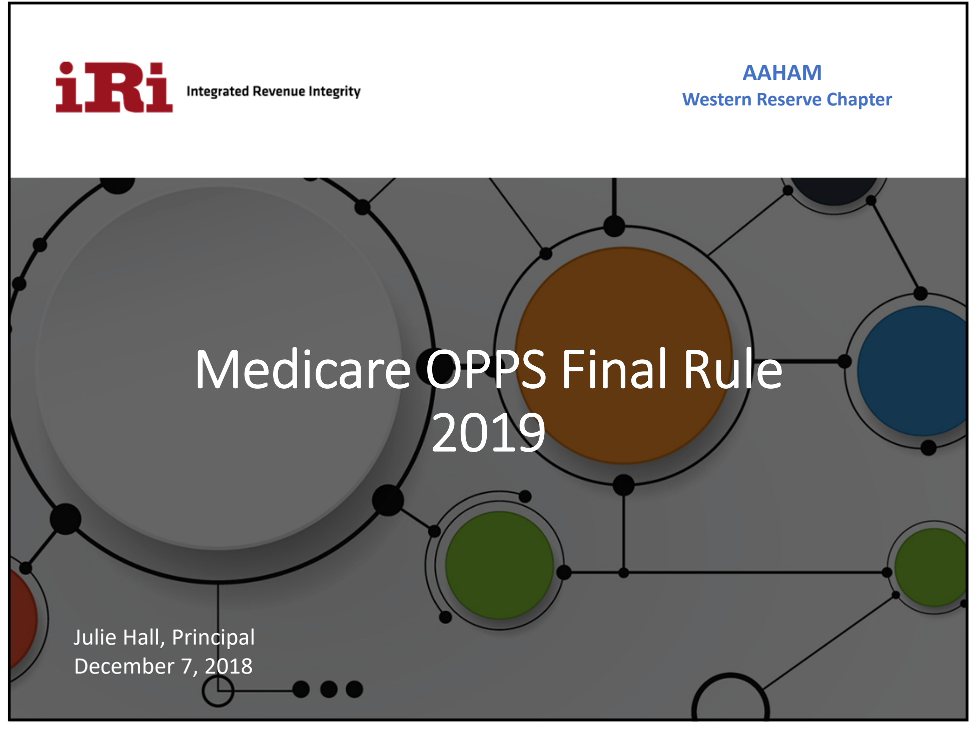
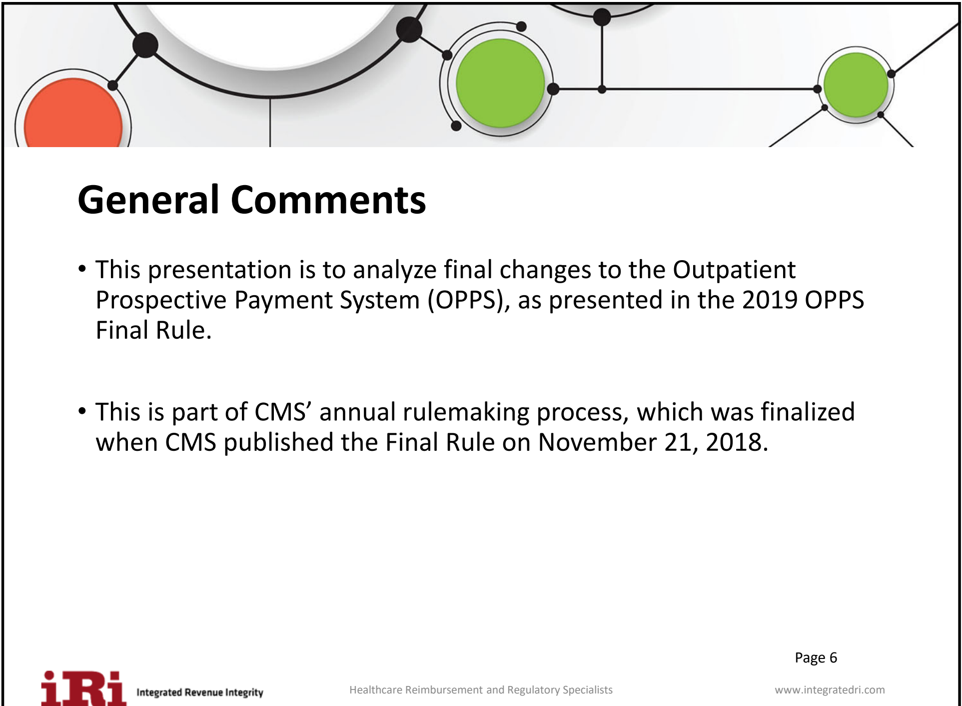

iRi Integrated Revenue Integrity
AAHAM
Western Reserve Chapter
Medicare OPPS Final Rule
2019
Julie Hall, Principal
December 7, 2018


General Comments
• This presentation is to analyze final changes to the Outpatient Prospective Payment System (OPPS), as presented in the 2019 OPPS Final Rule.
• This is part of CMS' annual rulemaking process, which was finalized when CMS published the Final Rule on November 21, 2018.
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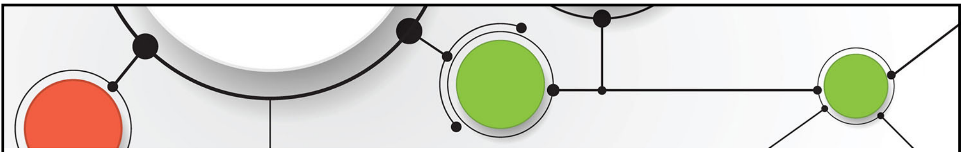
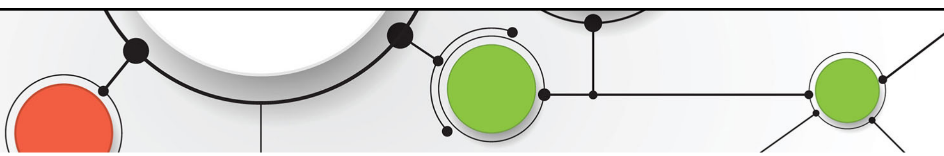


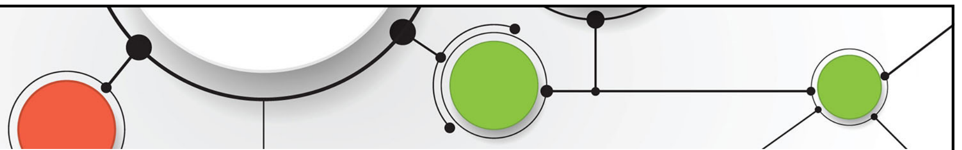
General Comments

- The Final Rule discusses changes that CMS is making to the OPPS and become effective January 1, 2019.
- Some of the issues raised in the Proposed Rule will be implemented as originally presented, while others have been accepted with modifications, or will not be implemented at all.

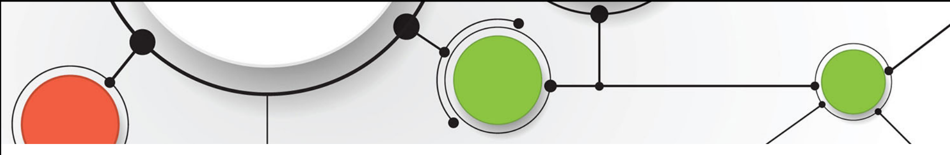


General Comments

- This presentation presents issues in the same general order that they are discussed in the Final Rule.
- Numbered tables used in this manual are obtained directly from the Final Rule
  - Additional tables have been created by IRI to provide additional details, as taken from the 2019 OPPS Final Rule Addenda, which are available here: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC.html

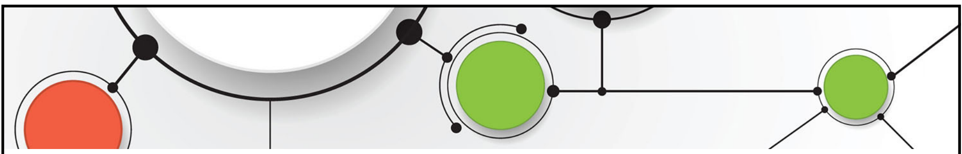


I. Summary and Background of the 2019 OPPS Final Rule



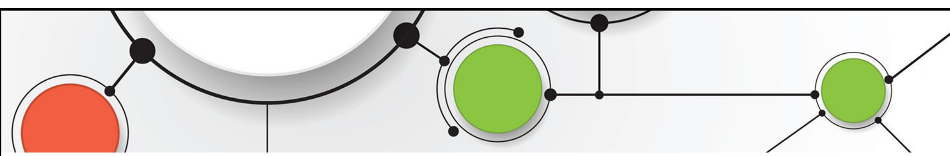
Executive Summary

- OPPS payment increase factor of 1.35%
- Continuation of 2% payment reduction for hospitals failing outpatient quality reporting requirements
- Creation of three new comprehensive APCs for ENT and vascular procedures



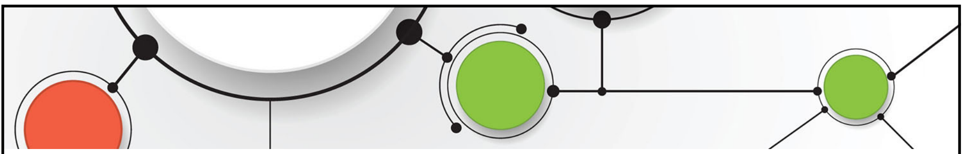
Executive Summary

- Removing four procedures and adding one to the inpatient only list
- Payment reduction to outpatient clinic visits performed in excepted off-campus provider-based outpatient departments paid under the OPPS; payment for 2019 will be 70% of OPPS rate and for 2020 it will be 40%
- No change in payment reduction to new service lines offered at excepted off-campus provider-based outpatient departments; CMS will continue to monitor



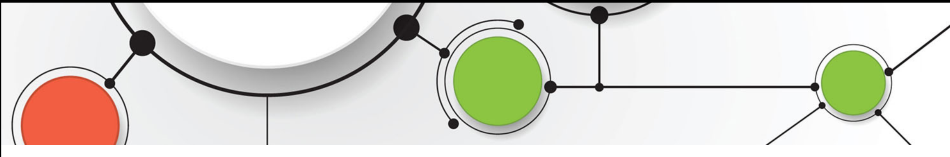
Executive Summary

- Application of 340B payment reduction to nonexcepted off-campus provider-based departments
- Payment for nonpass-through biosimilar drugs acquired under the 340B program at ASP – 22.5% of the biosimilar's own ASP, rather than the reference product's ASP
- Change in payment rate for certain drugs and biologicals where ASP data is not available



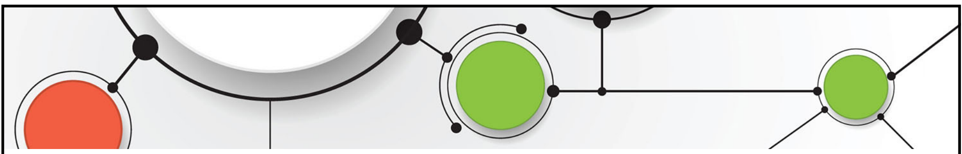
Executive Summary

- Modification of criteria for determining device intensive procedures
- Approval of one out of seven submitted pass-through device applications
- Revision of payment rate calculation for low-volume New Technology APC procedures



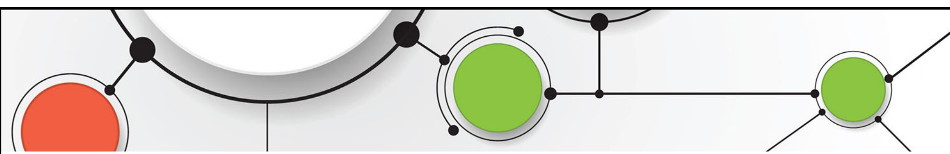
Executive Summary

- Continuation of cancer hospital payment adjustment, reduced by 1% to equal a PCR of 0.88
- Continuation of rural adjustment of 7.1% for SCHs and EACHs
- Updates to the Hospital Outpatient Quality Reporting (OQR) Program



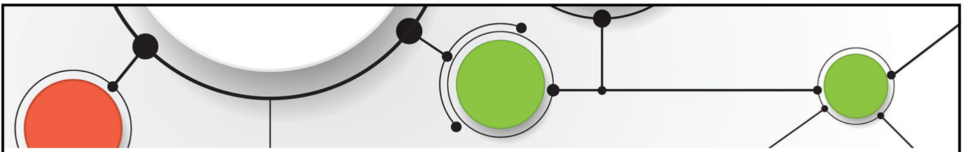
Summary of Costs and Benefits

- Update of wage indexes based on IPPS Proposed Rule results in no estimated payment changes for urban and a decrease of 0.2% for rural hospitals under the OPPS
- No significant impacts to payment policies for hospitals eligible for rural or cancer hospital adjustments



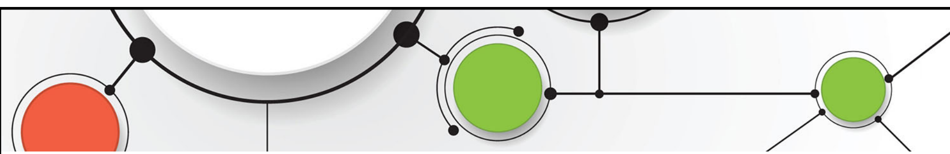
Summary of Costs and Benefits

- Estimated 0.6% overall increase in OPPS payments to providers (increase of approximately $360 million compared to CY 2018 payments)
- Impact of decrease in off-campus PBD clinics estimated to be 0.6% for urban, 0.6% for rural hospitals



Summary of Costs and Benefits

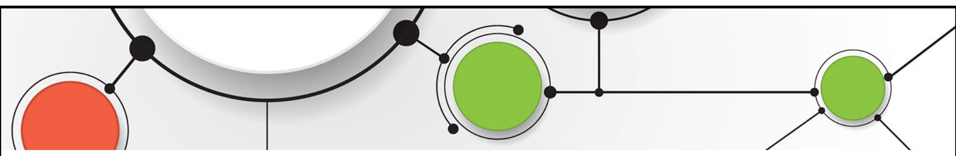
- Community Mental Health Centers (CMHCs), which are only paid for partial hospitalization under the OPPS, will have an estimated 15.1 percent decrease in CY 2019 payments compared to CY 2018 payments
- Changes to the Hospital Outpatient Quality Reporting (OQR) Program result in no estimated change in total collection of information burden or costs for the CY 2020 determination, and a reduction of 681,735 hours of information collection and $24.9 million in cost for the CY 2021 payment determination due to the removal of four specific measures



Legislative and Regulatory Authority for the Hospital OPPS

The OPPS was established to replace cost-based reimbursement, as mandated by the Balanced Budget Act of 1997.

- Prospective payment system was implemented August 1, 2000
- Since that time, the OPPS has been dramatically changed and reformed through OPPS Rulemaking and other regulatory changes

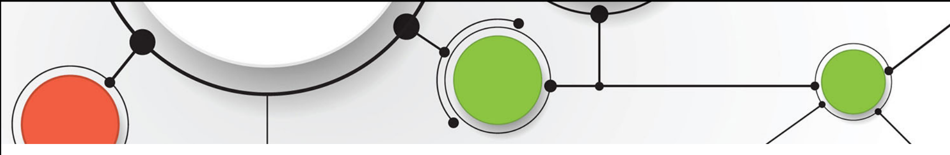


Legislative and Regulatory Authority for the Hospital OPPS

Items and Services Included Under the OPPS

The OPPS includes payment for most hospital outpatient services. Services which are excluded from the OPPS are discussed on the following page.

- Hospital outpatient services are paid based on the Ambulatory Payment Classification (APC) group that the service is assigned to



Excluded OPPS Services and Hospitals

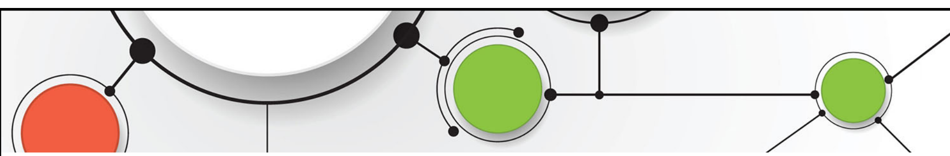
Items which are not included under the OPPS include:

- Ambulance services
- Physical and occupational therapy and speech language pathology
- Screening and diagnostic mammography
- Annual wellness visits

Excluded OPPS Services and Hospitals

Items which are not included under the OPPS include:

- Services paid under other fee schedules or payment systems
  - Professional services paid under the Physician Fee Schedule (PFS)
  - Certain lab tests paid under the Clinical Laboratory Fee Schedule (CLFS) (e.g., molecular pathology)
  - ESRD services paid under the ESRD prospective payment system
  - Services and procedures which require an inpatient stay and are paid under the IPPS
- Effective January 1, 2017 – Services furnished at a nonexcepted off-campus provider-based department



Excluded OPPS Services and Hospitals

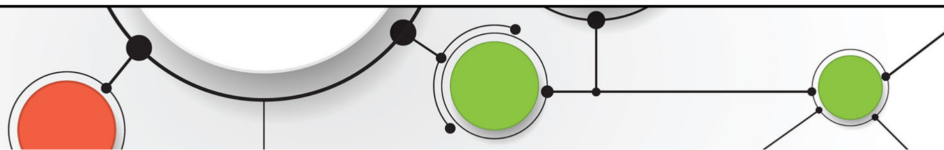
Provider types which are excluded from payment under the OPPS include:

- Critical Access Hospitals (CAHs)
- Maryland hospitals paid under the Maryland All-Payer Model
- Hospitals outside of the 50 states, DC and Puerto Rico
- Indian Health Service (IHS) hospitals

Prior Rulemaking

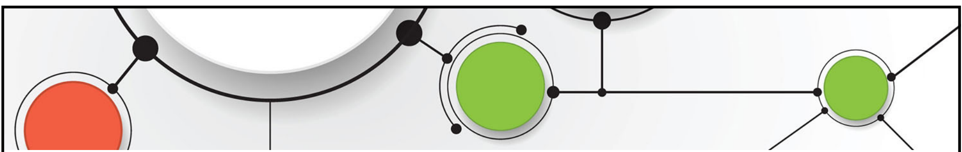
- Throughout the CY 2019 OPPS Final Rule CMS makes many references to Final Rules from prior years.
- Every Final Rule published since the inception of the OPPS can be viewed on the CMS website at:

  https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html



Public Comments Received on the CY 2019 OPPS/ASC Proposed Rule with Comment Period

- CMS received 2,990 timely pieces of correspondence regarding the CY 2019 Proposed Rule.
- Summaries of these comments are included in the CY 2019 Final Rule.



Public Comments Received on the CY 2018 OPPS/ASC Final Rule with Comment Period

- CMS received 125 timely pieces of correspondence regarding the CY 2018 Final Rule.
- Summaries of these comments are also included in the CY 2019 Final Rule.

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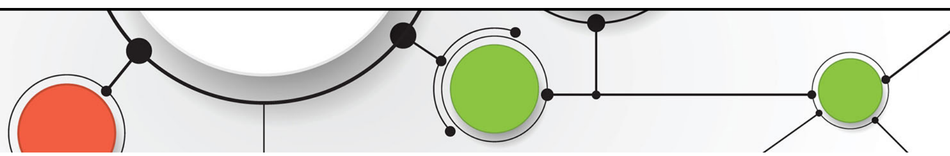

II. Updates Affecting OPPS Payments

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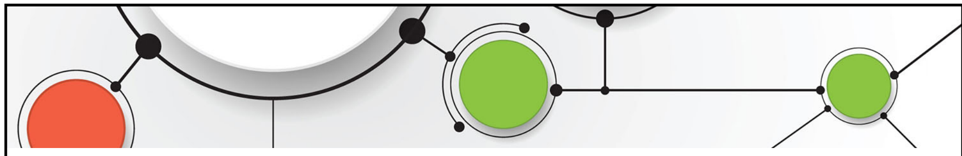
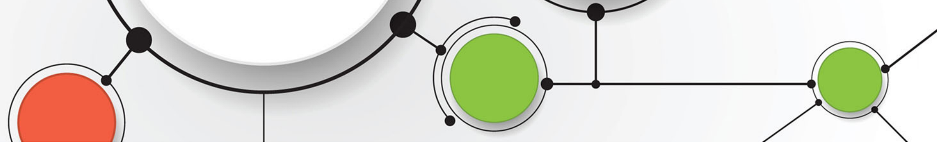


Recalibration of APC Relative Payment Weights

CMS is required by law to review and revise the relative payment weights for APCs at least annually.

