Medicare Bulletin

Jurisdiction 15

Reaching Out to the Medicare Community

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NEW MEDICARE BENEFICIARY IDENTIFIER (MBI) GET IT! USE IT! 
#NewCardNewNumber 

Contact Information for CGS Medicare Part B
To contact a CGS Customer Service Representative, call the CGS Provider Contact Center at 1.866.276.9558 and choose Option 1. Access the Kentucky & Ohio Part B “Contact Information” Web page at https://www.cgsmedicare.com/partb/cs/index.html for information about the Interactive Voice Response (IVR) system, as well as telephone numbers, fax numbers, and mailing addresses for other CGS departments.

MEDICARE BULLETIN GR 2019-05
MAY 2019

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Articles contained in this edition are current as of March 29, 2019.
Kentucky & Ohio Provider Contact Center (PCC) Training

Medicare is a continuously changing program, and it is important that we provide correct and accurate answers to your questions. To better serve the provider community, the Centers for Medicare & Medicaid Services (CMS) allows the provider contact centers the opportunity to offer training to our customer service representatives (CSRs). The list below indicates when the CGS Part B PCC (1.866.276.9558) will be closed for CSR training and staff development.

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<thead>
<tr>
<th>Date</th>
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<tr>
<td>Thursday, May 9, 2019</td>
<td>PCC Closed 9:00 – 11:00 a.m. Eastern Time</td>
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<td>Thursday, May 23, 2019</td>
<td>PCC Closed 9:00 – 11:00 a.m. Eastern Time</td>
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<td>Monday, May 27, 2019</td>
<td>Office Closed, Memorial Day</td>
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The Interactive Voice Response (IVR) (1.866.290.9481) is available for assistance in obtaining patient eligibility information, claim and deductible information, and general information. For information about the IVR, access the IVR User Guide at https://www.cgsmedicare.com/partb/cs/partb_ivr_user_guide.pdf on the CGS website. In addition, CGS’ Internet portal, myCGS, is available to access eligibility information through the Internet. For Additional Information, go to https://www.cgsmedicare.com/partb/index.html and click the “myCGS” button on the left side of the Web page.


Kentucky & Ohio Upcoming Educational Events

The CGS Provider Outreach and Education (POE) department offers educational events through webinars and teleconferences throughout the year. Registration for these events is required. For upcoming events, please refer to the Part B Calendar of Events Home page at https://www.cgsmedicare.com/medicare_dynamic/wrksht/pr/prtb_report.asp. CGS suggests that you bookmark this page and visit it often for the latest educational opportunities.

If you have a topic that you would like the CGS POE department to present, send us your suggestion to J15_PartB_Education@cgsadmin.com.
Kentucky & Ohio

New Local Coverage Determination Policy

CGS Administrators, LLC has two new policies that will take effect on April 1, 2019 and May 6, 2019. They are currently in notice period and all comments received are in the response to comment article that is attached to policies.

- MolDX: Breast Cancer Index™ (BCI) Gene Expression Test L37832 will be effective on April 1, 2019
- MolDX: MDS FISH L37608 will be effective on May 6, 2019.

Both policies will be available on the Medicare Coverage Database March 21, 2019.

Kentucky & Ohio

MM10865 Revised: NCD 20.4 Implantable Cardiac Defibrillators (ICDs)

MLN Matters Number: MM10865 Revised
Related CR Transmittal Number: R213NCD
Effective Date: February 15, 2018
Implementation Date: March 26, 2019 - MAC local edits

Provider Types Affected

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

CR 10865 and the Medicare National Coverage Determinations (NCD) Manual Transmittal reflects the Centers for Medicare & Medicaid Services (CMS) final decision dated February 15, 2018, regarding the reconsideration of NCD 20.4, Implantable Defibrillators (ICDs). Make sure your billing staffs are aware of this decision. Effective February 15, 2018, coverage policy is no longer contingent on participation in a trial/study/registry. Therefore, claims with a Date of Service (DOS) on an after February 15, 2018, no longer require any trial-related coding.

Background

An ICD is an electronic device designed to diagnose and treat life-threatening Ventricular Tachyarrhythmias (VTs). The device consists of a pulse generator and electrodes for sensing and defibrillating. This therapy has been shown in trials to improve survival and reduce sudden cardiac death in patients with certain clinical characteristics.

Section 20.4 of the Medicare NCD Manual establishes conditions of coverage for ICDs. In 1986, CMS first issued an NCD providing limited coverage of ICDs and the policy has been expanded over the years. CMS last reconsidered this NCD in 2005. Effective for claims with dates of service on or after February 15, 2018, CMS will cover ICDs for the following patient indications:

1. Patients with a personal history of sustained VT or cardiac arrest due to Ventricular Fibrillation (VF). Patients must have demonstrated:
   - An episode of sustained VT, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause; or
   - An episode of cardiac arrest due to VF, not due to a transient or reversible cause.

2. Patients with a prior MI and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
   - New York Heart Association (NYHA) classification IV heart failure; or,
- Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or,
- Had an MI within the past 40 days; or,
- Clinical symptoms and findings that would make them a candidate for coronary revascularization.

3. Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have New York Heart Association (NYHA) Class II or III heart failure, LVEF < 35%. Additionally, patients must not have:
   - Had a CABG, or PCI with angioplasty and/or stenting, within the past 3 months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

4. Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of cardiac arrest or sustained VT, NYHA Class II or III heart failure, LVEF < 35%, and been on optimal medical therapy for at least 3 months. Additionally, patients must not have:
   - Had a CABG or PCI with angioplasty and/or stenting, within the past 3 months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

5. Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.

For these patients identified in items 2 through 5 above, a formal shared decision-making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in Section 1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision-making encounter may occur at a separate visit.

For each of the 6 covered indications above, the following additional criteria must also be met:

1. Patients must be clinically stable (for example, not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
3. Patients must not have:
   - Significant, irreversible brain damage; or,
   - Any disease, other than cardiac disease (for example, cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or,
   - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Exceptions to waiting periods for patients that have had a CABG or PCI with angioplasty and/or stenting within the past 3 months, or had an MI within the past 40 days:

- Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in NCD 20.4 for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated;
• Replacement of ICDs: Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, ERI, or device/lead malfunction.

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, as with cardiac resynchronization therapy, when used as a bridge-to-transplant to prolong survival until a donor becomes available, MACs determine coverage of ICDs.

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B investigational device exemption (IDE) trials per regulation at 42 CFR 405.201.

Additional Information


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

Document History

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<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>February 26, 2019</td>
<td>We revised this article to reflect a revised CR10865 issued on February 15. CMS revised the CR to change the implementation date to March 26, 2019, and we revised the article accordingly. Also, we revised the CR release date, transmittal number, and the Web address of the CR. All other information is unchanged.</td>
</tr>
<tr>
<td>December 17, 2018</td>
<td>The article was revised to reflect a revised CR10865 issued on December 13. In the article, two sentences are added at the end of the Provider Action Needed section to emphasize that this coverage policy no longer requires trial-related coding on claims for dates of service on or after February 15, 2018. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information is unchanged.</td>
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<tr>
<td>December 3, 2018</td>
<td>This article was revised on December 3, 2018, to correct the implementation date in the banner above. That date should be February 26, 2019.</td>
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Kentucky & Ohio

MM10878 Revised: National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)

MLN Matters Number: MM10878 Revised
Related CR Transmittal Number: R214NCD
Effective Date: March 16, 2018
Related CR Release Date: March 6, 2019
Related Change Request (CR) Number: 10878
Implementation Date: April 8, 2019 - A/B MACs

Note: We revised this article on March 13, 2019, to reflect the revised CR 10878 issued on March 6. In this article, we revised the CR implementation date, the CR release date, transmittal number, and the web address of the CR. All other information remains the same.

Provider Type Affected

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 10878 informs, effective March 16, 2018, the Centers for Medicare & Medicaid Services (CMS) covers diagnostic laboratory tests using next generation sequencing when performed in a Clinical Laboratory Improvement Amendments- certified laboratory when ordered by a treating physician and when specific requirements are met. Make sure your billing staffs are aware of this change.
This revision to the “Medicare National Coverage Determinations Manual” is a national coverage determination (NCD). NCDs are binding on MACs with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR Section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

Background
Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. In vitro companion diagnostic laboratory tests provide a report of test results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product. NGS is one technique that can measure one or more genetic variation as a laboratory diagnostic test, such as when used as a companion in vitro diagnostic test.

Patients with advanced cancer can have recurrent, relapsed, refractory, metastatic, and/or stages III or IV of cancer. Clinical studies show that genetic variations in a patient’s cancer can, in concert with clinical factors, predict how each individual responds to specific treatments.

In application, a report of results of a diagnostic laboratory test using NGS (that is, information on the cancer’s genetic variations) can contribute to predicting a patient’s response to a given drug: good, bad, or none at all. Applications of NGS to predict a patient’s response to treatment occurs ideally prior to initiation of the drug.

CMS reviewed the evidence for laboratory diagnostic tests using NGS in patients with cancer, and determined that such tests with analytical and clinical validity, and clinical utility, could also improve health outcomes for Medicare beneficiaries with advanced cancer. Therefore, CMS shall cover certain diagnostic laboratory tests using NGS when requirements are met.

Effective for claims with dates of service on or after March 16, 2018, CMS has determined that the evidence is sufficient to cover diagnostic laboratory tests that use NGS under specified conditions. CMS will cover such testing under the Medicare program for beneficiaries with recurrent, relapsed, refractory, metastatic cancer, or advanced stages III or IV cancer if the beneficiary has either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician, and decided to seek further cancer treatment (for example, therapeutic chemotherapy). The test must be ordered by the treating physician, performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, and have all of the following requirements met:

- Food & Drug Administration (FDA) approval or clearance as a companion in vitro diagnostic;
- An FDA-approved or -cleared indication for use in that patient’s cancer; and,
- Results provided to the treating physician for management of the patient using a report template to specify treatment options.

