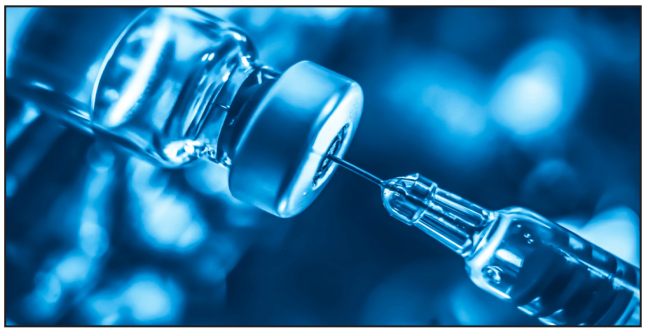
Medicare B CONNECTION
medicare.fcso.com
FIRST COAST SERVICE OPTIONS, INC.
A Newsletter for MAC Jurisdiction N Providers
December 2020

In this issue

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

Contents

The *Medicare B Connection* is published monthly by First Coast Service Options Inc.'s Provider Outreach & Education division to provide timely and useful information to Medicare Part B providers.

Articles included in the *Medicare B 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.

About the Medicare B Connection

The *Medicare B Connection* is a comprehensive publication developed by First Coast Service Options Inc. (First Coast) for Part B providers in Florida, Puerto Rico, and the U.S. Virgin Islands and is distributed on a monthly basis.

Important notifications that require communication in between publications will be posted to the First Coast Medicare *provider education website*. In some cases, additional unscheduled special issues may be posted.

Who receives the *Connection*

Anyone may view, print, or download the *Connection* from our provider education website(s). Providers who cannot obtain the *Connection* from the internet are required to register with us to receive a complimentary hardcopy.

Distribution of the *Connection* in hardcopy is limited to providers who have billed at least one Part B claim to First Coast Medicare during the twelve months prior to the release of each issue. Providers meeting these criteria are eligible to receive a complimentary copy of that issue, if a technical barrier exists that prevents them from obtaining it from the internet and they have returned a completed registration form to us.

Registration forms must be submitted annually or when you experience a change in circumstances that impacts your electronic access.

For additional copies, providers may purchase a separate annual subscription (see order form in the back of this issue). All issues published since 1997 may be downloaded from the internet, free of charge.

We use the same mailing address for all correspondence, and cannot designate that the *Connection* be sent to a specific person/department within a provider's office. To ensure continued receipt of all Medicare correspondence, providers must keep their addresses current with the Medicare provider enrollment department. Please remember that address changes must be done using the appropriate CMS-855.

Publication format

The *Connection* is arranged into distinct sections.

- The **Claims** section provides claim submission requirements and tips.
- The **Coverage/Reimbursement** section discusses specific CPT® and HCPCS procedure codes. It is arranged by categories (not specialties). For example,

"Mental Health" would present coverage information of interest to psychiatrists, clinical psychologists and clinical social workers, rather than listing articles separately under individual provider specialties. Also presented in this section are changes to the Medicare physician fee schedule, and other pricing issues.

- The section pertaining to **Electronic Data Interchange** (EDI) submission also includes information pertaining to the Health Insurance Portability and Accountability Act (HIPAA).
- The **Local Coverage Determination** section features summaries of new and revised local coverage determinations (LCDs) developed as a result of either local medical review or comprehensive data analysis initiatives.
- The **General Information** section includes fraud and abuse, and national provider identifier topics, plus additional topics not included elsewhere.
- In addition to the above, other sections include:
- **Educational Resources**, and
- **Contact information** for Florida, Puerto Rico, and the U.S. Virgin Islands.

The *Medicare B Connection* represents formal notice of coverage policies

Articles included in each edition represent formal notice that specific coverage policies either have or will take effect on the date given. Providers are expected to read, understand, and abide by the policies outlined in this document to ensure compliance with Medicare coverage and payment guidelines.

