

FIRST COAST SERVICE OPTIONS, INC.

December 2020

A Newsletter for MAC Jurisdiction N Providers

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MLN Connects® – Special Edition – Monday, December 14, 2020

COVID-19 Vaccine Codes: Updated Effective Date for Pfizer-BioNTech

On December 11, 2020, the U.S. Food and Drug Administration issued an *Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine* for the prevention of COVID-19 for individuals 16 years of age and older. Review Pfizer's *Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)* regarding the limitations of authorized use.

During the COVID-19 Public Health Emergency (PHE), Medicare will cover and pay for the administration of the vaccine (when furnished consistent with the EUA). Review our updated *payment and HCPCS Level I CPT code structure* for specific COVID-19 vaccine information. Only bill for the vaccine administration codes when you submit claims to Medicare; don't include the vaccine product codes when vaccines are free.

Related links:

- CMS COVID-19 Provider Toolkit
- CMS COVID-19 FAQs



- CDC COVID-19 Vaccination Communication Toolkit for medical centers, clinics, and clinicians
- FDA COVID-19 Vaccines webpage

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WHEN EXPERIENCE COUNTS & QUALITY MATTERS

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Your Feedback Matters

To ensure that our website meets the needs of our provider community, we carefully analyze your feedback and implement changes to better meet your needs. Discover the results of your feedback on our "*Website enhancements*" page. You'll find the latest enhancements to our provider websites and find out how you can share your thoughts and ideas with First Coast's Web team. The *Medicare A Connection* is published monthly by First Coast Service Options Inc.'s Provider Outreach & Education division to provide timely and useful information to Medicare Part A providers.

Articles included in the *Medicare A Connection* represent formal notice of coverage policies. Policies have or will take effect on the date given. Providers are expected to read, understand, and abide by the policies outlined within to ensure compliance with Medicare coverage and payment guidelines.

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Local Coverage Determinations

The *LCDs/Medical Affairs* section of our website provides you with the latest *medical affairs news*, *active LCDs*, and *proposed LCDs*. You can also find information on *selfadministered drug exclusions* and *clinical trials*.

First Coast has made it easy to locate active, proposed and retired LCDs on the *active LCD index*. The *LCD search tool* helps you find the coverage information you need quickly and easily. Just enter a procedure code, keyword, or the LCD's "L number," click the corresponding button, and the application will automatically display links to any LCDs applicable to the parameters you specified. Best of all, depending upon the speed of your internet connection, the LCD search process can be completed in less than 10 seconds.

In addition to using the search tools, First Coast's LCDs are available using the Centers for Medicare & Medicaid Services (CMS) *Medicare coverage database (MCD)*.

Reasonable and necessary guidelines

In the absence of a Local Coverage Determination (LCD) (*JN*), *national coverage determination (NCD)*, or the Centers for Medicare & Medicaid Services Manual Instruction, reasonable and necessary guidelines still apply.

Section 1862(a) (1) (A) of the Social Security Act directs the following:

"No payment may be made under Part A or Part B for any expenses incurred for items or services not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Note: malformed is defined as (of a person or part of the body) abnormally formed; misshapen.

The Medicare administrative contractor will determine if an item or service is "reasonable and necessary" under §1862(a) (1) (A) of the Act if the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency in terms of whether the service or item is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the beneficiary's medical needs and condition;
 - Ordered and furnished by qualified personnel; and
 - One that meets, but does not exceed, the beneficiary's medical need

For any service reported to Medicare, it is expected that the medical documentation clearly demonstrates that the service meets all of the above criteria. All documentation must be maintained in the patient's medical record and be available to the contractor upon request.



Medicare news

Advance beneficiary notice

Modifier GZ must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny an item or service as not reasonable and necessary and they have not had an advance beneficiary notification (ABN) signed by the beneficiary.

Note: line items submitted with the modifier GZ will be automatically denied and will not be subject to complex medical review.

Modifier GA must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny a service as not reasonable and necessary and they do have on file an ABN signed by the beneficiary.

All claims not meeting medical necessity of a local coverage determination must append the billed service with modifier GA or GZ.

2021 ICD-10-CM coding changes

The billing and coding articles were revised with the 2021 updates to the ICD-10-CM diagnosis coding structure effective for services rendered **on or after October 1, 2020.**

LCDs are available through the CMS Medicare coverage database at *https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*

A billing and coding article for a LCD (when present) may be found at the bottom of the LCD by selecting "Related Local Coverage Documents" in the "Section Navigation" drop-down menu at the top of the LCD page.

Note: to review active, future and retired LCDs, please *click here*.

LCDs

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Effective and notice dates

Effective dates are provided in each LCD, and are based on the date services are furnished unless otherwise noted in the LCD. Medicare contractors are required to offer a 45-day notice period for LCDs; the date the LCD is posted to the website is considered the notice date.

