

Clinical Policy Title:	Opioid Analgesics
Policy Number:	RxA.432
Drug(s) Applied:	Too many to list
Original Policy Date:	05/20/2020
Last Review Date:	03/09/2021
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.

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 naïve (no opioid use within 130 days) ≤ 90 MME/day
 - b. Non-opioid naïve ≤ 120 MME/day

Approval Duration:

Commercial: One time authorization for 5 days (3 days if member is less than 18 years of age)

Medicaid: One time authorization for 5 days (3 days if member is less than 18 years of age)

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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 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.
4. Total opioid dose (morphine milligram equivalents (MME)/day):
 - a. Opioid naive (no opioid use within 130 days) ≤ 90 MME/day
 - b. Not-opioid naive ≤ 120 MME/day (up to a maximum of 360MME/day)
5. If MME/day limit is exceeded (must meet a and b)
 - a. Prescriber to provide documentation of treatment plan/pain contract.
 - b. Prescriber has assessed appropriateness of naloxone for the member.

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- 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:
 - a. Opioid naive (no opioid use within 130 days) \leq 90 MME/day
 - b. Not-opioid naive \leq 120MME/day up to a maximum of 360MME/day
 6. If MME/day limit is exceeded (must meet a and b)
 - a. Prescriber to provide documentation of treatment plan/pain contract.
 - b. Prescriber has assessed appropriateness of naloxone for the member.

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

APPENDIX B: TIRF products

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

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.
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 February 19, 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.
4. Brown EG, Serrano D, Kirchmeyer K. Guidelines for Prescribing Controlled Substances for Pain. In: California MBo, editor. California. 2014; http://www.mbc.ca.gov/licenses/prescribing/pain_guidelines.pdf. Accessed February 19, 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” 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	02/19/2021	03/09/2021