Additionally, MACs may determine coverage of other diagnostic laboratory tests using NGS for patients with cancer only when the test is performed in a CLIA-certified laboratory, ordered by the treating physician and the patient has:

- Either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and,
- Either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and,
- Decided to seek further cancer treatment (for example, therapeutic chemotherapy).
A diagnostic laboratory test using NGS is non-covered when cancer patients do not have the above-noted indications for cancer under either national or local coverage criteria.

**Additional Information**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

**Document History**

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**Kentucky & Ohio**

**MM10907 Revised**

**Next Generation Accountable Care Organization (NGACO) Model Post Discharge Home Visit HCPCS**

<table>
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<th>MLN Matters Number: MM10907 Revised</th>
<th>Related CR Release Date: December 21, 2018</th>
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<td>Related CR Transmittal Number: R216DEMO</td>
<td>Related Change Request (CR) Number: 10907</td>
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<tr>
<td>Effective Date: January 1, 2019</td>
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**Note:** We revised this article on March 7, 2019, to reflect a revised CR10907 issued on December 21, 2018. The CR revisions had no impact on the substance of the article. However, we revised the article to show a revised CR release date, transmittal number, and web address of the CR. All other information remains the same.

**Provider Types Affected**

This MLN Matters® Article is for providers who are participating in Next Generation Accountable Care Organizations (NGACOs) and submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

**Provider Action Needed**

CR10907 makes modifications to the operations of a current benefit enhancement offered by the NGACO Model. Claims for Post Discharge Home Visit Waiver shall be processed for reimbursement and paid when they meet the appropriate payment requirements as outlined in CR10907. Make sure your billing staffs are aware of these changes.

**Background**

The Social Security Act (the Act) (Section 1115A; [https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm](https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm)) added by the Affordable Care Act (Section 3021; 42 U.S.C. 1315a; [https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf](https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf)) authorizes the Centers for Medicare & Medicaid Services (CMS) to test innovative health care payment and service delivery models that have the potential to lower Medicare, Medicaid, and the Child Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries’ care.

The aim of the NGACO Model is to improve the quality of care, population health outcomes, and patient experience for beneficiaries who choose traditional Medicare Fee-for-Service (FFS).
benefit provides greater alignment of financial incentives and greater access to tools that may aid beneficiaries and providers in achieving better health at lower costs.

In order to emphasize high-value services and support the ability of ACOs to manage the care of beneficiaries, CMS is issuing the authority under Section 1115A of the Act (added by Section 3021 of the Affordable Care Act) to conditionally waive certain Medicare payment requirements as part of the NGACO Model. An ACO may choose not to implement all or any of these benefit enhancements. Applicants will be asked questions specific to their proposed implementation of these benefit enhancements, but acceptance into the NGACO Model is not contingent upon an ACO implementing any particular benefit enhancement.

Participants in the NGACO Model are required to provide implementation information to CMS, which, upon approval, will enable the ACO’s use of the optional benefit enhancements. Each optional benefit enhancement will have such an “implementation plan” requiring, for example:

1. Descriptions of the ACO’s planned strategic use of the benefit enhancement
2. Self-monitoring plans to demonstrate meaningful efforts to prevent unintended consequences
3. Documented authorization by the governing body to participate in the benefit enhancement

Note: RTI International is the specialty contractor creating the Next Generation ACO provider alignment files.

For dates of service of April 1, 2019, and later, MACs will allow NGACO, including the Vermont (VT) ACO, post discharge home visit claims for licensed clinicians under the general supervision of an NGACO or VT ACO provider when this benefit enhancement is elected by the provider for the Date of Service (DOS) on the claims and only when the claim contains the following HCPCS codes: G2001; G2002; G2003; G2004; G2005; G2006; G2007; G2008; G2009; G2013; G2014; and G2015. This applies to Type of Bill (TOB) 85X, Rev Codes 96X; 97X; and 98X.

The payment rate for these HCPCS codes will be in the annual Medicare Physician Fee Schedule (MPFS). Medicare will reimburse Critical Access Hospital Method II providers billing on TOB 85X with Revenue codes 96X, 97X, and 98X based on the lesser of the billed charge or the MPFS rate.

Note that MACs will reject or return as unprocessable if a claim or if separate claims with the same DOS contains a Post Discharge Home Visit HCPCS code and a Care Management Home Visit HCPCS code.

Additional Information


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

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<td>We revised this article to reflect a revised CR10907 issued on December 21, 2018. The CR revisions had no impact on the substance of the article. However, we revised the article to show a revised CR release date, transmittal number, and web address of the CR. All other information remains the same.</td>
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<tr>
<td>November 29, 2018</td>
<td>The article was revised to reflect a revised CR10907 issued on November 28. The CR was revised to show the correct HCPCS codes of G2001 - G2009 and G2013 - G2015 for NGACO Model Post Discharge Home Visits. The article was revised accordingly. Also, the CR release date, transmittal number, and the Web address of the CR are revised in the article. All other information remains the same.</td>
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Kentucky & Ohio

MM11135: Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits

MLN Matters Number: MM11135
Related CR Transmittal Number: R4245CP
Effective Date: January 1, 2019

Provider Type Affected
This MLN Matters Article is intended for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed
CR11135 informs providers and MACs about the new HCPCS codes for 2019 that are subject to and excluded from Clinical Laboratory Improvement Amendments (CLIA) edits. Make sure your billing staffs are aware of these updates.

Background
The HCPCS codes that are considered a laboratory test under CLIA change each year. The following HCPCS codes were discontinued on December 31, 2017:

- 0004U - Test for detecting genes associated with antibiotic resistance in bacterial culture
- 0015U - Test for detecting genes associated with drug metabolism in blood or cheek swab.

The following HCPCS codes were discontinued on September 30, 2018:

- 0020U - Testing for presence of drug in urine with confirmation of positive results and specimen verification
- 0028U, Gene analysis (cytochrome P450, family 2, subfamily D, polypeptide 6) for copy number variants and common variants with follow-up targeted sequence analysis

The following HCPCS codes were discontinued on December 31, 2018:

- 78270 - Vitamin B-12 absorption study
- 78271 - Vitamin B-12 absorption study with factor necessary for absorption
- 78272 - Vitamin B-12 absorption study without then with factor necessary for absorption
- 81211 - Gene analysis (breast cancer 1 and 2) full sequence and common duplication or deletion variants
- 81213 - Gene analysis (breast cancer 1 and 2) uncommon duplication or deletion variants
- 81214 - Gene analysis (breast cancer 1) full sequence and common duplication or deletion variants

The following HCPCS codes are excluded from CLIA edits, and do not require a facility to have any CLIA certificate:

- 0061U - Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin – Effective July 1, 2018; and
- 0079U - Comparative Deoxyribonucleic Acid (DNA) analysis using multiple selected Single-Nucleotide Polymorphisms (SNPs), urine and buccal DNA, for specimen identity verification – Effective October 1, 2018.
The HCPCS codes listed below were added on October 1, 2017, were not mentioned in a previous transmittal, and are subject to CLIA edits. The HCPCS codes listed below require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) must not be permitted to be paid for these tests.

- **0018U** - Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy A3;
- **0019U** - Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents;
- **0021U** - Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5’-UTR-BM1, CEP 164, 3’-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score;
- **0022U** - Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider; and
- **0023U** - Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin.

The HCPCS code, **0011M**, Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk, was added on January 1, 2018, was not mentioned in a previous transmittal, and is subject to CLIA edits. This HCPCS code requires a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) will not be paid for these tests.

The HCPCS codes listed below were added on April 1, 2018, and are subject to CLIA edits. The HCPCS codes listed below require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) will not be paid for these tests.

- **0012M** - Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (mdk, hoxa13, cdc2 [cdk1], igfbp5, and ccr2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma
- **0013M** - Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (mdk, hoxa13, cdc2 [cdk1], igfbp5, and ccr2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma
- **0035U** - Testing for presence of prion protein in cerebrospinal fluid
- **0036U** - Exome gene analysis for somatic mutation in tumor tissue
- **0037U** - DNA gene analysis of 324 genes in solid organ tumor tissue
- **0038U** - Measurement of vitamin D in serum
- **0039U** - Testing for anti-DNA antibody
The HCPCS codes listed below were added on July 1, 2018, and are subject to CLIA edits. The HCPCS codes listed below require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) will not be paid for these tests.

- 0040U - BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative
- 0041U - IgM antibody detection test for Borrelia burgdorferi
- 0042U - IgG antibody detection test for Borrelia burgdorferi
- 0043U - IgM antibody detection test for Tick-Borne Relapsing Fever Borrelia group
- 0044U - IgG antibody detection test for Tick-Borne Relapsing Fever Borrelia group

The HCPCS codes listed below were added on October 1, 2018, and are subject to CLIA edits. The HCPCS codes listed below require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) will not be paid for these tests.