Electronic notification

To receive quick, automatic notification when new and revised LCDs are posted to the website, subscribe to the *First Coast eNews mailing list*.

Simply enter your email address and select the

subscription option that best meets your needs.

More information

For more information, or, if you do not have internet access, to obtain a hardcopy of a specific LCD, contact Medical Affairs at: First Coast Service Options Medical Affairs 2020 Technology Parkway Suite 100 Mechanicsburg, PA 17050-9419

Keep updated...

Use the tools and useful information found on *medicare.fcso.com* to stay updated on changes associated with the Medicare program.



Upcoming provider outreach and educational events

Stay updated regarding the Prior Authorization Program

Date: Tuesday, January 26 Time: 11:30 a.m. - 1 p.m. ET Type of Event: Webcast

View our complete calendar of events

Note: Unless otherwise indicated, designated times for educational events are stated as ET, and the focus is to Florida, Puerto Rico, and the U.S. Virgin Islands.

Two easy ways to register

Online – Visit our provider training website at *First Coast University*, log on to your account and select the course you wish to register. Class materials are available under "My Courses" no later than one day before the event.

First-time User? Set up an account by completing *Create User Account Form* online. Providers who do not have yet a national provider identifier may enter "99999" in the NPI field. You will receive logon information within 72 hours of your request.

Fax – Providers without internet access may request a fax registration form through our Registration Hotline at 1-904-791-8103. Class materials will be faxed to you the day of the event.

Please Note:

- Pre-registration is required for all teleconferences, webcasts and in-person educational seminars.
- Dates and times are subject to change prior to opening of event registration.

Registrant's Name:	
Registrant's Title:	
Provider's Name:	
Telephone Number:	Fax Number:
Email Address:	
Provider Address:	
City, State, ZIP Code:	

Keep checking our *website* for details and newly scheduled educational events (teleconferences, webcasts, etc.).

Never miss a training opportunity

If you or your colleagues were unable to attend one of our past Medicare educational webcasts, you still have the opportunity to learn about the topics covered during the training session. Visit the First Coast Medicare training website, download the recording of the event, and listen to the webcast when you have the time.

Take advantage of 24-hour access to free online training

In addition to live training events, we also offer you the advantage of self-paced, free online courses that will allow you and your staff to train when and where it is most convenient for you. In addition, our comprehensive course catalog allows you to find the Medicare training that fits your specific needs, and several of our online courses offer CEUs. Learn more on the First Coast Medicare training website and explore our catalog of online courses.

MLN Connects®

The Centers for Medicare & Medicaid Services (CMS) *MLN Connects*[®] is an official *Medicare Learning Network*[®] (*MLN*) – branded product that contains a week's worth of news for Medicare fee-for-service (FFS) providers. CMS sends these messages weekly to national health industry provider associations, who then disseminates the *MLN Connects*[®] to its membership as appropriate.

MLN Connects® for Thursday, November 19, 2020

Nursing Homes: Take COVID-19 Training

MLN Connects® for November 19, 2020

View this edition as a PDF 🔤

News

- CMS Releases Nursing Home COVID-19 Training Data with Urgent Call to Action
- Medicare FFS Estimated Improper Payments Decline by \$15 Billion Since 2016
- CMS Retiring Original Compare Tools on December 1
- COVID-19: Health Care Operations Lessons and Fostering Professional Resilience
- Medicare Diabetes Prevention Program: Become a Medicare-Enrolled Supplier

MLN Connects[®] for Wednesday, November 25, 2020

Hospital Price Transparency Webcast on 12/8

MLN Connects[®] for Wednesday, November 25, 2020

View this edition as a PDF

News

- CMS Announces Historic Changes to Physician Self-Referral Regulations
- Policy Will Increase Number of Lifesaving Organs by Holding OPAs Accountable through Transparency and Competition
- Prescription Drug Payment Model to Put American Patients First
- DMEPOS Competitive Bidding Program: Contract Suppliers for Round 2021
- Quality Payment Program APMs: Extended Deadline to Update Billing information — December 13
- Clinical Laboratory Fee Schedule: CY 2021 Final Payment Determinations
- Hospice Quality Reporting Program: November Refresh
- November is Home Care & Hospice Month
- World AIDS Day is December 1

 Recognizing Lung Cancer Awareness Month and the Great American Smokeout

Compliance

Hospice Care: Safeguards for Medicare Patients

Events

- CMS-CDC Fundamentals of COVID-19 Prevention for Nursing Home Management Call — November 19
- Hospital Price Transparency Webcast December 8

Multimedia

 Part A Cost Report Webcast: Audio Recording and Transcript

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Compliance

Polysomnography Services: Bill Correctly

Claims, Pricers & Codes

Medicare Diabetes Prevention Program: Valid Claims
Events

ents

- Long-Term Services and Supports Open Door Forum — December 1
- Hospital Price Transparency Webcast December 8
- Interoperability and Patient Access Final Rule Call December 9

