



Comprehensive APC Packaging Logic

Advisory Panel on Hospital Outpatient Payment Panel (HOP Panel)

August 26-27, 2024

Submitted By: The American Society of Transplantation and Cellular Therapy





Presentation Checklist

- Financial relationship – slide 3
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Financial Relationships

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Assistant Vice President - Revenue Cycle, Advocate Health; None

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

Description of the Issue: Reminder of HOP Panel Recommendation from August 2023 Meeting



- ASTCT presented on this topic at the August 2023 meeting of the HOP Panel
- We were pleased with the HOP Panel's recommendation as shown below

RECOMMENDATIONS

Centers for Medicare & Medicaid Services (CMS)

Advisory Panel on Hospital Outpatient Payment

August 21, 2023

8. The Panel recommends that CMS no longer package drugs with an SI of K into any comprehensive APC; instead, CMS should continue to provide separate payment for all drugs and biologicals above the drug packaging threshold.

- We appreciate for CY 2025 CMS has proposed to exclude CAR-T products with SI "K" from packaging for 1 year, however
- We request that the Panel reaffirm its original recommendation to unpackage all SI "K" drugs from C-APC packaging. Our rationale is the same as what we presented last year and included in the remaining slides.

Since CMS staff generally describe the issue, which we also outline in slides 6-9, we can move directly to our two requests outlined in Slide 10.



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 and currently there are about 70.
- A service described by a HCPCS code that CMS has designated 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 does its 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.

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 is met, CMS makes a single payment through C-APC 8011:
 - Does not contain a procedure described by a HCPCS code to which we have 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 we have assigned status indicator "J1".

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 which 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

Recommendation

- The ASTCT requests the HOP panel to once again recommend to CMS that it:
 - No longer package any status indicator "K" drug into any Comprehensive APC (C-APC) and instead continue to provide separate payment for all drugs and biologicals above the drug packaging threshold
 - If CMS does not make this change then it should finalize what is has proposed for CY 2025, which is to exclude cell and gene therapies listed in Table 1 from C-APC packaging



TABLE 1: Cell and Gene Therapies Proposed for Exclusion from C-APC Packaging

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Carvytki	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10 ¹⁵ vector genomes

Rationale for Recommendation



- There is effectively “no difference” between pass-through drugs/biologicals (status indicator “G”) and otherwise separately payable drugs/biologicals above the drug packaging threshold (both are paid 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 shows few status indicator “K” line-item charges appearing on C-APC claims, however we are starting to see more volume of high-cost cell therapies provided to hospital outpatients
- When C-APCs were created, specifically the Observation C-APC, 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 and this could result in the Observation C-APC being generated if criteria is met resulting in no separate ASP+6% payment.

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 nor would CMS 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

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