- 0045U - mRNA gene analysis of 12 genes in breast ductal carcinoma in situ tumor tissue
- 0046U - Gene analysis (fms-related tyrosine kinase 3) for internal tandem duplication variants
- 0047U - mRNA gene analysis of 17 genes in prostate tumor tissue
- 0048U - DNA gene analysis of 468 genes in solid organ tumor tissue
- 0049U - Gene analysis (nucleophosmin)
- 0050U - DNA gene analysis of targeted sequences in 194 genes for acute myelogenous leukemia
- 0051U - Testing for presence of 31 prescription drugs in urine
- 0052U - Measurement of all five major lipoprotein classes and subclasses in blood
- 0053U - FISH analysis of 4 genes in prostate needle biopsy specimen
- 0054U - Measurement of 14 or more drug classes in capillary blood
- 0055U - DNA gene analysis of 96 target sequences in plasma for heart transplant
- 0056U - Whole genome sequencing in blood or bone marrow for acute myelogenous leukemia
- 0057U - mRNA gene analysis of 51 genes in solid organ tumor tissue
- 0058U - Measurement of antibodies to Merkel cell polyoma virus oncoprotein in serum
- 0059U - Test for presence of antibodies to Merkel cell polyoma virus oncoprotein in serum
- 0060U - Gene analysis for identical twins in maternal blood

- 0062U - Autoimmune (systemic lupus erythematosus), igg and igm analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score
- 0063U - Neurology (autism), 32 amines by lc-ms/ms, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder
- 0064U - Antibody, treponema pallidum, total and rapid plasma reagin (rpr), immunoassay, qualitative
- 0065U - Syphilis test, non-treponemal antibody, immunoassay, qualitative (rpr)
0066U - Placental alpha-micro globulin-1 (pamg-1), immunoassay with direct optical observation, cervico-vaginal fluid, each specimen

0067U - Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [mmp-1], carcinoembryonic antigen-related cell adhesion molecule 6 [cecam6], hyaluronoglucosaminidase [hyal1], highly expressed in cancer protein [hec1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score

0068U - Candida species panel (c. albicans, c. glabrata, c. parapsilosis, c. kruseii, c tropicalis, and c. auris), amplified probe technique with qualitative report of the presence or absence of each species

0069U - Oncology (colorectal), micorna, RT-PCR expression profiling of mir-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score


0071U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, full gene sequence (list separately in addition to code for primary procedure)

0072U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, cyp2d6-2d7 hybrid gene) (list separately in addition to code for primary procedure)

0073U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, cyp2d7-2d6 hybrid gene) (list separately in addition to code for primary procedure)

0074U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, non-duplicated gene when duplication/multiplication is trans) (list separately in addition to code for primary procedure);

0075U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 5' gene duplication/multiplication) (list separately in addition to code for primary procedure)

0076U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 3' gene duplication/multiplication) (list separately in addition to code for primary procedure)

0077U - Immunoglobulin paraprotein (m-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype

0078U - Pain management (opioid-use disorder) genotyping panel, 16 common variants (ie, abcb1, comt, dat1, dbh, dor, drd1, drd2, drd4, gaba, gal, htr2a, httlpr, mthfr, muor, oprk1, oprm1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder

The HCPCS codes listed below are new for 2019 and are subject to CLIA edits. The list does not include new HCPCS codes for waived tests or provider-performed procedures. The HCPCS codes listed below require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) will not be paid for these tests.

0080U - Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy
- 0081U - Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis

- 0082U - Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service

- 0083U - Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations

- 81163 - BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis

- 81164 - BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)

- 81165 - BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis

- 81166 - BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)

- 81167 - BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)

- 81171 - AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles

- 81172 - AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile x mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)

- 81173 - AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, kennedy disease, X chromosome inactivation) gene analysis; full gene sequence

- 81174 - AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, kennedy disease, X chromosome inactivation) gene analysis; known familial variant

- 81177 - ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

- 81178 - ATXN1 (ATAXIN 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

- 81179 - ATXN2 (ATAXIN 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

- 81180 - ATXN3 (ATAXIN 3) (eg, spinocerebellar ataxia, machado-joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

- 81181 - ATXN7 (ATAXIN 7) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT abnormal (eg, expanded) alleles

- 81182 - atxn8os (atxn8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

- 81183 - ATXN10 (ATAXIN 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

- 81184 - CACNA1A (calcium voltage-gated channel subunit alpha1 a) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles

- 81185 - CACNA1A (calcium voltage-gated channel subunit alpha1 a) (eg, spinocerebellar ataxia) gene analysis; full gene sequence
81186 - CACNA1A (calcium voltage-gated channel subunit alpha1 a) (eg, spinocerebellar ataxia) gene analysis; known familial variant
81187 - CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (expanded) alleles
81188 - CSTB (cystatin B) (eg, unverricht-lundborg disease) gene analysis; evaluation to detect abnormal (expanded) alleles
81189 - CSTB (cystatin B) (eg, unverricht-lundborg disease) gene analysis; full gene sequence
81190 - CSTB (cystatin B) (eg, unverricht-lundborg disease) gene analysis; known familial variant(s)
81204 - AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, kennedy disease, x chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)
81233 - BTK (bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)
81234 - DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles
81236 - EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence;
81237 - EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)
81239 - DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)
81271 - HTT (huntingtin) (eg, huntington disease) gene analysis; evaluation to detect abnormal (expanded) alleles
81274 - HTT (huntingtin) (eg, huntington disease) gene analysis; characterization of alleles (eg, expanded size)
81284 - FXN (frataxin) (eg, friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles
81285 - FXN (frataxin) (eg, friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)
81286 - FXN (frataxin) (eg, friedreich ataxia) gene analysis; full gene sequence
81289 - FXN (frataxin) (eg, friedreich ataxia) gene analysis; known familial variant(s)
81305 - MYD88 (myeloid differentiation primary response 88) (eg, waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, P.LEU265PRO (L265P) variant
81312 - PABPN1 (poly[a] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (expanded) alleles
81320 - PLCG2 (phospholipase c gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)
81329 - SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes smn2 (survival of motor neuron 2, centromeric) analysis, if performed
81333 - TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)
• 81336 - SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence
• 81337 - smn1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)
• 81343 - PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
• 81344 - TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
• 81345 - TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)
• 81443 - genetic testing for severe inherited conditions (eg, cystic fibrosis, ashkenazi jewish-associated disorders [eg, bloom syndrome, canavan disease, fanconi anemia type C, mucolipidosis type vi, gaucher disease, tay-sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCRT7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)
• 81518 - Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR OF 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy
• 81596 - Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays; (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver
• 82642 - Dihydrotestosterone (DHT)
• 83722 - Lipoprotein, direct measurement; small dense LDL cholesterol

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate, laboratory claims are currently edited at the CLIA certificate level.

Remember that MACs will deny payment for a claim submitted with the HCPCS codes mentioned above as subject to CLIA edits to a provider without valid current CLIA certificate, with a CLIA certificate of waiver (certificate type code 2), or with a CLIA certificate for provider-performed microscopy procedures (certificate type code 4).

Note: MACs will not search their files to either retract payment for claims already paid or to retroactively pay claims. However, MACs will adjust claims that you bring to their attention.

Additional Information


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

Document History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>February 22, 2019</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>
Kentucky & Ohio

**MM11137 Revised: Evaluation and Management (E/M) When Performed with Superficial Radiation Treatment**

MLN Matters Number: MM11137 Revised
Related CR Transmittal Number: R4267CP
Related CR Release Date: February 22, 2019
Related Change Request (CR) Number: 11137
Implementation Date: March 25, 2019

**Note:** We revised this article on March 28, 2019, to reflect the revised CR 11137 that CMS posted on March 27. CMS revised the CR to clarify that providers need to bill the 25 modifier when performing E/M services with CPT code 77401. We revised the article to show that change. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information is unchanged.

**Provider Types Affected**
This MLN Matters Article is for physicians and other providers billing Medicare Administrative Contractors (MACs) for Evaluation and Management (E/M) related to radiation services provided to Medicare beneficiaries.

**Provider Action Needed**
CR11137 revises Chapter 13 of the Medicare Claims Processing Manual to allow providers to bill E/M codes 99211, 99212, and 99213 for Levels I through III, when performed with superficial radiation treatment delivery (up to 200 kV), when performed for the purpose of reporting physician work associated with:

- Radiation therapy planning
- Radiation treatment device construction
- Radiation treatment management when performed on the same date of service as superficial radiation treatment delivery

Make sure your billing staffs are aware of these revisions.

**Background**
Radiation treatment delivery codes recognize technical-only services and contain no physician work, while providers should use treatment management codes to report the professional component. According to Current Procedural Terminology (CPT) guidance, providers should not report superficial radiation (up to 200 kV) with CPT codes for planning and management.

Providers should report the professional component associated with this service with the appropriate E/M codes. According to Chapter 13 of the Medicare Claims Processing Manual, Medicare does not make separate payment for E/M services for established patients.

CR11137 revises Chapter 13 of the Manual to allow providers to bill E/M codes 99211, 99212, and 99213 for Levels I through III when performed for the purpose of reporting physician work associated with:

- Radiation therapy planning (including, but not limited to, clinical treatment planning, isodose planning, and physics consultation)
- Radiation treatment device construction
- Radiation treatment management when performed on the same date of service as superficial radiation treatment delivery

Billing of these E/M codes with modifier 25 may be necessary if National Correct Coding Initiative (NCCI) edits apply.

**Note:** MACs will not search their files for claims already paid or to retroactively pay claims. However, MACs will adjust affected claims that you bring to their attention.
**Additional Information**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

**Document History**

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<td>March 28, 2019</td>
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</tr>
<tr>
<td>March 1, 2019</td>
<td>We revised this article to correct an E/M code on page 2 of this article, which should have been E/M codes 99211.</td>
</tr>
<tr>
<td>February 25, 2019</td>
<td>Initial article released.</td>
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</table>

**Kentucky & Ohio**

**MM11163 Revised: Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2019 Update**

<table>
<thead>
<tr>
<th>MLN Matters Number: MM11163 Revised</th>
<th>Related CR Release Date: March 18, 2019</th>
</tr>
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<tbody>
<tr>
<td>Related CR Transmittal Number: R4258CP</td>
<td>Related Change Request (CR) Number: 11163</td>
</tr>
<tr>
<td>Effective Date: January 1, 2019</td>
<td>Implementation Date: April 1, 2019</td>
</tr>
</tbody>
</table>

**Note:** We revised this article on March 19, 2019, to reflect an updated Change Request (CR) that revised the attachment for codes G2014 and G2015 (see page 2 below). The CR release date, transmittal number and link to the transmittal was also changed. All other information remains the same.