MLN Matters® Articles

- Changes to the End-Stage Renal Disease (ESRD) PRICER to Accept the New Outpatient Provider Specific File Supplemental Wage Index Fields, the Network Reduction Calculation and New Value Code for Time on Machine
- Claim Status Category and Claim Status Codes Update
- Implementation of Two (2) New NUBC Condition Codes. Condition Code "90", "Service provided as Part of an Expanded Access Approval (EA)" and Condition Code "91", "Service Provided as Part of an Emergency Use Authorization (EUA)"





MLN Connects[®] – Special Edition – Tuesday, December 1, 2020

Trump Administration Finalizes Permanent Expansion of Medicare Telehealth Services and Improved Payment for Time Doctors Spend with Patients

On December 1, CMS released the annual Physician Fee Schedule (PFS) final rule, prioritizing CMS' investment in primary care and chronic disease management by increasing payments to physicians and other practitioners for the additional time they spend with patients, especially those with chronic conditions. The rule allows nonphysician practitioners to provide the care they were trained and licensed to give, cutting red tape so health care professionals can practice at the top of their license and spend more time with patients instead of on unnecessary paperwork. This final rule takes steps to further implement President Trump's Executive Order on Protecting and Improving Medicare for Our Nation's Seniors including prioritizing the expansion of proven alternatives like telehealth.

"During the COVID-19 pandemic, actions by the Trump Administration have unleashed an explosion in telehealth innovation, and we're now moving to make many of these changes permanent," said HHS Secretary Alex Azar. "Medicare beneficiaries will now be able to receive dozens of new services via telehealth, and we'll keep exploring ways to deliver Americans access to health care in the setting that they and their doctor decide makes sense for them."

"Telehealth has long been a priority for the Trump Administration, which is why we started paying for short virtual visits in rural areas long before the pandemic struck," said CMS Administrator Seema Verma. "But the pandemic accentuated just how transformative it could be, and several months in, it's clear that the health care system has adapted seamlessly to a historic telehealth expansion that inaugurates a new era in health care delivery."

Finalizing Telehealth Expansion and Improving Rural Health

Before the COVID-19 Public Health Emergency (PHE), only 15,000 Fee-for-Service beneficiaries each week received a Medicare telemedicine service. Since the beginning of the PHE, CMS has added 144 telehealth services, such as emergency department visits, initial inpatient and nursing facility visits, and discharge day management services, that are covered by Medicare through the end of the PHE. These services were added to allow for safe access to important health care services during the PHE. As a result, preliminary data show that between mid-March and mid-October 2020, over 24.5 million out of 63 million beneficiaries and enrollees have received a Medicare telemedicine service during the PHE.

This final rule delivers on the President's recent Executive Order on Improving Rural Health and Telehealth Access by adding more than 60 services to the Medicare



telehealth list that will continue to be covered beyond the end of the PHE, and we will continue to gather more data and evaluate whether more services should be added in the future. These additions allow beneficiaries in rural areas who are in a medical facility (like a nursing home) to continue to have access to telehealth services such as certain types of emergency department visits, therapy services, and critical care services. Medicare does not have the statutory authority to pay for telehealth to beneficiaries outside of rural areas or, with certain exceptions, allow beneficiaries to receive telehealth in their home. However, this is an important step, and as a result, Medicare beneficiaries in rural areas will have more convenient access to health care.

Additionally, CMS is announcing a commissioned study of its telehealth flexibilities provided during the COVID-19 PHE. The study will explore new opportunities for services where telehealth and virtual care supervision, and remote monitoring can be used to more efficiently bring care to patients and to enhance program integrity, whether they are being treated in the hospital or at home.

Payment for Office/Outpatient Evaluation and Management (E/M) and Comparable Visits

Last year, CMS finalized a historic increase in payment rates for office/outpatient face-to-face E/M visits that goes into effect in 2021. The Medicare population is increasing, with over 10,000 beneficiaries joining the program every day. Along with this growth in enrollment is increasing complexity of beneficiary health care needs, with more than two-thirds of Medicare beneficiaries having two or more chronic conditions. Increasing the payment rate of E/M office visits recognizes this demand and ensures clinicians are paid appropriately for the time they spend on coordinating care for patients, especially those with chronic conditions. These payment increases, informed by recommendations from the American Medical Association (AMA), support clinicians who provide crucial care for patients with dementia or manage transitions between the hospital, nursing facilities, and home.

Under this final rule, CMS continues to prioritize this investment in primary care and chronic disease management by similarly increasing the value of many

MLN SE 12/1

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services that are similar to E/M office visits, such as maternity care bundles, emergency department visits, end-stage renal disease capitated payment bundles, and physical and occupational therapy evaluation services. These adjustments ensure CMS is appropriately recognizing the kind of care where clinicians need to spend more face-to-face time with patients.

