

Recommendations for Ethical Allocation of Carboplatin and Cisplatin

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Disclaimer: This document summarizes recommendations to ethically address a critical drug shortage and relied on collaboration and input from: (1) an expert panel of physicians, pharmacist, ethicists, and Minnesota Department of Health (MDH) staff, (2) a working group of Minnesota health system medical directors; and (3) the MDH Science Advisory Team.

This document is not legal advice, it does not carry the force or effect of law, and it should not be construed as a statement of legal or regulatory requirements and protections.

Health care facilities or systems implementing strategies to manage critical drug shortages and other crisis situations are strongly encouraged to consult with legal counsel, and coordinate their efforts with health system leadership, Health Care Coalition (HCC) partners, and MDH.

Background

There is a national shortage of Carboplatin and Cisplatin that will likely last several months due to ongoing manufacturing challenges. This critical shortage has affected the ability of health systems in Minnesota to provide the drugs consistently and reliably to all patients.

This document provides a framework for the ethical allocation of these medications; it is intended to guide care delivery and organizational response during this period of critical shortage. It also aims to provide a basis for consistent response to this situation among institutions and systems across the State of Minnesota, to promote transparency, fairness, and equity. It is based on common ethical values collected through a public engagement process

regarding crisis response,¹ medical ethics literature,^{2,3} and guidance from national groups.^{4,5,6,7}

It incorporates the input of three statewide groups: (1) an expert panel of physicians, pharmacist, ethicists, and Minnesota Department of Health (MDH) staff; (2) a workgroup including the Medical Directors of the state's health systems to provide further input on these recommendations and facilitate its fair, consistent implementation; and (3) the MDH Science Advisory Team. The panel and workgroup consist of MDH staff and voluntary participants from across the state, convened by the Metro Health & Medical Preparedness Coalition at the request of health professionals involved in managing the shortage. The MDH Science Advisory Team is a multidisciplinary group of subject matter experts—including critical care physicians, primary care, psychiatrists, pharmacists, ethicists, hospital administration, legal and other disciplines—organized under a federally funded planning effort to provide recommendations to hospitals, health systems, and health care coalitions regarding crisis standards of care.

Ethical criteria for the allocation of Carboplatin and Cisplatin during the critical shortage

- **Responsibly steward supplies of carboplatin and cisplatin:**
 - Work to ensure each treatment plan is designed to provide the lowest effective dose of carboplatin or cisplatin at the most extended interval possible.
 - Reserve scarce supply for patients with curative treatment intent for whom alternatives are not available or appropriate (i.e., non-acceptable survival trade-off).

¹ Minnesota Department of Health (MDH). Minnesota Crisis Standards of Care Framework: Ethical Guidance. Updated: 01/10/2020. Available at <https://www.health.state.mn.us/communities/ep/surge/crisis/framework.pdf>.

² Yoram Unguru et al. An Ethical Framework for Allocating Scarce Life-Saving Chemotherapy and Supportive Care Drugs for Childhood Cancer. *JNCI: Journal of the National Cancer Institute*, Volume 108, Issue 6, June 2016. Available at <https://academic.oup.com/jnci/article/108/6/djv392/2412413>.

³ Philip M. Rosoff. Unpredictable Drug Shortages: An Ethical Framework for Short-Term Rationing in Hospitals. *The American Journal of Bioethics* 12:1, 2012: 1-9. Available at <https://www.tandfonline.com/doi/full/10.1080/15265161.2011.634483?scroll=top&needAccess=true&role=tab>.

⁴ Society of Gynecologic Oncology. SGO Statement: Carboplatin and Cisplatin Shortages. April 21, 2023. Available at <https://www.sgo.org/news/drugshortage/>.

⁵ SGO, FWC, and GOG-F* Communique: Considerations When Treating Persons With Ovarian, Fallopian Tube, and Peritoneal Cancers In The Setting Of Cisplatin And Carboplatin Shortages. May 24, 2023. Available at <https://www.sgo.org/news/drugshortages5/>.

⁶ National Comprehensive Cancer Network. National Comprehensive Cancer Network Statement on Mitigating the Impacts of Anti-cancer Drug Shortages. n.d. Available at <https://www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Statement-on-Anti-Cancer-Drug-Shortages.pdf>.

