; clarified that redirection in section C is to other formulary agents; notated that section C should apply for request for < 14 day supply; added HIM OH state requirements to policy from a previously approved policy.	09.10.18	
Provided specific examples of what is needed for medical justification for continued approval to section II D and extended approval to duration of request or 90 days	09.12.18	11.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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