"This finalized policy marks the most significant updates to E/M codes in 30 years, reducing burden on doctors imposed by the coding system and rewarding time spent evaluating and managing their patients' care," Administrator Verma added. "In the past, the system has rewarded interventions and procedures over time spent with patients – time taken preventing disease and managing chronic illnesses."

In addition to the increase in payment for E/M office visits, simplified coding and documentation changes for Medicare billing for these visits will go into effect beginning January 1, 2021. The changes modernize documentation and coding guidelines developed in the 1990s, and come after extensive stakeholder collaboration with the AMA and others. These changes will significantly reduce the burden of documentation for all clinicians, giving them greater discretion to choose the visit level based on either guidelines for medical decisionmaking (the process by which a clinician formulates a course of treatment based on a patient's information, i.e., through performing a physical exam, reviewing history, conducting tests, etc.) or time dedicated with patients. These changes are expected to save clinicians 2.3 million hours per year in administrative burden so that clinicians can spend more time with their patients.

Professional Scope of Practice and Supervision

As part of the Patients Over Paperwork Initiative, the Trump Administration is cutting red tape so that health care professionals can practice at the top of their license and

MLN

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- Implement Operating Rules Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
- National Coverage Determination (NCD 90.3): Chimeric Antigen Receptor (CAR) T-cell Therapy
- Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
- Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year (CY) 2021
- Update to Vaccine Services Editing
- Overview of the Repetitive Scheduled Non-emergent

spend more time with patients instead of on unnecessary paperwork. The PFS final rule makes permanent several workforce flexibilities provided during the COVID-19 PHE that allow non-physician practitioners to provide the care they were trained and licensed to give, without imposing additional restrictions by the Medicare program.

Specifically, CMS is finalizing the following changes

- Certain non-physician practitioners, such as nurse practitioners and physician assistants, can supervise the performance of diagnostic tests within their scope of practice and state law, as they maintain required statutory relationships with supervising or collaborating physicians
- Physical and occupational therapists will be able to delegate "maintenance therapy" – the ongoing care after a therapy program is established – to a therapy assistant
- Physical and occupational therapists, speech-language pathologists, and other clinicians who directly bill Medicare can review and verify, rather than re-document, information already entered by other members of the clinical team into a patient's medical record. As a result, practitioners have the flexibility to delegate certain types of care, reduce duplicative documentation, and supervise certain services they could not before, increasing access to care for Medicare beneficiaries.

For More Information:

- Final Rule
- Physician Fee Schedule Final Rule fact sheet
- Quality Payment Program Final Rule fact sheet and FAQs
- Medicare Diabetes Prevention Program fact sheet

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Ambulance Prior Authorization Model — Revised

- Billing for Home Infusion Therapy Services on or After January 1, 2021 — Revised
- Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2021 — Revised
- Update to Chapter 10 of Publication (Pub.) 100-08 -Enrollment Policies for Home Infusion Therapy (HIT) Suppliers — Revised

Publications

- DMEPOS Information for Pharmacies Revised
- DMEPOS Quality Standards Revised
- Advance Care Planning Revised

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MLN Connects[®] – Special Edition – Wednesday, December 2, 2020

Trump Administration Finalizes Policies to Give Medicare Beneficiaries More Choices around Surgery

Outpatient Prospective Payment System and Ambulatory Surgical Center final rule empowers beneficiary choices and unleashes competition to lower costs and improve innovation

On December 2, CMS finalized policy changes that will give Medicare patients and their doctors greater choices to get care at a lower cost in an outpatient setting. The Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) final rules will increase value for Medicare beneficiaries and reflect the agency's efforts to transform the health care delivery system through competition and innovation. These changes implement the Trump Administration's Executive Order on Protecting and Improving Medicare for Our Nation's Seniors, and will take effect on January 1, 2021. 35372) is a surgical procedure that removes chronic blood clots from the arteries in the lung. If this procedure is performed in an inpatient setting, a patient who has not had other health care expenses that year would have a deductible of about \$1500. In contrast, the copayment for this procedure for the same patient in the outpatient setting would be about \$1150. Patient safety and quality of care will be safeguarded by the doctor's assessment of the risk of a procedure or service to the individual beneficiary and their selection of the most appropriate setting of care based on this risk. This is in addition to state and local licensure requirements, accreditation requirements, hospital conditions of participation, medical malpractice laws, and CMS quality and monitoring initiatives and programs.

