**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0383

**Measure Title**: Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 4/9/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

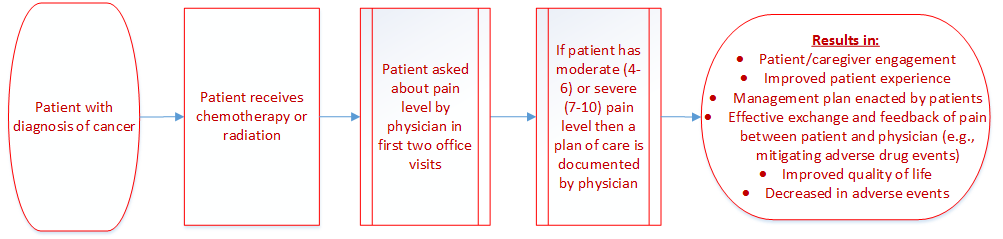
Process: Click here to name what is being measured

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.



A documented plan of care may include: use of opioids, nonopioid analgesics, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

ASCO has not conducted an assessment from patients on the benefits of this measure’s meaningfulness. However, we would refer the committee to the following recognized literature. It is undisputed that pain has a significant impact on a patient’s quality of life (1). Cancer pain has numerous psychosocial responses in patients (2,3). Patients report that pain not only prevents them from thinking or concentrating, but it also impacts their ability to perform normal daily activities (4). One study found that one-third of patients describe pain related to cancer as distressing and an intolerable aspect of cancer (4). The evidence suggests that adequate pain treatment can result in clinically relevant improvement in health related quality of life (5). Based on one systematic report performed in 2007 the authors found that the prevalence of cancer pain over a time of 40 years had not improved. (6). Despite increased attention on assessment and management, pain continues to be a prevalent symptom in patients with cancer (7). This measure seeks to address patient care by determining if a patient has moderate or severe pain, and developing a plan of care that will further the implementation of interventions needed to optimally manage pain in patients with cancer .

1. IASP. 2008-2009 Global Year Against Cancer Pain 2008. Available at: https://www.iasp-pain.org/GlobalYear/Cancer Pain. Accessed February 10, 2015.
2. Kroenke K, Theobald D, Wu J, et al. The association of depression and pain with health-related quality of life, disability, and health care use in cancer patients. J Pain Symptom Manage 2010;40:327e341.
3. Porter LS, Keefe FJ. Psychosocial issues in cancer pain. Curr Pain Headache Rep 2011;15:263e270.
4. Breivik H, Cherny N, Collett B, et al. Cancer-related pain: a pan-European survey of prevalence, treatment, and patient attitudes. Ann Oncol 2009;20:1420e1433.
5. Puetzler J, Feldmann RE Jr, Brascher AK, Gerhardt A, Benrath J. Improvements in health-related quality of life by comprehensive cancer pain therapy: a pilot study with breast cancer outpatients under palliative chemotherapy. Oncol Res Treat 2014;37:456e462.
6. van den Beuken-van Everdingen MH, de Rijke JM, Kessels AG, et al. Prevalence of pain in patients with cancer: a systematic review of the past 40 years. Ann Oncol 2007;18: 1437e1449
7. van den Beuken-van Everdingen, Marieke H.J. et al.Update on Prevalence of Pain in Patients With Cancer: Systematic Review and Meta-Analysis. J Pain Symptom Manage 2016;51:1070e1090.