**Provider Types Affected**

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

**Provider Action Needed**

This article informs you that the Centers for Medicare & Medicaid Services (CMS) has issued payment files to the MACs based upon the 2019 Medicare Physician Fee Schedule (MPFS) Final Rule. CR 11163 amends those payment files. Please be sure your billing staffs are aware of these changes.

**Background**


Below is a summary of the changes for the April update to the 2019 Medicare Physician Fee Schedule Database (MPFSD). These changes are effective for dates of service on and after January 1, 2019. CMS has added new HCPCS codes (G2001-G2009 and G2013-G2015) to the 2019 MPFSD and updated another code (G9987) as shown in the table below. CMS communicated instructions for these new codes (G2001-G2009 and G2013-G2015) through a separate CR (CR 10907). Please consult MLN Matters article MM10907 at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10907.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10907.pdf) for these instructions and other information.
Table: April Updates to the 2019 MPFSD

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>G9987</td>
<td>Assistant Surgery, Co-Surgeon, &amp; Team Surgeon indicator = 9</td>
</tr>
<tr>
<td>G2001</td>
<td>All MPFS indicators and RVUs = 99341</td>
</tr>
<tr>
<td>G2002</td>
<td>All MPFS indicators and RVUs = 99342</td>
</tr>
<tr>
<td>G2003</td>
<td>All MPFS indicators and RVUs = 99343</td>
</tr>
<tr>
<td>G2004</td>
<td>All MPFS indicators and RVUs = 99344</td>
</tr>
<tr>
<td>G2005</td>
<td>All MPFS indicators and RVUs = 99345</td>
</tr>
<tr>
<td>G2006</td>
<td>All MPFS indicators and RVUs = 99347</td>
</tr>
<tr>
<td>G2007</td>
<td>All MPFS indicators and RVUs = 99348</td>
</tr>
<tr>
<td>G2008</td>
<td>All MPFS indicators and RVUs = 99349</td>
</tr>
<tr>
<td>G2009</td>
<td>All MPFS indicators and RVUs = 99350</td>
</tr>
<tr>
<td>G2013</td>
<td>All MPFS indicators and RVUs = 99345</td>
</tr>
</tbody>
</table>

G2014 - Procedure Status = A; RVUs = Work 1.25, Non-Facility .85, Facility .85, MP 0.07, Multiple Surgery = 0, Bilateral Surgery = 0, Assistant at Surgery = 0, Co-Surgeons = 0, Team Surgeons = 0, PC/TC = 0

G2015 - Procedure Status = A; RVUs = Work 1.80, Non-Facility 1.14, Facility 1.14, MP .11, Multiple Surgery = 0, Bilateral Surgery = 0, Assistant at Surgery = 0, Co-Surgeons = 0, Team Surgeons = 0, PC/TC = 0

Note: MACs will not search their files to retract payment for claims already paid or to retroactively pay claims. However, MACs will adjust claims that you bring to their attention.

Additional Information


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

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<td>March 19, 2019</td>
<td>We revised this article to reflect an updated CR that revised the attachment for codes G2014 and G2015 (see page 2 above). The CR release date, transmittal number and link to the transmittal was also changed.</td>
</tr>
<tr>
<td>February 8, 2019</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

Kentucky & Ohio

**MM11204**: Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update

**MLN Matters Number**: MM11204  
**Related CR Transmittal Number**: R4253CP  
**Effective Date**: July 1, 2019  
**Related CR Release Date**: March 15, 2019  
**Related Change Request (CR) Number**: 11204  
**Implementation Date**: July 1, 2019

**Provider Type Affected**

This MLN Matters article is for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.
Provider Action Needed

CR11204 updates the Remittance Advice Remark Code (RARC) and Claims Adjustment Reason Code (CARC) lists and instructs the ViPS Medicare System (VMS) and Fiscal Intermediary Shared System (FISS) to update the Medicare Remit Easy Print (MREP) and PC Print software. Be sure your billing staffs are aware of these changes and obtain the updated MREP and PC Print if they use that software.

Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) instructs health plans to conduct standard electronic transactions adopted under HIPAA using valid standard codes. Medicare policy states that CARCs and RARCs, as appropriate, which provide either supplemental explanation for a monetary adjustment or policy information that generally applies to the monetary adjustment, are required in the remittance advice and coordination of benefits transactions.

The Centers for Medicare & Medicaid Services (CMS) instructs the MACs to conduct updates based on the code update schedule that results in publication three times per year – around March 1, July 1, and November 1.

CMS provides CR11204 as a code update notification indicating when the Washington Publishing Company (WPC) makes updated CARC and RARC lists available on its website. Medicare systems make required code deactivations, making sure that any deactivated code is not used in original business messages and allowing the deactivated code in derivative messages. Medicare does not report any deactivated code on or after the effective date for deactivation as posted on the WPC website. If any new or modified code has an effective date later than the implementation date specified in CR11204, MACs must implement on the date specified on the WPC website (http://wpc-edi.com/Reference/).

A discrepancy between the dates may arise, as the WPC only updates its website three times per year and may not match the CMS release schedule. The MACs must get the complete list for both CARC and RARC from the WPC website to obtain the comprehensive lists for both code sets and determine the changes that are included on the code list since the last code update CR (CR10620).

Additional Information


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

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<table>
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<tr>
<td>March 15, 2019</td>
<td>Initial article released.</td>
</tr>
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</table>

**Kentucky & Ohio**

**MM11232: April 2019 Update of the Ambulatory Surgical Center (ASC) Payment System**

MLN Matters Number: MM11232  
Related CR Transmittal Number: R4263CP  
Effective Date: April 1, 2019  
Related CR Release Date: March 22, 2019  
Related Change Request (CR) Number: 11232  
Implementation Date: April 1, 2019
Provider Types Affected
This MLN Matters Article is for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services subject to the Ambulatory Surgical Center (ASC) payment system and provided to Medicare beneficiaries.

Provider Action Needed
CR11232 describes changes to and billing instructions for various payment policies implemented in the April 2019 ASC payment system update. The CR also includes HCPCS updates. Please make sure your billing staffs are aware of these changes.

Background
This article includes Calendar Year (CY) 2019 payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG) files. The Centers for Medicare & Medicaid Services (CMS) is also including an April 2019 ASC Payment Indicator (ASC PI) file. CMS is not issuing April 2019 ASC Fee Schedule (ASCFS) and ASC Code Pair files in CR11232. The changes are as follows:

1. Drugs and Biologicals
   a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)
      Effective April 1, 2019
      For CY 2019, payment for non-pass-through drugs and biologicals continues to be made at a single rate of ASP + 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug or biological. Also, in CY 2019, a single payment of ASP + 6 percent continues for Outpatient Prospective Payment System (OPPS) pass-through drugs and biologicals to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items.

      Payments for drugs and biologicals based on ASPs will update on a quarterly basis as later quarter ASP submissions become available. Updated payment rates effective April 1, 2019, are available in the April 2019 update of ASC Addendum BB at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

   b. HCPCS Codes and Dosage Descriptors for Certain Drugs and Biologicals
      Effective April 1, 2019
      For CY 2019, seven new HCPCS codes were created for reporting drugs and biologicals in the ASC payment system where there have not previously been specific codes available. Table 1 shows these new codes.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>Short Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9040</td>
<td>Injection, fremanezumab-vfrm, 1mg</td>
<td>Injection, fremanezumab-vfrm</td>
<td>K2</td>
</tr>
<tr>
<td>C9041</td>
<td>Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg</td>
<td>Inj, coagulation factor Xa</td>
<td>K2</td>
</tr>
<tr>
<td>C9141</td>
<td>Injection, factor viii, (anthemophilic factor, recombinant), pegylated-auc (jivi) 1 i.u.</td>
<td>Factor viii pegylated-auc</td>
<td>K2</td>
</tr>
<tr>
<td>C9043</td>
<td>Injection, levoleucovorin, 1 mg</td>
<td>Injection, levoleucovorin</td>
<td>K2</td>
</tr>
<tr>
<td>C9044</td>
<td>Injection, cemiplimab-rwlc, 1 mg</td>
<td>Injection, cemiplimab-rwlc</td>
<td>K2</td>
</tr>
<tr>
<td>C9045</td>
<td>Injection, moxetumomab pasudotox-tdfk,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.01 mg</td>
<td>Moxetumomab pasudotox-tdfk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C9046</td>
<td>Cocaine hydrochloride nasal solution for topical administration, 1 mg</td>
<td>Cocaine hcl nasal solution</td>
<td>K2</td>
</tr>
</tbody>
</table>
c. **HCPCS Code Change for Certain Drugs and Biologicals Effective April 1, 2019**

One (1) code, HCPCS J3245, will be separately payable beginning April 1, 2019, and will have an ASC PI = K2 (Drugs and Biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate). This code was previously ASC PI = Y5 (Non-Surgical Procedure/item not valid for Medicare purposes because of coverage, regulation and/or statute; no payment made). Table 2 lists this code.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>Short Descriptor</th>
<th>Old ASC PI</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3245</td>
<td>Injection, tildrakizumab, 1 mg</td>
<td>Inj., tildrakizumab, 1 mg</td>
<td>Y5</td>
<td>K2</td>
</tr>
</tbody>
</table>


d. **Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates**

Some drugs and biologicals based on ASP methodology may have payment rates that CMS corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the CMS website on the first date of the quarter at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Restated-Payment-Rates.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Restated-Payment-Rates.html).

Suppliers who think they may have received an incorrect payment for drugs and biologicals impacted by these corrections may request MAC adjustment of the previously processed claims.

