Clinical Policy Title:	Opioid Analgesics
Policy Number:	RxA.432
Drug(s) Applied:	Too many to list
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Opioid analgesics exert their analgesic effect through opiate receptors distributed throughout the body and are indicated for the management and treatment of moderate to severe pain.

There are numerous narcotic analgesics used in clinical practice. Please refer to the prescribing information of the specific drug of interest for information on appropriate dosage, administration, contraindications and/or boxed warnings and product availability information.

Requirements for a MED limit (360MME/day) override can be found under step 5 for long term therapy approval criteria.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria and Continued Therapy Criteria

A. Short Acting Opioids (short-term therapy)

1. Request is for an immediate-release opioid [EXCEPT transmucosal immediate release fentanyl (TIRF)]
2. Age is 18 years or older and day supply per prescription fill is ≤ 5 days (must meet a and b)
   a. The 5-day supply limit applies to each of their first 4 fills
   b. ≤ 20 days in a 60-day period.
3. Age is 18 years or older and day supply per prescription fill is > 5 days (must meet a or b)
   a. Member has a diagnosis of chronic pain or acute pain supported by appropriate diagnosis code AND member has used an opioid medication for a cumulative day supply of ≤ 20 days in the past 60 days
   b. Irrespective of diagnosis, if member has used an opioid medication for a cumulative day supply >20 days, utilize long term therapy criteria.
4. Age is less than 18 years and the maximum day supply per prescription fill is 3 days (must meet a and b)
   a. The 3-day supply limit applies to each of their first 4 fills
   b. ≤ 12 days in a 60-day period.
5. Total opioid dose (morphine milligram equivalents (MME)/day limits:
   a. Opioid naive (no opioid use within 130 days) ≤ 90 MME/day
   b. Not-opioid naïve ≤ 120 MME/day

Approval Duration:

Commercial: One time authorization per request
Medicaid: One time authorization per request

B. Short Acting Opioids (long-term therapy)

1. Request is for an immediate release opioid
2. Request is for TIRF product (must meet a or b)
   a. Member is being treated for cancer-related breakthrough and member is taking another opioid for round-the-clock pain management.
   b. Member is in hospice or end-of-life/palliative care setting
3. Member meets one of the following criteria (a, b, or c):
   a. Member has a cancer diagnosis
   b. Member is in a hospice program, end-of-life care, or palliative care
   c. Member has chronic pain without a cancer diagnosis (must meet i, ii, and iii)
      i. Non-opioid therapies such as non-opioid medications [e.g. non-steroidal anti-inflammatory drugs {NSAIDs}, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors {SNRSs}, anti-convulsants], exercise therapy, weight loss, cognitive behavioural therapy etc have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician; AND
      ii. Member's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), unless unavailable in the state, according to the prescribing physician; AND
      iii. Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the member according to the prescribing physician.
4. Total opioid dose (morphine milligram equivalents (MME/day)):
   a. Opioid naïve (no opioid use within 130 days) ≤ 90 MME/day
   b. Not-opioid naïve ≤ 120 MME/day
5. If MME/day limit is exceeded:
   a. Prescriber should attest that member has a pain contract/treatment plan, AND that prescriber has assessed the appropriateness of naloxone in one of the following situations (i or ii):
      i. Opioid-naïve members whose total opioid dose is greater than 90 MME/day but less than 360 MME/day;
      ii. Members who are not opioid-naïve whose total opioid dose is greater than 120 MME/day but less than 360 MME/day;
   b. Members who are not opioid-naïve whose total opioid dose is greater than 360 MME/day, prescriber should provide documentation of treatment plan/pain contract AND attest that prescriber has assessed the appropriateness of naloxone.

Approval Duration
Commercial: Duration of treatment requested by prescriber or 12 months, whichever is shorter.
Medicaid: Duration of treatment requested by prescriber or 12 months, whichever is shorter.