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

Not Applicable

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Adult cancer pain. Swarm RA, Abernethy AP, Anghelescu DL, et al. 2017. <https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | For management of cancer-related pain in adults, the algorithm distinguishes three levels of pain intensity, based on a 0-10 numerical value obtained using numerical or the pictorial rating scale (with 0 being no pain to 10 being the worst pain). The three levels of pain intensity listed in the algorithm are mild pain (1-3); moderate pain (4-6); and severe pain (7-10).(Page 53)  The NCCN guidelines acknowledge the range of complex decisions faced in caring for these patients. As a result, they provide dosing guidelines for opioids, non-opioid analgesics, and adjuvant analgesics. They also provide specific suggestions for titrating and rotating opioids, escalation of opioid dosage, management of opioid adverse effects, and when and how to proceed to other techniques/interventions for the management of cancer pain.(Page 51)  The patient must be provided with a written follow-up pain plan including medications. It is important to ensure that the patient has adequate access to prescribed medications and maintains communication and coordination of care with relevant providers, especially during transitions between sites of care. (Page 57)  **For ALL levels of pain (Page 11)**   * Select the most appropriate medication based on the physiology of the patient’s pain * Consider acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) (See PAIN-K) * For opioid principles, prescribing, titration, and maintenance, (See PAIN-E) * Consider adding adjuvant analgesics (see PAIN-G) for specific syndromes (PAIN-D) * Anticipate and treat analgesics adverse effects (See PAIN-F) * Provide psychosocial support (See PAIN-H) * Provide patient and family/care giver education (See PAIN-I) * Optimize integrative interventions (See PAIN-J)   **Moderate pain 4-6 (Page 11)**   * See management for all levels of pain above   AND   * Rapidly titrate short acting opioid, (See PAIN-4) for initiating short-acting opioids   + Begin Bowel regimen   **Severe Pain 7-10 (Page 11)**   * Rapidly titrate short-acting opioid , (see PAIN-4) for initiating short acting opioids   🡪Begin Bowel regimen (See Pain-F)   * For acute, Severe Pain, or Pain Crisis, consider hospital or inpatient hospice admission to achieve patient-specific goal for comfort and function   *Note:* Opioid naïve includes patients who are not chronically receiving opioid analgesic on a daily basis and therefore have not developed significant tolerance. The FDA identifies tolerance as receiving at least 60 mg. or morphine daily at least 8 mg of morphine daily, at least 30 mg of oral oxycodone daily, or at least 8mg of oral hydropmorphone daily or an equianalgesic dose of another opioid for a week or longer. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Category 2A |
| Provide all other grades and definitions from the evidence grading system | NCCN Categories of Evidence and Consensus  Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.  Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| Grade assigned to the **recommendation** with definition of the grade | Category 2A |
| Provide all other grades and definitions from the recommendation grading system | NCCN Categories of Evidence and Consensus  Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.  Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The description of the evidence review in the NCCN guideline did not address the overall quantity of studies in the body of evidence. However, 255 articles are cited.  The quality of the body of evidence supporting the NCCN guideline recommendations are summarized according to the NCCN categories of evidence and consensus as being based on "lower-level evidence." Lower-level evidence is later described as evidence that may include non-randomized trials; case series; or when other data are lacking, the clinical experience of expert physicians. |
| Estimates of benefit and consistency across studies | Although there is no explicit statement regarding the overall consistency of results across studies in the NCCN guidelines supporting the measure, the recommendation received uniform NCCN consensus that the intervention is appropriate. |
| What harms were identified? | Adverse effects to opioids should be anticipated and should be managed aggressively. Pages 35-37 delineate how the adverse consequences can be mitigated including constipation, nausea, delirium, pruritus, respiratory depression, etc. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not Applicable |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Gordon DB; Dahl JL, Miaskowski C, et al. American Pain Society Recommendations for Improving the Quality of Acute and Cancer Pain Management: American Pain Society Quality of Care Task Force. Arch Intern Med. 2005;165:1574-1580.  [**https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/486669**](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/486669) |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | [C]linicians must respond to pain reports in a manner appropriate to the type of pain (eg, acute vs chronic) and setting (eg, inpatient vs outpatient)… Appropriate responses may not always include more opioids but rather more detailed assessments, use of nonopioid analgesics or techniques, or nonpharmacologic interventions (eg, education, relaxation, and use of heat or cold). (Page 1576) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Not Applicable |