Beginning January 1, 2021, we are adding eleven procedures to the ASC Covered Procedures List (CPL), including total hip arthroplasty (CPT 27130), under our

"President Trump's term in office has been marked by an unrelenting drive to level the playing field and boost competition at every turn," said CMS Administrator Seema Verma. "Today's rule is no different. It allows doctors and patients to make decisions about the most appropriate site of care, based on what makes the most sense for the course of treatment and the patient without micromanagement from Washington."



standard review process. Additionally, we are revising the criteria we use to add surgical procedures to the ASC CPL, providing that certain criteria we used to add surgical procedures to the ASC CPL in the past will now be factors for physicians to consider in deciding whether a specific beneficiary should receive a covered surgical procedure in an ASC. Using our revised criteria, we are adding an additional 267 surgical procedures to the ASC

In this final rule, CMS will begin eliminating the Inpatient Only (IPO) list of 1,700 procedures for which Medicare will only pay when performed in the hospital inpatient setting over a three-year transitional period, beginning with some 300 primarily musculoskeletal-related services. The IPO list will be completely phased out by CY 2024. This will make these procedures eligible to be paid by Medicare when furnished in the hospital outpatient setting when outpatient care is appropriate, as well as continuing to be payable when furnished in the hospital inpatient setting when inpatient care is appropriate, as determined by the physician. In the short term, as hospitals face surges in patients with complications from COVID-19, being able to provide treatment in outpatient settings will allow non-COVID-19 patients to get the care they need.

In addition to putting decisions on the best site of care in the hands of physicians, allowing more procedures to be done in an outpatient setting also provides for lower-cost options that benefit the patient.

For example, thromboendarterectomy (HCPCS code

CPL beginning January 1, 2021. Finally, we are adopting a notification process for surgical procedures the public believes can be added to the ASC CPL under the criteria we are retaining.

CMS is announcing that it will continue its policy of paying for 340B-acquired drugs at average sales price minus 22.5% after the July 31, 2020, decision of the Court of Appeals for the D.C. Circuit upholding the current policy. This policy lowers out-of-pocket drug costs for Medicare beneficiaries by letting them share in the discount that hospitals receive under the 340B program. Since this policy went into effect in 2018, Medicare beneficiaries have saved nearly \$1 billion on drug costs, with expected Medicare beneficiary drug cost savings of over \$300 million in CY 2021.

As part of the agency's Patients Over Paperwork Initiative, which is aimed at reducing burden for health care providers, CMS is establishing a simple updated methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). The Overall Star Rating

See MLN SE 12/2, page 10

MLN Connects® Thursday, December 3, 2020

Register for Physician Fee Schedule Call on 12/10

MLN Connects[®] for Thursday, December 3, 2020

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News

- Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge
- CMS Updates Coverage Policies for Artificial Hearts and Ventricular Assist Devices
- PEPPERs for Short-term Acute Care Hospitals: Download December 4 through 14
- Provider Enrollment Application Fee Amount for CY 2021

Compliance

Hospices: Create an Effective Plan of Care

Events

- Hospital Price Transparency Webcast December 8
- Interoperability and Patient Access Final Rule Call December 9

MLN SE 12/2

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summarizes a variety of quality measures published on the Medicare.gov Care Compare tool (the successor to Hospital Compare) for common conditions that hospitals treat, such as heart attacks or pneumonia. Along with publicly reported data on Care Compare, the Overall Star Rating helps patients make better-informed health care decisions. Veterans Health Administration hospitals will be added to CMS' Care Compare, which will help veterans understand hospital quality within the VA system. Overall, these changes will reduce provider burden, improve the predictability of the star ratings, and make it easier for patients to compare ratings between similar hospitals.

In response to stakeholder feedback about the current methodology used to calculate the Overall Star Rating, CMS is not finalizing its proposal to stratify readmission measures under the new methodology based on dually eligible patients, but will continue to study the issue to find Physician Fee Schedule Final Rule: Understanding 4 Key Topics Call — December 10

MLN Matters[®] Articles

 Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2021 — Revised

Publications

- Major Joint Replacement (Hip or Knee) Revised
- Provider Compliance Tips for Tracheostomy Supplies
 Revised

Multimedia

- Diagnosis Coding: Using the ICD-10-CM Web-Based Training Course — Revised
- Procedure Coding: Using the ICD-10-PCS Web-Based Training Course — Revised

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the best way to convey quality of care for this vulnerable population.

Finally, in order to address the ongoing public health emergency, CMS is finalizing a new requirement for the nation's 6,200 hospitals and critical access hospitals to report information about their inventory of therapeutics to treat COVID-19. This reporting will provide the information needed to track and accurately allocate therapeutics to the hospitals that need additional inventory to care for patients and meet surge needs.

For More Information:

- Final Rule
- Fact Sheet

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Medicare Learning Network®

The *Medicare Learning Network*[®] (*MLN*) is the home for education, information, and resources for the health care professional community. The *MLN* provides access to CMS Program information you need, when you need it, so you can focus more on providing care to your patients. Find out what the *MLN* has to offer you and your staff *here*.