C. Long-Acting Opioids (short-term and long-term therapy)

1. Request is for an extended-release opioid EXCEPT fentanyl patches.
2. Member is not opioid-naïve (has taken at least one (1) opioid medication in the past 130 days)
3. If the request is for fentanyl patches (must meet a or b)
   a. Member is opioid-tolerant *(see Appendix D for definition)* and requires daily, around-the clock, opioid treatment
   b. Member is being treated for chronic pain or has a diagnosis of cancer or is in hospice/palliative care setting

4. Member meets ONE of the following criteria (a, b, or c):
   a. Member has a cancer diagnosis
   b. Member is in a hospice program, end-of-life care or palliative care
   c. Member has chronic pain without a cancer diagnosis and meets the following (must meet I, ii, iii, and iv)
      i. Non-opioid therapies such as non-opioid medications [e.g. non-steroidal anti-inflammatory drugs {NSAIDs}, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors {SNRSs}, anti-convulsants], exercise therapy, weight loss, cognitive behavioral therapy etc have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician; AND
      ii. Member's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), unless unavailable in the state, according to the prescribing physician; AND
      iii. Risks (e.g., addiction, overdose) and realistic benefits of opioid therapy have been discussed with the member according to the prescribing physician.
      iv. Treatment plan (including goals for pain and function) is in place and reassessments (including pain levels and function) are scheduled at regular intervals according to the prescribing physician.
5. Total opioid dose morphine milligram equivalents (MME)/day limit: 120 MME/day
6. If MME/day limit is exceeded (must meet a or b):
   a. Members whose total opioid dose is greater than 120 MME/day but less than 360 MME/day, attestation that prescriber has assessed the appropriateness of naloxone.
   b. Members whose total opioid dose is greater than 360 MME/day, prescriber should provide documentation of treatment plan/pain contract AND attest that prescriber has assessed appropriateness of naloxone.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Appendices

APPENDIX A: Abbreviation/Acronym Key
MME: morphine milligram equivalent
NSAID: non-steroidal anti-inflammatory drug
PDMP: prescription drug monitoring program
TIRF: transmucosal immediate release fentanyl
MED: Morphine equivalent dose

APPENDIX B: TIRF products
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements:

- Actiq (fentanyl citrate) oral transmucosal lozenge and its generic equivalents
- Fentora (fentanyl citrate) buccal tablet and its generic equivalents
- Lazanda (fentanyl) nasal spray and its generic equivalents
- Onsolis (fentanyl) buccal soluble film and its generic equivalents
- Subsys(fentanyl) sublingual spray and its generic equivalents
- Fentanyl citrate sublingual tablets

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and

brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Refer to individual drug prescribing information
- Boxed Warning(s):
  - Refer to individual drug prescribing information

APPENDIX D: General Information

Opioid tolerant patients are defined as patients who are taking at least:

- Oral morphine 60mg/day, or
- Transdermal fentanyl 25mcg/hour, or
- Oral oxycodone 30mg/day, or
- Oral hydromorphone 8mg/day, or
- Oral oxymorphone 25mg/day, or
- Oral hydrocodone 60mg/day, or
- Equianalgesic dose of another opioid for at least 1 week

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. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm. Accessed August 23, 2021.
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. Accessed August 23, 2021.
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. Available at: https://pubmed.ncbi.nlm.nih.gov/26406300/. Accessed August 23, 2021.
4. Brown EG, Serrano D, Kirchmeyer K. Guidelines for Prescribing Controlled Substances for Pain. In: California MBo, editor. Calfornia. 2014; http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf. Accessed August 23, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	02/2020	03/06/2020
2Q2020 P&T Review: No clinical updates, references reviewed and updated, added Appendix B (TIRF Products)	04/2020	05/20/2020
Updated table to include “All lines of business” Updated background and added… “Please refer to…availability information”	02/19/2021	03/09/2021

1.A.3 – added clinical criteria 1.A.5 – changed language to describe opioid-naïve and non-opioid naïve members; deleted “All utilizers” 1.B.4.b – combined existing and all utilizers into a range of dosing based on MME/day; changed duration of approval to reflect prescriber intent, if available. 1.C.3.a – clarified requirement for member being opioid-tolerant; deleted “Member has received fentanyl patches within the past 60 days” 1.C.5 – b, combined existing and all utilizers into a range of dosing based on MME/day. Appendix C : updated Appendix D: updated to add definitions of Opioid-tolerant		
Policy was reviewed. 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial Approval Criteria I.A approval duration was updated to “one time authorization per request”. 3. Appendix A was updated to include abbreviation MED. 4. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.”. 5. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both	08/23/2021	09/14/2021

generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 6. References were reviewed and updated.		