Clinical Policy: Opioid Analgesics*

Reference Number: HIM.PA.139
Effective Date: 08.01.18
Last Review Date: 02.22
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 (PA) or any non-formulary opioid request.

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
Please note: For HIM-Arkansas – if a member's covered prescription pain medication requires a prior authorization, then the prior authorization shall not be denied if the member has a terminal illness.

A. Cancer or Palliative Care (must meet all)**:**
**Requests for transmucosal immediate-release fentanyl products (TIRFs) should be evaluated using the Fentanyl IR (Abstral, Actiq, Fentora, Lazanda, Subsys) policy – CP.PMN.127.*

1. Prescribed for pain associated with cancer or for palliative care (hospice or any terminal condition);
2. Member has failed an adequate trial of two formulary short-acting opioid analgesics that does not require PA, dosed around the clock, unless clinically significant adverse effects are experienced or all are contraindicated;
3. For OHIO requests ONLY: If total dose of opioid exceeds 80 morphine milligram equivalents (MME) per 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. Short-Acting Agents – Requests for ≤ a 14-day Supply (must meet all):

1. Prescribed for the treatment of pain unrelated to cancer or palliative care;

2. Member has failed an adequate trial of two formulary short-acting opioids analgesics that does not require PA, dosed around the clock, unless clinically significant adverse effects are experienced or all are contraindicated;
3. For OHIO requests ONLY: Total opioid dose does not exceed 80 MME per day or for members who are stable (history of > 7 days of therapy) on doses higher than 80 MME per 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

C. Long-Acting Agents OR Requests Exceeding a 14-day Supply Within 28 Days OR Requests Exceeding a 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, approve request for 6 months 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 formulary short-acting agent that does not require PA or member has failed an adequate trial of two formulary short-acting opioids analgesics, dosed around the clock, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. Failure of an adequate trial of two short-acting opioids analgesics, dosed around the clock, and:
      i. Failure of an adequate trial of two formulary long-acting agents, unless clinically significant adverse effects are experienced or all are contraindicated;
3. Failure of at least 2 non-opioid ancillary treatments (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], acetaminophen, anticonvulsants, antidepressants) unless clinically significant adverse effect are experienced or all are contraindicated;
4. For OHIO requests ONLY: Total opioid dose does not exceed 80 MME per day or for members who are stable (history of > 7 days of therapy) on doses higher than 80 MME per 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;
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:
Short-acting agents – Duration of request or 3 months (whichever is less)
Long-acting agents – 12 months

D. 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 ≥ 1,800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a formulary tricyclic antidepressant (TCA) (e.g., amitriptyline, nortriptyline, imipramine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Failure of a formulary serotonin-norepinephrine reuptake inhibitor (SNRI) (e.g., duloxetine, venlafaxine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
7. Dose does not exceed 500 mg per day.

Approval duration: Duration of request or 6 months (whichever is less)

E. Other diagnoses/indications – Not applicable

II. Continued Therapy

Please note: For HIM-Arkansas – if a member's covered prescription pain medication requires a prior authorization, then the prior authorization shall not be denied if the member has a terminal illness.

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

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

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. Short-Acting Agents – Requests for ≤ a 14-day Supply (must meet all):

1. Previously received medication via Centene benefit or has previously met the initial approval criteria;
2. For OHIO requests ONLY: Total opioid dose does 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 in 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

C. Long-Acting Agents OR Requests Exceeding a 14-day Supply Within 28 Days OR 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, approve request for 6 months 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;
4. For OHIO requests ONLY: Total opioid dose does 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 in 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:
Short-acting agents – Duration of request or 3 months (whichever is less)
Long-acting agents – 12 months

D. Diabetic Peripheral Neuropathy (must meet all)**:**
1. Request is for Nucynta ER;
2. Currently receiving Nucynta ER for the diagnosis of diabetic peripheral neuropathy or member has met initial approval criteria;
3. Provider submits medical justification supporting continued need of Nucynta ER;
4. If request is for a dose increase, new dose does not exceed 500 mg per day.

Approval duration: Duration of request or 6 months (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
MME: morphine milligram equivalents
NSAID: non-steroidal anti-inflammatory drug
PA: prior authorization
REMS: Risk Evaluation and Mitigation Strategy
SNRI: serotonin-norepinephrine reuptake inhibitor
TCA: tricyclic antidepressant

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): significant respiratory depression; acute or severe bronchial asthma; gastrointestinal obstruction, including paralytic ileus; hypersensitivity to the opioid active ingredient, salts, or any component of the product; concurrent use of monoamine oxidase inhibitors or use of these within the last 14 days (Nucynta ER only)
- Boxed warning(s): potential for addiction, abuse, and misuse; Risk Evaluation and Mitigation Strategy (REMS); life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; cytochrome P450 3A4 interactions; risks from concomitant use with benzodiazepines or other CNS depressants

Appendix D: General Information

Opioid Oral 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

Opioid Oral MME Conversion Factors	
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 opioid 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 opioid analgesics, please refer to the package insert of your drug of interest for product availability information.

VII. References

1. Nucynta ER Prescribing Information. Stoughton, MA: Collegium Pharmaceutical, Inc.; March 2021. Available at: https://www.nucynta.com/assets/pdf/2019_NER_PI.pdf. Accessed November 23, 2021.
2. 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.
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	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	
1Q 2019 annual review: no significant changes; references reviewed and updated.	11.05.18	02.19
1Q 2020 annual review; no significant changes; added HIM-Arkansas disclaimer re: coverage when the member has a terminal illness; references reviewed and updated.	11.26.19	02.20
Revised approval duration for short-acting agents from 30 days to 3 months, and for long-acting agents from 30 days to 12 months, per request from Ambetter Pharmacy Director and PA Ops.	12.01.20	12.20 (ad hoc)
1Q 2021 annual review: no significant changes; references reviewed and updated.	12.02.20	02.21
Revised wording in the Cancer/Palliative Care Initial Approval section to clarify the circumstances under which the requirement for a trial of two formulary short-acting agents would apply.	08.24.21	
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.23.21	02.22
Removed reference to HIM.PA.103; aligned step therapy verbiage in sections IA,B,C with NF criteria in HIM.PA.103; For section IB (short-acting agents), removed "requiring PA" from title; For diabetic peripheral neuropathy, revised approval duration from 180 days to 6 months for initial therapy and 30 days to 6 months for continued therapy, removed drug specific (Nucynta ER) call out in title, and moved criteria to end of sections I and II.	07.18.22	

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

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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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