

<b>Clinical Policy Title:</b>	Opioid Analgesics
<b>Policy Number:</b>	RxA.432
<b>Drug(s) Applied:</b>	Too many to list
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	10/19/2023
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## 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  $\geq$  18 years:
  - a. Opioid naïve patients (no opioid use within past 130 days):
    - i. Requests cannot be for more than a 5-day supply;
    - ii. Patients must have received 20 days of SAO therapy within the past 60 days to obtain more than a 5-day supply regardless of chronic or acute pain diagnosis; once the patient has met the 20 days supply of SAO therapy within the past 60 days requirement, these requests will be reviewed utilizing the long-term therapy criteria labeled “chronic pain without cancer diagnosis” listed below.
  - b. Opioid tolerant (opioid use within past 130 days) and patients must have a cumulative 20 days of SAO within the past 60 days in order to obtain more than a 5 day supply:
    - i. For those requests not meeting the cumulative 20 days supply of SAO within 60 days requirement, patients will be capped at a 5-day supply per request until the cumulative 20 days supply is met;
    - ii. For requests where the cumulative 20 days supply of SAO within past 60 days is met, requests will be reviewed utilizing the long-term therapy criteria below.
3. Age  $\leq$  18 years:
  - a) Opioid naïve patients (no opioid use within past 130 days):
    - i. Requests cannot be for more than a 3-day supply;
    - ii. Patient must have received 12 days of SAO therapy within the past 60 days to obtain more than a 3-day supply regardless of chronic or acute pain diagnosis; once the patient has met the 12 days supply of SAO therapy within the past 60 days requirement, these requests will be reviewed utilizing the long-term criteria labeled “chronic pain without cancer diagnosis” listed below.
  - b) Opioid tolerant patients (opioid use within past 130 days) and patients must have a cumulative 12 days of SAO therapy within the past 60 days in order to obtain more than a 3 day supply;
    - i. For those requests not meeting the cumulative 12 days supply of SAO within 60 days requirement, patients will be capped at a 3-day supply per request until the cumulative 12 days supply is met;
    - ii. For requests where the cumulative 12 days supply of SAO within past 60 days is met, request will be reviewed using the long-term therapy criteria below.

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.

5. Total opioid dose (morphine milligram equivalents (MME)/day limits:
  - a. Opioid naïve (no opioid use within 130 days)  $\leq$  90 MME/day
  - b. Not-opioid naïve  $\leq$  120 MME/day
6. 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:** 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 {SNRIs}, 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)  $\leq$  90 MME/day
  - b. Not-opioid naïve  $\leq$  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:** 6 months if the expected duration of therapy is less than 6 months and 12 months if the expected duration of therapy is more than 6 months

**Medicaid:** 6 months if the expected duration of therapy is less than 6 months and 12 months if the expected duration of therapy is more than 6 months

**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 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 {SNRIs}, 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.
4. Total opioid dose morphine milligram equivalents (MME)/day limit: 120 MME/day
5. 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

**References**

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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 April 24, 2023.
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 April 24, 2023.
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 April 24, 2023.
4. Brown EG, Serrano D, Kirchmeyer K. Guidelines for Prescribing Controlled Substances for Pain. In: California MBo, editor. California. 2014. Available at: [http://www.mbc.ca.gov/licensees/prescribing/pain\\_guidelines.pdf](http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf). Accessed April 24, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	02/2020	03/06/2020
Policy was reviewed	04/2020	05/20/2020
<ol style="list-style-type: none"> <li>1. Updated table to include “All lines of business”</li> <li>2. 1.A.3 – added clinical criteria</li> <li>3. 1.A.5 – changed language to describe opioid-naïve and non-opioid naïve members; deleted “All utilizers”</li> <li>4. 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.</li> <li>5. 1.C.3.a – clarified requirement for member being opioid-tolerant; deleted “Member has received fentanyl patches within the past 60 days”</li> <li>6. 1.C.5 – b, combined existing and all utilizers into a range of dosing based on MME/day.</li> </ol>	02/19/2021	03/09/2021
Policy was reviewed. <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A approval duration was updated to “one time authorization per request”.</li> <li>2. References were reviewed and updated.</li> </ol>	08/23/2021	09/14/2021
Policy was reviewed. <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.2: Updated from : Age is 18 years or older and day supply per prescription fill is ≤ 5 days (must meet a and b)</li> </ol>	12/1/2021	12/07/21

