

CMS' Preliminary Decisions on the Recommendations of the Hospital Outpatient Payment Panel on Supervision Levels for Select Services

In the Calendar Year 2012 Hospital Outpatient Prospective Payment System /Ambulatory Surgical Center Final Rule, the Centers for Medicare & Medicaid Services (CMS) established a process to obtain independent advice from the Advisory Panel on Hospital Outpatient Payment (The Panel) regarding the appropriate supervision levels for individual hospital outpatient therapeutic services (76 Fed. Reg. 74360). CMS charged the Panel with recommending at the request of the agency or the public the supervision level that will ensure the appropriate quality and safety for delivery of a given service as defined by its Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology code. In order to make its recommendations, the Panel uses clinical and other criteria that were established in the final rule.

Based on the Panel's recommendations at its meeting on March 10, 2014, CMS is proposing the following changes to the current supervision requirements. These preliminary decisions are open to public comment through 5:00pm ET on April 30, 2014. Comments may be submitted via email to HOPSupervisionComments@cms.hhs.gov. As we indicated in the final rule, we will post final decisions after considering any comments that we receive and those decisions will be effective on July 1, 2014.

1) SERVICES CURRENTLY REQUIRING DIRECT SUPERVISION

CMS Proposes Changing Supervision Level from Direct to General

We would accept the Panel's recommendation to change the supervision level from direct to general for the following services.

- G0176, *Activity therapy, such as music, dance, art or play therapies not for recreation related to the care and treatment of patient's disabling mental health problems, per session (45 minutes or more)*
- 36593, *Dec clotting by thrombolytic agent of implanted vascular access device or catheter*
- 36600, *Arterial puncture, withdrawal of blood for diagnosis*
- 94667, *Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation*
- 94668, *Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; subsequent*

CMS Proposes Not to Change from Direct to General Supervision

We would not accept the Panel's recommendation to change the supervision level from direct to general for the following services. These CPT codes describe injection and intravenous infusion of chemotherapy or other highly complex drugs or complex biological agents.

- 96401, *Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic*
- 96402, *Chemotherapy administration, subcutaneous or intramuscular; hormonal*

anti-neoplastic

- 96409, *Chemotherapy administration; intravenous, push technique, single or initial substance/drug*
- 96411, *Chemotherapy administration; intravenous, push technique, each additional substance/drug (list separately in addition to code for primary procedure)*
- 96413, *Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug*
- 96415, *Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)*
- 96416, *Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump*
- 96417, *Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (list separately in addition to code for primary procedure)*
- 97597, *Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less*

We propose to continue requiring direct supervision for these services but are seeking further public comment on this issue. We believe the supervision standard for chemotherapy and other complex drugs and biologics is a clinical issue. While the HOP Panel as a whole adopted a recommendation for general supervision, the majority of physicians on the Panel voted in favor of direct rather than general supervision and continued to express concerns about the safety of general supervision for chemotherapy, especially absent a quality standard or guideline from oncology professional associations endorsing general supervision.

In the CY 2011 OPPTS/ASC Final Rule (75 FR, 72011), we noted that the American Society of Clinical Oncology/Oncology Nursing Society (ASCO/ONS) Chemotherapy Administration Safety Standards are consistent with Medicare's direct supervision standard for outpatient chemotherapy, and we stated that we would prioritize these services for CMS' independent review process. The ASCO/ANS standard¹ updated in 2013 is the end result of a highly structured, multi-stakeholder process, reflecting the judgment of medical oncologists, oncology nurses, oncology pharmacists, social workers, practice administrators, and patient advocates, as well as representatives from the American Cancer Society, Association of Community Cancer Centers, National Quality Forum, National Coalition for Cancer Survivorship, the Joint Commission, and Institute for Safe Medication Practices. The standard recommends that in all

¹ http://www.asco.org/sites/www.asco.org/files/asco_ons_safety_standards_2013_0.pdf; 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 Setting. Published online ahead of print at jop.ascopubs.org on December 13, 2011.

settings, a licensed independent practitioner (including a physician, nurse practitioner, clinical nurse specialist or physician assistant) is on site and immediately available during all chemotherapy administration in licensed infusion centers and acute care settings. A licensed practitioner should be on site for the initiation of first doses of parenteral chemotherapy and should remain available throughout the administration unless the patient is transitioned to a home care or nonacute facility setting. The ASCO/ONS standard also recommends competency training and assessment, preparatory measures, and monitoring and documentation guidelines.

While we are proposing to maintain the direct supervision standard for chemotherapy administration, we are raising the question of whether to distinguish the supervision level between initial and subsequent administrations of a given chemotherapeutic or biological agent. We are seeking public comment, especially clinical input, regarding the appropriate supervision level for the initial and subsequent administrations of chemotherapy and other highly complex drugs or complex biological agents described by the CPT codes listed above when provided in a hospital or CAH outpatient department. We will consider all the public comments we receive and may re-assess these services again at our summer HOP Panel meeting.

We also note that oncologists have consistently advised CMS in other contexts that chemotherapy administration involves a substantial amount of physician work which is recognized in the physician work relative value unit (RVU) assigned to these codes. We appreciate the difficulty for smaller institutions to provide access to certain services for patients, while assuring high quality and safe care. We are requesting comments on how to provide a targeted approach that could ensure access while maintaining safety.

Regarding CPT 97597, this code includes debridement with a sharp instrument which is not generally within nursing scope of practice and we believe is not safe for general supervision.

CMS Proposes Changing Supervision Level from Direct to “Extended Duration”

- 36430, *Transfusion, blood or blood components*

While we would not accept the Panel’s recommendation that CMS change the supervision level to general for CPT code 36430, we would designate this code as a Non-Surgical Extended Duration Therapeutic Services (or “extended duration services”), which would require an initial period of direct supervision with potential transition of the patient to general supervision. The Panel raised the possibility of designating blood transfusion as an extended duration service rather than assigning general supervision, but it is not in the Panel’s scope to designate extended duration as a supervision level. We agree that blood transfusion is a good candidate for an extended duration service, as it is delivered over a period of time and has a low risk of adverse effects once infusion is underway. We believe blood transfusion warrants direct supervision initially to manage potential adverse events and reactions.

2) SERVICES CURRENTLY DESIGNATED “EXTENDED DURATION”

CMS Proposes Changing Supervision Level from “Extended Duration” to General

- 96370, *Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)*

This code refers to a subsequent infusion of a previously administered drug or substance where direct or extended duration supervision would apply. We would accept the Panel’s recommendation that this service could be conducted under general supervision in accordance with applicable Medicare regulations and policies.

CMS Does Not Propose Changing Supervision Level from “Extended Duration” to General

- 96369, *Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)*
- 96371, *Subcutaneous infusion for therapy or prophylaxis (specify substance or drug)*

These codes may involve administration of a new drug or substance. We would not accept the Panel’s recommendation that this service could be conducted under general supervision. Instead we would apply the rationale that we use in assigning supervision levels to other infused extended duration services (such as intravenous drug administration), where we believe the patient should be monitored for adverse events under direct supervision during an initial monitoring period when *new* drugs or substances are infused.

Service Considered by the Panel and No Recommendation Made

- 94640, *Pressurized or nonpressurized inhalation treatment for acute airway obstruction or for sputum induction for diagnostic purposes (eg, with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing [IPPB] device)*