Comprehensive APC Packaging Logic

Advisory Panel on Hospital Outpatient Payment Panel (HOP Panel)

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Submitted By: The American Society of Transplantation and Cellular Therapy

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CPT/HCPCS Codes and APC Groups the Presentation Covers

- All Comprehensive APCs (C-APCs), with a focus on the Observation C-APC 8011

- All status indicator "K" HCPCS codes

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Description of the Issue: Clinical Summary of C-APCs

- A Comprehensive APC (C-APC) is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. CMS established C-APCs in CY 2015 (79 FR 66809 through 66810) and began with 25 C-APCs; currently there are about 70 C-APCs.
- A service described by an HCPCS code designated by CMS as a primary service (identified by OPPS status indicator "J1 or J2") is assigned to a single C-APC group and, with few exceptions, a single payment is made.
  - A single payment is made because CMS sees all of the other items and services reported (with few exceptions) on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service. This is what CMS collectively refers to as "adjunctive services" and/or viewed as components of a complete comprehensive service (78 FR 74865 and 79 FR 66799).
  - Payments for these adjunctive services are packaged into the payments for the primary services and, when CMS performs rate-setting, the comprehensive service is based on the costs of all reported services at the claim level.
  - Services excluded from the C-APC policy include those that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid.
    - Examples include: certain mammography and ambulance services; brachytherapy seeds; pass-through payment drugs and devices; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B; and certain preventive services.

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Description of the Issue: Clinical Summary of Observation C-APC 8011

- In the CY 2016 OPPS/ASC final rule, CMS added Comprehensive Observation Services C–APC 8011.
- Services within this APC are assigned status indicator "J2".
- When the following criteria are met, CMS makes a single payment through C-APC 8011:
  - Does not contain a procedure described by an HCPCS code to which CMS has assigned status indicator "T";
  - Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
  - Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT codes 99281 - 99285 (Emergency Department visit codes Level 1-5) or HCPCS code G0380 - G0384 (Type B Emergency Department visit Level 1-5); CPT code 99291 (Critical care, evaluation, and management of the critically ill or critically injured patient; first 30-74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and
  - Does not contain services described by a HCPCS code to which CMS has assigned status indicator "J1".

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Description of the Issue: Codes Excluded as Clinical Services in C-APCs

- OPPS Addendum J indicates that following services are excluded from being packaged into C-APCs.
- If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C-APC service when it appears on an outpatient claim with a primary C-APC service.

CY 2024 Comprehensive APC Payment Policy Exclusions
Ambulance services
Brachytherapy
Diagnostic and mammography screenings
Physical therapy, speech-language pathology and occupational therapy services reported on a separate facility claim for recurring services
Pass-through drugs, biologicals, and devices
Preventive services defined in 42 CFR 410.2
Self-administered drugs (SADs) - Drugs that are usually self-administered and do not function as supplies in the provision of the comprehensive service
Services assigned to OPPS status indicator “F” (certain CRNA services, Hepatitis B vaccines and corneal tissue acquisition)
Services assigned to OPPS status indicator “L” (influenza, pneumococcal pneumonia, and COVID-19 vaccines)
Certain Part B inpatient services – Ancillary Part B inpatient services payable under Part B when the primary “J1” service for the claim is not a payable Medicare Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only)
Services assigned to a New Technology APC
Any drug or biological described by HCPCS code C9399

Description of the Issue: High-Cost Drugs Exceeding C-APC payment

- *"Items included in the packaged payment provided in conjunction with the primary service…include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status…"* (CMS)
- In situations where status indicator "K" items have an ASP+6% payment that exceeds the payment for the C-APC, the drug or biological product cannot reasonably be considered adjunctive or secondary; it is essentially the primary service and the most-costly procedure at the claim level.
- ASTCT's immediate concern is that cell therapies such as Chimeric Antigen Receptor T-cell (CAR-T) therapies with status indicator "K" will be subject to CMS' packaging logic when administered to hospital outpatients who might also receive an observation service that results in an Observation C-APC 8011.
- This packaging of high-cost drugs into a C-APC will result in large financial losses for hospitals.

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Recommendation

- The ASTCT requests the HOP panel recommend to CMS that the agency:
  - No longer package status indicator "K" drugs into any Comprehensive APC (C-APC); instead, CMS should continue to provide separate payment for all drugs and biologicals above the drug packaging threshold.
  - If CMS does not make this change for all C-APCs, it should at least implement this change for the Observation C-APC.

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Rationale for Recommendation

- There is effectively no difference between pass-through drugs/biologicals (status indicator [SI] "G") and otherwise separately payable drugs/biologicals above the drug packaging threshold (status indicator "K") since both are paid at ASP+6%.
- Once pass-through expires, there is no separate or packaged payment for these products when a C-APC is triggered, until such time that CMS' rate-setting process packages these costs into C-APCs.
- Packaging low-cost drugs and supplies into C-APCs is appropriate, but we do not believe it was ever CMS' intent to package high-cost drugs and biologicals into C-APCs.
- Current claims data show few status indicator "K" line-item charges appearing on C-APC claims; however, we are starting to see a higher volume of high-cost cell therapies provided to hospital outpatients.
- When the Observation C-APC was created, high-cost cell therapies like CAR-T were not FDA-approved. Today, when CAR-T is administered to hospital outpatients, observation services may be ordered post-infusion to address signs and symptoms related to a complication; this could result in the Observation C-APC being generated if criteria are met.
  - The result for status indicator "K" CAR-T products: separate ASP+6%-based payment would not be generated.
  - CAR-T products are beginning to transition from SI-G to SI-K; two products currently have SI-K, with all current products expected to transition with the next few years

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Expected Outcome

- By not packaging status indicator "K" drugs into C-APCs, CMS will enable providers to continue receiving separate payment for drugs and biologicals above the drug packaging threshold—just as they did when the status indicator was a "G".
- Providers will not have to rely on inadequate outlier dollars to generate payment for status indicator "K" drugs when a C-APC is generated.
- The outlier threshold will not be inflated as a result of the status indicator "K" drugs being converted to status indicator "N" under C-APC logic; CMS would not have a large outlay of payment for the status indicator "K" drugs, given how few appear on claims to-date.
- C-APCs will not get distorted over time as a result of packaging dollars for high-cost drugs and biologicals being included; this is particularly true for the Observation C-APC and CAR-T products.

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Potential Consequences if Not Changed

- Primary consequence: continuing to package high-cost drugs and biologicals with status indicator "K" into C-APCs will result in hospitals not being appropriately paid and, therefore, these therapies may no longer be provided to hospital outpatients.
- Secondary consequence: CMS will package high-cost drugs and biologicals into C-APCs, like CAR-T cell therapies into the Observation C-APC, which could inflate the rate of that C-APC beyond what CMS intends or expects it to pay, on average, and also inflate the outlier threshold.

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