Never miss an appeals deadline again

When it comes to submitting a claims appeal request, *timing is everything*. Don't worry – you won't need a desk calendar to count the days to your submission deadline. Try our *"time limit" calculators on our Appeals of claim decisions page*. Each calculator will *automatically calculate* when you must submit your request based upon the date of either the initial claim determination or the preceding appeal level.

Medicare Part B advance beneficiary notices

Medicare Part B allows coverage for services and items deemed medically reasonable and necessary for treatment and diagnosis of the patient.

For some services, to ensure that payment is made only for medically necessary services or items, coverage may be limited based on one or more of the following factors (this list is not inclusive):

- Coverage for a service or item may be allowed only for specific diagnoses/conditions. Always code to the highest level of specificity.
- Coverage for a service or item may be allowed only when documentation supports the medical need for the service or item.
- Coverage for a service or item may be allowed only when its frequency is within the accepted standards of medical practice (i.e., a specified number of services in a specified timeframe for which the service may be covered).

If the provider believes that the service or item may not be covered as medically reasonable and necessary, the patient must be given an acceptable advance notice of Medicare's possible denial of payment if the provider does not want to accept financial responsibility for the service or item. Advance beneficiary notices (ABNs) advise beneficiaries, before items or services actually are furnished, when Medicare is likely to deny payment.

Patient liability notice

The Centers for Medicare & Medicaid Services' (CMS) has developed the Advance Beneficiary Notice of Noncoverage (ABN) (Form CMS-R-131), formerly the "Advance Beneficiary Notice." Section 50 of the *Medicare Claims Processing Manual* provides instructions regarding the notice that these providers issue to beneficiaries in advance of initiating, reducing, or terminating what they believe to be noncovered items or services. The ABN must meet all of the standards found in Chapter 30. Beginning March 1, 2009, the ABN-G and ABN-L was no longer valid; and notifiers must use the revised Advance Beneficiary Notice of Noncoverage (CMS-R-131). *Section 50 of the Medicare Claims Processing Manual*.

Reproducible copies of Form CMS-R-131 ABNs (in English and Spanish) and other BNI information may be found *here*.

ABN modifiers

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting modifier GA (waiver of liability statement on file) or GZ (item or service expected to be denied as not reasonable and necessary) with the service or item.

Failure to report modifier GA in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

Modifier GZ may be used in cases where a signed ABN is not obtained from the patient; however, when modifier GZ is billed, the provider assumes financial responsibility if the service or item is denied.

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

GA modifier and appeals

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting the modifier GA (waiver of liability statement on file).

Failure to report modifier GA in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

Nonassigned claims containing the modifier GA in which the patient has been found liable must have the patient's written consent for an appeal. Refer to the applicable contact section located at the end of this publication for the address in which to send written appeals requests.

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 *self-administered 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*.

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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

CCM: Principal care management services (B)

Date: January 27
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®

CMS 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

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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
- 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

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

Compliance

- Polysomnography Services: Bill Correctly

Claims, Pricers & Codes

- Medicare Diabetes Prevention Program: Valid Claims

Events

- 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)"

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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 non-physician 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

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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 decision-making (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 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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- 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 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

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.

"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."

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 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 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 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 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

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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
- 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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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 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*

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

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.

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

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, 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*

MLN Connects® for Thursday, December 10, 2020

Flu & Pneumonia Vaccines: Protect Your Patients

MLN Connects® for Thursday, December 10, 2020

View this edition as a PDF

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 January 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

- 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

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

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.

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*

MLN Connects® for Thursday, December 17, 2020

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

MLN Connects® for December 17, 2020

View this edition as a PDF

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

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 consumer-friendly 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*.