MLN Connects[®] – Special Edition – Thursday, December 3, 2020

COVID-19 Antibody Treatment and Enforcement Discretion Reminder

- CMS Takes Further Steps to Ensure Medicare Beneficiaries Have Wide Access to COVID-19 Antibody Treatment
- COVID-19 Vaccines and Monoclonal Antibody Infusion: Enforcement Discretion Relating to SNF Consolidated Billing

CMS Takes Further Steps to Ensure Medicare Beneficiaries Have Wide Access to COVID-19 Antibody Treatment

The U.S. Food and Drug Administration issued an Emergency Use Authorization (EUA) for the investigational monoclonal antibody therapy, casirivimab and imdevimab, administered together, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. Casirivimab and imdevimab, administered together, may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the Emergency Medical System (EMS), as necessary. Review the Fact Sheet for Health Care Providers EUA of Casirivimab and Imdevimab regarding the limitations of authorized use when administered together.

During the COVID-19 Public Health Emergency (PHE), Medicare will cover and pay for these infusions the same way it covers and pays for COVID-19 vaccines (when furnished consistent with the EUA).

CMS identified specific code(s) for the monoclonal antibody product and specific administration code(s) for Medicare payment: Regeneron's Antibody Casirivimab and Imdevimab (REGN-COV2) EUA effective November 21, 2020.

Q0243:

Long descriptor: Injection, casirivimab and imdevimab, 2400 mg Short descriptor: casirivimab and imdevimab

In Case You Missed It: CMS Announces Guidance for Medicare Coverage of COVID-19 Antibody Treatment

On December 9, CMS posted updates to FAQs and an infographic about coverage and payment for monoclonal antibodies to treat COVID-19. The FAQs include general payment and billing guidance for these products, including questions on different setting types. The infographic has key facts about expected Medicare payment to providers and information about how Medicare beneficiaries can receive these innovative COVID-19 treatments with no cost-sharing during the public health emergency (PHE). CMS' November 10, 2020 announcement about coverage of monoclonal antibody therapies allows a broad range of providers and suppliers, including freestanding and hospital-based infusion centers, home health agencies,

M0243:

Long Descriptor: intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring

Short Descriptor: casirivi and imdevi infusion

Additional Resources

- List COVID-19 monoclonal antibody infusion billing codes, payment allowances and effective dates
- Monoclonal Antibody COVID-19 Infusion Program Instruction
- CMS COVID-19 Vaccine Provider Toolkit

COVID-19 Vaccines and Monoclonal Antibody Infusion: Enforcement Discretion Relating to SNF Consolidated Billing

To facilitate the efficient administration of COVID-19 vaccines to Skilled Nursing Facility (SNF) residents, CMS is exercising *enforcement discretion* with respect to statutory provisions requiring consolidated billing by SNFs as well as any associated statutory references and implementing regulations, including as interpreted in pertinent guidance. Through the exercise of this discretion, we will allow Medicare-enrolled immunizers working within their scope of practice and subject to applicable state law, including, but not limited to, pharmacies working with the United States, as well as infusion centers, and home health agencies, to bill directly and receive direct reimbursement from the Medicare program for vaccinating Medicare Part A SNF residents. This enforcement discretion, and accordingly the ability for entities other than the SNF to submit claims for these monoclonal antibody products and their administration furnished to Medicare Part A SNF residents, is limited to the period described in the above-cited enforcement discretion notice.

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MLN Connects[®] – Special Edition – Wednesday, December 9, 2020

nursing homes, and entities with whom nursing homes contract, to administer this treatment in accordance with the Food & Drug Administration's Emergency Use Authorization (EUA), and bill Medicare to administer these infusions. Currently, two monoclonal antibody therapies have received EUA's for treatment of COVID-19.

For More Information:

- Therapeutics Coverage Infographic
- Section BB of the FAQs: billing and payment for COVID-19 monoclonal antibody treatments Monoclonal Antibody COVID-19 Infusion Program Instruction
- Monoclonal toolkit and program guidance

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MLN Connects[®] for Thursday, December 10, 2020

Flu & Pneumonia Vaccines: Protect Your Patients

MLN Connects[®] for Thursday, December 10, 2020

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News

- Flu & Pneumonia Vaccines: Protect Your Patients
- VBID Model: Hospice Benefit Component .
- Open Payments: Review and Dispute Data by . December 31
- Hospital Price Transparency: Requirements Effective Januarv 1
- Annual Participation Enrollment Period Extended to January 31
- 2020 MIPS Extreme and Uncontrollable **Circumstances Exception Application: Deadline** February 1
- COVID-19: Hospital Operations Toolkit

Compliance

Telehealth Services: Bill Correctly

Claims, Pricers & Codes

- ICD-10 MS-DRG Grouper V38.1 & 2021 ICD-10-PCS • Code Files
- Average Sales Price Files: January 2021

Events

CMS-CDC Fundamentals of COVID-19 Prevention for Nursing Home Management Call — December 10 & January 7

MLN Matters[®] Articles

Update to Rural Health Clinic (RHC) All Inclusive Rate (AIR) Payment Limit for Calendar Year (CY) 2021

CMS Proposes New Rules to Address Prior Authorization and Reduce Burden on **Patients and Providers**

On December 10, under President Trump's leadership, CMS issued a proposed rule that would improve the electronic exchange of health care data among payers, providers, and patients and streamline processes related to prior authorization to reduce burden on providers and patients. By both increasing data flow and reducing burden, this proposed rule would give providers more time to focus on their patients and provide better quality care.



