

## **American Society of Clinical Oncology Position Statement Home Infusion of Anticancer Therapy**

**Approved by the ASCO Board of Directors June 23, 2020**

### **OVERVIEW**

The safety of patients is of utmost importance for oncologists and health care teams providing cancer care. Anticancer drugs, particularly infusions of cytotoxic chemotherapy, can be extremely dangerous if administered incorrectly, spilled, or mishandled. For these reasons, ASCO and the Oncology Nursing Society (ONS) released chemotherapy administration safety standards in 2009,<sup>1,2</sup> and last updated the standards in 2016.<sup>3</sup> In 2019, ASCO also published standards for the safe workplace handling of hazardous oncology drugs.<sup>4</sup> Collectively, these standards call for rigorous safeguards to ensure proper practitioner certification, patient education, treatment monitoring, accurate drug preparation/handling/administration, and related health care setting policies to protect both patients and staff (e.g., for life-threatening emergencies).

As the COVID-19 crisis evolved into a pandemic, and the number of infected Americans grew from under 10,000 to over 100,000 during March 2020, the Centers for Medicare & Medicaid Services (CMS) released numerous regulatory flexibilities to assist health care settings coping with the crisis. Examples included expanded reimbursement for telemedicine as well as exemptions to increase workforce capacity.<sup>5</sup> Among these flexibilities were new provisions that enabled providers to deliver care in a setting most appropriate—and safest—for individual patient circumstances. This flexibility opened the path for potential increases in use of home infusion for anticancer therapy.

ASCO is concerned that routine use of home infusions for anticancer therapy could potentially fail to provide the safeguards to both patients and health care providers called for in existing safety standards, thereby exposing both to unnecessary risk. We also note that continuous infusion over multiple hours or days (e.g., via an infusion pump), that is both initiated and disconnected within the health care setting, is outside the scope of this statement. ASCO's concerns focus exclusively on the intravenous infusion of anticancer agents at a patient's home by health care personnel. This statement summarizes ASCO's position on home infusion of anticancer therapy, including the risks

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<sup>1</sup> Jacobson JO, Polovich M, McNiff KK, et al: American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. *J Clin Oncol* 27:5469-5475, 2009.

<sup>2</sup> Jacobson JO, Polovich M, Gilmore TR, et al: Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards: Expanding the scope to include inpatient settings. *J Oncol Pract* 8:2-6, 2012.

<sup>3</sup> Neuss, Michael N., et al. 2016 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards, including standards for pediatric oncology. *J Oncol Pract* 12.12 (2016): 1262-1271.

<sup>4</sup> Celano, Paul, et al. Safe handling of hazardous drugs: ASCO standards. *J Clin Oncol* 37.7 (2019): 598-609.

<sup>5</sup> <https://www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public>

and potential benefits for patients and their oncology providers, during the COVID-19 crisis and beyond.

## **BACKGROUND**

Antineoplastic drugs are effective at treating cancer but can be extremely toxic to normal human cells. A well-characterized list of negative health effects includes genotoxicity, teratogenicity, acute allergic reactions, carcinogenicity, and reproductive risks among others, potentially affecting both patients and health care personnel.<sup>6,7</sup> It was concern over safety issues that originally prompted the development of the ASCO-ONS chemotherapy administration-related safety standards. Importantly, these standards were written largely with the safe administration of chemotherapy in the outpatient health care setting in mind, rather than in the home-based setting.

There is a paucity of evidence directly comparing the safety of chemotherapy infusions in the home and outpatient settings. The vast majority of the literature examines home infusion in general, which is of limited utility given the toxicity and hazardous materials specific to chemotherapy. There is limited data from other countries demonstrating that, under certain circumstances and for specific agents, home infusion can be safe, well-tolerated, and may be preferred by some patients.<sup>8</sup> However, multiple criteria in ASCO's existing safety standards may be difficult to satisfy in the home infusion context. For example, safety principles emphasize using more than one practitioner to verify and document patient name, drug name, dosage, infusion volume, route/rate of administration, etc., to minimize errors and prevent patient harm. Within a health care setting additional trained staff are available for such verification. In the home infusion setting, these verifications need to be performed virtually and with multiple forms of identification, as sending multiple health workers to supervise home infusions may not be practical or feasible. Most importantly, certain adverse events that may quickly escalate and become life-threatening emergencies may not be able to be safely resolved in the patient's home. This risk could be minimized by initiating treatment with any new agents within an outpatient setting, but life-threatening adverse events remain an ongoing concern for routine home infusion of chemotherapy. Ensuring the satisfactory cleaning of hazardous spills (to prevent subsequent exposure of people in the household) is also more difficult in the home setting.

These tradeoffs may be acceptable given specific clinical contexts or patient needs (for example, during the COVID-19 crisis), while emphasizing the role of physician discretion during shared decision making with patients. Clinical trial participation during the COVID-19 crisis has also relied upon home infusion to maintain adherence to treatment schedules. With respect to removing obstacles to accessing routine cancer treatment (e.g., for rural populations), home infusion may represent a promising option, but there is insufficient evidence demonstrating feasibility and safety. It is also important to acknowledge that the safety concerns posed are not uniform across

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<sup>6</sup> Hoffman, D. M. "Reproductive risks associated with exposure to antineoplastic agents: a review of the literature." *Hospital pharmacy* 21.10 (1986): 930-2.