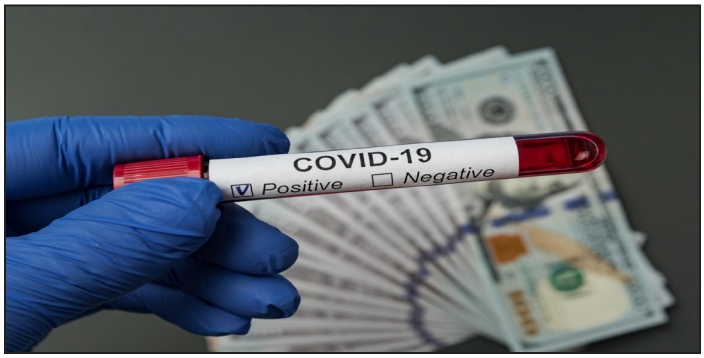
Visit the *Hospital Price Transparency* website for additional information and resources to help hospitals prepare for compliance, including:

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

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 Add-on 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.



Where do I find...

Looking for something specific and don't know where to find it? Find out how to perform routine tasks or locate information that visitors frequently visit our site to accomplish or find. Check out the "Where do I find" page.

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Provider Contant Center
866-454-9007
877-660-1759 (speech and hearing impaired)

Electronic data interchange (EDI)
888-670-0940

Fax number (for general inquiries)
904-361-0696

Interactive voice response (IVR) system
877-847-4992

Provider enrollment
888-845-8614
877-660-1759 (TTY)
FAX: 904-361-0737

The SPOT help desk
855-416-4199
FCSOSPOTHelp@FCSO.com

Addresses

Claims
First Coast Service Options
Part B Claims and Claims ADR FL P.O. Box 2009
Mechanicsburg, PA 17055-0709

Redeterminations
Medicare Part B Redetermination
P.O. Box 3411
Mechanicsburg, PA 17055-1850

Redetermination of overpayments
First Coast Service Options Inc.
Overpayment Redetermination, Review Request
P.O. Box 3411
Mechanicsburg, PA 17055-1850

Reconsiderations
C2C Innovative Solutions Inc.
QIC Part B South
P.O. Box 45300
Jacksonville, FL 32232-5300

General inquiries
General inquiry request
P.O. Box 3411
Mechanicsburg, PA 17055-1850
EDOC-CS-FLINQB@fcso.com>>
Online form

Provider enrollment
Provider Enrollment
P.O. Box 3409
Mechanicsburg, PA 17055-1849

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

Medical Affairs
First Coast Service Options
Medical Affairs
2020 Technology Parkway
Suite 100
Mechanicsburg, PA 17050-9419
medicalaffairs@guidewellsource.com

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Mechanicsburg, PA 17055-0709

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

Overpayments
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JN Part B Florida Debt Recovery and Check Mail
P.O. Box 3092
Mechanicsburg, PA 17055-1810

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FAX: 904-361-0407
elearning@fcso.com

Fraud and abuse
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JN Part A and B Complaint Processing Unit P.O. Box 3419
Mechanicsburg, PA 17055-1859

Freedom of Information Act requests
JN FOIA requests
P.O. Box 3425
Mechanicsburg, PA 17055-1825

Overnight mail and/or special courier service
First Coast Service Options Inc.
Attention: (Dept. or Work Type)
2020 Technology Parkway
Suite 100
Mechanicsburg, Pa 17050-9419

Websites

Provider
First Coast Service Options Inc. (First Coast), your CMS-contracted Medicare administrative contractor

Find your *other contractors* (e.g. DME, HHA, etc)
Centers for Medicare & Medicaid Services

E-learning Center
First Coast University

Beneficiaries
Centers for Medicare & Medicaid Services
medicare.gov

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First Coast Service Options
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Mechanicsburg, PA 17055-1851

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Mechanicsburg, PA 17055-1861

Overpayments

First Coast Service Options
JN Part B Puerto Rico and Virgin
Islands Debt Recovery and Check Mail
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medicare.gov

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Provider Contact Center
1-877-715-1921
1-888-216-8261 (speech and hearing impaired)

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Language preference: **English** [ ] **Español** [ ]				
Please write legibly			Subtotal	$
			Tax (***add % for your area***)	$
			Total	$

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