- Update to the Federally Qualified Health Center (FQHC) Prospective Payment System (PPS) for Calendar Year (CY) 2021 - Recurring File Update
- New & Expanded Flexibilities for RHCs & FQHCs during the COVID-19 PHE - Revised
- Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2020 - Revised
- Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2021 — Revised

Publications

- Medicare Provider Enrollment Revised
- Provider Compliance Tips Revised

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MLN Connects[®] – Special Edition – Thursday, December 10, 2020

For More Information:

- Proposed Rule: Comment period closes January 4
- Full press release
- Fact sheet
- Blog
- CMS Interoperability and Patient Access Final Rule webpage
- Register for December 16 listening session

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MLN Connects[®] for Thursday, December 17, 2020

Physician Fee Schedule Final Rule Summary: Telehealth, Preventive Services & More

MLN Connects® for December 17, 2020

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News

- MLN Web-Based Training: Complete Training & Save Certificates by January 31
- IRF Quality Reporting Program: December Refresh
- LTCH Quality Reporting Program: December Refresh
- COVID-19: Stress & Resilience, Crisis Standards of Care
- COVID-19: Designated Hospitals Lessons Learned and Patient Surge Management Strategies

Compliance

Ambulance Fee Schedule and Medicare Transports

MLN Matters® Articles

 2021 Annual Update of Per-Beneficiary Threshold Amounts

- CY 2021 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
- Summary of Policies in the Calendar Year (CY) 2021 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, CT Modifier Reduction List, and Preventive Services List
- International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--April 2021 — Revised

Publications

- Opioid Treatment Programs (OTPs) Medicare Enrollment — Revised
- Opioid Treatment Programs (OTPs) Medicare Billing and Payment — Revised

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MLN Connects® – Special Edition – Friday, December 18, 2020

Monitoring for Hospital Price Transparency

Hospital Price Transparency requirements go into effect January 1, 2021. CMS plans to audit a sample of hospitals for compliance starting in January, in addition to investigating *complaints that are submitted to CMS* and reviewing analyses of non-compliance, and hospitals may face civil monetary penalties for noncompliance.

Is your institution prepared to comply with the requirements of the *Hospital Price Transparency Final Rule*? Effective January 1, 2021, each hospital operating in the United States is required to provide publicly accessible standard charge information online about the items and services they provide in 2 ways:

- Comprehensive machine-readable file with all items and services
- Display of 300 shoppable services in a consumerfriendly format

In the final rule, CMS outlined a monitoring and enforcement plan to ensure compliance with the requirements. We finalized a policy that CMS monitoring activities may include, but would not be limited to, the following, as appropriate:

- Evaluation of complaints made by individuals or entities to CMS
- Review of individuals' or entities' analysis of noncompliance
- Audit of hospital websites

If we conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, we may take any of the following actions, which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s)
- Request a Corrective Action Plan (CAP) if noncompliance constitutes a material violation of one or more requirements
- Impose a civil monetary penalty not in excess of \$300 per day and publicize the penalty on a CMS website if the hospital fails to respond to our request to submit a CAP or comply with the requirements of a CAP

See 45 CFR part 180 Subpart C- Monitoring and Penalties for Noncompliance.

Visit the *Hospital Price Transparency* website for additional information and resources to help hospitals prepare for compliance, including:

- FAQs (PDF)
- 8 Steps to a Machine-Readable File (PDF)
- 10 Steps to a Consumer-Friendly Display (PDF)
- Quick Reference Checklists (PDF).

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MLN Connects® – Special Edition – Friday, December 18, 2020

COVID-19: Add-on payment for new treatments

CMS issued an *Interim Final Rule with Comment Period*, which established the New COVID-19 Treatments Addon Payment (NCTAP) under the Medicare Inpatient Prospective Payment System (IPPS), effective from November 2, 2020, until the end of the Public Health Emergency (PHE) for COVID-19. To mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments during the COVID-19 PHE, the Medicare program will provide an enhanced payment for eligible inpatient cases that involve use of certain new products with current Food and Drug Administration approval or emergency use authorization to treat COVID-19. Visit the *NCTAP* webpage for more information.



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Updates to nursing and allied health education Medicare Advantage payment policies

Transmittal 10486, dated November 19, 2020, is being rescinded and replaced by transmittal 10520, dated December 14, 2020, to revise the implementation date from December 14, 2020, to December 21, 2020. All other information remains the same.

https://www.cms.gov/files/document/r10520otn.pdf

Contact Information

First Coast Service Options Phone Numbers

(Note: Specific geographic contact information is noted when phone numbers and addresses are different for providers in Florida, U.S. Virgin Islands or Puerto Rico.