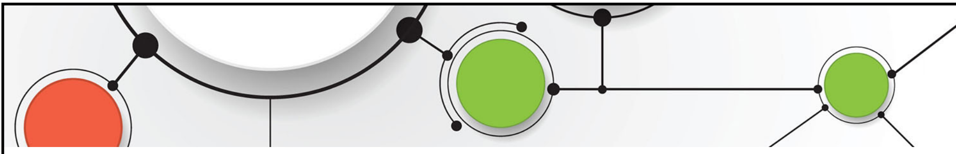
The same basic process for recalibrating payment weights is used for CY 2019.

CMS uses claims data combined with cost report data to determine payment weights.



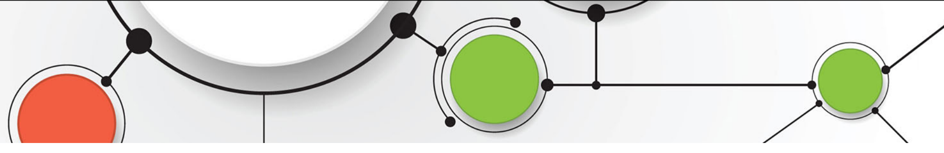
Recalibration of APC Relative Payment Weights

- For 2019, payment rates are recalibrated using the most recent full calendar year of claims data (1/1/17 through 12/31/17) and the most recently available cost report data (mostly from 2016)
- The charges reported on these claims are converted to estimated costs by utilizing hospital specific cost-to-charge ratios (CCRs) at the most detailed level possible (e.g., department-specific CCRs).
- Payment rates are calculated using the geometric mean cost across all facilities.



Recalibration of APC Relative Payment Weights

- This is the first year that CMS has claims data for services reported with the PN modifier (nonexcepted items or services furnished and billed by off-campus provider-based departments).
- Because services reported with this modifier are not paid under the OPPS, CMS removed claim lines with this modifier from claims data used for rate setting.
- The final process resulted in 91 million claims for 2017 which were used for CY 2019 rate setting.

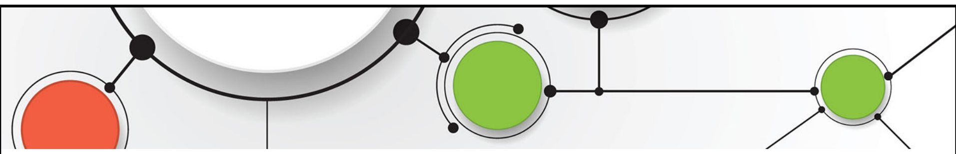


Extension of Transition Period for CT and MRI Cost Centers

In 2014, CMS finalized the creation of new cost centers and distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

At the time, commenters expressed concern that many providers were using an imprecise “square feet” allocation methodology for the costs of large moveable equipment such as CT scan and MRI machines.

CMS recommends two alternative methods, “direct assignment” or “dollar value” as more accurate for directly assigning equipment costs, but only approximately half of providers were using those methodologies at the time.

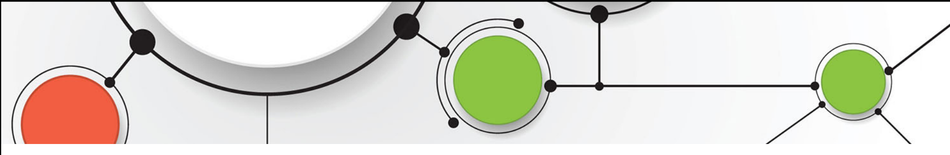


Extension of Transition Period for CT and MRI Cost Centers

In response to provider concerns and to provide added flexibility for hospitals to improve their cost allocation methods, CMS has finalized extension of the transitional period for one more year.

This provides a 6-year total transition period.

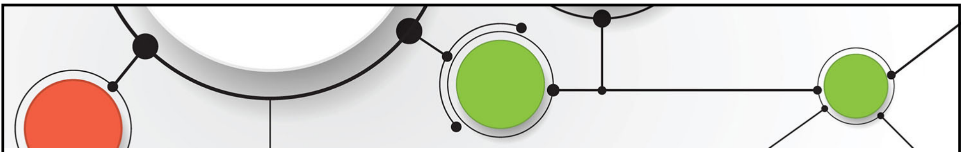
CMS does not believe that another extension will be warranted and expects to determine imaging APC payment rates using data from all providers for CY 2020, regardless of the cost allocation method employed.



Blood and Blood Products

CMS will continue to establish payment rates for blood and blood products using blood-specific cost-to-charge ratios (CCRs) for those hospitals with blood-specific cost centers, and to use simulated blood-specific CCRs for those hospitals without a blood-specific cost center, as has been done since 2005.

There is a significant difference in CCRs for those hospitals that report blood-specific cost centers versus those that do not. Defaulting to the overall hospital CCR for hospitals without blood-specific cost centers results in an underestimation of true hospital costs for blood and blood products.



Blood and Blood Products

CMS will continue to simulate blood CCRs for hospitals that do not report blood-specific cost centers.

- CMS calculates the ratio of blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers
- This mean ratio is then used for hospitals which do not have blood-specific cost centers.
- Simulating a blood-specific CCR more accurately captures the true costs of blood and blood products.

Pathogen-Reduced Platelets Payment Rate

Due to concerns about the original code describing both pathogen-reduced platelets and significantly less costly rapid bacterial testing, CMS did not use 2016 claims data to establish a payment rate for P9073 in 2018. Rather, CMS continued to crosswalk to P9037.

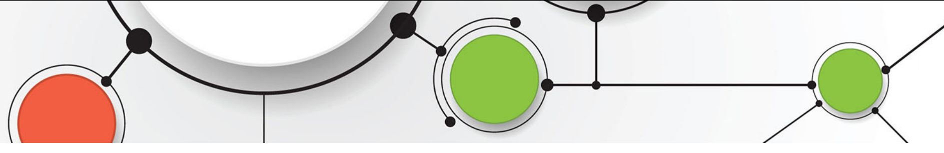
For 2019, CMS has analyzed claims data for all of the predecessor codes (P9072, Q9987, Q9988) and believes that they have been able to differentiate between the costs for pathogen-reduced platelets and rapid bacterial testing.

Pathogen-Reduced Platelets Payment Rate

CMS proposed to use actual claims data to determine the cost of P9073 going forward and no longer cross walk to P9037.

For CY 2019 this would have resulted in a significant proposed payment reduction, from $624.66 in CY 2018, to $445.68 in CY 2019 (-28.65%).

Commenters were opposed to this due to many code changes which led to billing errors and incorrect data analysis.

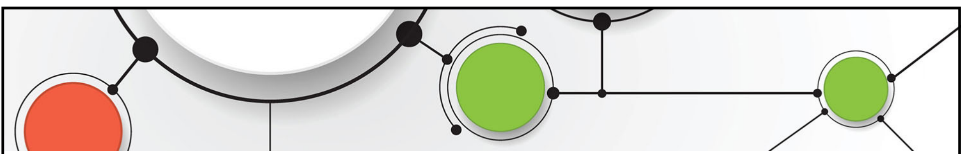


Pathogen-Reduced Platelets Payment Rate

CMS agreed and will not finalize their original proposal.

P9073 will continue to be cross walked to P9037 for one more year.

The unadjusted payment rate for P9073 for 2019 is $624.93.

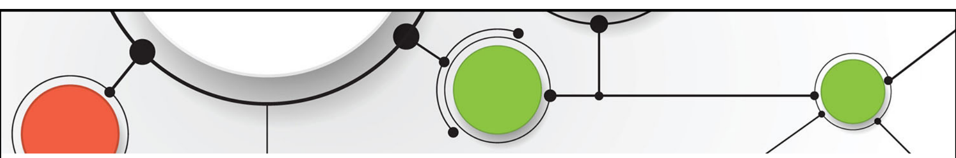


Brachytherapy Sources

CMS will continue to set payment rates for brachytherapy sources using the established general prospective payment methodology based on geometric mean costs. The Status Indicator will continue to be “U”.

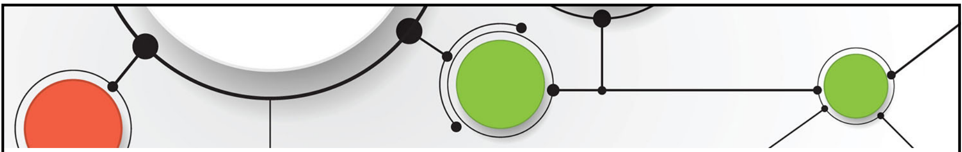
The following current payment policies for brachytherapy sources will continue to apply:

- Both stranded and non-stranded “not otherwise specified” (NOS) codes, C2698 and C2699, will be paid at the lowest stranded or non-stranded payment rate
- Payment for new brachytherapy sources for which there is no claims data will continue to be based on external data and other relevant information regarding the expected costs of the sources to hospitals



Brachytherapy Sources

HCPCS Code	Short Descriptor	2018 SI	2018 Payment Rate	2019 SI	2019 Payment Rate	%Diff
A9527	Iodine i-125 sodium iodide	U	$26.65	U	$37.87	42%
C1716	Brachytx, non-str, gold-198	U	$122.61	U	$86.29	-30%
C1717	Brachytx, non-str,hdr ir-192	U	$294.59	U	$290.78	-1%
C1719	Brachytx, ns, non-hdrir-192	U	$19.16	U	$84.92	343%
C2616	Brachytx, non-str,yttrium-90	U	$16,717.59	U	$16,625.88	-1%
C2634	Brachytx, non-str, ha, i-125	U	$117.66	U	$138.59	18%
C2635	Brachytx, non-str, ha, p-103	U	$25.94	U	$27.12	5%
C2636	Brachy linear, non-str,p-103	U	$27.08	U	$49.33	82%
C2638	Brachytx, stranded, i-125	U	$34.73	U	$36.40	5%
C2639	Brachytx, non-stranded,i-125	U	$34.66	U	$35.01	1%
C2640	Brachytx, stranded, p-103	U	$78.72	U	$74.67	-5%
C2641	Brachytx, non-stranded,p-103	U	$64.27	U	$60.13	-6%
C2642	Brachytx, stranded, c-131	U	$87.89	U	$79.94	-9%
C2643	Brachytx, non-stranded,c-131	U	$87.40	U	$78.36	-10%
C2644	Brachytx cesium-131 chloride	U	$105.09	E2		-100%
C2645	Brachytx planar, p-103	U	$4.69	U	$4.69	0%
C2698	Brachytx, stranded, nos	U	$34.73	U	$36.40	5%
C2699	Brachytx, non-stranded, nos	U	$19.16	U	$27.12	42%



Brachytherapy Sources

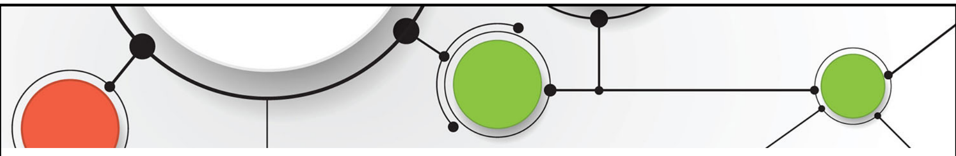
- HCPCS C2644 will be assigned status indicator E2 (non-covered) due to having no claims data reported for CY 2017
- HCPCS C2645 will continue to be assigned status indicator U and be priced at $4.69 per sq mm based upon external data (invoice prices) and other relevant information

Comprehensive APCs (C-APCs) for CY 2019

Background

Comprehensive APC: provision of a primary service and all adjunctive services provided to support delivery of the primary service

Adjunctive Services: all other items and services reported on the hospital outpatient claim which are integral, ancillary, supportive, dependent and adjunctive to the primary service and representing components of a complete comprehensive service.



Comprehensive APCs (C-APCs) for CY 2019

Comprehensive APCs (C-APCs) were established as part of the 2014 OPPS Final Rule, with implementation delayed until January 1, 2015.

- A total of 25 C-APCs were implemented with modifications and clarifications to the policy in 2015
- An additional 10 C-APCs were established for CY 2016, including the new Comprehensive Observation APC, assigned status indicator J2
- 25 additional C-APCs were established for CY 2017, dramatically increasing the number of HCPCS codes classified as comprehensive services
- No additional C-APCs were established for CY 2018.

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Comprehensive APCs (C-APCs) for CY 2019

Payment for most adjunctive services is packaged into the payment for procedures which are classified as comprehensive.

Excluded from packaging are services that:

- Are not covered services
- Cannot be paid under the OPPS by statute
- Are required to be separately paid by statute
- CMS publishes the list of services excluded from C-APC packaging in Addendum J of the Final Rule, as seen on the following page.

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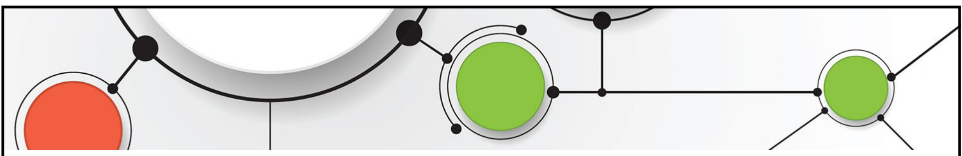

Comprehensive APCs (C-APCs) for CY 2019

Final CY 2019 Comprehensive APC Payment Policy Exclusions

Final CY 2019 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 CFR410.2
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 and pneumococcal pneumonia 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

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Comprehensive APCs (C-APCs) for CY 2019

If multiple procedures that are assigned status indicator J1 are reported on the same claim, the highest ranked APC is paid and the other procedure is packaged, unless a code pair results in a complexity adjustment.

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Comprehensive APCs (C-APCs) for CY 2019

Complexity Adjustments:

- Certain combinations of J1 procedures or certain combinations of add-on codes reported with J1 procedures result in the assignment of a higher paying APC via a complexity adjustment
- These combinations have been determined to represent a more complex version of the primary service

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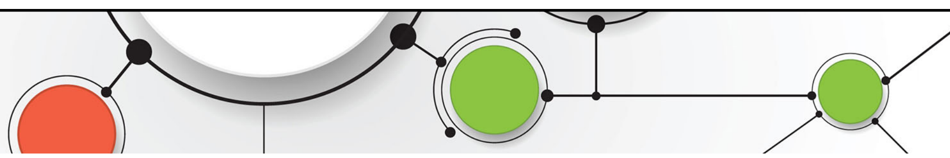

Comprehensive APCs (C-APCs) for CY 2019

Complexity Adjustments:

- Complexity adjustments apply when:
  - There is a minimum of 25 claims submitted with the same code pair combination (frequency threshold)
  - There is a violation of the 2 times rule in the originating C-APC (cost threshold)

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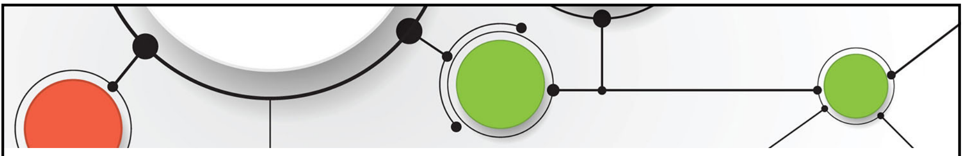
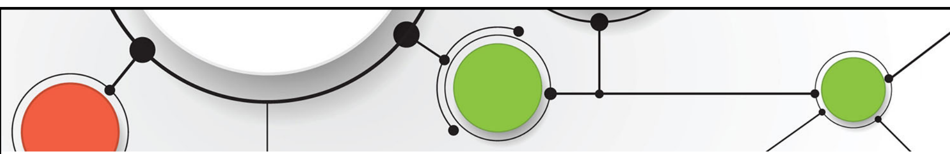


Comprehensive APCs (C-APCs) for CY 2019

Complexity Adjustments:

- Complexity adjustment promotes the comprehensive service to the next higher APC within the same clinical family, unless it is already assigned to the highest ranked APC. If so, no adjustment will be made.

See addendum J of this Final Rule for the complete list of code combinations that will qualify for complexity adjustments in 2019.

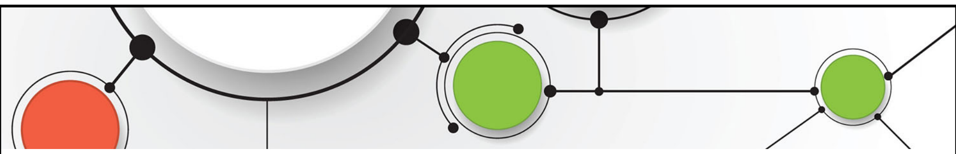


Additional C-APCs for CY 2019

CMS will continue to apply the current C-APC payment policy for CY 2019 and subsequent years.

Additionally, CMS has established three new C-APCs for CY 2019.

- C-APC 5163 Level 3 ENT Procedures
- C-APC 5183 Level 3 Vascular Procedures
- C-APC 5184 Level 4 Vascular Procedures



Additional C-APCs for CY 2019

This adds an additional 146 HCPCS codes which would be assigned status indicator J1, bringing the total number of HCPCS assigned to SI J1 to 2,968.

CMS states that these APCs are similar to existing C-APCs because:

- They include primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services
- There are higher APC levels within these clinical families which are already classified as comprehensive APCs

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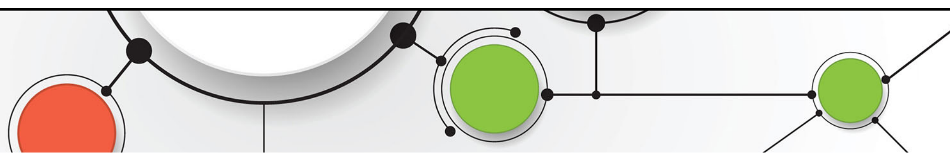

Exclusion of Procedures Assigned to New Technology APCs from the Comprehensive APC (C-APC) Policy

Services assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish accurate payment for the procedures.

CMS retains procedures in these APCs until enough cost data is obtained.

Currently, procedures assigned to New Technology APCs are packaged into comprehensive APCs when reported on the same claim.

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Exclusion of Procedures Assigned to New Technology APCs from the Comprehensive APC (C-APC) Policy

Because the New Technology APC is not paid in this scenario, this reduces the number of paid claims available for use in determining future payment rates for the new procedures.

CMS believes this is contrary to the objective of New Technology APCs, which is to gather sufficient claims data to enable appropriate assignment to a clinical APC.

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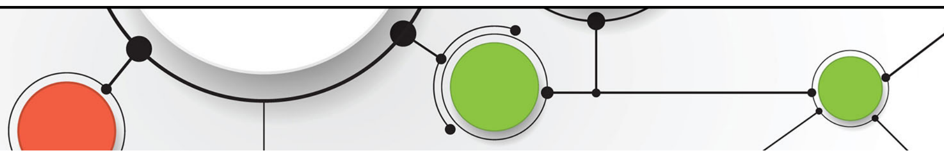

Exclusion of Procedures Assigned to New Technology APCs from the Comprehensive APC (C-APC) Policy

This is especially important for low-volume services. For example:

- CPT 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy)
- This New Technology procedure was reported just seven times in CY 2017, and two of the seven were not paid due to being reported with a comprehensive APC

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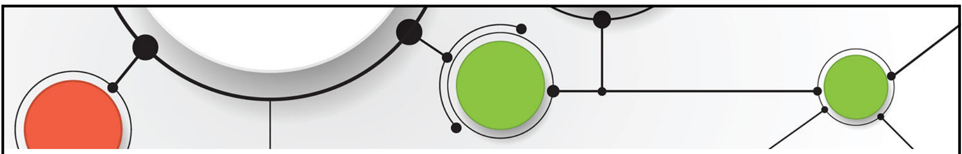
Exclusion of Procedures Assigned to New Technology APCs from the Comprehensive APC (C-APC) Policy

Numerous commenters supported this proposal. Therefore, for CY 2019 CMS will exclude from packaging into C-APCs any procedure assigned to a New Technology APC (APCs 1491-1599 and 1901-1908).

Composite APCs

Composite APCs – groups of services typically performed together during a single clinical encounter resulting in provision of a complete service; paid under one Composite APC which provides a payment rate higher than the sole service APC payment rate but lower than the aggregate sum of the sole service APC rates.

- Composite APCs were first introduced in 2008 to incentivize high quality and efficient care
- Multiple composite APCs have been replaced by comprehensive APCs since their implementation in 2015, with only two composite APCs remaining
- CMS will continue composite APC payment policies for the last remaining APCs, mental health services and multiple imaging services



Mental Health Services Composite APC

CMS will continue to cap the maximum payment amount for multiple outpatient mental health services provided in a single day at the payment amount for a day of partial hospitalization services.

CMS considers partial hospitalization to be the most resource intensive mental health service furnished on an outpatient basis, and therefore believes that individual mental health services should not be paid at a higher rate than partial hospitalization per diem payments.