<p>a) The 5-day supply limit applies to each of their first 4 fills .</p> <p>b) ≤ 20 days in a 60-day period.to add clarifying language to include the incoming request in the calculation of cumulative days supply in the 60 day look back period.</p> <p>2. To Age is 18 years or older and day supply per prescription fill is less than or equal to 5 days (must meet a and b)</p> <p>a) The 5-day supply limit applies to each of their first 4 fills. (If the incoming claim is after the 4<sup>th</sup> fill, then the 5-day supply limit does not apply).</p> <p>b) If member has used an opioid medication for a cumulative day supply less than or equal to 20 days (including the incoming request) in the past 60-day period, continue review using the short-term criteria. If member has used an opioid medication for a cumulative day supply more than 20 days in the past 60-day period, refer to long-term therapy criteria.</p> <p>3. Initial Approval Criteria I.A.6: Updated to add If MME/day limit is exceeded:</p> <p>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):</p> <p>I. Opioid-naïve members whose total opioid dose is greater than 90 MME/day but less than 360 MME/day;</p> <p>II. Members who are not opioid-naïve whose total opioid dose is greater than 120 MME/day but less than 360 MME/day</p> <p>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</p>		
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the appropriateness of naloxone.		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.2.a and I.A.2.b, I.A.3.a and I.A.3.b : Updated from Age is 18 years or older and day supply per prescription fill is less than or equal to 5 days (must meet a and b)               <ol style="list-style-type: none"> <li>a) The 5-day supply limit applies to each of their first 4 fills. (If the incoming claim is after the 4<sup>th</sup> fill, then the 5-day supply limit does not apply).</li> <li>b) If member has used an opioid medication for a cumulative day supply less than or equal to 20 days (including the incoming request) in the past 60-day period, continue review using the short-term criteria. If member has used an opioid medication for a cumulative day supply more than 20 days in the past 60-day period, refer to long-term therapy criteria.</li> </ol> </li> <li>2. Age is 18 years or older and day supply per prescription fill is more than 5 days (must meet a or b)               <ol style="list-style-type: none"> <li>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 less than or equal to 20 days (including incoming claim) in the past 60 days</li> <li>b) Irrespective of diagnosis, if member has used an opioid medication for a cumulative day supply more than 20 days (including the incoming claim), refer to long term therapy criteria to</li> </ol> </li> <li>3. Age is 18 years or older:               <ol style="list-style-type: none"> <li>a) Opioid naïve patients (no opioid use within past 130 days):                   <ol style="list-style-type: none"> <li>i. Requests cannot be for more than a 5-day supply;</li> <li>ii. Patients must have received 20 days of SAO therapy within</li> </ol> </li> </ol> </li> </ol>	3/2/2022	4/18/2022

<p>the past 60 days to obtain more than a 5-day supply regardless of chronic or acute pain diagnosis; once the patient has met the 20 days supply of SAO therapy within the past 60 days requirement, these requests will be reviewed utilizing the long-term therapy criteria labeled “chronic pain without cancer diagnosis” listed below.</p> <p>b) Opioid tolerant (opioid use within past 130 days) and patients must have a cumulative 20 days of SAO within the past 60 days in order to obtain more than a 5 day supply:</p> <ul style="list-style-type: none"><li>I. For those requests not meeting the cumulative 20 days supply of SAO within 60 days requirement, patients will be capped at a 5-day supply per request until the cumulative 20 days supply is met;</li><li>II. For requests where the cumulative 20 days supply of SAO within past 60 days is met, requests will be reviewed utilizing the long-term therapy criteria below.</li></ul> <p>4. Initial Approval Criteria I. 4.a and I.4.b: Updated from Age is less than 18 years and the maximum day supply per prescription fill is 3 days (must meet a and b)</p> <ul style="list-style-type: none"><li>a) The 3-day supply limit applies to each of their first 4 fills. (If the incoming claim is after the 4th fill, then the 3-day supply limit does not apply).</li><li>b) If member has used an opioid medication for a cumulative day supply less than or equal to 12 days (including the incoming request) in the past 60-day period, continue review using the short-term</li></ul>		
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<p>criteria. If member has used an opioid medication for a cumulative day supply more than 12 days in the past 60-day period, refer to long-term therapy criteria. To I.A.3.a and I.A.3.b: Age is less than 18:</p> <p>c) Opioid naïve patients (no opioid use within past 130 days):</p> <ul style="list-style-type: none"> <li>i. Requests cannot be for more than a 3-day supply;</li> <li>ii. Patient must have received 12 days of SAO therapy within the past 60 days to obtain more than a 3-day supply regardless of chronic or acute pain diagnosis; once the patient has met the 12 days supply of SAO therapy within the past 60 days requirement, these requests will be reviewed utilizing the long-term criteria labeled “chronic pain without cancer diagnosis” listed below.</li> </ul> <p>d) Opioid tolerant patients (opioid use within past 130 days) and patients must have a cumulative 12 days of SAO therapy within the past 60 days in order to obtain more than a 3 day supply;</p> <ul style="list-style-type: none"> <li>i. For those requests not meeting the cumulative 12 days supply of SAO within 60 days requirement, patients will be capped at a 3-day supply per request until the cumulative 12 days supply is met;</li> <li>ii. For requests where the cumulative 12 days supply of SAO within past 60 days is met, request will be reviewed using the long-term therapy criteria below.</li> </ul>		
<p>Policy was reviewed:</p> <p>1. Initial Approval and Continued Therapy Approval Criteria I.B (Short Acting Opioids long-term therapy): Updated</p>	<p>06/30/2022</p>	<p>07/18/2022</p>



<p>Commercial and Medicaid approval duration from duration of treatment requested by prescriber or 12 months, whichever is shorter to 6 months if the expected duration of therapy is less than 6 months and 12 months if the expected duration of therapy is more than 6 months.</p>		
<p>Policy was reviewed:            1. References were reviewed and updated.</p>	<p>04/24/2023</p>	<p>07/13/2023</p>
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>