2. **Reassignment of Skin Substitute Products from the Low-Cost Group to the High-Cost Group**

Payments for skin substitute products that do not qualify for hospital OPPS pass-through status are packaged into the OPPS payment for the associated skin substitute application procedure. CMS also implements this policy in the ASC payment system. The skin substitute products were divided into two groups for packaging purposes:

1. High-cost skin substitute products
2. Low-cost skin substitute products

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>ASC PI</th>
<th>Low/High-Cost Skin Substitute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4183</td>
<td>SurgiGraft, 1 sq cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4184</td>
<td>Cellesta, 1 sq cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4194</td>
<td>Novachor 1 sq cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4203</td>
<td>Derma-gide, 1 sq cm</td>
<td>N1</td>
<td>High</td>
</tr>
</tbody>
</table>

ASCs should not separately bill for packaged skin substitutes (ASC PI = N1). You should only use high-cost skin substitute products in combination with the performance of one of the skin application procedures described by the Current Procedural Terminology (CPT) codes 15271-15278. You should only use low-cost skin substitute products in combination with the performance of one of the skin application procedures described by HCPCS codes C5271-C5278. You should bill all OPPS pass-through skin substitute products (ASC PI = K2) in combination with one of the skin application procedures described by CPT codes 15271-15278.

The skin substitute products in Table 3 are reassigned from the low-cost skin substitute group to the high-cost skin substitute group based on updated pricing information.

3. **Coverage Determinations**

The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate under the ASC payment system does not imply coverage by the Medicare...
program, but indicates only how the product, procedure, or service may be paid if covered by the program. MACs determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary’s condition and whether to exclude it from payment.

**Additional Information**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

**Document History**

<table>
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<tr>
<td>March 22, 2019</td>
<td>Initial article released.</td>
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**Kentucky & Ohio**

**MM11224: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2019**

**MLN Matters Number:** MM11224  
**Related CR Transmittal Number:** R4265CP  
**Effective Date:** July 1, 2019  
**Related CR Release Date:** March 22, 2019  
**Related Change Request (CR) Number:** 11224  
**Implementation Date:** July 1, 2019

**Provider Type Affected**

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

**What You Need to Know**

CR 11224 announces the changes that will be in the July 2019 quarterly release of the edit module for clinical diagnostic laboratory services. Please be sure your billing staffs are aware of these updates.

**Background**

CR 11224 announces the changes that will be in the July 2019 quarterly release of the edit module for clinical diagnostic laboratory services. The National Coverage Determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee, and the final rule was published on November 23, 2001. Nationally uniform software was developed and incorporated in the Medicare shared systems so that laboratory claims subject to one of the 23 NCDs, found in the Medicare National Coverage Determinations (NCD) Manual, Sections 190.12 - 190.34, were processed uniformly throughout the nation, effective April 1, 2003.

In accordance with the Medicare Claims Processing Manual, Chapter 16, Section 120.2, the laboratory edit module is updated quarterly as necessary to reflect ministerial coding updates and substantive changes to the NCDs developed through the NCD process. The changes are a result of coding analysis decisions developed under the procedures for maintenance of codes in the negotiated NCDs and biannual updates of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. This instruction communicates requirements to Shared System Maintainers (SSMs) and contractors, notifying them of changes to the laboratory edit module to update it for changes in laboratory NCD code lists for July 2019.
Additional Information

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

Document History

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<td>March 27, 2019</td>
<td>Initial article released.</td>
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Kentucky & Ohio

MM11225: July 2019 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

MLN Matters Number: MM11225
Related CR Transmittal Number: R4264CP
Effective Date: July 1, 2019

Provider Type Affected
This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for Medicare Part B drugs provided to Medicare beneficiaries.

Provider Action Needed
CR 11225 provides the quarterly update for Average Sales Price (ASP) and ASP Not Otherwise Classified (NOC) Medicare Part B Drug Pricing Files and Revisions to the prior quarterly pricing files. CR11225 instructs MACs to download and implement the July 2019 and, if released, the revised April 2019, January 2019, October 2018, and July 2018 files. Make sure your billing staffs are aware of these updates.

Payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions that are in chapter 4, section 50 of the Medicare Claims Processing Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf. Make sure that your billing staffs are aware of these changes.

Background
The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply the MACs with the ASP and ASP NOC drug pricing files for Medicare Part B drugs on a quarterly basis. CR 11225 addresses the following pricing files:

- File: July 2019 ASP and ASP NOC — Effective Dates of Service: July 1, 2019, through September 30, 2019
- File: April 2019 ASP and ASP NOC — Effective Dates of Service: April 1, 2019, through June 30, 2019
- File: January 2019 ASP and ASP NOC — Effective Dates of Service: January 1, 2019, through March 31, 2019
- File: October 2018 ASP and ASP NOC — Effective Dates of Service: October 1, 2018, through December 31, 2018
File: July 2018 ASP and ASP NOC — Effective Dates of Service: July 1, 2018, through September 30, 2018

For any drug or biological not listed in the ASP or NOC drug pricing files, your MACs will determine the payment allowance limits in accordance with the policy in the Medicare Claims Processing Manual, Chapter 17, Section 20.1.3 at https://www.cms.gov/Regulations-and-Guidance/Guidance-Manuals/Downloads/clm104c17.pdf.

For any drug or biological not listed in the ASP or NOC drug pricing files that is billed with the KD modifier, MACs will determine the payment allowance limits in accordance with instructions for pricing and payment changes for infusion drugs furnished through an item of Durable Medical Equipment (DME) on or after January 1, 2017, associated with the passage of the 21st Century Cures Act which is available at https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf.

Note: MACs will not search and adjust claims that they already processed unless you bring such claims to their attention.

Additional Information


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

Document History

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Kentucky & Ohio

SE18006 Revised: New Medicare Beneficiary Identifier (MBI) Get It, Use It

MLN Matters Number: SE18006 Revised
Related CR Transmittal Number: N/A
Effective Date: N/A

Article Release Date: March 6, 2019
Related Change Request (CR) Number: N/A
Implementation Date: N/A

Note: We revised this article on March 6, 2019, to add language that the MBI look-up tool can be used to obtain an MBI even for patients in a Medicare Advantage Plan. All other information remains the same.

Provider Type Affected

This Special Edition MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment MACs (DME MACs) and Home Health and Hospice MACs, for services provided to Medicare beneficiaries.

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) is mailing the new Medicare cards with the MBI in phases by geographic location (https://www.cms.gov/Medicare/New-Medicare-Card/NMC-Mailing-Strategy.pdf). There are 3 ways you and your office staff can get MBIs:

1. Ask your Medicare patients

   Ask your Medicare patients for their new Medicare card when they come for care. If they haven’t received a new card at the completion of their geographic mailing wave, give them the “Still Waiting for Your New Card?” handout (in English (https://www.cms.gov/
2. Use the MAC’s secure MBI look-up tool

You can look up MBIs for your Medicare patients when they don’t or can’t give them. Sign up for the Portal to use the tool. You can use this tool even after the end of the transition period – it doesn’t end on December 31, 2019. Even if your patient is in a Medicare Advantage Plan, you can look up the MBI to bill for things like indirect medical education.

Your patient’s Social Security Number (SSN) is required for the search and may differ from their Health Insurance Claim Number (HICN), which uses the SSN of the primary wage earner. If your Medicare patients do not want to give their SSN, they can log into https://mymedicare.gov to get their MBI.

If the look-up tool returns a last name matching error and the beneficiary last name includes a suffix, such as Jr. Sr. or III, try searching without and with the suffix as part of the last name.

3. Check the remittance advice

Starting in October 2018 through the end of the transition period, we’ll also return the MBI on every remittance advice when you submit claims with valid and active HICNs.

You can start using the MBIs even if the other health care providers and hospitals who also treat your patients haven’t. When the transition period ends on December 31, 2019, you must use the MBI for most transactions.

Background

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS to remove Social Security Numbers from all Medicare cards by April 2019. A new, randomly generated Medicare Beneficiary Identifier, or MBI, is replacing the SSN-based HICN. The new MBI is noticeably different than the HICN. Just like with the HICN, the MBI hyphens on the card are for illustration purposes: don’t include the hyphens or spaces on transactions. The MBI uses numbers 0-9 and all uppercase letters except for S, L, O, I, B, and Z. We exclude these letters to avoid confusion when differentiating some letters and numbers (e.g., between “0” and “O”).

The Railroad Retirement Board (RRB) is also mailing new Medicare cards with the MBI. The RRB logo will be in the upper left corner and “Railroad Retirement Board” at the bottom, but you can’t tell from looking at the MBI if your patients are eligible for Medicare because they’re railroad retirees. You’ll be able to identify them by the RRB logo on their card, and we’ll return a “Railroad Retirement Medicare Beneficiary” message on the Fee-For-Service (FFS) MBI eligibility transaction response.
Use the MBI the same way you use the HICN today. Put the MBI in the same field where you’ve always put the HICN. This also applies to reporting informational only and no-pay claims. **Don’t use hyphens or spaces with the MBI to avoid rejection of your claim.** The MBI will replace the HICN on Medicare transactions including Billing, Eligibility Status, and Claim Status. The effective date of the MBI, like the old HICN, is the date each beneficiary was or is eligible for Medicare. Until December 31, 2019, you can use either the HICN or the MBI in the same field where you’ve always put the HICN. After that the remittance advice will tell you if we rejected claims because the MBI wasn’t used. It will include Claim Adjustment Reason Code (CARC) 16, “Claim/service lacks information or has submission/billing error(s),” along with Remittance Advice Remark Code (RARC) N382 “Missing/incomplete/invalid patient identifier”.