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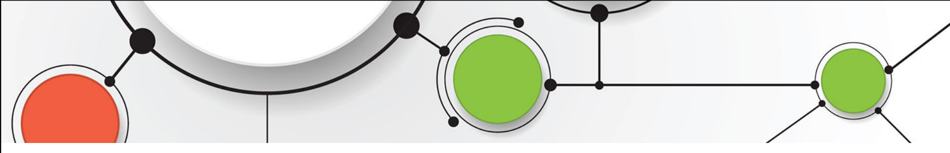

Mental Health Services Composite APC

Composite Rule:

If the total payment amount for multiple mental health services provided to a beneficiary on a single date of service exceeds the maximum per diem rate for partial hospitalization services (APC 5863), a single payment of composite APC 8010 will be made for all mental health services.

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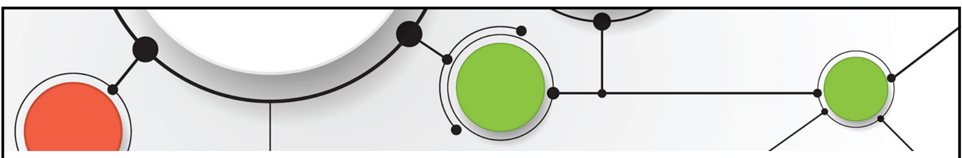

Mental Health Services Composite APC

Final 2019 Payment:

The below table shows the 2019 mental health composite payment rate compared to the current 2018 payment rate.

Composite APC	CY 2018 Payment	2019 Payment	Percent Difference
8010– Mental Health Services Composite	$208.23	$220.86	6%

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Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

For CY 2019, CMS will continue the same payment methodology used for the multiple imaging composite APCs.

Composite Rule:

- A single payment will be made each time more than one imaging procedure within the same imaging “family” is billed on the same date of service.
- There are three OPPS imaging families which are divided into five composite APCs to allow payment for exams performed with or without contrast.

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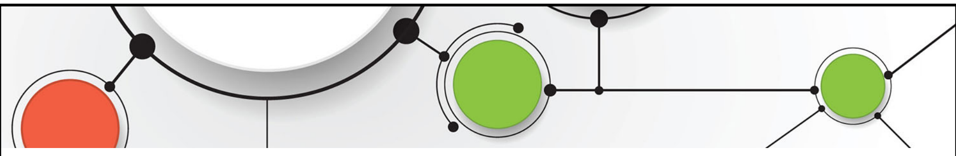

Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

If one or more exam is performed with contrast and others are performed without, the composite APC for with contrast is assigned.

Family 1 – Ultrasound – Composite APC 8004

Family 2 – CT and CTA w/o contrast – Composite APC 8005
CT and CTA with contrast – Composite APC 8006

Family 3 – MRI and MRA w/o contrast – Composite APC 8007
MRI and MRA with contrast – Composite APC 8008

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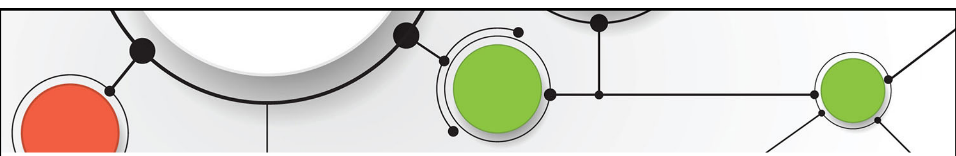

Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Final 2019 Payment:

The below table shows the final multiple imaging composite payment rates compared to the current 2018 payment rates.

Composite APC	CY 2018 Payment	2019 Payment	Percent Difference
8004 – Ultrasound Composite	$299.89	$299.62	
8005 – CT and CTA without Contrast Composite	$274.84	$264.95	-3.6%
8006 – CT and CTA with Contrast Composite	$500.85	$480.77	-4.00%
8007 – MRI and MRA without Contrast Composite	$556.17	$544.22	-2.15%
8008 – MRI and MRA with Contrast Composite	$871.86	$855.60	-1.86%

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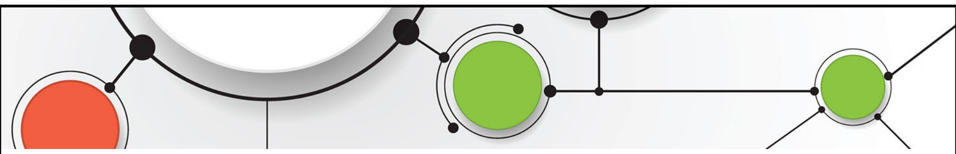

Packaging Policy for Non-Opioid Pain Management Treatments

CMS received a recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis to examine payment policies for non-opioid pain management treatments which are packaged as drugs that function as a supply.

- Recommended that CMS "review and modify rate setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain."

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Packaging Policy for Non-Opioid Pain Management Treatments

- Suggested that current CMS policy to package "supplies" related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for postsurgical pain rather than administering non-opioid pain medications.

- CMS currently provides one all-inclusive bundled payment to hospitals for all 'surgical supplies,' which includes hospital-administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon administers a non-opioid medication or not.

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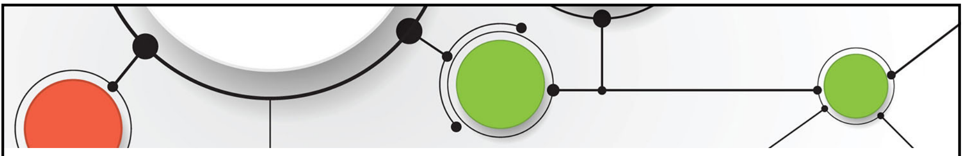

Packaging Policy for Non-Opioid Pain Management Treatments

CMS has concluded that there is no evidence to support the notion that the OPPS packaging policy has an unintended consequence of discouraging use of non-opioid treatment for postsurgical care in hospital OPDs.

No changes were proposed to the packaging policy under the OPPS.

However, CMS did notice different effects on Exparel utilization due to packaging policies under the ASC payment system, noting significantly decreased utilization.

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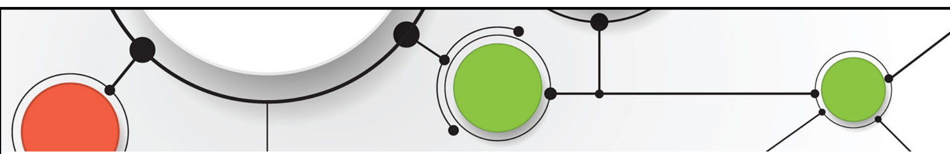

Packaging Policy for Non-Opioid Pain Management Treatments

CMS notes that ASCs may be more acutely impacted by packaging decisions than hospitals are under the OPPS, due to more specialized services and lower payment rates.

For CY 2019, CMS proposed to unpackage and pay separately for non-opioid pain management drugs that function as supplies when furnished in an ASC setting.

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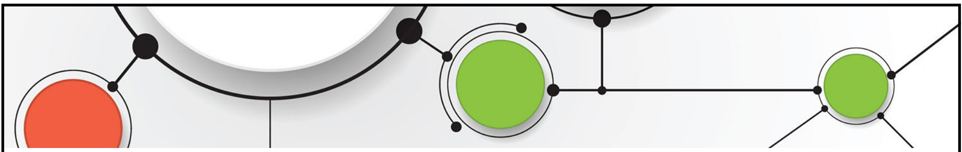
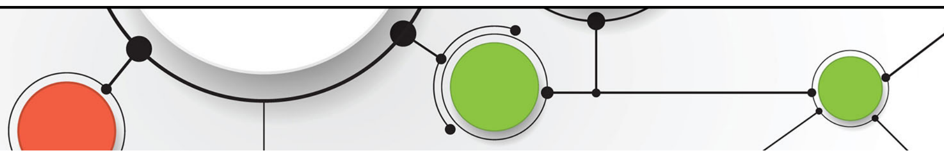


Packaging Policy for Non-Opioid Pain Management Treatments

CMS received many comments and ideas to help prevent opioid abuse and improve access to treatment under the Medicare program.

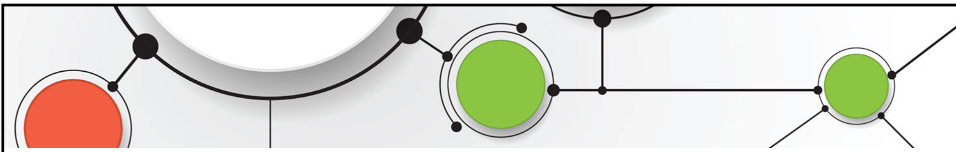
Some comments included:

- Separate payment under the OPPS for non-opioid drugs used during surgery
- Separate payment for alternatives for pain management, such as spinal cord stimulators used to treat chronic pain (e.g., HCPCS codes C1820, C1822, C1767)
- Add-on payment for APCs that used a non-opioid pain management drug, device, or service
- Restructuring of the two-level Nerve Procedure APCs (5431 and 5432) for more payment granularity



Packaging Policy for Non-Opioid Pain Management Treatments

After all considerations CMS is finalizing without modification the proposal to unpackage and pay separately at ASP+6% non-opioid pain management drugs that function as a supply in the ASC setting for CY 2019.



Calculation of OPPS Scaled Payment Weights

CMS proposed no changes to the method for calculating OPPS scaled payment weights for CY 2019.

- CMS standardizes all relative payment rates to APC 5012 (Level 2 Examinations and Related Services)
- This APC includes HCPCS G0463 for hospital outpatient visits
- CMS uses this APC, as this represents one of the most frequently provided OPPS services

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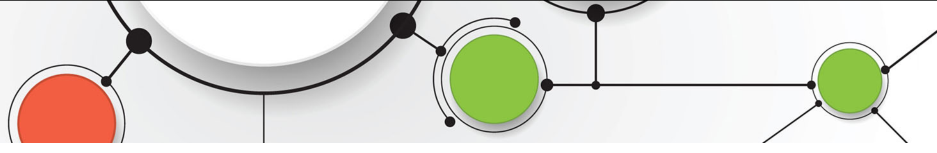

Calculation of OPPS Scaled Payment Weights

- The choice of APC on which to standardize relative payment weights does not affect payments made under the OPPS, as CMS scales weights for budget neutrality purposes
- The law requires that APC reclassifications and recalibrations, wage index changes, and other adjustments be made in a budget neutral manner, meaning that the estimated aggregate weight under the OPPS is neither greater than nor less than the estimated aggregate weight would be without the changes

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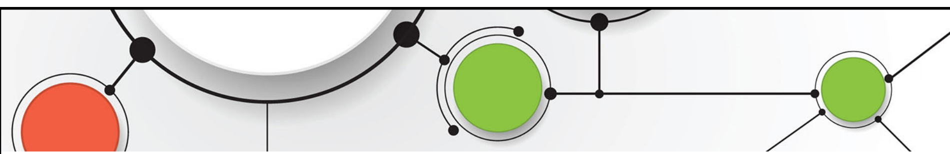
Calculation of OPPS Scaled Payment Weights

For 2019, CMS will assign APC 5012 a relative payment weight of 1.00

- The geometric mean cost of each APC is divided by the cost of APC 5012 to calculate the unscaled relative payment weight for each APC
- Unscaled relative payment rates are multiplied by a weight scalar for purposes of budget neutrality (for 2019, the weight scalar is 1.4574)
- The scaled relative payment rate is multiplied by the conversion factor to calculate OPPS payment rates

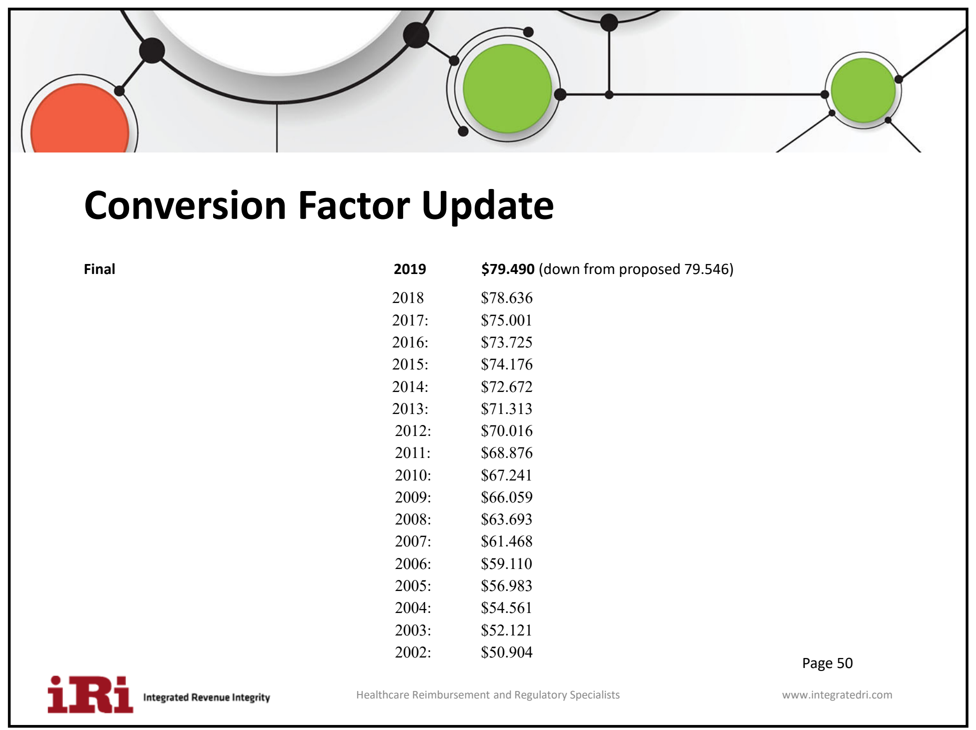


Conversion Factor Update

The conversion factor is used to determine payment rates under OPPS and is required to be updated annually by applying the OPD fee schedule increase factor.

The OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges (IPPS FY % increase).

The CY 2019 fee schedule increase factor is 2.9%, less mandatory adjustments (ACA and other regulations, budget neutrality adjustments, etc.) which result in a final increase factor of 1.35%.



Conversion Factor Update

Hospitals that fail to meet the Hospital OQR Program requirements will continue to be subject to an additional 2% reduction, which would result in a decrease factor of -0.65%.

This results in a conversion factor of $77.900.

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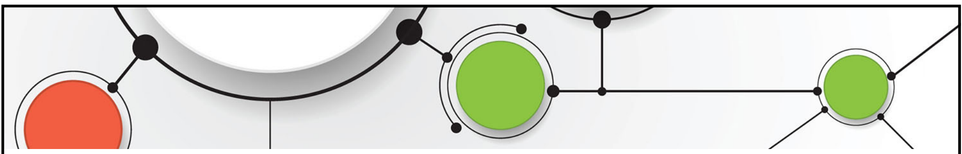
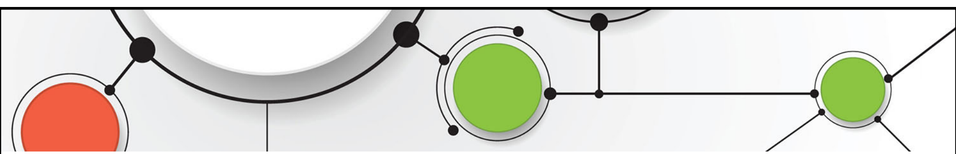


Wage Index Changes

No changes are made to the calculation formula for wage adjustments for CY 2019.

- OPPS labor-related portion of payment rates will remain 60% in 2019
- Wage adjustment for OPPS will continue to be the same as the IPPS wage index (IPPS wage index effective 10/1/18 is the OPPS wage index effective 1/1/19)
- Hospitals which are paid under the OPPS, but not under the IPPS, will be assigned wage index that would be applicable if the hospital were to be paid under the IPPS, based on geographic location and any applicable wage index adjustments

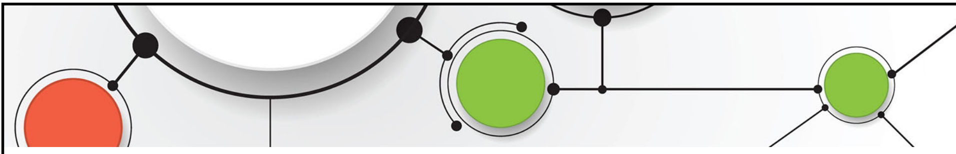


Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using cost-to-charge ratios to set payment rates for individual APCs based upon charges reported on claims, CMS also uses overall hospital-specific CCRs to determine outlier payments and payments for pass-through devices.

When MACs cannot calculate a hospital's CCR (new hospital, hospitals that have not submitted cost report, hospitals that have biased CCR), CMS uses the statewide average default CCR to determine these payments.

For CY 2019, CMS will continue to calculate statewide average CCRs using the same hospital CCR data which is used for setting CY 2018 payment rates.



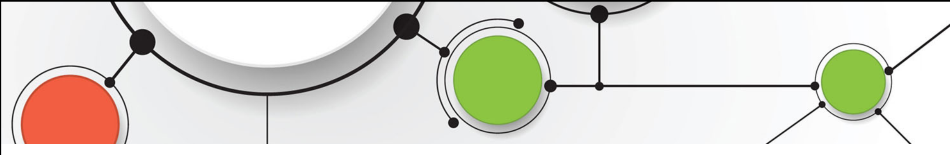
Payment Adjustment for Rural SCHs and EACHs

CMS will continue providing a 7.1 percent payment adjustment to sole community hospitals (SCHs) and essential access community hospitals (EACHs) for all services and procedures paid under the OPPS, except separately payable drugs and biologicals, pass-through devices, and items paid at cost.

This is provided due to differences in costs realized by these rural facilities.

The adjustment is made in a budget neutral manner.

Currently only two hospitals in the country are classified as EACHs, and as of 1998, a hospital can no longer become newly classified as an EACH.



Payment Adjustment for Cancer Hospitals

CMS will continue to pay cancer hospitals such that payments in CY 2019 for each cancer hospital's payment-to-cost ratio (PCR) is equal to the weighted average PCR of other OPPS hospitals.

This is necessary due to the higher costs incurred by these facilities in comparison with other OPPS facilities.

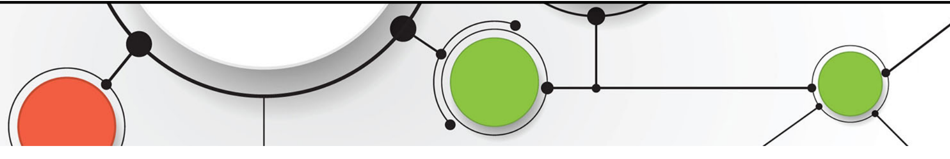
This adjustment applies to the 11 hospitals that meet the definition of cancer hospitals a defined in section 1866(d)(1)(B)(v) of the Act.

Payment Adjustment for Cancer Hospitals

Section 16002(b) of the 21st Century Cures Act requires CMS to reduce the target PCR of cancer hospitals by 1 percentage point less than what would otherwise apply, effective January 1, 2018. It also authorizes CMS to consider making an additional percentage point reduction to the target PCR.

OPPS payments to non-cancer hospitals in CY 2019 are estimated to be approximately 89 percent of reasonable cost.

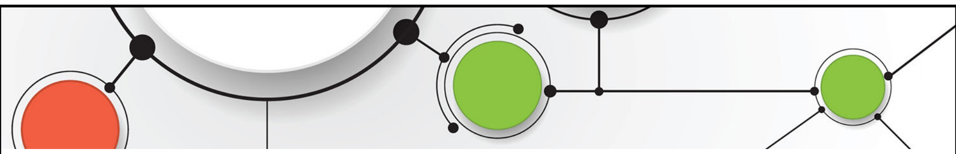
CMS will apply the one percentage point reduction, adjusting cancer hospital's payments to reach a PCR of 0.88.



Payment Adjustment for Cancer Hospitals

TABLE 10.—ESTIMATED CY 2019 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2019 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	37.1%
050660	USC Norris Cancer Hospital	13.4%
100079	Sylvester Comprehensive Cancer Center	21.0%
100271	H. Lee Moffitt Cancer Center & Research Institute	22.3%
220162	Dana-Farber Cancer Institute	43.7%
330154	Memorial Sloan-Kettering Cancer Center	46.4%
330354	Roswell Park Cancer Institute	16.2%
360242	James Cancer Hospital & Solove Research Institute	22.6%
390196	Fox Chase Cancer Center	8.4%
450076	M.D. Anderson Cancer Center	53.6%
500138	Seattle Cancer Care Alliance	54.3%



Hospital Outpatient Outlier Payments

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss.

CMS will continue to use the same methodology for calculating outpatient outlier payments in CY 2019.