Customer service

Monday to Friday 8:00 a.m. to 4:00 p.m 888-664-4112 (FL/USVI) 877-908-8433 (Puerto Rico) 877-660-1759 (TDD-FL/USVI) 888-216-8261 (TDD-Puerto Rico)

Electronic data interchange 888-670-0940 (FL/USVI) 888-875-9779 (Puerto Rico)

Interactive Voice Response 877-602-8816

Overpayments 904-791-6029

SPOT Help Desk FCSOSPOTHelp@fcso.com

855-416-4199

Provider websites English

Spanish

First Coast Service Options Addresses

Claims/correspondence

Florida/ U.S. Virgin Islands

First Coast Service Options Inc. Medicare Part A Claims 2020 Technology Parkway Suite 100 Mechanicsburg, PA 17050-9419

Puerto Rico

First Coast Service Options Medicare Part A Claims PR P.O. Box 2001 Mechanicsburg, PA 17055-0733

Medicare EDI Electronic claim filing

First Coast Service Options Inc. Attention: JN EDI PO Box 3703 Mechanicsburg, PA 17055-1861

Fraud and abuse

First Coast Service Options Inc. JN Part A and B Complaint Processing Unit P.O. Box 3419 Mechanicsburg, PA 17055-1859

FOIA requests Provider audit/reimbursement

(relative to cost reports and audits) JN FOIA requests P.O. Box 3425 Mechanicsburg, PA 17055-1825

General Inquiries Online Form (Click here) EDOC-CS-FLINQA@fcso.com (FL/USVI)

EDOC-CS-PRINQA@fcso.com (PR)

Local coverage determinations

First Coast Service Options Medical Affairs 2020 Technology Parkway Suite 100 Mechanicsburg, PA 17050-941

Medicare secondary payer (MSP)

JN Part A Florida Debt Recovery and Check Mail P.O Box 3162 Mechanicsburg, PA 17055-1837

Hospital audits

JN Part A Florida Debt Recovery and Check Mail P.O Box 3162

Mechanicsburg, PA 17055-1837

MSPRC DPP debt recovery, auto accident settlements/lawsuits, liabilities First Coast Service Options Inc. P.O. Box 3162 Mechanicsburg, PA 17055-1837

Overpayment collections and

debt recovery

Repayment, cost reports, receipts and acceptances, tentative settlement determinations, provider statistical and reimbursement reports, cost report settlement, TEFRA target limit and SNF routine cost limit exceptions

First Coast Service Options Inc. JN Provider Audit & Reimbursement 2020 Technology Parkway, Suite 100 Mechanicsburg, PA 17050

Credit balance reports

First Coast Service Options Inc. Medicare Part A Debt Recovery 2020 Technology Parkway Suite 100 Mechanicsburg, PA 17050

Post-pay medical review

Part A and Part B Post Pay Medical Review P.O. Box 3701 Mechanicsburg, PA 17055-1860

Provider enrollment

CMS-855 Applications P. O. Box 3409

Mechanicsburg, PA 17055-1849

Special or overnight deliveries Provider Enrollment 2020 Technology Parkway Suite 100 Mechanicsburg, PA 17050

Redetermination

Florida: First Coast Service Options JN Redeterminations Part A/B FL P.O. Box 3411

Mechanicsburg, PA 17055-1851

U.S. Virgin Islands:

First Coast Service Options JN Redeterminations Part A/B P.O. Box 3412 Mechanicsburg, PA 17055-1851 **Puerto Rico**

First Coast Service Options JN Redeterminations Part A/B P.O. Box 3412 Mechanicsburg, PA 17055-1851

Special delivery/courier services

First Coast Service Options Inc. Medicare Part A Claims 2020 Technology Parkway Suite 100 Mechanicsburg, PA 17050-9419

Other Medicare carriers and intermediaries

DME regional carrier (DMERC)

DME, orthotic, prosthetic device, takehome supply, oral anti-cancer drug claims CGS Administrators, LLC P. O. Box 20010 Nashville, Tennessee 37202

Railroad Medicare

Palmetto GBA P. O. Box 10066 Augusta, GA 30999-0001

Regional home health/hospice intermediary

Palmetto GBA Medicare Part A 34650 US HWY 19N Palm Harbor, FL 34684

Contact CMS

Centers for Medicare & Medicaid Services (CMS)

Centers for Medicare & Medicaid Services, Division of Financial Management and Fee for Service Operations

ROATLFM@CMS.HHS.GOV

Office of Inspector General (OIG) Medicare fraud hotline 800-HHS-TIPS (800-447-8477)

Beneficiary customer service

1-800-MEDICARE (1-800-633-4227)

Hearing and speech impaired (TDD) 1-800-754-7820