Guideline Title


Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the rating of evidence (High, Intermediate, Low, Insufficient); types of recommendations (Evidence-Based, Formal Consensus, Informal Consensus, No Recommendation); and strength of recommendations (Strong, Moderate, Weak) are provided at the end of the "Major Recommendations" field.

The following recommendations are evidence based, informed by generally small randomized controlled trials (RCTs), and guided by clinical experience. Ratings for benefits, harms, evidence quality, and recommendation strength are provided in Table 3 in the original guideline document.

Prevention of Chemotherapy-Induced Peripheral Neuropathy (CIPN)

There are no established agents recommended for the prevention of CIPN in patients with cancer undergoing treatment with neurotoxic agents. This is based on the paucity of high-quality, consistent evidence and a balance of benefits versus harms.

Clinicians should not offer the following agents for the prevention of CIPN to patients with cancer undergoing treatment with neurotoxic agents:

- Acetyl-L-carnitine (ALC)
- Amifostine
- Amitriptyline
- CaMg for patients receiving oxaliplatin-based chemotherapy
- Diethyldithiocarbamate (DDTC)
- Glutathione (GSH) for patients receiving paclitaxel/carboplatin chemotherapy
- Nimodipine
- Org 2766
- All-trans-retinoic acid
- Recombinant human leukemia inhibitory factor (RhuLIF)
- Vitamin E

Venlafaxine is not recommended for routine use in clinical practice. Although the venlafaxine data resulted in some support for its utility, the data were not strong enough to recommend its use in clinical practice until additional supporting data become available.

No recommendations can be made on the use of N-acetylcysteine, carbamazepine, glutamate, GSH (for patients receiving cisplatin or oxaliplatin-based chemotherapy), goshajinkigan (GJG), omega-3 fatty acids, or oxcarbazepine for the prevention of CIPN at this time.

Treatment of CIPN

For patients with cancer experiencing CIPN, clinicians may offer duloxetine.

No recommendations can be made on the use of:

- ALC, noting that a positive phase III abstract supported its value, but this work has not yet been published in a peer-reviewed journal, and a prevention trial suggested that this agent was associated with worse outcomes.
- Tricyclic antidepressants; however, based on the limited options that are available for this prominent clinical problem and the demonstrated efficacy of these drugs for other neuropathic pain conditions, it is reasonable to try a tricyclic antidepressant (e.g., nortriptyline or desipramine) in patients suffering from CIPN after a discussion with the patients about the limited scientific evidence for CIPN, potential harms, benefits, cost, and patient preferences.
- Gabapentin, noting that the available data were limited regarding its efficacy for treating CIPN. However, the panel felt that this agent is reasonable to try for selected patients with CIPN pain given (1) that only a single negative randomized trial for this agent was completed, (2) the established efficacy of gabapentin and pregabalin for other forms of neuropathic pain, and (3) the limited CIPN treatment options. Patients should be informed about the limited scientific evidence for CIPN, potential harms, benefits, and costs.
- A topical gel treatment containing baclofen (10 mg), amitriptyline HCL (40 mg), and ketamine (20 mg), noting that a single trial supported that this product did decrease CIPN symptoms. Given the available data, the panel felt that this agent is reasonable to try for selected patients with CIPN pain. Patients should be informed about the limited scientific evidence for the treatment of CIPN, potential harms, benefits, and costs.

**Definitions:**

**Guide for Rating Strength of Evidence**

<table>
<thead>
<tr>
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<tr>
<td>High</td>
<td>High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits versus harms) and further research is very unlikely to change either the magnitude or direction of this net effect.</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Moderate confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research is unlikely to alter the direction of the net effect however it might alter the magnitude of the net effect.</td>
</tr>
<tr>
<td>Low</td>
<td>Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.</td>
</tr>
<tr>
<td>Insufficient</td>
<td>Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.</td>
</tr>
<tr>
<td>Inconclusive</td>
<td>There is conflicting evidence of effectiveness and further research is needed to inform the topic.</td>
</tr>
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**Guide for Types of Recommendations**
There was sufficient evidence from published studies to inform a recommendation to guide clinical practice. Therefore, the expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak"). The results of the formal consensus process are summarized in the guideline and reported in an online data supplement (see the "Availability of Companion Documents" field).