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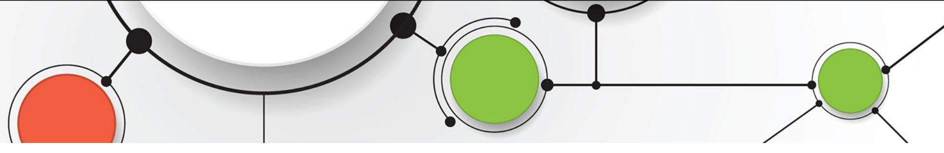

Hospital Outpatient Outlier Payments

Outliers are provided on a service by service basis when the cost of the service:

1. exceeds 1.75 times the APC payment amount (multiplier threshold)
   and
2. exceeds the sum of the APC payment amount plus a fixed dollar threshold

When both conditions are met, an outlier payment equaling 50% of the amount by which the service exceeds 1.75 times the APC payment amount is made.

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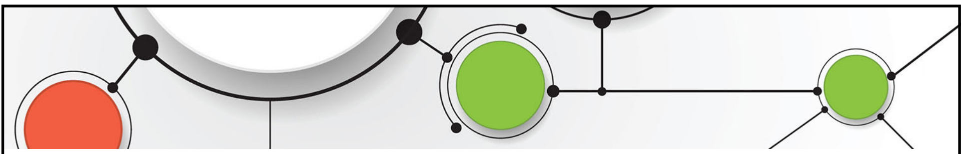


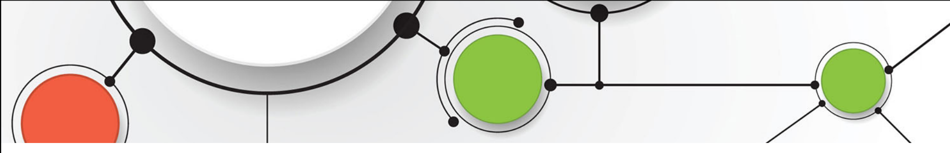
Hospital Outpatient Outlier Payments

Cost is calculated by multiplying the price of the service (including a pro rata portion of the total packaged services on the claim) times the hospital's cost-to-charge ratio.

Any payment for pass-through devices is added to the payment for the associated procedure.

CMS sets outlier criteria with the goal of total aggregate outlier payments equaling 1.0 percent of total payments under the OPPS.

For CY 2019 the CMS fixed dollar threshold is $4,825 (up $225 from the PR $4,600) – an increase of $675 from the current 2018 threshold of $4,150.



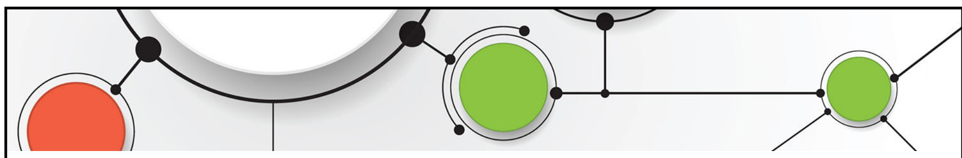
Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

The method for calculating adjusted Medicare payment rates will remain the same for CY 2019.

Labor adjustments will apply to services assigned any of the status indicators listed below:

"J1," "J2," "P," "Q1," "Q2," "Q3," "Q4," "S," "T," or "V"

The labor-adjusted rate is calculated by multiplying 60% of the APC reimbursement amount by the wage index and then adding this number to the remaining 40% of the APC reimbursement amount.

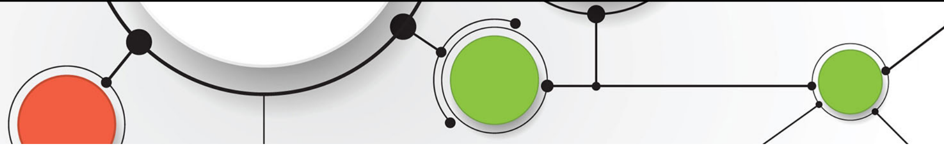


Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

Example of Wage Adjustment Calculation

ABC Hospital   Wage Index = 1.1872   CPT 76604– Ultrasound Exam Chest

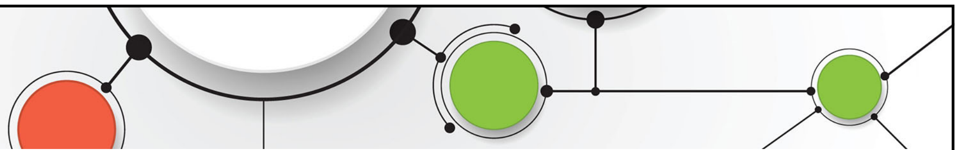
Unadjusted payment CY 2019	$112.51
60% of unadjusted APC	$67.51
40% of unadjusted APC	$45.00
Wage index X 60% of unadjusted APC	$80.15 ($67.51 x 1.1872)
Adjusted APC = $80.15 + $45.00	$125.15 (increase of $12.64)



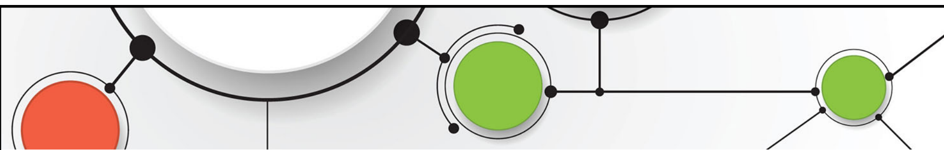
Beneficiary Copayments

No changes are made to the methodology for calculating beneficiary copayments for CY 2019.

- Copayments may not exceed 40 percent of the APC payment rate
- Copayments cannot be less than 20 percent of the APC payment rate
- Beneficiary copayment for a procedure cannot exceed the amount of the inpatient deductible for that year ($1,364 for CY 2019)
  - When calculated coinsurance exceeds this amount, the coinsurance is reduced to match the inpatient deductible and the remaining amount is added to the provider payment
- Copayments are waived for certain preventive services
- The continued consolidation of more services under single APCs should continue to result in reductions to beneficiary copayments



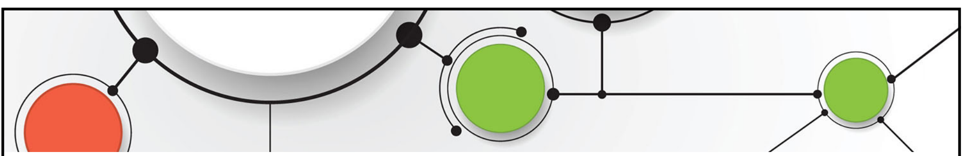
III. OPPS Ambulatory Payment Classification (APC) Group Policies



OPPS Treatment of New CPT and Level II HCPCS Codes

CMS recognizes the following three types of codes on OPPS claims:

- Category I CPT codes – describe surgical procedures and medical services, maintained by the AMA, updated annually in January (plus in July for certain vaccine codes)
- Category III CPT codes – describe new and emerging technologies, services, and procedures, maintained by the AMA, updated semi-annually in January and July
- Level II HCPCS codes – describe products, supplies, temporary procedures, and services not described by CPT codes, maintained by the CMS HCPCS workgroup, updated quarterly in January, April, July, and October



OPPS Treatment of New CPT and Level II HCPCS Codes

CMS implements new codes throughout the year via the quarterly OPPS update transmittals.

New codes are assigned interim status indicators and payment rates and comments regarding their assignments are solicited from the public during either the Proposed Rule or the Final Rule comment periods, depending on when the codes are released.

Status indicators and payment rates are finalized in the subsequent Final Rule.

OPPS Treatment of New CPT and Level II HCPCS Codes

TABLE 11.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2018	Level II HCPCS Codes	April 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
July 1, 2018	Level II HCPCS Codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) CPT Codes, Category III CPT codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
October 1, 2018	Level II HCPCS Codes	October 1, 2018	CY 2019 OPPS/ASC final rule with comment period	CY 2020 OPPS/ASC final rule with comment period
January 1, 2019	Category I and III CPT Codes	January 1, 2019	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2019	CY 2019 OPPS/ASC final rule with comment period	CY 2020 OPPS/ASC final rule with comment period

Treatment of New Level II HCPCS and CPT Codes Effective April 1, 2018 and July 1, 2018

Nine new HCPCS codes were released in the April 2018 OPPS update. These codes were open for comment in the Proposed Rule. Status indicator assignments and payment rates are finalized in this Final Rule.

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Treatment of New Level II HCPCS and CPT Codes Effective April 1, 2018 and July 1, 2018

TABLE 12.—NEW LEVEL II HCPCS CODES EFFECTIVE APRIL 1, 2018

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462
C9463	J0185	Injection, aprepitant, 1 mg	G	9463
C9464	J2797	Injection, rolapitant, 0.5 mg	G	9464
C9465	J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	G	9465
C9466	J0517	Injection, benralizumab, 1 mg	G	9466
C9467	J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467
C9468	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468
C9469*	J3304*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469
C9749	C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	J1	5164

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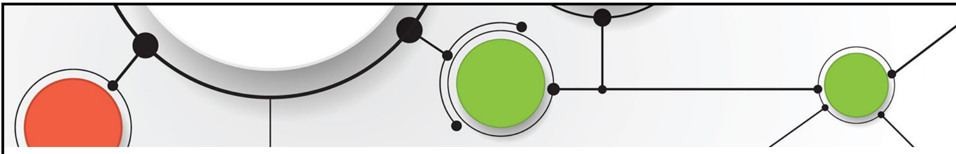

Treatment of New Level II HCPCS and CPT Codes Effective April 1, 2018 and July 1, 2018

Several new laboratory codes for multianalyte assays with algorithmic analysis (MAAAs) and proprietary laboratory analysis (PLA) tests were also released for April 2018, but too late to be included in the April OPPS update.

These codes were added to the I/OCE in the July 2018 update, with an effective date of April 1, 2018.

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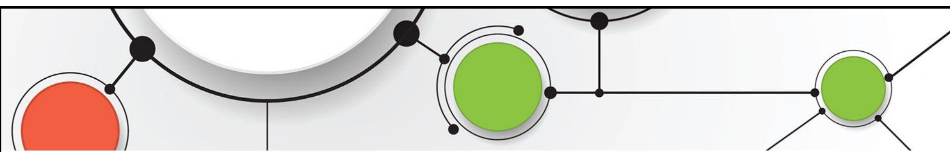

Treatment of New Level II HCPCS and CPT Codes Effective April 1, 2018 and July 1, 2018

In the July 2018 OPPS update, fourteen additional HCPCS were established which are shown in Table 14 starting on page 68.

PLA codes were also released for July 2018, but not in time for the July OPPS update. These PLA codes, shown in Table 15 below, were added to the I/OCE for the October 1, 2018 update with an effective date of July 1, 2018.

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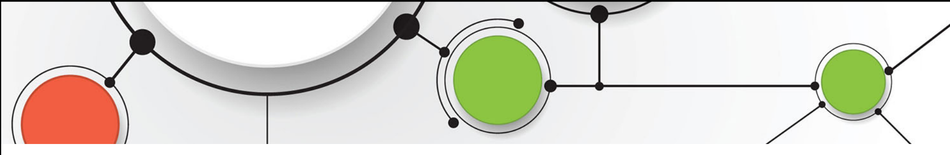
Process for New Level II HCPCS Codes That Are Effective October 1, 2018 or Will Be Effective January 1, 2019

CMS will continue to assign interim status indicator and APC assignments for Level II HCPCS codes which were released for October 2018 and January 2019.

The assignments will be finalized in the CY 2020 Final Rule.

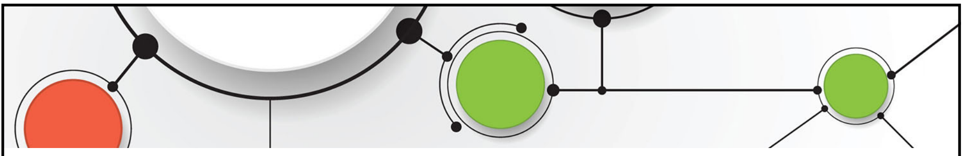


OPPS Changes—Variations Within APCs

CMS is required to review and revise APC groups, relative payment weights, and the wage and other adjustments at least annually. The purpose is to account for:

- Changes in medical practice
- Changes in technology
- New services
- New cost data
- Other relevant information and factors

This is to ensure that APC groupings of HCPCS codes are reasonable based upon similarity of costs, considering the 2 times rule.



OPPS Changes—Variations Within APCs

Application of the 2 Times Rule

A 2 times rule violation occurs when the highest cost item within an APC group exceeds two times the lowest cost item within the same APC group.

CMS considers only HCPCS codes that are significant when identifying 2 times rule violations. Significant codes:

- Have more than 1,000 single major claims; or
- Have both greater than 99 single major claims and contribute to at least 2 percent of the single major claims used to establish the APC cost

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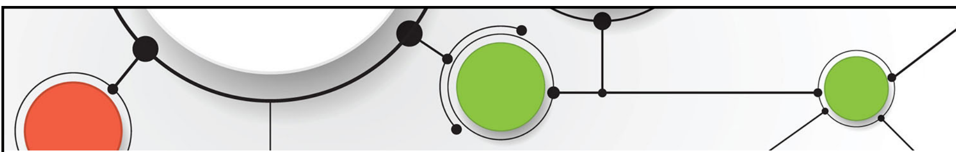

OPPS Changes—Variations Within APCs

Application of the 2 Times Rule

Procedure codes which do not meet these criteria would have negligible impact on the APC cost.

Most 2 times rule violations are corrected by reassigning certain procedures to different APCs. The violations mostly occur due to changes in costs of services that were reported for CY 2017 claims.

Status indicator reassignments can be seen in Addendum B, identified with a comment indicator “CH.”

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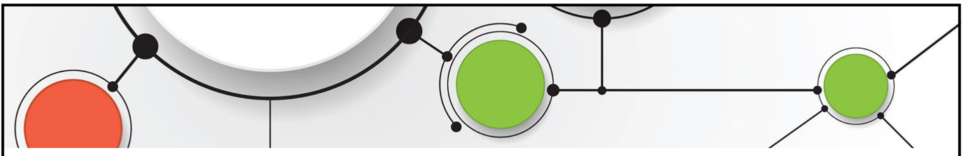

OPPS Changes—Variations Within APCs

Application of the 2 Times Rule

CMS is authorized to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services.

CMS uses the following criteria to evaluate whether to propose exceptions to the 2 times rule:

- Resource homogeneity
- Clinical homogeneity
- Hospital outpatient setting utilization
- Frequency of service (volume)
- Opportunity for up-coding and code fragments

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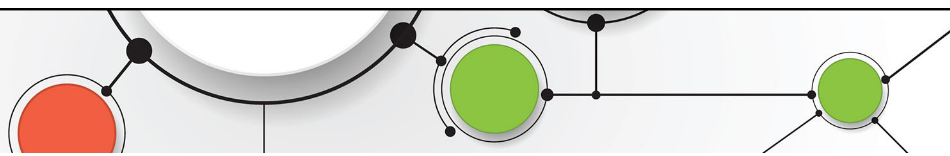

OPPS Changes—Variations Within APCs

Application of the 2 Times Rule

In the proposed rule, CMS identified 16 APCs that were proposed to be exceptions to the 2 times rule.

Based on updated claims data:

17 APCs had violations of the 2 times rule

15 were identified in the proposed rule

2 were newly identified

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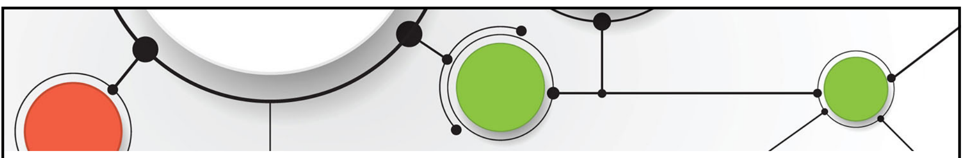

OPPS Changes—Variations Within APCs

TABLE 16.— APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2019

CY 2019 APC	CY 2019 APC Title
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5113	Level 3 Musculoskeletal Procedures
5193	Level 3 Endovascular Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5724	Level 4 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5732	Level 2 Minor Procedures
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

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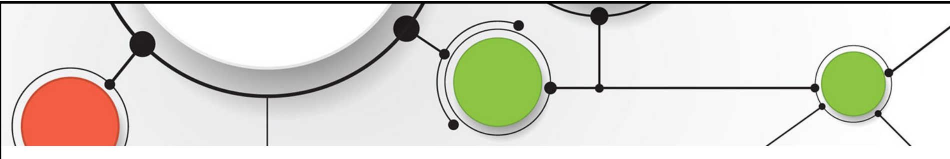

New Technology APCs

Background

New technology services are placed in New Technology APCs until there is sufficient claims data available for assignment into a clinically appropriate APC group.

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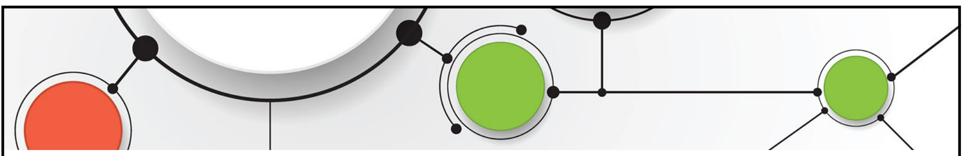
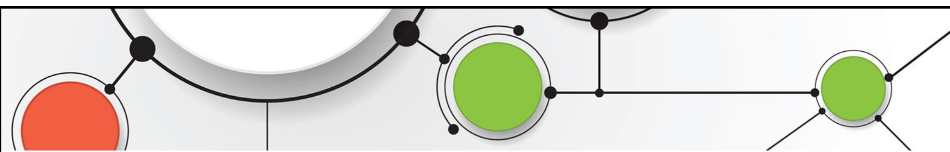


New Technology APCs

Background

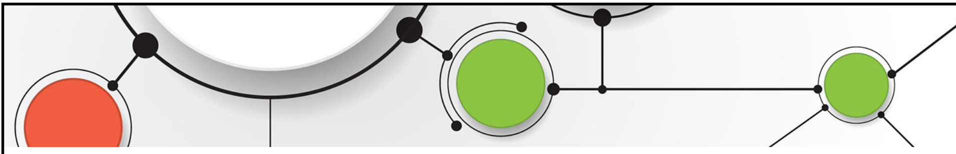
- For CY 2018 there are 52 levels of New Technology APCs (expanded from 51 in 2017, and 48 in 2016)
- Each level is assigned a cost band which new technology procedures can fall under (from Level 1A $0-$10 to Level 52 $145,001-$160,000)
- There are two parallel sets of Level 1-52 New Technology APCs, one set assigned to status indicator "S" (Significant Procedures, Not Discounted when Multiple) and the other assigned to status indicator "T" (Significant Procedure, Multiple Reduction Applies)
- Payment for each APC is made at the mid-point of the APC's cost band (e.g., APC 1507 "New Technology - Level 7 $501-$600" is paid $550.50)



Establishing Payment Rates for Low-Volume New Technology Procedures

CMS proposed a change to the methodology for calculating payment rates for New Technology procedures with very low annual volume, which CMS defines as fewer than 100 claims.

- Low-volume procedures often have wide variations in payment rates from year to year
- This may result in even lower utilization and potential barriers in access to new technologies



Establishing Payment Rates for Low-Volume New Technology Procedures

- CMS proposed to use their "equitable adjustment" authority under the Act which allows them to establish budget neutral adjustments as determined to be necessary to ensure equitable payments
- CMS has used this authority in the past on a case-by-case basis
- Proposal was to adopt a permanent adjustment to mitigate wide payment fluctuations and provide more predictable payment for these services

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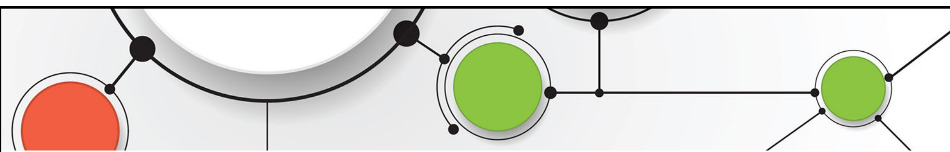

Establishing Payment Rates for Low-Volume New Technology Procedures

Final for CY 2019

- CMS may use up to 4 years of claims data for calculating payment rates for low volume New Technology procedures for the prospective year.
- CMS will use the geometric mean cost (which "trims" the costs of certain claims out), the median, or the arithmetic mean and present the result in the annual rule making.
- Once the payment rate is determined, CMS will assign the service to a New Technology APC with the applicable payment band.

