

June 5, 2014

Supervision of Chemotherapy and Complex Drugs or Biologic Agents Administration

On March 10, 2014, the Advisory Panel on Hospital Outpatient Payment (the Panel) met and reviewed the supervision levels in the hospital outpatient setting for the following 8 CPT codes for the administration of chemotherapy, complex drugs or biologic agents: 96401, 96402, 96409, 96411, 96413, 96415, 96416, and 96417. The Panel recommended that these codes be changed from direct to general supervision. On March 31, 2014, in accordance with our process for reviewing Panel recommendations for supervision levels, we posted our preliminary decisions based upon the Panel's recommendations on the CMS website for public comment. The CMS preliminary decision for these codes was to maintain direct supervision because we believed that the appropriate supervision level for these services is inherently a clinical issue; all but one physician on the Panel recommended direct rather than general supervision, and we are not aware of a standard or guideline from a physician or nurse specialty association endorsing general supervision. We solicited public comment on the clinical standards for appropriate supervision in the hospital outpatient setting, particularly initial versus subsequent administrations of these complex drugs and biologic agents.

The public comments appeared to misunderstand our intent with respect to suggesting a different supervision level for the initial or first time a drug is being administered and when that same drug is being administered in a subsequent encounter. For this reason and because there was no consensus among hospital or professional associations regarding the appropriate supervision level, we are referring these services back to the Panel for further deliberations at the August 2014 Panel meeting.

In formulating a second recommendation, CMS asks the Panel to weigh supervision levels as recommended in relevant clinical guidelines from professional associations, such as the [2013 Updated ASCO/ONS Chemotherapy Administration Safety Standards](#) with the realities of hospital operations and patient care in rural areas. Our suggestion for direct supervision for the initial or first time a drug is being administered and general supervision when that same drug is being administered in a subsequent encounter was an attempt to balance these competing clinical and operational perspectives. At this time, we are uncomfortable defaulting to general supervision, as recommended by the panel, in light of prominent clinical guidelines suggesting this practice is unsafe. To this end, we are seeking advice on the specific question of whether the supervision level should be direct for the initial administration (first administration in a series of administrations of the same drug) followed by general for subsequent administrations of the same drug. We welcome other suggested approaches that balance professional and hospital viewpoints.