The available evidence was deemed insufficient to inform a recommendation to guide clinical practice, based on informal consensus of the expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., "strong," "moderate," or "weak").

There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.

<table>
<thead>
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<tr>
<td>Evidence-Based Consensus</td>
<td>The available evidence was deemed sufficient to inform a recommendation to guide clinical practice. Therefore, the expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., &quot;strong,&quot; &quot;moderate,&quot; or &quot;weak&quot;). The results of the formal consensus process are summarized in the guideline and reported in an online data supplement (see the &quot;Availability of Companion Documents&quot; field).</td>
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<td>Informal Consensus</td>
<td>The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., &quot;strong,&quot; &quot;moderate,&quot; or &quot;weak&quot;).</td>
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<tr>
<td>No Recommendation</td>
<td>There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.</td>
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Guide for Strength of Recommendations

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<td>Strong</td>
<td>There is high confidence that the recommendation reflects best practice. This is based on: a) strong evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, with no or minor exceptions; c) minor or no concerns about study quality; and/or d) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation. Furthermore, the balance of benefits versus harms substantially favors the benefits and most patients would want the intervention.</td>
</tr>
<tr>
<td>Moderate</td>
<td>There is moderate confidence that the recommendation reflects best practice. This is based on: a) good evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, with minor and/or few exceptions; c) minor and/or few concerns about study quality; and/or d) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation. Most patients would want the intervention, but many would not.</td>
</tr>
<tr>
<td>Weak</td>
<td>There is some confidence that the recommendation offers the best current guidance for practice. This is based on: a) limited evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, but with important exceptions; c) concerns about study quality; and/or d) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation. Some patients would want the intervention, some would not. Shared decision-making that incorporates benefits and risks is necessary.</td>
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Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)
Chemotherapy-induced peripheral neuropathy (CPIN)

Guideline Category
Management
Prevention
Treatment
Clinical Specialty

Medical Genetics
Neurology
Oncology
Pharmacology

Intended Users

Advanced Practice Nurses
Allied Health Personnel
Nurses
Pharmacists
Physician Assistants
Physicians

Guideline Objective(s)

To provide evidence-based guidance on the optimum prevention and treatment approaches in the management of chemotherapy-induced peripheral neuropathies (CIPN) in adult cancer survivors

Target Population

Adult cancer survivors

Interventions and Practices Considered

Duloxetine (for treatment of chemotherapy-induced peripheral neuropathy [CIPN])

Note: See the "Major Recommendations" field for interventions that were considered but not recommended for the prevention and treatment of CIPN.

Major Outcomes Considered

- Incidence and severity of neuropathy
- Neurophysiologic changes
- Symptom relief
- Patient-reported outcomes (PROs)
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Strategy

Ovid MEDLINE (1946 to April week 2, 2013), EMBASE (1980 to 2013 week 16), and AMED (Allied and Complementary Medicine; 1985 to April 2013) databases were searched for evidence reporting on outcomes of interest. Before the systematic search of the medical literature, an environmental scan was conducted for existing reviews regarding the management of chemotherapy-induced peripheral neuropathy (CIPN). With no recent guidelines identified, older reviews with contents related to the clinical questions had their included studies cross-referenced to the guideline panel’s literature search. Reference lists from other published seminal papers were scanned for additional citations. The literature search strategy is available in Appendix Table A3 in the original guideline document.

Study Selection Criteria

Articles were selected for inclusion in the systematic review of the evidence if they:

- Focused on chemotherapy-induced neuropathy
- Included cancer survivors
- Considered neuropathy as an important outcome of study
- Were randomized trials (phase II and III)

Articles were excluded from the systematic review if they:

- Were phase I studies, other noncomparative studies, case reports, editorial letters, or newspaper articles
- Only involved individuals under 18 years of age
- Were animal studies
- Were published in a language other than English
- Included less than 10 participants
- Focused on radiation therapy related neuropathy or stem-cell transplantation–related neuropathy

Number of Source Documents

The literature search identified 1,252 potentially relevant citations. Of these, 250 were examined in detail, and a total of 48 randomized controlled trials (RCTs) ultimately met eligibility criteria and comprise the evidentiary basis for the guideline recommendations.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Guide for Rating Strength of Evidence

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Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Literature search results were reviewed and deemed appropriate for full-text review by an American Society of Clinical Oncology (ASCO) staff member in consultation with the Co-Chairs. Data were extracted in duplicate by two ASCO staff members. Disagreements were resolved through discussion and consultation with the Co-Chairs, if necessary.