| Provide all other grades and definitions from the evidence grading system | Not Applicable |
| Grade assigned to the **recommendation** with definition of the grade | Not Applicable |
| Provide all other grades and definitions from the recommendation grading system | Not Applicable |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Similarly, the description of the evidence review in the APS guideline did not address the overall quantity of studies in the body of evidence. However, 82 articles are cited.  The quality of the body of evidence supporting the APS guideline recommendation is not provided. |
| Estimates of benefit and consistency across studies | The consistency of results across the body of evidence supporting the APS guideline recommendation is not provided. |
| What harms were identified? | None were identified |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not Applicable |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Update on Prevalence of Pain in Patients With Cancer: Systematic Review and Meta-Analysis. Van den Beuken-van Everdingen, Marieke H.J. et al. 2016. Journal of Pain and Symptom Management , Volume 51 , Issue 6 , 1070 - 1090.e9  [**http://www.jpsmjournal.com/article/S0885-3924(16)30048-3/fulltext**](http://www.jpsmjournal.com/article/S0885-3924(16)30048-3/fulltext) |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Of 4117 titles, 122 studies were selected for the meta-analyses on pain (117 studies, n = 63,533) and pain severity (52 studies, n = 32,261). Pain prevalence rates were 39.3% after curative treatment; 55.0% during anticancer treatment; and 66.4% in advanced, metastatic, or terminal disease. Moderate to severe pain (numerical rating scale score >= 5) was reported by 38.0% of all patients. Despite increased attention on assessment and management, pain continues to be a prevalent symptom in patients with cancer. Worldwide, over one-third of patients after curative treatment, over half of patients during anticancer treatment, and two-third of patients with advanced, metastatic, or terminal disease have pain. Overall, more than one-third of patients graded their pain as moderate or severe.  Based on the data of 122 articles, pain prevalence rates were 39.3% after curative treatment; 55.0% during anticancer treatment; 66.4%in advanced, metastatic, or terminal disease and 50.7% in all cancer stages. The 52 studies that reported on pain severity resulted in a 38.0% prevalence of moderate to severe pain.  With reference to types of cancer, lower pain prevalence rates were demonstrated in prostate cancer compared to head and neck, lung, and breast cancer. A possible explanation could be found in group assignment: 1180 of 1493 included patients with prostate cancer belonged to the group after curative treatment. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Not Applicable |
| Provide all other grades and definitions from the evidence grading system | Not Applicable |
| Grade assigned to the **recommendation** with definition of the grade | Not Applicable |
| Provide all other grades and definitions from the recommendation grading system | Not Applicable |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Based on the data of 122 articles, pain prevalence rates were 39.3% after curative treatment; 55.0% during anticancer treatment; 66.4%in advanced, metastatic, or terminal disease and 50.7% in all cancer stages. The 52 studies that re-ported on pain severity resulted in a 38.0% prevalence of moderate to severe pain.  With reference to types of cancer, lower pain prevalence rates were demonstrated in prostate cancer compared to head and neck, lung, and breast cancer. A possible explanation could be found in group assignment: 1180 of 1493 included patients with prostate cancer belonged to the group after curative treatment.  Higher prevalence rates also were seen in studies from Asia compared to Europe, in studies that used point or week prevalence compared to recall periods of a month or year, and in studies that included patients with an ECOG of 2 and 3 compared to an ECOG of 1. Age and race as well as method of data collection were not associated with overall pain prevalence rates  Methodological quality assessment was performed by using criteria developed for prevalence studies based on Leboeuf-Yde and Lauritsen. Criteria relate to the representativeness of the sample (three items); quality of the data (three items); description of the methods and results (three items); and deﬁnition of pain prevalence (one item). Weighting factors were introduced for each criterion. In the previous review, 7 criteria speciﬁcally for lower back pain were revised and replaced by criteria with an adequate description of the disease stage and/or condition for cancer. For this review, the quality assessment was further reﬁned by upgrading studies that provided an adequate description of the stage of disease and downgrading studies that relied on either proxy reporting or retrospective medical records. Differences in quality assessments were resolved using a discussion and consensus approach. Articles with a predeﬁned quality score of <=15 points, which equals 75% of the maximum 20 points, 12 were accepted for inclusion in the meta-analyses.  To see the methodological quality criteria for prevalence studies go to table 1: Page 1071. |