<sup>7</sup> Valanis, Barbara G., et al. "Association of antineoplastic drug handling with acute adverse effects in pharmacy personnel." *American Journal of Hospital Pharmacy* 50.3 (1993): 455-462.

<sup>8</sup> Larsen, Finn Ole, et al. "Safety and feasibility of home-based chemotherapy." *Dan Med J* 65.5 (2018).

anticancer therapies, varying by drug or by class of drug. Establishing safe home infusion will require programs to be flexible and rely upon oncology experts to determine the optimal and safest plan for any individual patient.

In accordance with the 21<sup>st</sup> Century Cures Act, CMS finalized a rule in 2019 for a home infusion therapy services benefit, to be implemented beginning in 2021.<sup>9</sup> While it remains to be seen what, if any, shift away from outpatient infusion facilities will occur, it is important to note that patient groups have also expressed concern regarding home infusion of chemotherapy including adverse event management, household member safety, and safe handling of cancer drugs. The new benefit could nevertheless enable collection of data that lead to better insight regarding optimal implementation of home infusion for anticancer therapies and other drugs in the future. For this to occur, however, the reporting mechanisms tied to home infusion should include oncology-specific measures, to enable assessment of safety in this specific population. The new home infusion benefit also has potential to improve limited patient access to treatment.

### **IMPACT ON PATIENTS AND THEIR PROVIDERS**

ASCO members' concerns are focused on patient safety. Although ASCO understands the desire for increased flexibility for patients, serious adverse events do occur and require special expertise of oncologists to either prevent or address them during drug preparation and administration. It is not clear that, should home infusion of anticancer therapy proliferate, it would be the treating physician's office/hospital preparing the infusion drug. Ceding this role to another entity in the pharmacy supply chain network could compromise safety and quality. For this reason, ASCO has long opposed any policy that would allow delivery of chemotherapy directly to a patient's home for home infusion, and we would strongly urge any payer to work with oncologists prior to implementing a system that delivered pre-prepared antineoplastic drugs to clinical staff that are not part of the patient's care team. Related to this is the issue of liability. An oncologist can currently accept liability for their patient's safety because they oversee all aspects of their care. It is unclear whether and how liability would be assigned in the home infusion setting, and when the managing care team is no longer responsible for all aspects of patient care.

In addition to safety concerns outlined above, there are workforce and reimbursement issues that present challenges with home infusion of anticancer therapy. An oncology nurse in a clinical setting can safely supervise infusion of multiple patients at once, compared to single-patient oversight in the home setting. There may therefore be insufficient oncology nursing expertise to widely adopt home infusion and substituting generalist infusion nurses does not provide the same level of patient safety. Regardless of the setting, any anticancer therapy administration should adhere to ASCO's infusion safety standards. Importantly, any teleconferences between physicians and nurses administering home infusions to ensure proper oversight should be adequately reimbursed.

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<sup>9</sup> <https://www.govinfo.gov/content/pkg/FR-2018-11-13/pdf/2018-24145.pdf>

## **CONCLUSION AND RECOMMENDATIONS**

ASCO appreciates the intention to improve access—especially in the context of COVID-19—by expanding the scope of home infusion services and providers,<sup>10</sup> including the recently released guidance from CMS.<sup>11</sup> We understand this may be an option in certain disease states and for certain infusion treatments as a result of informed, shared decision making between the physician and patient. However, while such an expansion may be appropriate for patients in certain disease settings, ASCO does not generally support such an expansion in the context of anticancer therapy services in the absence of circumstances where the benefits of doing so outweigh the potential risks.

Oncologists are making difficult decisions to delay or adjust care during this crisis. Despite a desire to mitigate disruptions in care, patient safety must continue to be the first priority in making such determinations. The decision to administer anticancer therapy in a home setting should be made by the treating physician in consultation with the patient, and after consideration of precautions necessary to protect medical staff, patients and caregivers from adverse events associated with drug infusion and disposal. Our recommendations are as follows:

- Independent research to evaluate the safety and effectiveness of home infusion of anticancer therapy should be supported by public funds.
- CMS should not extend the temporary flexibility related to home infusion for Part B cancer drugs that was approved as part of their response to the public health emergency.
- CMS should consult closely with oncology experts prior to implementation of its home infusion benefit in 2021, to ensure that it is only used when determined by the treating physician and patient to be the most appropriate setting for certain classes of drugs. Quality reporting for home infusion therapy services should require collection of oncology-specific measures to enable evaluation of safety related to anticancer therapy administration.
- In the context of anticancer therapy, home infusion benefit policies from public and commercial payers should be strictly limited to exceptional circumstances where the benefits of home infusion outweigh the potential risks to patients.
- Any public or commercial payer designing a system to deliver pre-prepared antineoplastic drugs to clinical staff should consult with treating oncologists prior to implementation.
- Home infusion benefit policies from public and commercial payers should require verification that necessary safety protocols and precautions are in place to protect health care personnel, patients and caregivers.

*Questions? Contact Allyn Moushey at [Allyn.Moushey@asco.org](mailto:Allyn.Moushey@asco.org) or 571-483-1738.*

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<sup>10</sup> <https://www.govinfo.gov/content/pkg/FR-2018-11-13/pdf/2018-24145.pdf>

<sup>11</sup> <https://www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public>