⁷ American Society of Clinical Oncology. Clinical Guidance. (n.d.) Available at <https://old-prod.asco.org/practice-patients/practice-support/drug-shortages/clinical-guidance>.

- Switch patients with palliative (or non-curative) intent to evidence-based alternatives if possible.
- **Maximize benefit of these scarce resources while minimizing harms or inequities:**
 - Prioritize patients who have high likelihood of cure, survival, or substantial prevention of disease progression, for whom substitutes are not available or appropriate.
 - Clinical prognosis should drive allocation decisions.
 - Decisions about allocation priorities **should not** consider or be based upon:
 - Race, ethnicity, gender, gender identity, sexual orientation or preference, religion, citizenship or immigration status, or socioeconomic status
 - Ability to pay
 - Age as a criterion in and of itself (this does **not** limit consideration of a patient’s age in clinical prognostication of likelihood to survive their cancer)
 - Disability status as a criterion in and of itself (this does **not** limit consideration of a patient’s physical condition in clinical prognostication of likelihood to survive their cancer)
 - Predictions about baseline life expectancy beyond the current episode of care (i.e., life expectancy if the patient were not facing the current crisis), unless the patient is imminently and irreversibly dying or terminally ill with life expectancy under 6 months (e.g., eligible for admission to hospice)
 - First come, first served
 - Judgments that some people have greater “quality of life” than others
 - Judgments that some people have greater “social value” than others
 - Weight (when weigh-based dosing is used, weight should not factor into allocation decisions even though considering it might maximize available drug. Prioritizing smaller patients to conserve supply would unjustifiably discriminate against larger patients.)
 - “[C]ancer care disparities may emerge or worsen in times of resource scarcity. As treatment recommendations are adjusted during this shortage, identifying patients at risk for experiencing structural barriers to care—and having a plan to mitigate those barriers—must be considered as part of each institution’s strategic plan.”⁸
 - While all health systems/facilities in the state are affected by the critical shortage of these medications, the severity of shortages may vary across facilities. *If a facility is caring for a patient who qualifies for prioritized allocation of scarce medication, but*

⁸ SGO, FWC, and GOG-F* Communique: Considerations When Treating Persons With Ovarian, Fallopian Tube, and Peritoneal Cancers In The Setting Of Cisplatin And Carboplatin Shortages. May 24, 2023. Available at <https://www.sgo.org/news/drugshortages5/>

lacks supply to provide treatment, that facility may reach out to the Regional Healthcare Preparedness Coordinator (RHPC) for the Metro Region at 612-873-9911 to help identify available supply for that patient.

- The Metro RHPC will coordinate the following decision-making process:
 - Identify whether another system and facility may be able to support the patient’s needs.
 - Rapidly convene a group of subject experts (SMEs) to review the case to determine the optimal strategy, either transferring the medication across system/facilities, or transferring the patient’s care to the accepting system/facility.
 - If both options are possible, it would be more equitable to transfer medication doses between systems/facilities, since this will avoid unduly disadvantaging the patient by requiring travel, additional expense, or other burdens to access the drugs. In some cases, there may be barriers to transferring medications, however. MDH and other state agencies may be able to assist with addressing barriers to transferring medications, if any. If it is not possible to resolve the barriers, the only available option may be to transfer the patient to the system or facility with available supply of the medication.
 - The group of SMEs will include ethics as well as providers with relevant expertise/roles from facilities across the state.
 - The facility seeking treatment options for their patient will present a brief, de-identified cases summary including the patient’s diagnosis, comorbidities, whether treatment intent is curative or not, and other relevant information (for example, the patient’s ability to travel to another system to seek care, whether the patient’s insurance would permit transfer to another system).
 - The group of SMEs will discuss requests to access treatment on a case-by-case basis, consistent with the recommendations provided in this ethical framework, to promote fairness and equity.
 - New patients—including both newly diagnosed patients already affiliated with the health system, and unaffiliated patients who cannot access medication at their usual point of care—should be triaged using these same principles.
- **Implement fair processes for allocation of these resources:**
 - Health systems/facilities should implement a transparent, fair, and equitable process to assess the needs of affected patients, to ensure the ethical allocation of carboplatin and cisplatin during this period of critical shortage.
 - Where possible, include a streamlined, time-limited process for review of allocation decisions at provider request. To minimize burden on systems/facilities, these reviews should be limited to cases in which the requestor provides:

- Objective information that the allocation decision was based upon misinformation about allocation criteria such as the patient's prognosis; or
- Objective information that the decision was based upon a deviation from (1) the ethical considerations specified in this framework, or (2) the system/facility's established decision-making process.