Study Quality

Study quality was formally assessed for the 48 identified randomized controlled trials (RCTs) (see Table 1 in the original guideline document). Design aspects related to the individual study quality were assessed by one reviewer for factors such as blinding, allocation concealment, placebo control, intention to treat, funding sources, and so on.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Panel Composition

To address the clinical question, an Expert Panel with multidisciplinary representation in medical oncology, community oncology, nursing, pain research, genetics, neurology, pharmacology, patient representation, and guideline methodology was convened. The Expert Panel was led by two Co-chairs who had the primary responsibility for the development and timely completion of the guideline. The Expert Panel members are listed in Appendix Table A2 of the original guideline document.

Guideline Development Process

The Expert Panel members, who met via teleconference and corresponded through e-mail, were asked to contribute to the development of the guideline, provide critical review, interpret evidence, and finalize the guideline recommendations based on consideration of the evidence. Members of the Expert Panel were responsible for drafting the penultimate version of the guideline, which was then circulated for external review.

Rating Scheme for the Strength of the Recommendations

Guide for Types of Recommendations

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Informal Consensus

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No Recommendation

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<td><strong>Weak</strong></td>
<td>There is some confidence that the recommendation offers the best current guidance for practice. This is based on: a) limited evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, but with important exceptions; c) concerns about study quality; and/or d) the extent of panelists’ agreement. Other considerations (discussed in the guideline’s literature review and analyses) may also warrant a weak recommendation. Some patients would want the intervention, some would not. Shared decision-making that incorporates benefits and risks is necessary.</td>
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Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

All American Society of Clinical Oncology (ASCO) guidelines are reviewed and approved by the ASCO Clinical Practice Guideline Committee before publication.

The Clinical Practice Guideline Committee approved this guideline update on November 19, 2013.

External Review

A draft of the clinical practice guideline was reviewed by two Clinical Practice Guideline Committee members and 12 Survivorship Guideline Advisory Group members. In addition to providing comment and feedback, practitioners were asked to judge the evidence review and agreement with the recommendations. One additional reviewer was asked to assess the clarity of the recommendations and ease of implementation. The evidence review was rated as high quality, and there was high agreement with the substance of the recommendations.

The compounded topical baclofen-amitriptyline-ketamine gel was identified as having barriers to implementation. The product was created by one compounding pharmacy for a trial, and the combination is not US Food and Drug Administration (FDA) approved. Lack of insurance

Type of Recommendation

Definition

Guide for Strength of Recommendations
Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see Table 3 in the original guideline document).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate prevention and management of chemotherapy-induced peripheral neuropathy (CPIN) in adult cancer survivors

Potential Harms

See Table 3 in the original guideline document for an assessment of the harms for each intervention.

Qualifying Statements

- The clinical practice guidelines and other guidance published herein are provided by the American Society of Clinical Oncology, Inc. (ASCO) to assist providers in clinical decision making. The information therein should not be relied on as being complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time information is developed and when it is published or read. The information is not continually updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified therein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Further, the information is not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients. Recommendations reflect high, moderate or low confidence that the recommendation reflects the net effect of a given course of action. The use of words like "must," "must not," "should," and "should not" indicate that a course of action is recommended or not recommended for either most or many patients, but there is latitude for the treating clinician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. ASCO provides this information on an "as is" basis, and makes no warranty, expressed or implied, regarding the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.

- A number of nonpharmacologic interventions have been investigated for their role in preventing or treating peripheral neuropathy. However, the paucity of randomized controlled trial (RCT) evidence prohibited inclusion of those studies in this systematic review. Moreover, the studies were often conducted in diabetic populations, with no specific focus on chemotherapy-induced peripheral neuropathy (CIPN). Nevertheless, several of the interventions have been tested in populations that included patients with cancer experiencing CIPN and, as such, merit further examination.