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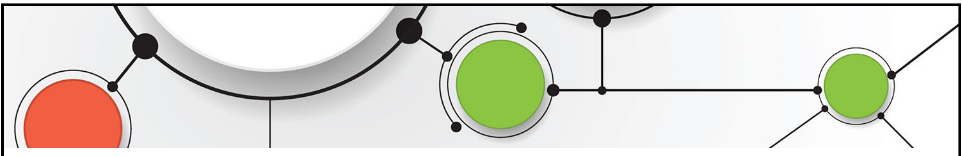

Procedures Assigned to New Technology APC Groups for CY 2019

Procedures are retained in New Technology APCs until CMS has obtained sufficient claims data to justify reassignment to a clinically appropriate APC.

In cases where CMS finds that the initial placement into a New Technology APC was based on inaccurate or inadequate information, CMS may reassign the procedure into a more appropriate New Technology APC level.

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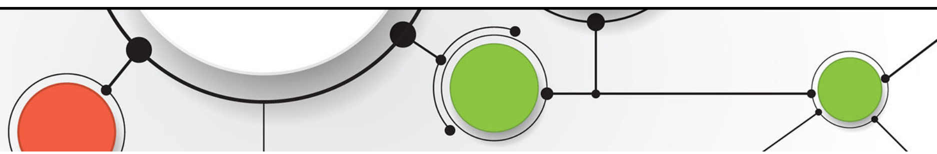

Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414)

Original Proposal

- Arithmetic mean = $12,849.11
- Geometric mean = $8,579.91
- Median = $4,676.77

CMS believes that the arithmetic mean is the most appropriate representative cost of the procedure described by CPT 0398T, which considers the payment rates established in CY 2017 and 2018, without any trimming.

CMS proposed New Technology APC 1575- Level 38 with a payment rate of $12,500.50.

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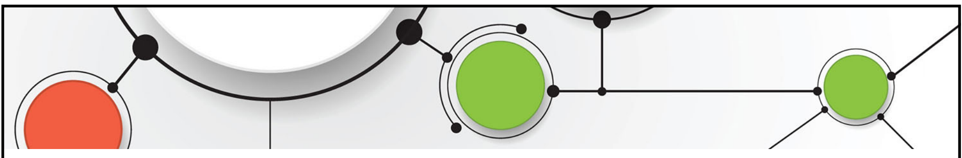

Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414)

Additional Review

Based on updated claims data, an additional 11 paid claims for 0398T were present and showed following:

- Arithmetic mean = $6,654.68
- Geometric mean = $5,360.99
- Median = $4,581.45

Commenters stated the proposed payment rate would not cover the cost of the procedure.

Another commenter stated this would be problematic since MACs are issuing LCDs to allow the procedure to be covered more widely by Medicare.

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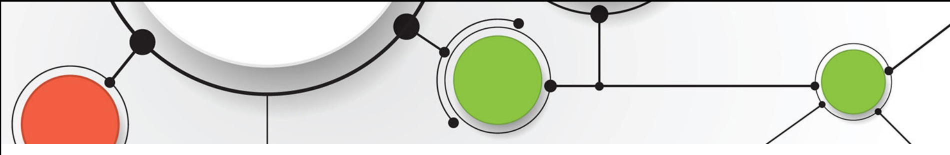

Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414)

Final CY 2019

CMS stated although the proposed rate is a decrease from the current rate, they feel it is appropriate to finalize the new rate to mitigate an even sharper decline in payment from one year to the next.

CPT 0398T will be assigned APC 1575 with a payment rate of $12,500.50

See Table 17

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Retinal Prosthesis Implant Procedure

CPT 0100T - (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy)

- Used to report procedures involving the Argus® II Retinal Prosthesis System.
- Device approved by the FDA in 2013 and granted pass-through status under HCPCS C1841 (Retinal prosthesis, includes all internal and external components)
- Pass-through status expired 12/31/2015, and device was packaged into the payment rate for the associated procedure
- Payment rates have since fluctuated significantly year by year
- CMS felt it was important to mitigate significant payment differences of tens of thousands of dollars

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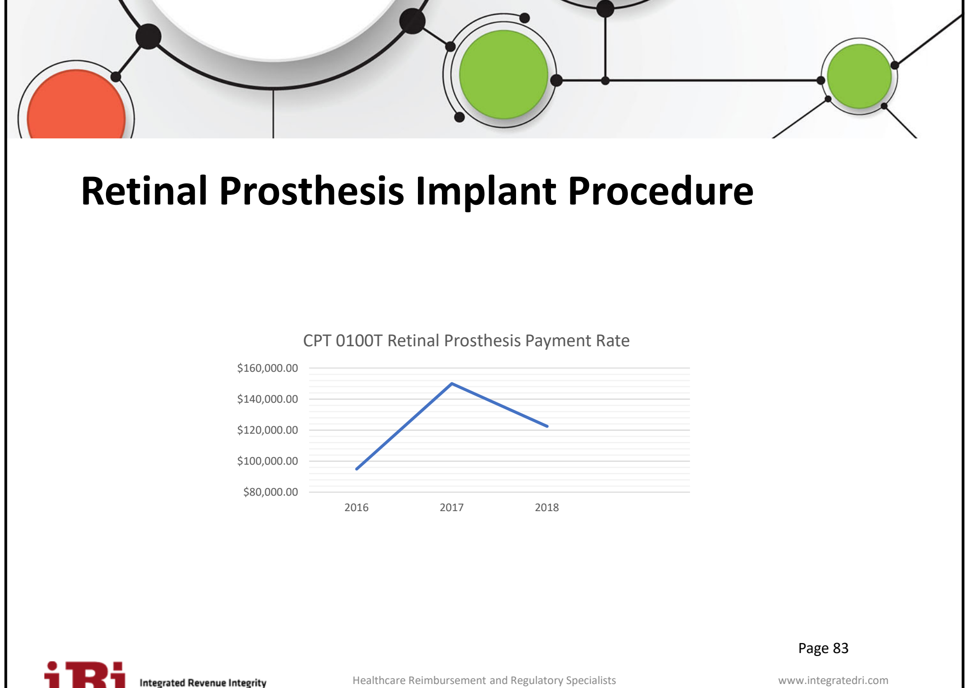
Retinal Prosthesis Implant Procedure



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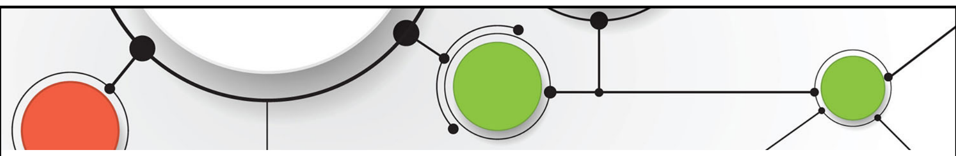

Retinal Prosthesis Implant Procedure

Original Proposal

Using three years of claims data since pass-through payment expired (CY 2015 – 2017) CMS calculated the following costs:

- Geometric mean = $129,891
- Arithmetic mean = $134,619
- Median = $133,679

CMS proposed to use the arithmetic mean and to assign CPT 0100T to APC 1906 (New Technology – Level 51) with a proposed payment of $137,500.50.

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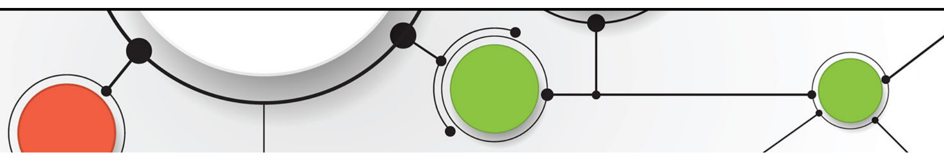

Retinal Prosthesis Implant Procedure

Additional Review

Based on updated claims data

- Geometric mean = $145,808
- Arithmetic mean = $151,367
- Median = $151,266

All three methods would put the procedure in APC 1908 NT Level 52 with a payment rate of $152,500.50.

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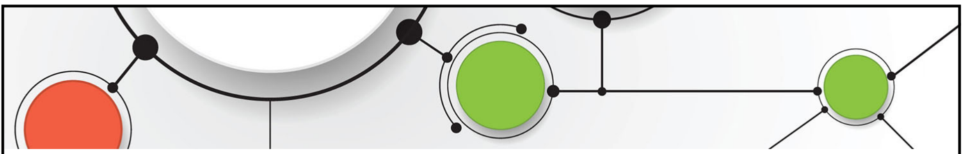
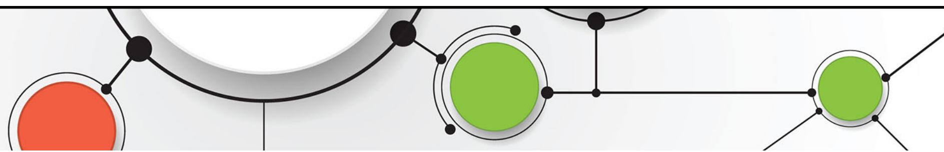


Retinal Prosthesis Implant Procedure

Final CY 2019

CPT 0100T will be assigned to APC 1908.

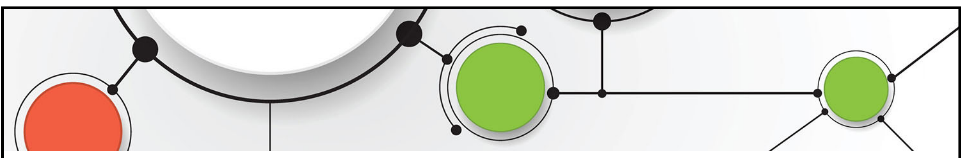
CMS also noted that the new policy in this final rule excluding packaging of New Technology APCs into comprehensive APCs (discussed on page 33 of this manual) would assist in obtaining more cost information for this procedure, which has been identified as having been packaged into some C-APCs in CY 2017 claims data.



Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy

CMS has created new HCPCS code C9751 Bronchoscopy transbronchial ablation.

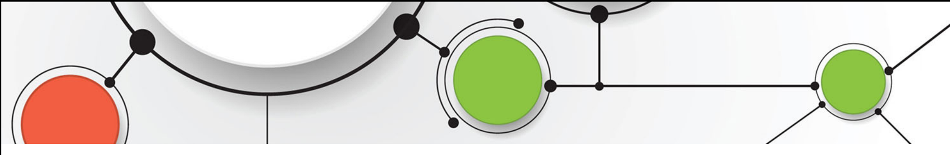
Based on NT APC application and clinical similarity to existing services CMS has assigned this procedure code to APC 1571 New Technology Level 34 with a payment rate of $8,250.50 for CY 2019.



Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy

TABLE 18.—INFORMATION FOR HCPCS CODE C9751 ASSIGNED TO A NEW TECHNOLOGY APC

CY 2019 HCPCS Code	Long Descriptor	CY 2019 OPPS SI	CY 2019 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1571



OPPS APC-Specific Policies

- Each year, CMS revises APC groupings based on the latest hospital outpatient cost data to appropriately place procedures and services in APCs based on clinical characteristics and resource similarity.
- Not every change is discussed in the Final Rule, but every change is listed in Addendum B of the rules, identified with a “CH” comment indicator.
- CMS discussed 20 APC specific assignments in the final rule.

OPPS APC-Specific Policies

Highlights of these discussions include:

- No changes to the current APC structures for Endovascular, Musculoskeletal and Radiology procedures
- Modifications were made to proposed APCs for Cardiac Resynchronization Therapy and Non-Ophthalmic Fluorescent Vascular Angiography
- Modifications were made to proposed APCs and SIs for CAR T-Cell Therapy
- Modifications were made to proposed APCs for Intraocular Procedures

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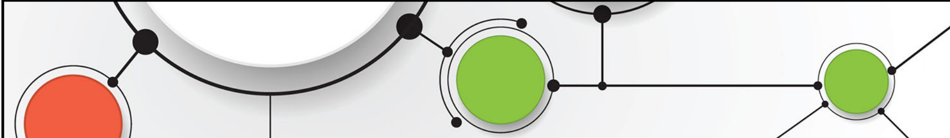

OPPS APC-Specific Policies

CMS reiterated the following message in response to commenter statements related to the APC payment would not cover the cost of services provided:

> *It is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. We rely on hospitals to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, and to report services on claims and charges and costs for the services on their Medicare hospital cost report*
>
> *We state in Chapter 4 of the Medicare Claims Processing Manual that "it is extremely important that hospitals report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged" to enable CMS to establish future ratesetting for OPPS services.*

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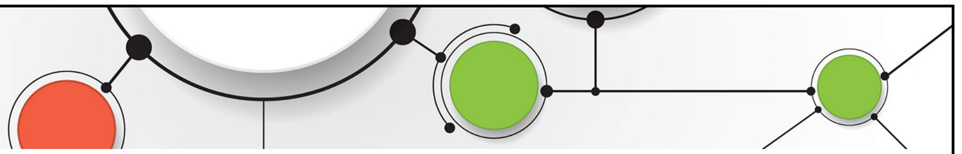
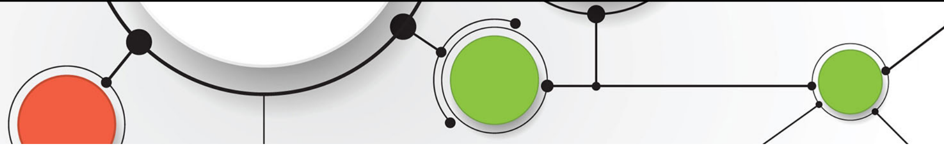


IV. OPPS Payment for Devices



Pass-Through Payments for Devices

Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

Pre-2017 Policy:

- Pass-through device eligibility began on the date that CMS established a new pass-through category (new codes can be established during any quarter)
- Eligibility period is for at least two years, but no longer than three years
- Pass-through expiration is finalized during the annual rulemaking process

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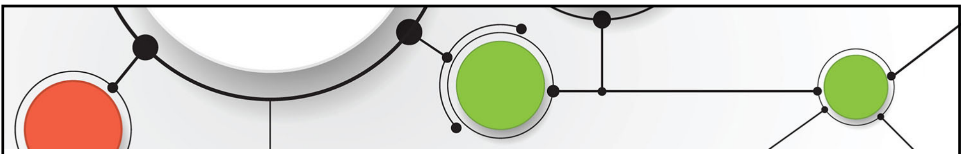
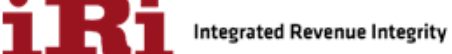


Pass-Through Payments for Devices



Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

Policy Effective 2017 and subsequent years:

In the 2017 OPPS Final Rule, CMS implemented three changes to the pass-through device payment policy.

1. Pass-through eligibility now begins on the first date on which pass-through payment is made under the OPPS
2. Eligibility period is always a full three years
3. Pass-through expiration may occur quarterly, via the OPPS update transmittals

There are no device categories eligible for pass-through payment in CY 2018.

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New Device Pass-Through Applications

CMS accepts applications for new pass-through device categories quarterly.

Beginning in CY 2016, all applications are subject to notice-and-comment rulemaking via the Proposed and Final Rules.

All applications that are preliminarily approved by CMS upon quarterly review are automatically included in the next applicable OPPS rulemaking cycle.

Applications that are not approved may be withdrawn by the submitter or have the option of being included in the next applicable OPPS rulemaking cycle. New evidence, clinical trial results, or other materials can be presented during the rulemaking process.

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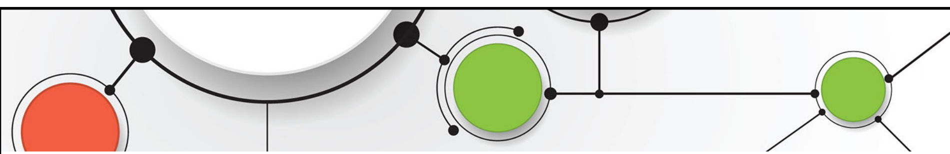
New Device Pass-Through Applications

To be considered for a new pass-through category the device must:

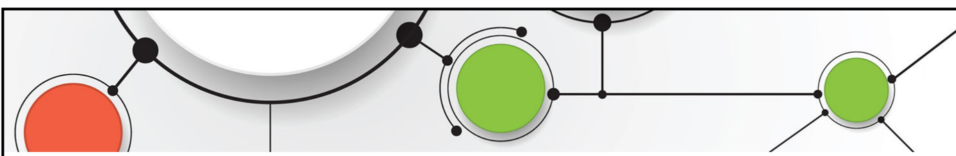
- Be FDA approved (if required) within the last three years
- Be reasonable and necessary
- Be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion
- Not be appropriately described by an existing category or category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996
- Have an average cost that is not "insignificant" relative to the payment amount for the procedure or service which the device is associated with
- Demonstrate a substantial clinical improvement



Applications Received for Device Pass-Through Payment for CY 2019

CMS received seven applications for pass-through device categories in time to be included in the Proposed Rule.

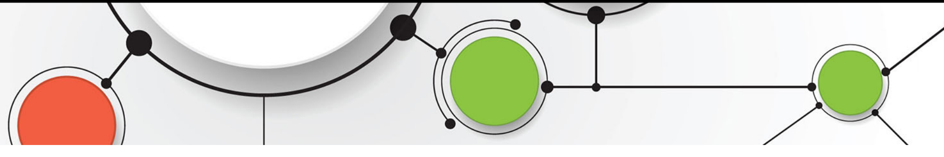
After receiving additional product information and public comments from the proposed rule, CMS approved one of the applications for pass-through payment.



Applications Received for Device Pass-Through Payment for CY 2019

Not approved:

- AquaBeam System- Aquablation)
- BioBag®
- BlastX™
- EpiCord®
- Restrata® Wound Matrix
- SpaceOAR®

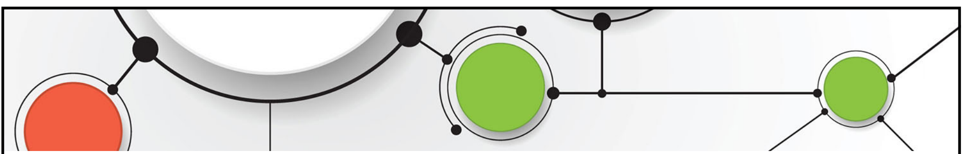


Applications Received for Device Pass-Through Payment for CY 2019

Approved:

remedē® System Transvenous Neurostimulator – an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients

New HCPCS – C1823 -Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads



Device-Intensive Procedures

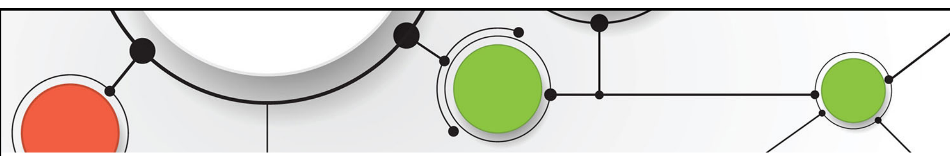
Background

Prior to 2017, CMS classified device intensive APCs.

In the 2017 OPPS Final Rule, CMS finalized a policy to instead classify specific HCPCS codes as representing device-intensive procedures.

Device-intensive procedure criteria:

- Procedure must involve implantable devices that would be reported if device insertion procedures were performed;
- Device must be surgically inserted or implanted and remain in the patient's body at the conclusion of the procedure (at least temporarily)
- Device cost must be significant (exceeding 40 percent of the procedure's mean cost)

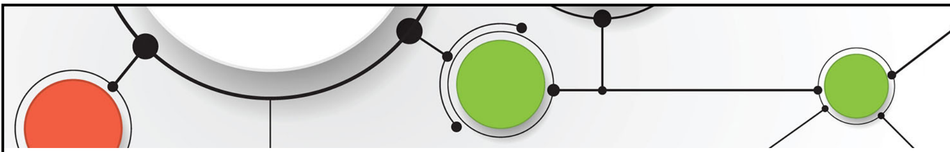


Device-Intensive Procedures

Background

For new HCPCS codes without claims data that describe procedures which require the implantation of medical devices, CMS applies a default offset of 41 percent until claims data are available.

CMS may temporarily assign a higher offset percentage if warranted.