The beneficiary or their authorized representative can request an MBI change. CMS can also initiate a change to an MBI. An example is if the MBI is compromised. There are different scenarios for using the old or new MBIs:

**FFS claims submissions with:**
- Dates of service before the MBI change date – use the old or new MBI.
- Span-date claims with a “From Date” before the MBI change date – use the old or new MBI.
- Dates of service that are entirely on or after the effective date of the MBI change – use the new MBI.

**FFS eligibility transactions when the:**
- Inquiry uses new MBI – we’ll return all eligibility data.
- Inquiry uses the old MBI and request date or date range overlap the active period for the old MBI – we’ll return all eligibility data. We’ll also return the old MBI termination date.
- Inquiry uses the old MBI and request date or date range are entirely on or after the effective date of the new MBI – we’ll return an error code (AAA 72) of “invalid member ID.”

When the MBI changes, we ask the beneficiary to share the new MBI with you. You can also get the MBI from your MACs secure MBI lookup tool.

**Protect the MBI as Personally Identifiable Information (PII); it is confidential like the HICN.**

Submit all HICN-based claims by the end of the transition period, December 31, 2019. On January 1, 2020, even for dates of services before this date, you must use MBIs for all transactions; there are a few exceptions when you can use either the HICN or MBI:
- Appeals – You can use either the HICN or MBI for claim appeals and related forms.
- Claim status query – You can use HICNs or MBIs to check the status of a claim (276 transactions) if the earliest date of service on the claim is before January 1, 2020. If you are checking the status of a claim with a date of service on or after January 1, 2020, you must use the MBI.
- Span-date claims – You can use the HICN or the MBI for 11X-Inpatient Hospital, 32X-Home Health (home health claims and Request for Anticipated Payments [RAPs]) and 41X-Religious Non-Medical Health Care Institution claims if the “From Date” is before the
This newsletter should be shared with all health care practitioners and managerial members of the provider/supplier staff. Newsletters issued after February 1997 are available at no cost from our website at http://www.cgsmedicare.com.

The MBI does not change Medicare benefits. Medicare beneficiaries may start using their new Medicare cards and MBIs as soon as they get them. Use MBIs as soon as your patients share them. The new cards are effective the date beneficiaries are eligible for Medicare.

Medicare Advantage and Prescription Drug plans continue to assign and use their own identifiers on their health insurance cards. For patients in these plans, continue to ask for and use the plans’ health insurance cards.

Additional Information
If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

To sign up for your MAC’s secure portal MBI look-up tool, visit https://www.cms.gov/Medicare/New-Medicare-Card/Providers/MACs-Provider-Portals-by-State.pdf.

The MBI format specifications, which provide more details on the construct of the MBI, are available at https://www.cms.gov/Medicare/New-Medicare-Card/Understanding-the-MBI.pdf.


Document History

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<td>March 6, 2019</td>
<td>We revised this article to add language that the MBI look-up tool can be used to obtain an MBI even for patients in a Medicare Advantage Plan. All other information remains the same.</td>
</tr>
<tr>
<td>December 10, 2018</td>
<td>The article was revised to update the language regarding when MACs can return an MBI through the MBI look up tool (page 1). All other information remains the same.</td>
</tr>
<tr>
<td>July 11, 2018</td>
<td>This article was revised to provide additional information regarding the format of the MBI not using letters S, L, O, I, B, and Z (page 2).</td>
</tr>
<tr>
<td>June 25, 2018</td>
<td>This article was revised to provide additional information regarding the ways your staff can get MBIs (page 1).</td>
</tr>
<tr>
<td>June 21, 2018</td>
<td>The article was revised to emphasize the need to submit the MBI without hyphens or spaces to avoid rejection of your claim.</td>
</tr>
<tr>
<td>May 25, 2018</td>
<td>Initial article released.</td>
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Kentucky & Ohio

SE19006: Medicare Part B Clinical Laboratory Fee Schedule: Revised Information for Laboratories on Collecting and Reporting Data for the Private Payor Rate-Based Payment System

MLN Matters Number: SE19006
Related CR Transmittal Number: N/A
Effective Date: N/A
Article Release Date: February 27, 2019
Related Change Request (CR) Number: N/A
Implementation Date: N/A
Provider Type Affected
This article is for Medicare Part B clinical laboratories who submit claims to Medicare Administrative Contractors (MACs) for services furnished to Medicare beneficiaries.

Provider Action Needed
This article will assist the laboratory community in meeting the requirements under Section 1834A of the Social Security Act (the Act) for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). It includes clarifications for determining whether a hospital outreach laboratory meets the requirements to be an “applicable laboratory,” the applicable information (that is, private payor rate data) that must be collected and reported to the Centers for Medicare & Medicaid Services (CMS), the entity responsible for reporting applicable information to CMS, the data collection and reporting periods, and the schedule for implementing the next private payor-rate based CLFS update. Also, this revised article includes information about the condensed data reporting option for reporting entities. CMS previously issued additional information about the CLFS data collection system and Advanced Diagnostic Laboratory Tests (ADLTs) through separate instructions.

Background
Section 1834A of the Act, as established by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for clinical diagnostic laboratory tests under the CLFS. The CLFS final rule Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F, https://www.gpo.gov/fdsys/pkg/FR-2016-06-23/pdf/2016-14531.pdf) was displayed in the Federal Register on June 17, 2016, and was published on June 23, 2016. The CLFS final rule implemented Section 1834A of the Act.

Under the CLFS final rule, reporting entities must report to CMS certain private payor rate information (applicable information) for their component applicable laboratories. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, is equal to the weighted median of private payor rates determined for the test, based on the applicable information that laboratories collect during a data collection period and report to CMS during a data reporting period. CMS uses crosswalking or gapfilling methods to establish payment amounts for new Clinical Diagnostic Laboratory Tests (CDLTs) and CDLTs for which CMS receives no applicable information.

CMS published the Physician Fee Schedule (PFS) final rule entitled Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019 (CMS-1693-F, https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf) November 23, 2018. In this final rule, CMS made two revisions to the regulatory definition of applicable laboratory:

1. Medicare Advantage plan revenues are excluded from total Medicare revenues, the denominator of the majority of Medicare revenues threshold
2. Hospitals that bill for their non-patient laboratory services use Medicare revenues from the Form CMS-1450 14x Type of Bill (TOB) to determine whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold.

In addition, for the January 1, 2020, through March 31, 2020 data reporting period, CMS will allow reporting entities the option to condense certain applicable information at the Tax Identification Number (TIN)-level, instead of reporting for each applicable laboratory individually at the National Provider Identifier (NPI) level.

Applicable Laboratory
Section 1834A of the Act defines an applicable laboratory as a laboratory which receives the majority of its Medicare revenues under the CLFS and/or PFS. It also provides the authority to establish a low volume or low expenditure threshold.
Under the revised final policies for the Medicare CLFS, an applicable laboratory is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory (that is, 42 C.F.R. § 493.2) that bills Medicare Part B under its own NPI or for hospital outreach laboratories, bills Medicare Part B on the Form CMS-1450 under bill type 14x. In addition, the laboratory must meet a “majority of Medicare revenues” threshold, that is, in a data collection period it receives more than 50 percent of its Medicare revenues from one or a combination of the CLFS or the PFS. It also must meet a low expenditure threshold, that is, it receives at least $12,500 of its Medicare revenues from the CLFS in a data collection period.

For purposes of determining applicable laboratory status under the CLFS, a hospital outreach laboratory is a hospital-based laboratory that furnishes laboratory tests to patients other than admitted inpatients or registered outpatients of the hospital. A hospital outreach laboratory bills for Medicare Part B services it furnishes to non-hospital patients using the Form CMS-1450 14x Type of Bill (TOB).

I. Determination of Applicable Laboratory Status Based on the NPI

This section includes information on how independent laboratories and physician office laboratories that bill Medicare Part B under their own NPI and hospital outreach laboratories that bill Medicare Part B under their own NPI (separate from the hospital’s NPI) determine whether they are an applicable laboratory. As discussed later in this article, hospital outreach laboratories that bill Medicare Part B using the hospital’s NPI must determine applicable laboratory status based on its revenues attributed to the Form CMS-1450 14x TOB.

There are four steps in determining whether a laboratory meets the requirements to be an applicable laboratory based on the laboratory’s own billing NPI:

1. Is the laboratory certified under CLIA?
2. Does the CLIA-certified laboratory bill Medicare Part B under its own NPI?
3. Does the laboratory meet the majority of Medicare revenues threshold?
4. Does the laboratory meet the low expenditure threshold?

Step 1: CLIA Certification

The CLIA applies to all laboratories performing testing on human specimens for a health purpose. A laboratory must be a CLIA-certified laboratory to receive Medicare payment. Therefore, the first step in identifying an applicable laboratory is to determine whether the laboratory is CLIA certified. The CLIA regulatory definition of a laboratory is codified in regulation in 42 CFR 493.2. Note that a facility that receives any CLIA certificate (including a CLIA certificate of waiver) is considered a laboratory as defined in 42 CFR 493.2.

Step 2: NPI

The second step is to determine whether the CLIA-certified laboratory bills Medicare Part B under its own NPI. The NPI is the standard unique health identifier used by health care providers for billing Medicare and other payors. The National Plan and Provider Enumeration System assigns NPIs, per 45 CFR 162. CMS uses the laboratory’s own billing NPI as the mechanism for defining an applicable laboratory.

Step 3: Majority of Medicare Revenues Threshold

For a CLIA-certified laboratory that bills Medicare Part B under its own NPI, to be an applicable laboratory it must meet the majority of Medicare revenues threshold. A laboratory, by its own billing NPI, meets the majority of Medicare revenues threshold if it receives more than 50 percent of its total Medicare revenues from payments under the

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1 The Form CMS-1450 14x is a type of bill as defined by the National Uniform Billing Committee. It is used in hospital claims submission and is associated with hospital laboratory services provided to non-hospital patients.
Medicare CLFS and/or Medicare PFS. The CLFS and PFS are under Medicare Part B, also known as Original Medicare or Fee-For-Service (FFS) Medicare.