Ethical Duties to Provide Support

- Health systems and facilities should identify a process for ethics support for clinicians to address moral distress related to this resource shortage.
- Health systems and facilities should also establish resources for mental/behavioral health and spiritual care for providers, patients, and their families affected by the shortage, given the distressing nature of challenges posed by the crisis.
- Health systems and facilities should create tools for communicating to patients and clinicians about the shortage and what is being done to address it. This framework offers some suggested scripts in appendices as a starting point. Institutions should also assist patients with special communications needs, such as interpreters.

Clinical Recommendations

- Conservation strategies
 - Reserve scarce supply of carboplatin and cisplatin for patients with curative treatment intent for whom alternatives are not available or appropriate (i.e., non-acceptable survival trade-off).
 - Provide the lowest effective dose of carboplatin or cisplatin at the most extended interval possible.
- Treatment/Substitution strategies
 - Prioritize allocation of carboplatin and cisplatin to patients with a high likelihood of cure, survival, or substantial prevention of disease progression, for whom substitutes are not available or appropriate. Where substitutes are available and appropriate, use another therapy.
 - Diagnoses associated with higher likelihood of cure, survival or substantial disease progression, without available or appropriate medication substitutes, may include bladder cancer, testicular cancer, cervical cancer, head and neck cancers, triple negative breast cancer, and early stage lung cancers.
 - There may not be evidence-based substitutes for pediatric patients.
 - There may be no evidence-based substitutes for pediatric patients. Treatment decisions should consider not only the type of cancer, but curative treatment intent, likelihood of cure, survival or substantial prevention of disease progression, and availability of appropriate medication substitutes.

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- Switch patients with palliative (or non-curative) intent to evidence-based alternatives, if possible.

Appendix 1: Information for Care Teams About Critical Shortage of Carboplatin and Cisplatin

This Appendix offers sample language for health care facilities and systems to consider when communicating with staff and care teams. Facilities and systems are responsible for developing their own communication strategies and are strongly encouraged consult with legal counsel and institutional leadership throughout this process. Note the FAQs reflect the same information included in the first half of this document. Both formats for providing information are included for the convenience of facilities, so they can choose which works best for their teams.

There is a national shortage of Carboplatin and Cisplatin that will likely last several months due to ongoing manufacturing challenges. National pharmacy organizations are working with the Biden Administration, the US Food and Drug Administration, and the US Congress to address the problem of medication shortages. This critical shortage has affected our care system's ability to provide the drugs consistently and reliably to all our patients.

Here are a few key things to know about our response:

- Our teams are monitoring the shortage and working hard to manage and extend our supply to continue providing treatment for our patients.
- A statewide expert panel of physicians, pharmacists, ethicists, and Minnesota Department of Health staff has been convened to evaluate the situation and produce recommendations for the ethical allocation of these medications. Further input has been provided by a group of Medical Directors from health systems across the state. These panels are a voluntary workgroup convened by the Metro Health Care Coalition, though they include experts from across the state. Guidelines developed through this process are based on scientific evidence, ethical values, and guidance from national groups.
- Our institution has a process for evaluating each patient and determining when evidence-based medication substitutes or other changes -- such as reducing the patient's dose or changing the frequency of their dose -- are appropriate. Treatment decisions consider the recommendations from the statewide groups of experts.
- Please discuss any changes to patient treatment plans with them.

Thank you for your partnership to ensure our patients continue to be well cared for during this time. Please contact your leader if you have any questions.

In addition, a document for patients has been created to provide them with information about this shortage and its possible impact on their care.

Frequently Asked Questions (FAQ):

Q: What is happening? A: There is a national drug shortage of carboplatin and cisplatin due to ongoing manufacturing challenges. The shortage has affected our ability to provide the drug to all our patients.