Changes to the Device-Intensive Procedure Policy for CY 2019

1. Procedures that involve surgically inserted or implanted single-use devices that meet the offset percentage threshold will qualify as device intensive, regardless of whether the device remains in the patient's body at the conclusion of the procedure

- CMS no longer believes that whether a device remains in the patient's body should affect its designation as a device-intensive procedure because such devices still compromise a large cost of the applicable procedure

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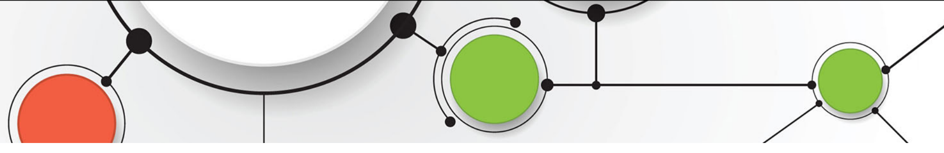

Changes to the Device-Intensive Procedure Policy for CY 2019

2. Lowering the device offset percentage threshold from 40 percent to 30 percent

- Allows a greater number of procedures to qualify as device-intensive
- CMS feels this will help ensure that these additional procedures receive more appropriate payment in the ASC setting, which will encourage performance of these procedures in ASCs
- Subjects more procedures which use high-cost devices to device dependency edits, which leads to more correctly coded claims and greater accuracy in CMS claims data

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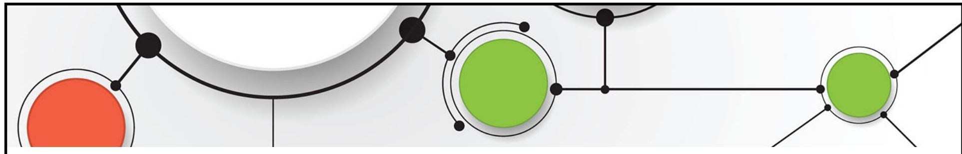

Changes to the Device-Intensive Procedure Policy for CY 2019

2. Lowering the device offset percentage threshold from 40 percent to 30 percent

- New HCPCS codes without claims data that describe procedures which require the implantation of medical devices will now have a default offset of 31 percent applied until claims data are available
- CMS may continue to temporarily assign a higher offset percentage if warranted

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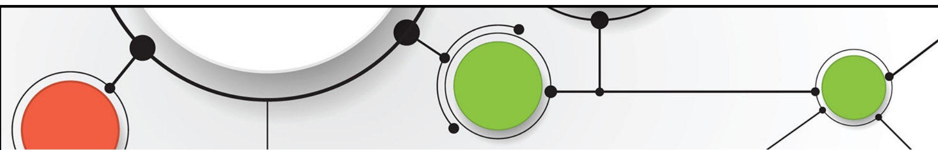

Changes to the Device-Intensive Procedure Policy for CY 2019

CMS provides a complete list of all device-intensive HCPCS codes in Addendum P.

There are 358 device-intensive HCPCS for CY 2019, up significantly from the 181 device-intensive HCPCS codes in CY 2018.

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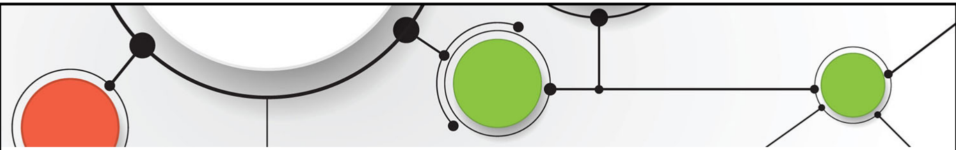
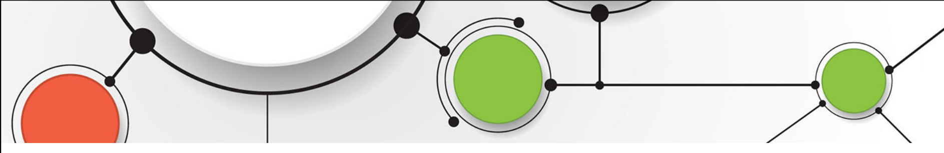


V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals



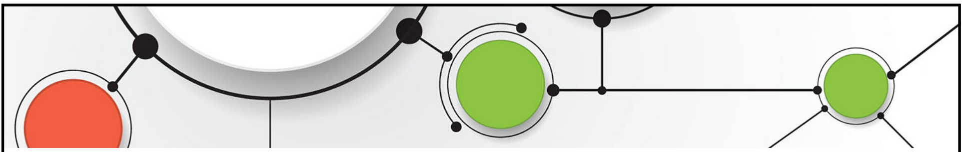
OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

Background

Pass-through payments are provided for certain new drugs and biologicals whose cost is "not insignificant" in relation to OPPS payments for the procedures or services associated with the new drug or biological.

Prior to 2017, pass-through eligibility lasted for a period of at least two years, but no more than three years, and eligibility expired as part of the annual rulemaking process.

Like pass-through eligibility for devices, CMS finalized a policy in the 2017 OPPS Final Rule to allow a quarterly expiration of pass-through status that would result in pass-through eligibility of as close to three full years as possible.



Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2018

CMS finalized the pass-through status of 23 drugs and biologicals will expire on December 31, 2018, as listed in Table 37 below.

- Three will be assigned status indicator N and be packaged
- 20 will be paid separately under status indicator K

See Table 37.

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Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2019

For CY 2019 there are 49 drugs and biologicals that will continue to have pass-through payment status.

This includes five drugs that have already had three years of pass-through eligibility, but for which pass-through payment status is being extended for an additional two years, as discussed in the next section of this manual.

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Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2019

CMS will continue to pay for pass-through drugs and biologicals at ASP +6%.

See Table 38.

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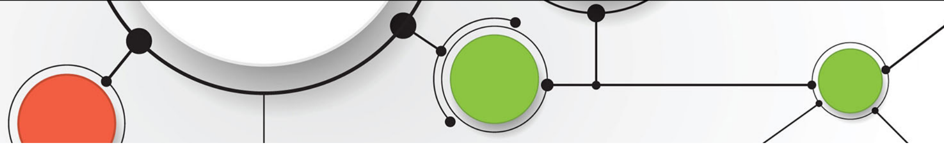

Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141)

Section 1301(a)(1) of the Consolidated Appropriations Act of 2018 requires that pass-through payment status is extended for two years for drugs and biologicals whose pass-through payment status ended on 12/31/17 and were packaged as of 1/1/2018.

The extended pass-through payment period is effective 10/1/18 through 9/30/2020.

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Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141)

Additionally, the Act requires that the payment for these drugs will be the greater of:

- the payment amount that would otherwise apply under section 1833(t)(6)(D)(i) of the Act for such drug or biological during such period; or
- the payment amount that applied under section 1833(t)(6)(D)(i) of the Act for such drug or biological on December 31, 2017

CMS states that the payment rate for these drugs for the last quarter of 2018 will be addressed through program instruction (e.g., transmittals).

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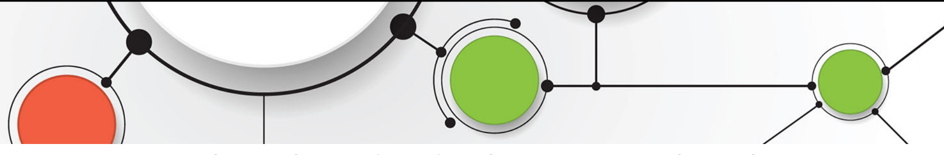

Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141)

For January 1, 2019 through March 31, 2019, CMS proposed that the pass-through payment for these drugs will be the greater of:

- ASP +6% based on current ASP data; or
- The payment rate for the drug or biological on December 31, 2017

For April 1, 2019 through December 31, 2019 CMS proposed that the pass-through payment amount for these drugs would be the amount that applies under section 1833(t)(6)(D)(i) of the Act.

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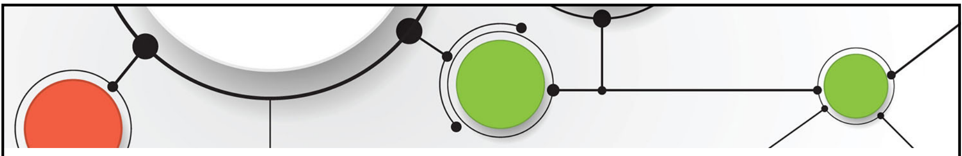

Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141)

TABLE 39.—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019 IN ACCORDANCE WITH PUBLIC LAW 115-141

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018
Q4172	Q4195	Puraply, per square centimeter	G	9175	10/01/2018
Q4172	Q4196	Puraply AM, per square centimeter	G	9176	10/01/2018
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018

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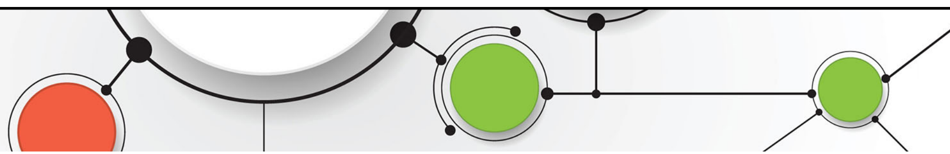

Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

CMS will continue to apply payment offsets to certain pass-through drugs which would be policy-packaged if not eligible for pass-through payment.

The payment for the pass-through drug is reduced by the portion of the APC payment that is determined to be associated with the usually packaged drug.

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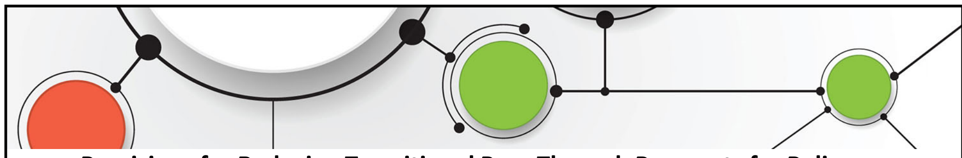

Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

Pass-through offsets will continue to apply to:

- Diagnostic radiopharmaceuticals
- Contrast agents
- Stress agents
- Drugs and biologicals that function as supplies in surgical procedures
  - Skin substitutes
  - Other surgical supply drugs and biologicals

There are no changes to the APCs for which these offsets apply.

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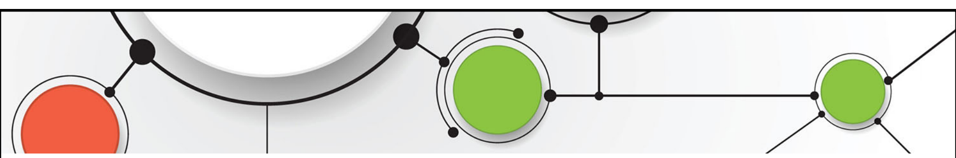

Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

TABLE 40.—APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2019

CY 2019 APC	CY 2019 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

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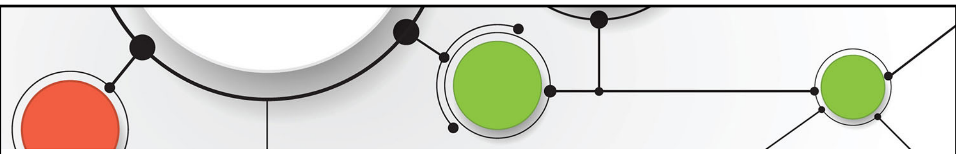
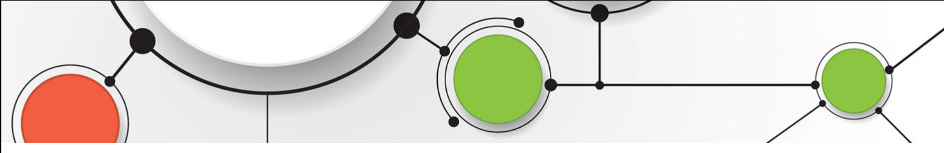


OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status



Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

The drug packaging threshold for CY 2019 is $125, up from $120 in CY 2018.

- If the estimated per day cost of a drug is > threshold, drug will be paid separately
- If per day cost is < threshold, drug will be packaged

Calculation of per day cost of drugs and biologicals in this Final Rule was performed using third quarter 2018 ASP data.

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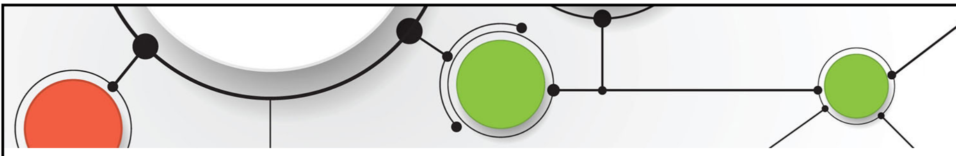

High Cost/Low Cost Threshold for Packaged Skin Substitutes

CMS will continue to package skin substitute products and classify as high cost or low cost based upon the mean unit cost (MUC) or the per day cost (PDC).

Skin substitute products that exceed the MUC or PDC cost thresholds will be classified as high cost, while products that do not exceed either threshold will be classified as low cost.

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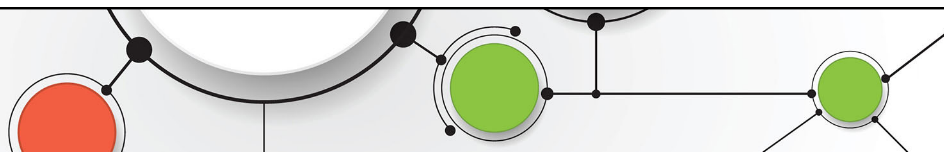

High Cost/Low Cost Threshold for Packaged Skin Substitutes

Final 2019 Thresholds:

- MUC $49 per sq. cm (up $3.00 from 2018)
- PDC $872.00 (up $11.00 from 2018)

Skin substitute products with pass-through payment status will be assigned high cost category.

Products with pricing but without claims data will be assigned high or low-cost status based upon the product's ASP +6% payment rate as compared to the MUC threshold.

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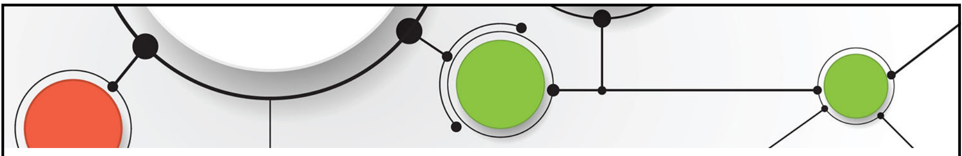

High Cost/Low Cost Threshold for Packaged Skin Substitutes

If ASP data is not available, CMS will use wholesale acquisition cost (WAC) +3% (instead of current rate of WAC +6%).

If WAC data is not available, CMS will use 95% of average wholesale price (AWP).

New skin substitute products without pricing or claims data will be assigned to low cost category until pricing information is available.

Some skin substitute manufactures have expressed concern about the significant fluctuation in both the MUC and PDC thresholds from year to year.

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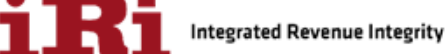

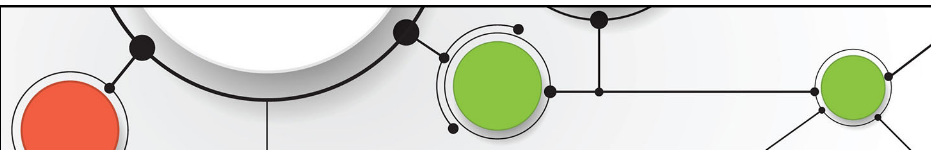

High Cost/Low Cost Threshold for Packaged Skin Substitutes

Fluctuation in thresholds results in reassignment of skin substitute products from high to low and low to high cost categories. This can lead to differences in payment rates of over $1,000 for the same procedure.

CMS agrees that payment stability is preferable for these products and has attempted to limit year to year shifts.

For CY 2018, CMS finalized a proposal to keep all skin substitute products which were classified as high cost for CY 2017 in the high cost group for CY 2018, even if they did not exceed the latest MUC or PDC thresholds.

This was proposed to allow additional time to evaluate concerns.

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High Cost/Low Cost Threshold for Packaged Skin Substitutes

CMS received numerous comments and has identified four potential methodologies for use in CY 2020.

CMS will once again retain skin substitute products that are classified as high cost in CY 2018 in the high cost group for CY 2019, even if they do not exceed the updated MUC or PDC thresholds, to allow time for stakeholders to comment on the potential new methodologies.

The four methodologies are discussed next.

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High Cost/Low Cost Threshold for Packaged Skin Substitutes

1. *Establish a lump-sum "episode-based" payment for a wound care episode*
2. *Eliminate the high cost/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products*
3. *Allow for the payment of current add-on codes or create additional procedure codes to pay for skin graft services between 26 cm^2 and 99 cm^2 and substantially over 100 cm^2*
4. *Keep the high cost/low cost skin substitute categories, but change the threshold used to assign skin substitutes in the high-cost or low-cost group*

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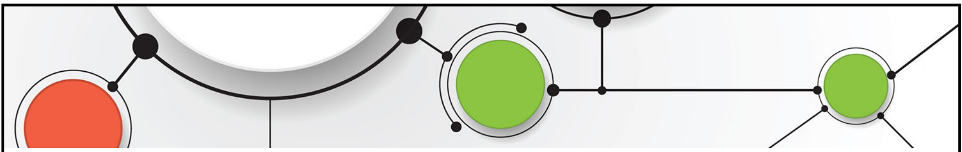
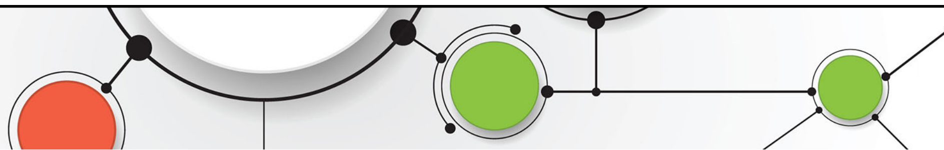


Skin Substitutes

CMS received several comments related to the proposed options, both supportive of and opposing each method. CMS will continue to study issues related to changing the methodology for paying for skin substitute products and will take these comments into consideration for CY 2020 rulemaking.

See Table 41 for the high/low cost category assignments for CY 2019.



Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

CMS will continue drug-specific packaging for CY 2019.

Drugs with multiple HCPCS codes (differing by dosage) will be priced specific to the drug rather than the HCPCS code using aggregated CY 2017 claim data and ASP pricing information.

This eliminates incentives for hospitals to report certain HCPCS codes, while allowing flexibility to report different dosages using the lowest dose HCPCS codes.

Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

The following drugs did not have pricing information available, but based upon mean unit cost from CY 2017 claims data they will be packaged in CY 2019

- J1840 Injection, kanamycin sulfate, up to 500 mg
- J1850 Injection, kanamycin sulfate, up to 75 mg
- J3472 Injection, hyaluronidase, ovine, preservative free, per 1000 usp units
- J7100 Infusion, dextran 40,500 ml
- J7110 Infusion, dextran 75,500 ml

See Table 42 on page 114.

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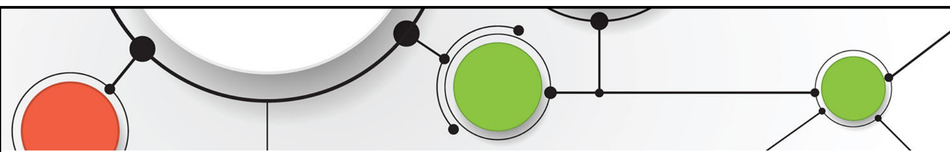

Payment for Drugs and Biologicals without Pass-Through Status That Are Not Packaged

For CY 2019, CMS will continue the current payment methodology for payment of non-pass-through drugs which are not packaged (SI=K), with one exception.

- Separately payable non-pass-through drugs will be paid at ASP +6%, which includes payment for acquisition and pharmacy overhead costs
- Separately payable non-pass-through drugs acquired through the 340B Program will be paid at ASP -22.5%
- For drugs and biologicals during an initial sales period in which data on the prices for the drug are not available, CMS will make payment based on the wholesale acquisition cost (WAC) +3%, which is a reduction from current payment of WAC +6%

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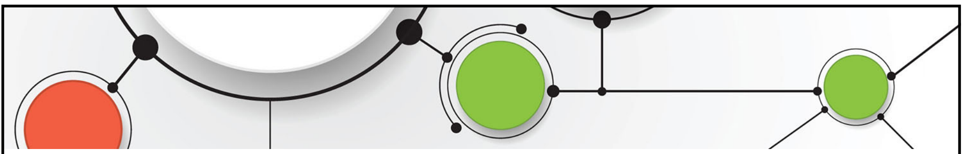

Payment for Biosimilar Drugs

CMS will continue the following CY 2018 policies for biosimilar drugs:

- All new biosimilar products will be eligible for pass-through payment status (not just the first biosimilar product for a reference product)
- Biosimilar products are paid at their own ASP, +6% of the reference product's ASP

Biosimilar products without pass-through status that are acquired under the 340B drug discount program are currently paid at their own ASP minus 22.5% of the reference product's ASP.

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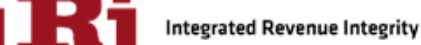

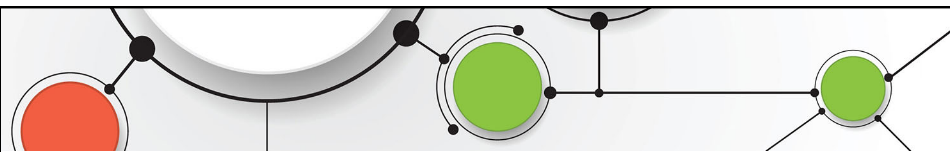

Payment for Biosimilar Drugs

Stakeholders had raised concern that this policy could unfairly lower the OPPS payment for biosimilars without pass-through status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar.