To determine whether a laboratory meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims from their MAC received by their own billing NPI during the data collection period. See the Applicable Information Section below for additional information on the concept of final paid claims.

The three steps to determine whether a laboratory meets the majority of Medicare revenues threshold are:

- First, sum the CLFS and PFS payment amounts received by the laboratory’s own billing NPI during the data collection period. The revenues from the CLFS include payments for all laboratory services under the CLFS. The revenues from the PFS include all payments from all services paid under the PFS (for instance, laboratory services and services that are not laboratory services such as pathology services, evaluation and management services, and radiology services). The sum of CLFS and PFS revenues is the numerator of the majority of Medicare revenues threshold equation.

- Next, sum the total Medicare revenues received by the laboratory’s own billing NPI during the data collection period. Total Medicare revenues include the sum of all FFS payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period. The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation.

  Note: Effective January 1, 2019, Medicare Advantage plan payments under Medicare Part C shall not be included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation.

- Finally, divide the sum of CLFS and PFS revenues by the sum of total Medicare revenues received during the data collection period. We provide additional information on the data collection period below.

If the Medicare revenues received from the CLFS and/or PFS are greater than 50 percent of the total Medicare revenues for the laboratory’s billing NPI, the laboratory meets the majority of Medicare revenues threshold.

The majority of Medicare revenues threshold equation is:

\[
\text{If:} \quad \frac{\text{Medicare CLFS revenues (for billing NPI)} + \text{Medicare PFS revenues (for billing NPI)}}{\text{Total Medicare revenues (for billing NPI)}} \geq 50\%
\]

Then: The laboratory meets the majority of Medicare revenues threshold.

**Step 4: Low Expenditure Threshold**

An applicable laboratory must also meet the low expenditure requirements. A laboratory (as defined under the CLIA regulations) meets the low expenditure threshold if, by its own billing NPI, receives at least $12,500 in Medicare revenues from the CLFS (under Medicare Part B) during the data collection period. To meet the low expenditure threshold, the laboratory must look to its final Medicare paid claims from the MAC received by its own billing NPI during the data collection period.

To determine whether the laboratory meets the low expenditure threshold, sum all final payments for the laboratory’s own billing NPI received from Medicare CLFS services during the data collection period (completed under Step 3: Majority of Medicare Revenues Threshold). It is important to note that the low expenditure threshold applies only to CLFS services. It does not include revenues received under the PFS. In other words, to meet the low expenditure threshold, the laboratory’s own billing NPI must receive at least $12,500 under only the CLFS during the data collection period.
The low expenditure threshold equation is:
Medicare CLFS revenues (for billing NPI) ≥ $12,500.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold are applied to the CLIA-certified laboratory's own billing NPI for purposes of determining whether the laboratory is an applicable laboratory:

Example 1: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has its own unique NPI and bills the Medicare Program (and other payors) for laboratory tests separately under each NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to each NPI in the laboratory organization. That is, individually determine whether each laboratory meets the majority of revenues threshold and low expenditure threshold. Even though all five laboratories may be under the same TIN, CMS considers each to be a separate laboratory for purposes of determining an applicable laboratory because each bills Medicare Part B for laboratory tests using its own unique NPI.

Example 2: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has the same NPI and bills for laboratory tests under the same NPI for each of its CLIA-certified laboratories. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all CLIA-certified laboratories in the organization that use the same billing NPI. In other words, for purposes of applying the applicable laboratory thresholds, CMS considers all five CLIA-certified laboratories in the laboratory organization to be a single laboratory because they all bill Medicare Part B using the same NPI.

Example 3: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has its own unique NPI. However, only one laboratory’s NPI is used for billing all laboratory tests furnished by all five laboratories in the laboratory organization. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the one NPI used for billing all tests furnished by the laboratory organization.

Example 4: An entity consists of five physician offices and one CLIA-certified laboratory. All five physician offices and the CLIA-certified laboratory have the same NPI and bill for services under the same NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all components of the entity that bill for services under the same NPI. In other words, since the physician offices and CLIA-certified laboratory all have the same NPI and bill Medicare Part B under the same NPI, CMS considers the entity to be a single laboratory for purposes of applying the majority of Medicare revenues threshold and low expenditure threshold.

Example 5: An entity consists of five physician offices and one CLIA-certified laboratory. Each of the five physician offices and the CLIA-certified laboratory have unique NPIs. The laboratory bills for laboratory tests under its own unique NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are only applied to the CLIA-certified laboratory’s own billing NPI.

Example 6: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients has its own unique NPI separate from the hospital’s NPI. The hospital outreach laboratory bills Medicare Part B for laboratory tests it furnishes to non-hospital patients using its own unique NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory’s own unique NPI and not to the hospital’s NPI.

Example 7: A hospital includes three CLIA-certified hospital outreach laboratories that perform laboratory services for non-hospital patients. Each CLIA-certified hospital
outreach laboratory has the same NPI, separate from the hospital’s NPI, and bills Medicare Part B separately for laboratory tests under the same NPI for each of its CLIA-certified hospital outreach laboratories. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all CLIA-certified hospital outreach laboratories of the hospital that use the same billing NPI that is separate from the hospital’s NPI. In other words, for purposes of applying the applicable laboratory thresholds, CMS considers all three CLIA-certified hospital outreach laboratories of the hospital to be a single laboratory because they all bill Medicare Part B using the same unique billing NPI.

**Example 8:** A hospital includes three CLIA-certified hospital outreach laboratories. Each CLIA-certified hospital outreach laboratory has its own unique NPI separate from the hospital’s NPI. However, the three CLIA-certified outreach laboratories use only one outreach laboratory’s NPI for billing all laboratory tests furnished by all three hospital laboratory outreach laboratories of the hospital. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the one NPI used for billing all tests furnished by the three hospital outreach laboratories of the hospital.

**Example 9:** A hospital includes three CLIA-certified hospital outreach laboratories. However, only one (out of the three) has its own unique NPI separate from the hospital’s NPI and bills Medicare Part B for laboratory services performed for non-hospital patients using its own unique NPI. Two (out of the three) hospital outreach laboratories bill for laboratory services performed for non-hospital patients using the hospital’s NPI. In this example, the hospital outreach laboratory that bills Medicare Part B under its own unique NPI separate from the hospital’s NPI uses the Medicare revenues attributed to its own billing NPI to determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold.

The two hospital outreach laboratories that bill for laboratory services performed for non-hospital patients under the hospital’s NPI must determine applicable laboratory status based on revenues attributed to the Form CMS-1450 14x TOB. Below, we provide instructions for determining applicable laboratory status for hospital outreach laboratories that bill Medicare Part B using the hospital’s NPI.

**II. Hospital Outreach Laboratories That Bill Medicare Part B under the Hospital’s NPI**

Similar to the preceding section, in order for hospital outreach laboratories that bill Medicare Part B using the hospital’s NPI to be an applicable laboratory, the hospital outreach laboratory must be a laboratory as defined under the CLIA regulatory definition of a laboratory in 42 C.F.R. § 493.2 and meet the majority of Medicare revenues threshold and low expenditure threshold.

However, a hospital outreach laboratory that bills Medicare Part B using the hospital’s NPI must determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold based on revenues attributed to the Form CMS-1450 14x TOB. In other words, when using the CMS Form-1450 14x TOB for determining applicable laboratory status, the majority of Medicare revenues threshold and low expenditure threshold only applies to the hospital outreach laboratory portion of the hospital’s NPI, rather than to the NPI of the entire hospital.

Therefore, if a CLIA-certified hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI meets the requirements of an applicable laboratory, CMS only considers the hospital outreach laboratory to be an applicable laboratory. The hospital laboratory components furnishing laboratory services to hospital patients are not part of the applicable laboratory determination.

**Majority of Medicare Revenues Threshold**

To be an applicable laboratory, a hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI must meet the majority of Medicare revenues threshold. A
hospital outreach laboratory, by its revenues attributed to the Form CMS-1450 14x TOB, meets the majority of Medicare revenues threshold if it receives more than 50 percent of its total Medicare revenues from payments under the Medicare CLFS and/or Medicare PFS. The CLFS and PFS are under Medicare Part B, also known as Original Medicare or Fee-For-Service (FFS) Medicare.

To determine whether the hospital outreach laboratory (that bills using the hospital's NPI) meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims from the MAC for the 14x TOB received during the data collection period. See the Applicable Information Section below for additional information on the concept of final paid claims.

The same three steps (as discussed in the previous section) are used to determine whether a hospital outreach laboratory (that bills Medicare Part B under the hospital's NPI) meets the majority of Medicare revenues threshold:

- First, sum the CLFS and PFS payment amounts received by the hospital outreach laboratory attributed to the 14x TOB during the data collection period. The sum of CLFS and PFS revenues is the numerator of the majority of Medicare revenues threshold equation.

- Next, sum the total Medicare revenues received by the hospital outreach laboratory under the 14x TOB during the data collection period. Total Medicare revenues include the sum of all FFS payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period. The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation. As noted previously, effective January 1, 2019, Medicare Advantage plan payments under Medicare Part C shall not be included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation.

- Finally, divide the sum of CLFS and PFS revenues by the sum of total Medicare revenues received during the data collection period. We provide additional information on the data collection period below.

If the Medicare revenues received from the CLFS and/or PFS are greater than 50 percent of the total Medicare revenues received during the data collection period, the hospital outreach laboratory meets the majority of Medicare revenues threshold.

