

***Title: Opioid Quantity Limitations (including, but not limited to, OxyContin<sup>®</sup> and Duragesic<sup>®</sup>)***

<b>Origination:</b> 04/16/01	<b>Revised:</b> 12/26/07	<b>Annual Review:</b> 12/15/11
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Background Information:**

***Medication Summary***

- OxyContin<sup>®</sup> is a controlled-release oral formulation of oxycodone hydrochloride and FDA approved for every 12 hour dosing for the management of moderate to severe pain where use of an opioid analgesic is needed for an extended period of time. Quantity limitations are 60 tablets per 30-day supply for all strengths excluding 80mg. The quantity limit for 80mg tablets is 120 tablets per 30-day supply since the discontinuation of the 160mg tablet.
- Duragesic<sup>®</sup> is a transdermal formulation of fentanyl and FDA approved in opiate tolerant patients with persistent, moderate to severe chronic pain that require continuous, around-the-clock opioid administration for an extended time period. Most patients can be maintained adequately with fentanyl transdermal systems applied every 72 hours. However, some patients may require application of the systems at 48-hour intervals to maintain adequate analgesia. Quantity limitations are 10 patches for 30-day supply for all strengths.

***Reference Statement***

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

***Eligibility Criteria***

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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**Procedure:**

- 1.0 Request for ***initial therapy*** that exceeds quantity limit for OxyContin<sup>®</sup> or Duragesic<sup>®</sup> requires documentation from the Member's medical records maintained by the requesting independent practitioner including:
  - 1.1 Pain management medical summary should include (most of this information can be found in a Member's H & P):
    - 1.1.1 Etiology of Chronic pain (i.e., nociceptive pain, neuropathic pain, and/or mixed) and/or condition (cancer, non-malignant pain);
    - 1.1.2 Period of time Member has been managed by requesting MD;
    - 1.1.3 Opioid medication history, specifically length of current treatment (i.e., how long has the member been on this particular dose);
    - 1.1.4 Pain level documentation (i.e., visual analog scale 0-10);
    - 1.1.5 Documentation as to whether opioid agreements/contracts and/or drug urinalysis are utilized as part of ongoing treatment plan;
    - 1.1.6 Pain management treatment plan (types of modalities being utilized other than medication may include physical therapy, TENS unit, epidural steroid/anesthetic injections, biofeedback, etc.); **AND**
  - 1.2 Verify (via PBM processing system) Member is currently obtaining opioids from only one (1) prescribing physician (or group of physicians in same practice site) and only one (1) pharmacy provider; **AND**
  - 1.3 Verify dose is within normal guidelines:
    - 1.3.1 OxyContin<sup>®</sup> every 12 hours for initiation, every 8 hrs for documented end-of-dose failure;
    - 1.3.2 Duragesic<sup>®</sup> every 72 hours for initiation, every 48 hours for documented end-of-dose failure;

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**Procedure, continued:**

- 1.0 Request for ***initial therapy*** that exceeds quantity limit for OxyContin<sup>®</sup> or Duragesic<sup>®</sup> requires documentation from the Member's medical records maintained by the requesting independent practitioner including, continued:
  - 1.4 If all criteria have been met, initial quantity override may be approved for a maximum of three (3) months according to the following:
    - 1.4.1 OxyContin<sup>®</sup> (oxycodone CR) up to 120 tablets of per month;
    - 1.4.2 Duragesic<sup>®</sup> (fentanyl) up to 15 patches per month.
- 2.0 Request for ***continuation of therapy*** from previous physician beyond initial authorization period requires documentation from the Member's medical records maintained by the requesting independent practitioner including:
  - 2.1 Member has shown favorable response (noted improvement and/or maintained pain levels, functionality, and absence of adverse drug reactions); **AND**
  - 2.2 Verify (via PBM processing system) Member is currently obtaining opioids from only one (1) prescribing physician (or group of physicians in same practice site) and only one (1) pharmacy provider;
  - 2.2 If all criteria have been met, may approve for (6) months.

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**References:**

1. Purdue Pharma L.P. *OxyContin* (oxycodone HCL controlled-release). Full Prescribing Information. Stamford, CT. September 7, 2007.
2. Alza Corporation. *Duragesic* (Fentanyl Transdermal System). Full Prescribing Information. Mountain View, CA. April 2007.
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4. Trescot AM, Boswell MV, Atluri SL, Hansen NC, Deer TR, Abdi S, Jasper JF, Singh V, Jordan AE, Johnson BW, Cicala RS, Dunbar EE, Helm S II, Varley KG, Suchdev PK, Swicegood JR, Calodney AK, Ogoke BA, Minore WS, Manchikanti L. Opioid guidelines in the management of chronic non-cancer pain. *Pain Phys* 2006;9(1):1-39.
5. Chou R, Qassem A, Snow V, Casey D, Cross JT, Shekelle P, Owens D. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society, *Annals of Internal Medicine*, 2 October 2007, Volume 147 Issue 7, Pages 478-491.
6. Prescribing Issue - Opioid Agreements & Contracts: The American Academy of Pain Management. <http://www.aapainmanage.org/literature/Articles/OpioidAgreements.pdf> Accessed 11/15/2007.
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8. Wisconsin Medical Society Task Force on Pain Management. Guidelines for the assessment and management of chronic pain. *WMJ*. 2004;103:13-42.



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**Disclaimer Information:**

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.