CMS agreed with this concern and proposed the following for CY 2019 and subsequent years:

Biosimilar products without pass-through status which are acquired under the 340B program will be paid at ASP minus 22.5% of the biosimilar's ASP, instead of the reference product's ASP

Most commenters agreed with CMS and this proposal is finalized for CY 2019.

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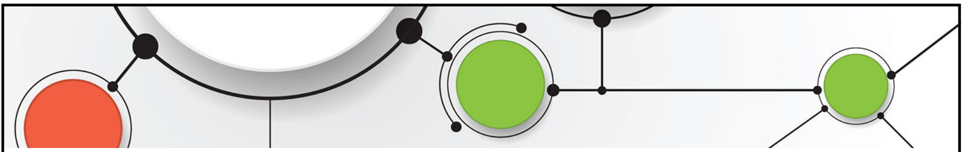
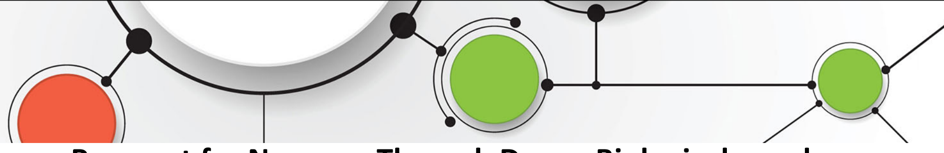


Payment Policy for Therapeutic Radiopharmaceuticals

CMS will continue to also pay for therapeutic radiopharmaceuticals at ASP +6% for CY 2019.

This has been the payment policy since CY 2010.

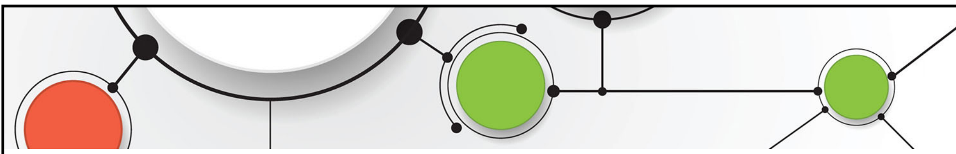


Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes But Without OPPS Hospital Claims Data

CMS will continue to use the same payment policy as in previous years for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data.

These codes will be assigned a non-covered status indicator (E2) until payment information becomes available.

If pricing information becomes available, status indicator K will be assigned and separate payment will be made for the remainder of the year.



CY 2019 OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 Final Rule, CMS finalized a policy to pay for separately payable drugs and biologicals which are acquired under the 340B Program at a rate of ASP minus 22.5%.

Excludes pass-through drugs (which are required to be paid at ASP +6%) and vaccines (which are excluded from the 340B Program)

This was implemented to more appropriately reflect resources and acquisition costs for these drugs which have been being acquired with significantly discounted pricing.

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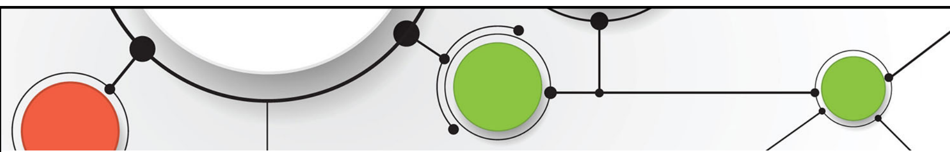

CY 2019 OPPS Payment Methodology for 340B Purchased Drugs

CMS has received questions regarding how the 340B payment reduction is being applied for drugs without ASP data available.

CMS clarified in the Proposed Rule that the payment reduction does apply to drugs priced using WAC or AWP methods.

- The payment adjustment for WAC-priced drugs is WAC minus 22.5%
- The payment adjustment for AWP-priced drugs is 69.46 percent of AWP
  - This is calculated by first reducing the original 95 percent of AWP price by 6% to generate a value similar to the ASP or WAC with no percentage markup and then applying a minus 22.5% adjustment

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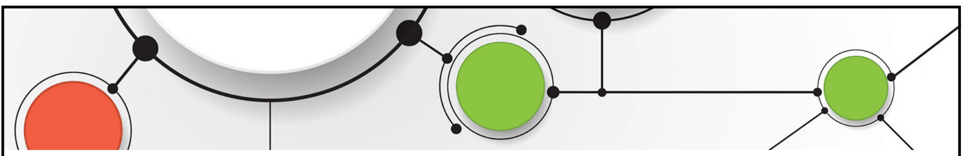

CY 2019 OPPS Payment Methodology for 340B Purchased Drugs

Modifier JG was established to report 340B-acquired drugs for hospitals paid under the OPPS subject to the payment reduction.

Modifier TB was established as an informational modifier to report 340B-acquired drugs for hospitals not subject to the payment reduction.

CMS will continue to apply the payment rate of ASP minus 22.5% for separately payable drugs paid under the OPPS which are acquired through the 340B Program when billed by a hospital that is not excepted from the payment adjustment.

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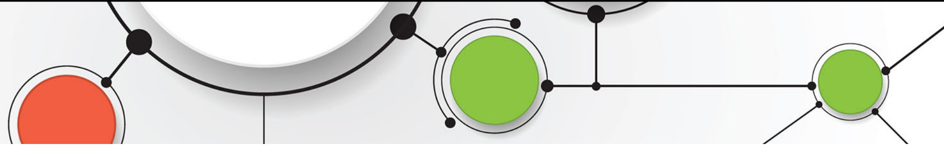

CY 2019 OPPS Payment Methodology for 340B Purchased Drugs

CMS will also continue to require reporting of information modifier TB for hospitals that are not subject to payment reduction.

See page 145 of this manual for CY 2019 changes impacting 340B drugs acquired by nonexcepted off-campus departments of a hospital that are not paid under the OPPS

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VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

Pass-through spending will remain limited to 2.0% of total OPPS spending, as it has been since 2004.

Estimated total pass-through spending for CY 2019 is $100.8 million, which represents 0.14% of the total projected OPPS payments for CY 2019 (~$74 billion).

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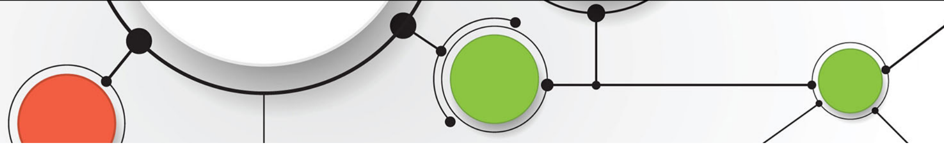

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2019, CMS is not making any changes to current hospital outpatient visit and emergency department (ED) visit payment policies. CMS also did not propose any changes to current payment policy for critical care services.

However, CMS is making a major change to "control unnecessary increase in the volume of covered outpatient department services" which significantly impacts payment for certain outpatient visits at off-campus provider-based departments, as is discussed beginning on page 138 of this manual.

Additionally, significant changes related to documentation and payment for outpatient clinic visits under the Physician Fee Schedule can be found in the CY 2019 PFS Rule (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-F.html).

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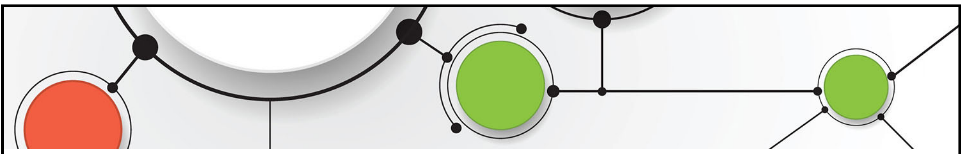


VIII. Payment for Partial Hospitalization Services

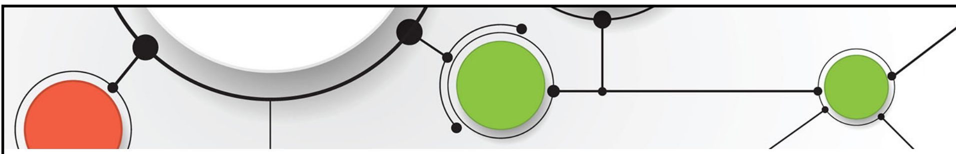
For CY 2017, CMS finalized a policy to combine the Level 1 and Level 2 Partial Hospitalization (PHP) APCs for both hospitals and community mental health centers (CMHCs) into one level for each provider type.

CMS will continue to use the same procedure for CY 2019, calculating the geometric mean per diem cost for each provider type.

VIII. Payment for Partial Hospitalization Services

Below are the final rates in comparison with the current rates for CY 2018.

APC	APC Description	CY 2018 Payment	CY 2019 Payment	%Diff
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$143.31	$120.58	-15.86%
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$208.23	$220.86	6.0%

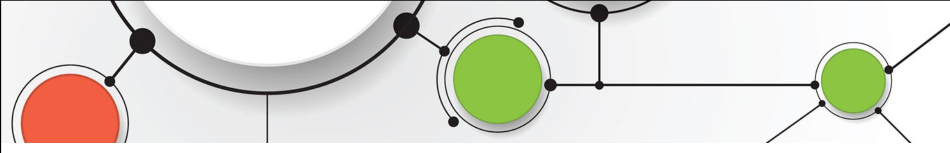


Changes to the Revenue-Code-to-Cost Center Crosswalk

In the CY 2017 OPPS Final Rule, CMS received comments identifying a cost-reporting issue believed to be contributing to a decreased cost for hospital-based PHPs.

Comments stated that lack of a standardized PHP cost center on the Medicare cost report allows hospital PHP costs to be combined with the costs of less expensive non-PHP mental health services, thus “diluting” the CCR values.

CMS agreed with commenters.

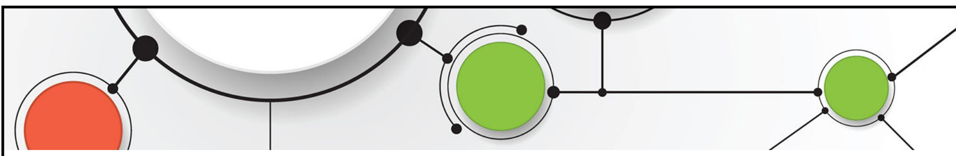


Changes to the Revenue-Code-to-Cost Center Crosswalk

On November 17, 2017, in Transmittal 12, CMS added a new cost center, “Partial Hospitalization Program” on line 93.99 of Worksheet A, for cost reporting periods ending on or after August 31, 2017.

Transmittal 13 on January 30, 2018 subsequently changed the implementation period to cost reporting periods on or after September 30, 2017.

Effective on this date, providers are to report the costs of proving a hospital-based PHP program on this line and should not include costs for non-PHP outpatient mental health services.



Changes to the Revenue-Code-to-Cost Center Crosswalk

When CMS calculates payment rates for PHP programs, costs are estimated by multiplying revenue code charges on the claim by the appropriate cost center-level CCR from the hospital cost report.

The appropriate cost center-level CCR is identified by using the OPPS Revenue-Code-to-Cost-Center crosswalk.

The current crosswalk file is available for download here: https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPPS-FR-Revenue-Code-to-Cost-Center-Crosswalk.zip

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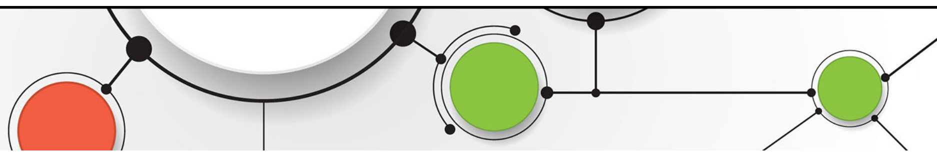

Changes to the Revenue-Code-to-Cost Center Crosswalk

There will be one exception to this policy, for the mapping for revenue code 0904, which is the only PHP-allowable revenue code in the existing crosswalk with a tertiary cost center source for the CCR.

- For revenue code 0904, the secondary cost center will be the existing secondary cost center 3550 (“Psychiatric/Psychological Services”)
- The tertiary cost center will be existing tertiary cost center 9000 (“Clinic”)

CMS did not receive any public comments and therefore will finalize this for CY 2019.

See Table 44 for crosswalk.

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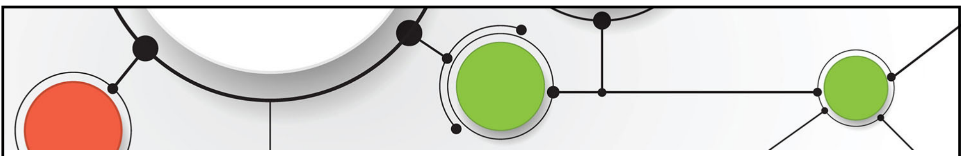

PHP Service Utilization Updates

In recent years CMS has expressed concern regarding the low frequency of individual therapy provided to PHP beneficiaries.

CMS was also concerned that the consolidation of PHP APCs into a single APC for 3 or more services would influence a change in service provision due to providers being able to obtain a payment rate that was heavily weighted to the cost of providing 4 or more services.

It is CMS's expectation that days with only 3 services are meant to be an exception, and not the typical PHP day.

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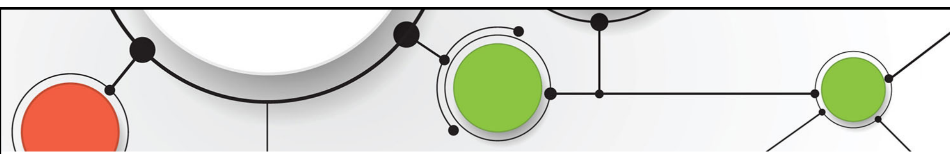

PHP Service Utilization Updates

Providing 3 services is the *minimum* units acceptable. CMS states that the typical PHP day should generally consist of 5 or 6 units of service.

If a PHP were only to provide days with 3 services, it would be difficult for patients to meet the eligibility requirement of a minimum of 20 hours of therapeutic services per week.

CMS has been monitoring claims data to ensure that beneficiaries are receiving the necessary amount of care under PHP programs.

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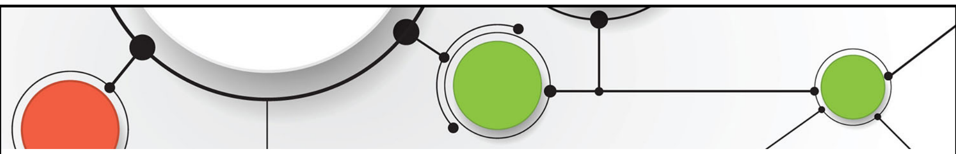

PHP Service Utilization Updates

Review of CY 2017 claims data (the first year of claims data since consolidation to single APC) shows that hospitals have greatly increased the provision of individual therapy, as well as days providing five or more services.

CMS is not making any changes for CY 2019 but will continue monitoring this data.

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Proposed Update to PHP Allowable HCPCS Codes

The AMA will be deleting six and adding nine CPT codes that will impact PHPs in CY 2019.

CMS did not discuss these changes in detail in the Proposed Rule and therefore are including them in this Final Rule and will consider public comments and seek to finalize proposed actions in the CY 2020 Final Rule.

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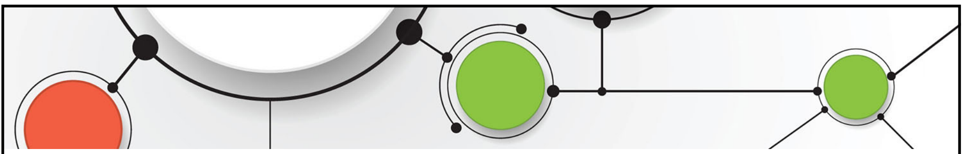

Proposed Update to PHP Allowable HCPCS Codes

TABLE 47.--PROPOSED CHANGES TO THE ALLOWABLE CPT CODES FOR CMHC PHP APC 5853 and HOSPITAL-BASED PHP APC 5863

Existing Code	Proposed Action	Proposed Replacement(s)	Proposed APC Action
96101	Delete	96130, 96131, and may also include 96136, 96137, 96138, 96139, 96146	Add
96102	Delete	96130, 96131, and may also include 96136, 96137, 96138, 96139, 96146	Add
96103	Delete	96130, 96131, and may also include 96136 96137, 96138, 96139, 96146	Add
96118	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add
96119	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add
96120	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add

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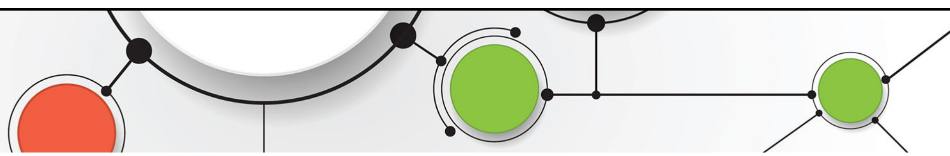
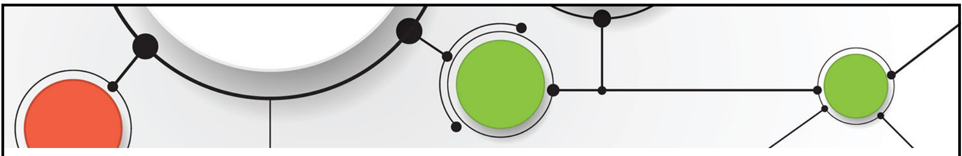


IX. Procedures That Would Be Paid Only as Inpatient Procedures



Changes to the Inpatient Only (IPO) List

Removed:

31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)
00670	Anesthesia for extensive spine and spinal cord procedures (eg, spinal instrumentation or vascular procedures)

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Changes to the Inpatient Only (IPO) List

Added:

C9606 Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel

The complete list of inpatient only procedures can be found in Addendum E.

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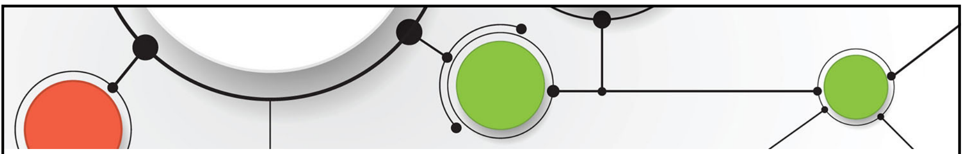

X. Nonrecurring Policy Changes

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Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

The June 2017 Report to Congress by the Medicare Payment Advisory Commission (MedPAC) states that, in recent years, there has been significant growth in the number of health care facilities located apart from hospitals that are devoted primarily to emergency department services.

CMS has observed a noticeable increase in the number of hospital outpatient emergency department visits furnished under the OPPS since 2010.

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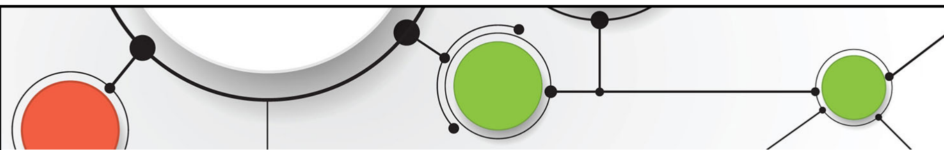
Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

MedPAC and other entities have expressed concern that services may be shifting to the higher acuity and higher cost emergency department setting due to:

(1) higher payment rates for services performed in off-campus provider- based emergency departments compared to similar services provided in other settings (such as physician offices or urgent care clinics); and

(2) the exemption of emergency department services from payment reductions included under section 603 of the Bipartisan Budget Act of 2015



Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

MedPAC recommended that CMS require hospitals to append a modifier to claims for all services furnished in off-campus provider-based emergency departments, so that CMS can track the growth of OPPS services provided in this setting.

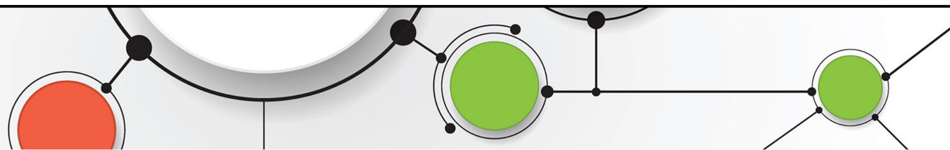
CMS agrees with this recommendation.

Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

CMS announced the implementation of a new HCPCS modifier that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department.

ER - Items and services furnished by a provider-based off-campus emergency department

Critical access hospitals (CAHs) are not required to report this new modifier.