Q: When will this be resolved? A: The answer to this question is not clear at this time, but the shortage will likely last several months and possibly longer.

Q: What is being done to address the shortage? A: Action is being taken at our health system, in our state, and nationally to address the shortage.

- Our teams are regularly monitoring the shortage and working hard to manage and extend our supply of carboplatin and cisplatin to continue providing the most effective treatment for our patients.
- A statewide expert panel of physicians, pharmacists, ethicists, and staff from the Minnesota Department of Health has been convened to evaluate the situation and produce recommendations for ethical allocation of these medications. Further input has been provided by a group of Medical Directors from health systems across the state. Guidelines developed through this process are based on scientific evidence, ethical values, and guidance from national groups.
- In addition, national pharmacy organizations are working with the Biden Administration, the US Food and Drug Administration, and the US Congress to address the problem of medication shortages.

Q: How will this affect our patients? A: Our institution has a process for reviewing the care of all affected patients and deciding the course of action. This may include reducing their current dose, changing the frequency of their dose, or using an evidence-based medication substitute. Treatment decisions consider the recommendations from the statewide group of experts. Care teams will talk to patients about any changes to their treatment plans.

Appendix 2: Patient Information About Critical Shortage of Carboplatin and Cisplatin

This Appendix offers sample language for health care facilities and systems to consider when communicating with patients and their families. Facilities and systems are responsible for developing their own communication strategies and are strongly encouraged consult with legal counsel and institutional leadership throughout this process. Note that the FAQs reflect the same information included in the first half of this document. Both formats for providing information are included for the convenience of facilities, so they can choose which works best for their teams.

There is a national shortage of Carboplatin and Cisplatin due to ongoing manufacturing challenges. National pharmacy organizations are working with the Biden Administration, the US Food and Drug Administration, and the US Congress to address the problem of medication shortages. It is not clear when this shortage will be resolved, but the shortage will likely last several months and possibly longer.

This critical shortage has affected our care system's ability to provide the drugs consistently and reliably to all our patients.

Here are a few key things to know about your care:

- Our teams are monitoring the shortage and working hard to manage and extend our supply to continue providing treatment for our patients.
- A statewide expert panel of physicians, pharmacists, ethicists, and Minnesota Department of Health staff has been convened to evaluate the situation and produce recommendations for the ethical allocation of these medications. Further input has been provided by a group of Medical Directors from health systems across the state. Guidelines developed through this process are based on scientific evidence, ethical values, and guidance from national groups.
- Your care team is reviewing your care and deciding the course of action. This may include reducing your current dose, changing the frequency of your dose, or using a different medication based on evidence about what will work for you. *Care teams are using the recommendations developed by the statewide expert panels in reviewing your care.*
- Any changes to your treatment plans will be discussed with you.

Thank you for understanding this difficult situation. Please contact your care team if you have any questions.

Frequently Asked Questions (FAQ)

Q: What is happening? A: There is a national drug shortage of carboplatin and cisplatin. The shortage has affected our ability to provide the drug to all our patients.

Q: Why is this happening? A: This drug shortage is due to ongoing manufacturing challenges, and it affects patients across the country.

Q: When will this be resolved? A: The answer to this question is not clear at this time, but the shortage will likely last several months and possibly longer.

Q: What are you doing to address the shortage? A: Action is being taken at our health system, in our state, and nationally to address the shortage.

- Our teams are monitoring the shortage and working hard to manage and extend our supply to continue providing treatment for our patients.
- A statewide expert panel of physicians, pharmacists, ethicists, and Minnesota Department of Health staff has been convened to evaluate the situation and produce recommendations for the ethical allocation of these medications. Further input has been provided by a group of Medical Directors from health systems across the state. Guidelines developed through this process are based on scientific evidence, ethical values, and guidance from national groups.
- In addition, national pharmacy organizations are working with the Biden Administration, the US Food and Drug Administration, and the US Congress to address the problem of medication shortages.

Q: How will this affect my treatment? A: Your care team is reviewing your care and deciding the course of action. This may include reducing your current dose, changing the frequency of your dose, or using an evidence-based medication substitute. Treatment decisions consider the recommendations from the statewide group of experts. Your care team will talk to you about any changes to your treatment plan.