Implementation of the Guideline

Description of Implementation Strategy
Description of Implementation Strategy

Guideline Implementation

American Society of Clinical Oncology (ASCO) guidelines are developed for implementation across health settings. Barriers to implementation include the need to increase awareness of the guideline recommendations among front-line practitioners and cancer survivors, and also to provide adequate services in the face of limited resources. The guideline Bottom Line was designed to facilitate implementation of recommendations. This guideline will be distributed widely through the ASCO Practice Guideline Implementation Network. ASCO guidelines are posted on the ASCO Web site and most often published in Journal of Clinical Oncology and Journal of Oncology Practice.

For additional information on the American Society for Clinical Oncology (ASCO) implementation strategy, please see the ASCO Web site.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)


Adaptation
Not applicable: The guideline was not adapted from another source.

Date Released

2014 Jun 20

Guideline Developer(s)

American Society of Clinical Oncology - Medical Specialty Society

Source(s) of Funding

American Society of Clinical Oncology

Guideline Committee

American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee

Composition of Group That Authored the Guideline

Committee Members: Charles Loprinzi, MD (Co-Chair), Mayo Clinic; Dawn Hershman, MD (Co-Chair), Columbia University Medical Centre; Maryam Lustberg, MD, Ohio State University; Tom Smith, MD, Johns Hopkins; Nina Wagner-Johnston, MD, Washington University; Judith Paice, PhD, Northwestern University; Ellen Smith, PhD, University of Michigan; Robert H. Dworkin, PhD, University of Rochester; Bryan Schneider, MD, Melvin and Bren Simon Cancer Center, Indiana University; Jonathan Bleeker, MD, Mayo Clinic; Shelby Terstriep, MD, Sanford Roger Maris Cancer Center; Guido Cavaletti, MD, University of Milano-Bicocca, Italy; Patrick Gavin, RPh, Patrick Gavin R.Ph. Consulting LLC; Cynthia Chauhan, The Mayo Clinic Breast SPORE; Mary Lou Smith, Research Advocacy Network; Antoinette Lavino, RPh., BCOP, Massachusetts General North Shore Cancer Center Massachusetts

Financial Disclosures/Conflicts of Interest

The Expert Panel was assembled in accordance with the American Society of Clinical Oncology (ASCO) Conflict of Interest Management Procedures for Clinical Practice Guidelines (Procedures; summarized at [http://www.asco.org/guidelinescoi](http://www.asco.org/guidelinescoi)). Members of the Panel completed ASCO’s disclosure form, which requires disclosure of financial and other interests that are relevant to the subject matter of the guideline, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as the result of promulgation of the guideline. Categories for disclosure include employment relationships, consulting arrangements, stock ownership, honoraria, research funding, and expert testimony. In accordance with the Procedures, the majority of the members of the Panel did not disclose any such relationships.

Authors' Disclosures of Potential Conflicts of Interest

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: None Consultant or Advisory Role: Robert Dworkin, Acorda (C), Anika (C), Avanir (C), Bayer (C), Charleston (C), Concert (C), DePuy (C), Flexion (C), Genentech (C), Johnson & Johnson (C), Lilly (C), Lpath (C), Nektar (C), Neura (C), Olatec (C), Omeros (C), Periphagenics (C), Pfizer (C), Phosphagenics (C), Prolong (C), Q-Med (C), Regenesis (C), Sanofi (C), Spinifex (C), Taris (C), Teva (C); Bryan Schneider, Novartis (C), Genentech (C) Stock Ownership: None Honoraria: Bryan Schneider, Novartis, GileadSmithKline, Genentech Research Funding: Robert Dworkin, Eli Lilly, Pfizer, Sanofi, Bayer; Ellen M. Lavoie Smith, Lilly, National Institutes of Health, University of Michigan; Charles L. Loprinzi, Pfizer, Competitive Technologies Expert Testimony: None Patents, Royalties, and Licenses:
Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site.

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 2318 Mill Rd, Suite 800, Alexandria, VA 22314; E-mail: guidelines@asco.org.

Availability of Companion Documents

The following are available:


Patient Resources

The following is available:


Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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