Method to Control for Unnecessary Increases in the Volume of Outpatient Services

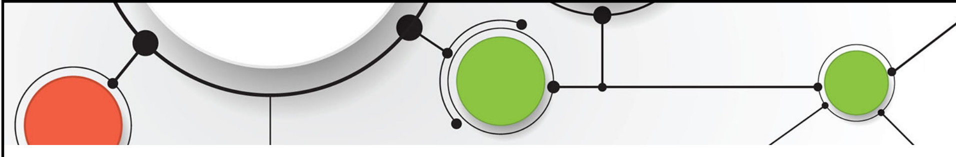
Several studies have been performed by MedPAC and have noted:

- A large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of an unnecessary shift of services from physician offices to HOPDs
- Over the decade ending in 2015, volume per beneficiary grew by 47 percent
- One-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of evaluation and management (E&M) visits billed as outpatient services

Method to Control for Unnecessary Increases in the Volume of Outpatient Services

Several studies have been performed by MedPAC and have noted:

- This growth in part reflects hospitals purchasing freestanding physician practices and converting the billing from the PFS to higher paying hospital outpatient department (HOPD) visits
- From 2012 to 2015, hospital-based E&M visits per beneficiary grew by 22 percent, compared with a 1-percent decline in physician office–based visits
- MedPAC recommended that the payment rates for E&M visits provided in HOPDs be reduced to be the same, whether the service is provided in a hospital outpatient department or a physician office



Section 603 of the Bipartisan Budget Act

- However, the majority of hospital off-campus PBDs continue to receive full OPPS payment (including off-campus emergency departments and excepted off-campus departments of a hospital).
- Facilities not subject to the payment reduction report services with modifier “PO.”
- The most frequently billed service with the “PO” modifier is HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient).

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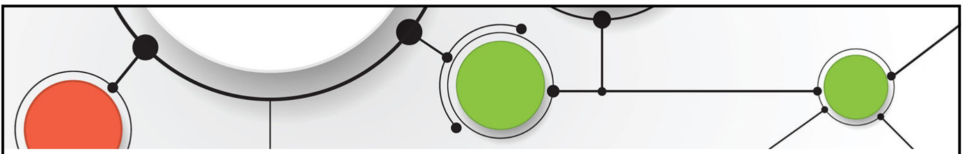

Proposed Payment Adjustment for CY 2019

CMS believes that capping the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed.

CMS proposed to use their authority under the Act related to controlling unnecessary increases in the volume of covered outpatient services to apply the PFS-equivalent payment rate for HCPCS code G0463 when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines)

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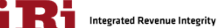

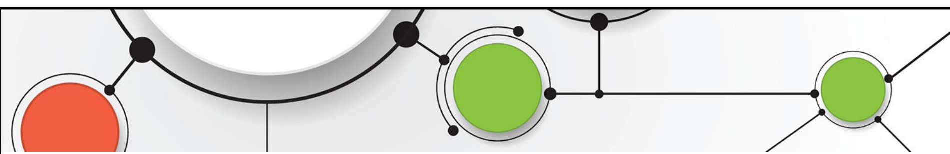

Proposed Payment Adjustment for CY 2019

- Off-campus PBDs that are not excepted from section 603 (departments that bill the modifier "PN") already receive a PFS-equivalent payment rate for the clinic visit
- An excepted off-campus PBD would continue to bill HCPCS code G0463 with the "PO" modifier in CY 2019, but the payment rate would now be equivalent to the payment rate for services described by HCPCS code G0463 when billed with modifier "PN"

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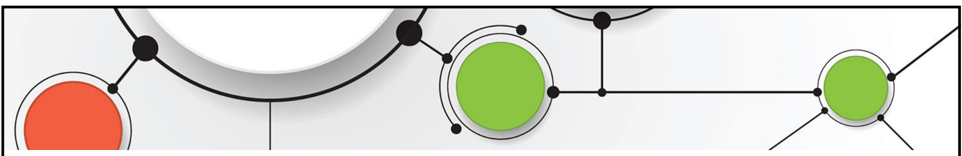

Proposed Payment Adjustment for CY 2019

The standard unadjusted Medicare OPPS proposed payment for CY 2019 for a clinic visit is approximately $116, with approximately $23 being the average copayment.

The proposed PFS equivalent rate for a clinic visit would be approximately $46 and the copayment would be approximately $9.

This would save beneficiaries an average of $14 per visit.

CMS proposed to implement this reduction in a **non-budget neutral manner**.

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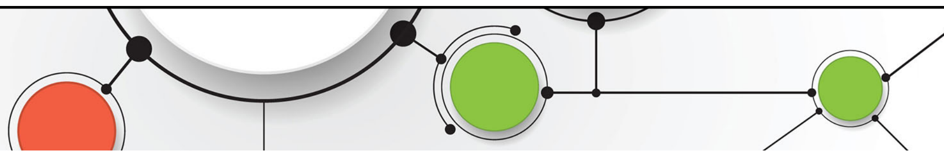

Proposed Payment Adjustment for CY 2019

This means that the cost savings from this proposal would not be redistributed throughout the rest of the OPPS.

CMS is generally required to make changes under the OPPS in a budget neutral manner, but states that this does not apply to the volume control method under the Act.

The section of the Act related to budget neutrality adjustments provides that if "the Secretary makes *adjustments* under subparagraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made (emphasis added)."

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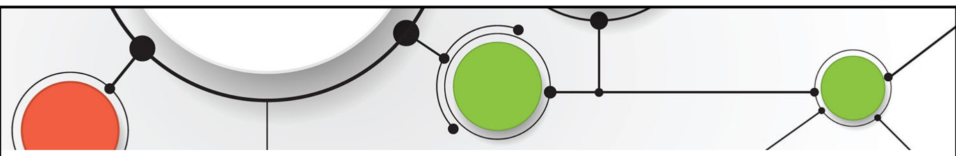

Proposed Payment Adjustment for CY 2019

Comments received included:

- Support for the reduced payments to help control costs for both beneficiaries and the Medicare program
- Support of the nonbudget neutral manner
- Urging CMS to continue on a path to bring full parity in payment for outpatient services, regardless of the site of service

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Proposed Payment Adjustment for CY 2019

Comments received included:

- MedPAC recommended reduced payments, however over a 3-year phase in approach
- Disagreement of CMS' interpretation of section 1833(t)(2)(F) of the Act
- Concern that shift from inpatient to outpatient services, including the 2-midnight policy might be driving increases in volume of outpatient services
- HOPDs serve unique patient populations and provide services to medically complex beneficiaries

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Proposed Payment Adjustment for CY 2019

CMS' response included the following GAO findings:

- E&M office visit per beneficiary performed in HOPDs was generally higher in vertical consolidation; e.g., when hospitals purchased physician practices
- The study did not support patients seen in HOPDs were sicker than those seen in physician offices
- The study suggested providers responded to financial incentive
- The current site-based payment creates an incentive for an unnecessary increase in the volume of this type of OPD service
- CMS would not be able to adequately address the unnecessary increases in the volume of clinic visits in HOPDs if we did not apply this policy to all off-campus HOPDs
- The volume control method is not one of the adjustments that must be included in the budget neutrality

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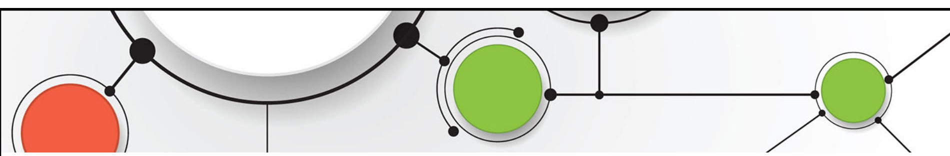

Final Payment Adjustment for CY 2019

CMS will pay for a clinic visit service (G0463) when provided at an excepted off-campus PBD and billed with modifier PO equal to the site-specific PFS payment rate for nonexcepted PBD.

This payment change will be made in a nonbudget neutral manner.

This reduction in payment will be phased in over a two-year period of time.

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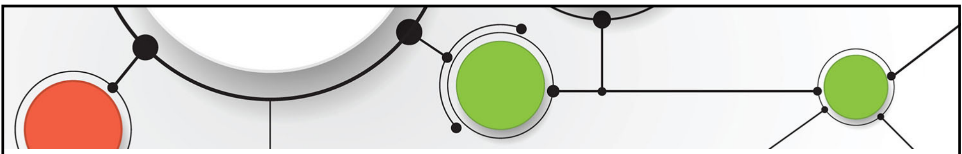

Final Payment Adjustment for CY 2019

The current PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40% of OPPS or a 60% reduction.

Excepted PBD clinic visits will be paid as follows:

- CY 2019 30% reduction to the OPPS rate will be made
  - 70% of OPPS rate
  - Estimated savings for CY 2019 $380 million
- CY 2020 payment will match PFS payment rate for nonexcepted PBDs

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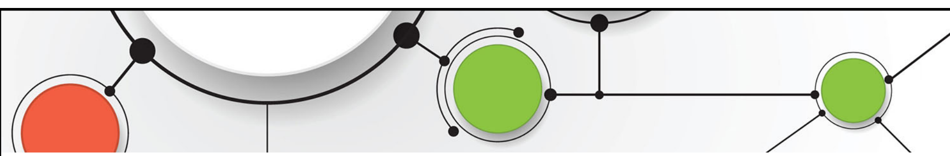

Final Payment Adjustment for CY 2019

CY 2019 Excepted PBD Clinic Visit (with PO modifier)

Code	Description	CY 2018 Payment	CY 2019 Payment	%Diff
G0463	Hospital outpatient clinic visit	$113.69	$79.58	-30%

CMS solicited comments and received feedback that will be taken into consideration for future rule making.

Page 142-144

Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

The current payment rate of ASP minus 22.5% for drugs acquired under the 340B Program is applicable to separately payable drugs and biologicals paid under the OPPS (except for pass-through drugs and vaccines).

Nonexcepted items and services furnished by nonexcepted off-campus provider-based departments are not paid under the OPPS, and therefore are not subject to the payment reduction.

These drugs are paid in the same way that drugs are paid in physician office settings, ASP +6%.

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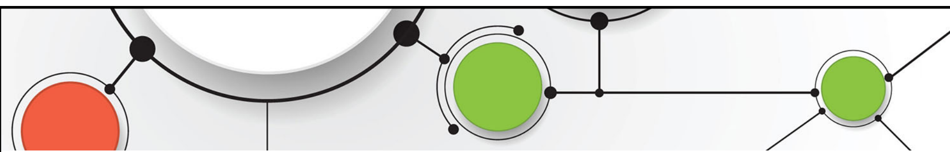

Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

Comments received on the CY 2018 OPPS Final Rule suggested that the 340B payment reduction should apply to nonexcepted off-campus PBDs as well. Not applying to these facilities could result in behavioral changes that undermine the goals of lowering beneficiary cost-sharing and moving towards site neutrality.

CMS stated that this would be considered for future rulemaking.

CMS agrees with commenters that the difference in payment rates for 340B-acquired drugs in excepted versus nonexcepted off-campus PBDs creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount.

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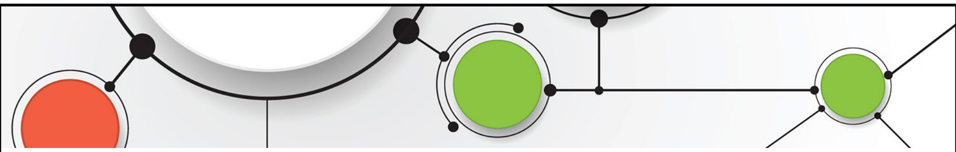
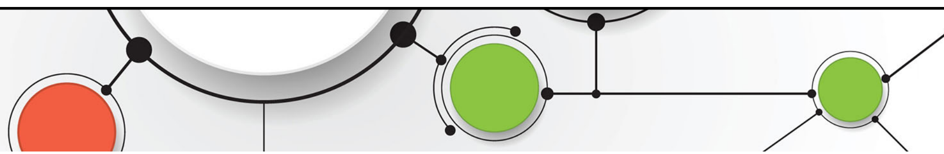


Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

Proposal

For CY 2019 and subsequent years, CMS proposed to apply the payment amount of ASP minus 22.5% for separately payable drugs and biologicals acquired under the 340B program when furnished by nonexcepted off-campus PBDs.

CMS also proposed to exclude from the payment adjustment rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals.



Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

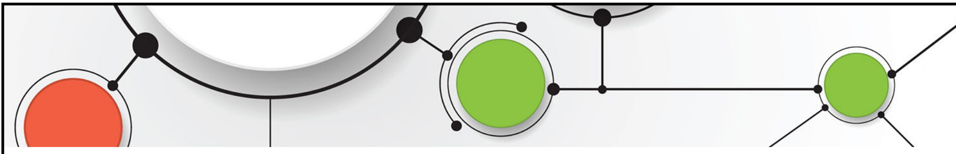
Final CY 2019

Payment for separately payable 340B-acquired drugs furnished by nonexcepted off-campus departments of a hospital under the PFS will subject to the 340B payment reduction and the payment rate for those drugs will be ASP minus 22.5 percent.

- Drugs with a status indicator K
- Modifier JG present

Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment.

- These facilities must use modifier TB for 340B-acquired drugs for information purposes
- Payment will be ASP +6%



Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

CY 2019 Proposal

CMS continues to have the same concerns about hospitals purchasing additional physician practices and expanding services at existing excepted off-campus PBDs.

For CY 2019 and subsequent years CMS proposed the following:

- If an excepted off-campus PBD furnishes services from any clinical family of services from which it did not furnish an item or service during a baseline period from November 1, 2014 through November 1, 2015 (and subsequently bill under the OPPS for that item or service), items and services from these new clinical families of services would not be excepted and, thus, would not be covered OPD services

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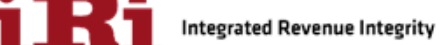

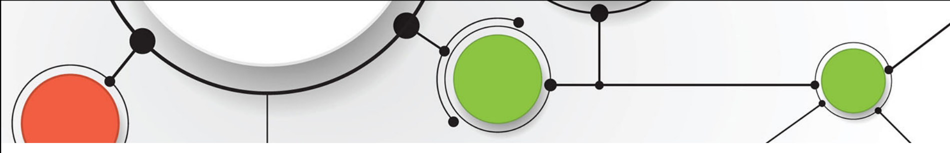

Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

CY 2019 Proposal

For CY 2019 and subsequent years CMS proposed the following:

- These services would instead be subject to the alternative payment system (MPFS) (Modifier “PN”)
- Clinical families are broken up by APC and provided in Table 32 of the Proposed Rule (and on the following page)
- If a new service is added to an APC within an existing clinical family (e.g., new technology or innovation) and this clinical family of services was previously furnished by an excepted PBD, this will not be considered a “service expansion” and will continue to be paid under the OPPS

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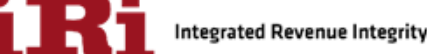
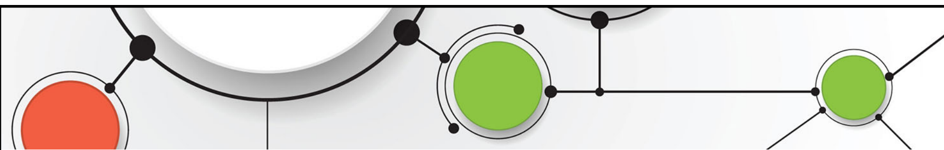
Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

CY 2019 Proposal

For CY 2019 and subsequent years CMS proposed the following:

- To determine the types of services provided at an excepted off-campus PBD, for purposes of OPPS payment eligibility, excepted off-campus PBDs will be required to ascertain the clinical families from which they furnished services from November 1, 2014 through November 1, 2015 (that were subsequently billed under the OPPS)
- Providers that met the mid-build requirement will have a 1-year baseline period that begins on the first date the off-campus PBD furnished a service billed under the OPPS



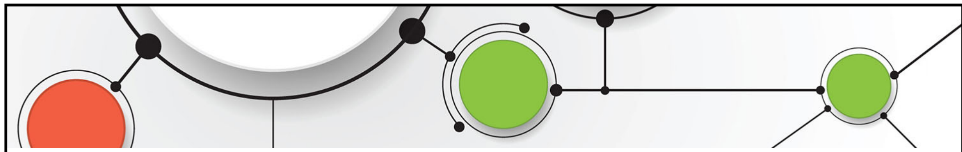


Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

CY 2019 Proposal

See Table 32 for the Proposed Clinical Families.

CMS selected the year prior to the date of enactment of the Bipartisan Budget Act of 2015 as the baseline period because it is the most recent year preceding the date of enactment of section 603.



Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

Comments

Many comments from hospitals, medical associations, MedPAC and the GAO were against this proposal, specifically stating:

- Modification to the proposed clinical family APCs is needed
- Requests to change the baseline period from 12 months to 6 months; another commenter wanted it increased to three years
- Eliminate this proposal all together for excepted PBDs

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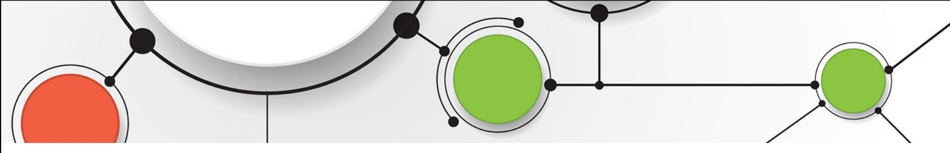

Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

Final CY 2019

CMS will **not** be finalizing this proposal but will continue to monitor expansion of services in off-campus PBDs.

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XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

The Hospital OQR Program is a pay-for-reporting quality program for services rendered in the outpatient hospital setting.

The program requires facilities to meet quality reporting requirements or receive a reduction of 2.0 percentage points in their annual payment update if they fail to meet these requirements.

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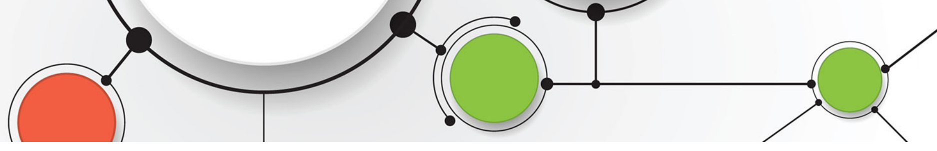

Removal of Quality Measures from the Hospital OQR Program Measure Set

CMS had proposed to remove 10 measures. After further review and based on comments received, CMS will remove 8 measures from the program. No measures will be added to the program.

Measure OP-27 is removed for the CY 2020 payment determination. The remaining measures are removed for the CY 2021 payment determination.

See the table starting on page 157 for a summary of the changes.

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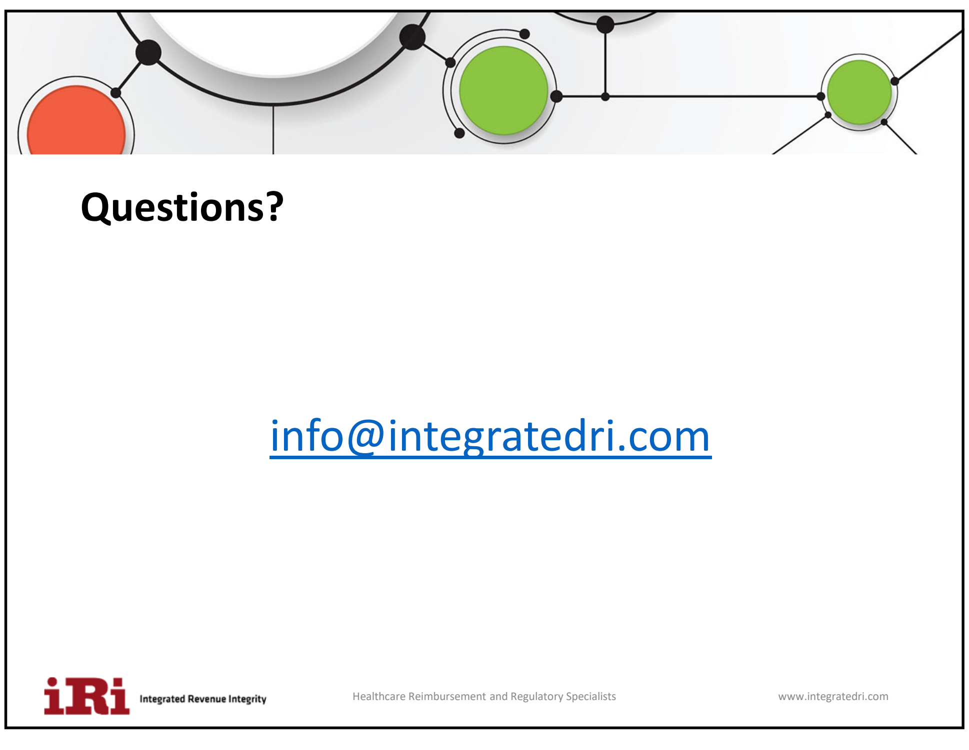
Questions?
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