| Estimates of benefit and consistency across studies | Pooled prevalence rates, precision (95% CI), and statistical signiﬁcance (deﬁned as P < 0.05) were determined for each group with reference to pain and pain severity. The reciprocal of the variance from individual studies was used as a weighting factor, which relates closely to the sample size. This weighting factor was chosen to reﬂect the amount of information that each study contained. A test for homogeneity was carried out to investigate whether the variation in prevalence rates between studies was more than could be attributed to chance alone. In case this test appeared to be signiﬁcant, the extra variation was incorporated into the analysis using a random-effects model. To examine whether pooled prevalence rates for pain were signiﬁcantly different between groups, meta-regression analyses were performed. |
| What harms were identified? | Not Applicable |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | None |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Management of Cancer Pain: ESMO Clinical Practice Guidelines.*C. I. Ripamonti, D. Santini, E. Maranzano, M. Berti, F. Roila* . Ann Oncol 2012; 23 (Suppl 7): vii39-vii154.  [**http://www.esmo.org/Guidelines/Supportive-and-Palliative-Care/Management-of-Cancer-Pain**](http://www.esmo.org/Guidelines/Supportive-and-Palliative-Care/Management-of-Cancer-Pain) |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 1. Paracetamol and/or a NSAID are effective for treating all intensities of pain, at least in the short term and unless contraindicated [I, A]. (vii141) 2. Patients should be informed about pain and pain management and be encouraged to take an active role in their pain management [II, B]. (vii141) 3. The assessment of all components of suffering such as psychosocial distress should be considered and evaluated [II, B]. (vii140) 4. The analgesic treatment should start with drugs indicated by the WHO analgesic ladder appropriate for the severity of pain [II, B]. (vii142) 5. The opioid of ﬁrst choice for moderate to severe cancer pain is oral morphine [IV, D] (vii143)   Although the oral route of administration is advocated, patients presenting with severe pain that needs urgent relief should be treated and titrated with parenteral opioids, usually administered by the subcutaneous (s.c.) or intravenous (i.v.) route. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 1. Level of Evidence [I] 2. Level of Evidence [II] 3. Level of Evidence [II] 4. Level of Evidence [II] 5. Level of Evidence [IV] |
| Provide all other grades and definitions from the evidence grading system | Level of Evidence:  I Evidence from at least one large randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well- conducted randomised trials without heterogeneity  II Small randomised trials or large randomised trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity  III Prospective cohort studies  IV Retrospective cohort studies or case–control studies  V Studies without control group, case reports, expert opinions |
| Grade assigned to the **recommendation** with definition of the grade | 1. Grade of Recommendation [A] 2. Grade of Recommendation [B] 3. Grade of Recommendation [B] 4. Grade of Recommendation [B] 5. Grade of Recommendation [D] |
| Provide all other grades and definitions from the recommendation grading system | Grades of recommendation:  A Strong evidence for efficacy with a substantial clinical benefit, strongly recommended  B Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended  C Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs, ...), optional  D Moderate evidence against efficacy or for adverse outcome, generally not recommended  E Strong evidence against efficacy or for adverse outcome, never Recommended |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | 17 clinical trials/22 systematic reviews are cited in the ESMO guideline.  The ESMO guideline does not summarize the quality of different randomized clinical trials nor the systematic reviews. |
| Estimates of benefit and consistency across studies | Not Available |
| What harms were identified? | Many patients develop adverse effects such as constipation, nausea/vomiting, urinary retention, pruritus and central nervous system (CNS) toxicity (drowsiness, cognitive impairment, confusion, hallucinations, myoclonic jerks and—rarely—opioid-induced hyperalgesia/allodynia). Sometimes, the reduction of the opioid dose may reduce the incidence and/or severity of adverse events. This may be achieved by using a coanalgesic or an alternative approach such as a nerve block or radiotherapy (RT). Other strategies include the continued use of antiemetics for nausea, laxatives for constipation, major tranquilizers for confusion and psychostimulants for drowsiness. However, since some of the side effects may be caused by a Dose reduction or opioid switching is a potential effective way to manage delirium, hallucination, myoclonus and hyperalgesia. Treatment of opioid-related constipation: there is a strong recommendation to routinely prescribe laxatives for prophylaxis and management of opioid-induced constipation. Methylnaltrexone administered by subcutaneous injection should be used in the treatment of opioid-related constipation resistant to traditional laxatives. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not Applicable |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

Not Applicable

**1a.4.2 What process was used to identify the evidence?**

Not Applicable

**1a.4.3.** **Provide the citation(s) for the evidence.**

Not Applicable