For hospital outreach laboratories that bill Medicare Part B under the hospital's NPI, the majority of Medicare revenues threshold equation is:

\[
\text{If:} \\
\frac{\text{Medicare CLFS revenues (based on 14x TOB)}}{\text{Medicare PFS revenues (based on 14x TOB)}} + \frac{\text{Medicare PFS revenues (based on 14x TOB)}}{\text{Medicare CLFS revenues (based on 14x TOB)}} \text{ is } > 50\%
\]

Then: The laboratory meets the majority of Medicare revenues threshold.

**Note:** Hospital outreach laboratories that bill Medicare Part B under the hospital’s NPI, and therefore determine applicable laboratory status based on its Medicare revenues from the 14x TOB, will most likely meet the majority of Medicare revenues threshold. They will most likely meet the majority of Medicare revenues threshold because their Medicare revenues are primarily, if not entirely, derived from the CLFS and or PFS. In other words, the revenues from the CLFS and or PFS services included in the numerator are essentially the same as the total Medicare revenues included in the denominator.

**Low Expenditure Threshold**

To be an applicable laboratory, a hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI must also meet the low expenditure threshold requirement.
A CLIA-certified hospital outreach laboratory meets the low expenditure threshold if, by the Form CMS-1450 14x TOB, receives at least $12,500 in Medicare revenues from the CLFS (under Medicare Part B) during the data collection period. To meet the low expenditure threshold, the hospital outreach laboratory must look to its final Medicare paid claims from the MAC received under the 14x TOB during the data collection period.

To determine whether the hospital outreach laboratory that bills Medicare Part B under the hospital's NPI meets the low expenditure threshold, sum all final payments attributed to the 14x TOB received from Medicare CLFS services during the data collection period.

It is important to note that the low expenditure threshold applies only to CLFS services. It does not include revenues received under the PFS. In other words, to meet the low expenditure threshold, the hospital outreach laboratory must receive at least $12,500 under only the Medicare CLFS during the data collection period.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold are applied to the CLIA-certified hospital outreach laboratory using the Form CMS-1450 14x TOB for purposes of determining whether the hospital outreach laboratory is an applicable laboratory:

**Example 1:** A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients bills Medicare Part B using the same NPI as the hospital. In other words, laboratory services performed for non-hospital patients are billed on the Form CMS-1450 14x TOB using the hospital’s NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory’s Medicare revenues received from the 14x TOB.

**Example 2:** A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients has its own unique NPI separate from the hospital’s NPI but does not use it to bill Medicare Part B. Instead, the hospital outreach laboratory continues to bill Medicare Part B for laboratory tests it furnishes to non-hospital patients using the hospital’s NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to Medicare revenues received from the 14x TOB. In other words, since laboratory services performed for non-hospital patients are billed using the hospital’s NPI (and not the hospital outreach laboratory’s own unique billing NPI), the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory’s Medicare revenues received from the 14x TOB.

**Example 3:** A hospital includes three CLIA-certified hospital outreach laboratories that perform laboratory services for non-hospital patients. Each CLIA-certified hospital outreach laboratory bills Medicare Part B under the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues attributed to the 14x TOB of all CLIA-certified hospital outreach laboratories of the hospital.

In summary, applicable information (as discussed in the next section) from all applicable laboratories must be collected during the data collection period and reported by reporting entities to CMS during the data reporting period. CMS uses the applicable information reported to CMS to establish payment rates under the CLFS. All CLIA-certified laboratories (that is, both applicable laboratories and laboratories that are not applicable laboratories) are subject to the Medicare Part B private payor rate-based CLFS.

**Applicable Information**

The applicable laboratory along with its reporting entity (we provide more information about reporting entities below) are responsible for collecting applicable information and reporting that data to CMS.
Applicable information includes three major components:

1. The specific HCPCS code associated with the test;
2. The private payor rate for each test for which final payment has been made during the data collection period;
3. The associated volume for each test.

**Private Payor Defined**

The definition of the term “private payor” is:

1. A health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service (PHS) Act; Or
2. A group health plan as defined in Section 2791(a)(1) of the PHS Act; Or
3. A Medicare Advantage plan under Part C as defined in Section 1859(b)(1) of the Social Security Act (the Act); Or
4. A Medicaid Managed Care Organization (MCO) (as defined in Section 1903(m) of the Act).

**Note:** Applicable information does not include information on tests for which payment is made on a capitated basis, where payments do not reflect specific HCPCS code-level amounts. (See below for additional information on payments made on a capitated basis.) Therefore, private payor rates from Medicaid MCO plans are considered applicable information only to the extent that the individual HCPCS code for the test, private payor rate specific to the test, and the volume paid at the specific rate for the test can be identified.

These specific private payor claims data are included as applicable information:

- **Laboratory tests subject to the data collection and reporting requirements.**
  Applicable information includes the specific HCPCS code for the test, each different private payor rate for the test, and the volume associated with each private payor rate for the test. You can find a list of laboratory tests subject to the data collection and data reporting requirements at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html and select: CLFS Applicable Information HCPCS Codes [ZIP, 57KB].

- **Final amount paid by a private payor for laboratory tests after all private payor price concessions are applied.** A final paid claim is the final amount paid by a private payor for a laboratory test during the data collection period. If a private payor pays a laboratory for a test but subsequent post-payment activities during the data collection period change that initial payment amount, the final payment is the private payor rate for purposes of determining applicable information. For example, if an initial claim was paid in error 3 months before a data collection period and then the initial claim is corrected, with final payment made by the private payor during the data collection period, the final corrected payment amount for the test is considered the private payor rate for purposes of determining applicable information. However, if an initial claim was paid in error during a data collection period and then corrected, with final payment made after the data collection period, the payment amount is not a private payor rate for purposes of applicable information and, therefore, is not reported to CMS.

- **Payments from secondary insurance payors.** Final payments from secondary insurance payors are considered in calculating private payor rates if the final payment was made during the data collection period. The private payor rate is 100 percent of the primary private payors’ fee schedule amount which includes the final amount the primary private payor paid for the test, any patient cost sharing responsibilities required by the primary private payor (such as patient deductible and coinsurance amounts) and any payments received from a secondary insurer (if applicable). The important concept here is the reporting entity reports 100 percent of the primary private payors’ fee schedule amount for the laboratory test. Reporting entities should not report payments received from secondary insurers separately.
• **Any patient cost sharing amounts, if applicable.** For purposes of applicable information, the private payor rate for a test should include any patient cost sharing responsibilities required by the private payor (for instance, patient deductible and/or coinsurance amounts). In other words, as noted above, the private payor rate is 100 percent of the private payor’s fee schedule amount for the test.

• **Multiple payment rates for the same test.** If an applicable laboratory receives more than one payment rate from the same private payor for the same test or more than one payment rate from different private payors for the same test, each unique payment rate along with the associated volume for the test code at each such rate is included as applicable information. In this case, the reporting entity must report each unique payment rate and the associated volume for the test at each such rate.

• **Appeals resolved during the data collection period.** Include payment rates (and the associated volume of tests) for claims under appeal as applicable information if the final payment amount is determined and paid by the private payor during the data collection period. For example, if a laboratory filed an appeal for a test furnished prior to a data collection period and resolved the appeal so that final payment for the test was made during the data collection period, the final rate paid is considered applicable information.

• **Non-contracted amounts for out-of-network laboratories or services.** Applicable information includes private payor rates for out-of-network laboratories if the private payor made final payment for the laboratory test during the data collection period. Non-contracted amounts paid to laboratories include any patient cost sharing amounts (for example, deductible and coinsurance responsibilities, if applicable).

**Exclude** these specific private payor claims data from applicable information:

• **Private payor rates for laboratory test codes paid only under the PFS.** If a laboratory test code is not paid under the CLFS and is paid under the PFS, the test code, private payor rate, and the test volume associated with the private payor rate is not applicable information.

• **Price concessions applied by a laboratory.** A laboratory’s decision to waive a patient’s deductible, copay, and/or coinsurance responsibility for a given test(s) must not be factored into the determination of the private payor rate for a test. Although laboratories may provide concessions to patients, it does not reflect the rates paid by private payors. As noted above, the private payor rate is 100 percent of the private payor’s fee schedule amount for the test.

• **Information about denied payments.** When a private payor denies payment for a laboratory test, payments of $0.00 are not considered a private payor rate for purposes of determining applicable information under the new CLFS. In other words, when the final determination by the private payor during the data collection period is to deny the claim and therefore does not make a payment, do not report $0.00 for a laboratory test code. Report only the final paid claim amount and the associated volume of tests paid at the final paid claim amount.

• **Unresolved appeals.** Where a laboratory test claim is still under review by the private payor or is under appeal during a data collection period, the amount that has already been paid is not considered a final payment rate and therefore is not considered applicable information. Additionally, if the appeal was settled during the data collection period but final payment was not made by the private payor until after the data collection period, the payment amount cannot be used for a private payor rate and therefore is excluded from applicable information.

• **Payments made on a capitated basis.** Generally, a capitated payment is made for health care services based on a set amount for each enrolled beneficiary in the plan for a given period, regardless of whether the beneficiary receives services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there is no way to determine payment specifically for a given test, it cannot be reported as applicable information. Therefore, applicable information does not include information about a test for which payment is made on a capitated basis.
• Payments where the associated test volume cannot be determined. As discussed above, the associated volume of tests performed corresponding to each private payor rate is a component of the definition of applicable information. Where the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payor’s remittance, CMS does not consider those payment amounts as applicable information and you should not report them to CMS.

• Remittances where the payor has grouped individual HCPCS code payments into an encounter or claim level payment. When a private payor groups payments for individual HCPCS codes into a single encounter or claim-level payment that is not represented by another HCPCS code, those payments are not applicable information. In other words, if a laboratory bills individual HCPCS codes and the payor bundles the individual HCPCS codes into groups not represented by other HCPCS codes, the payor’s bundled payment amount is not considered applicable information.

Note: In general, if a laboratory cannot correlate a private payor payment amount and the associated volume paid at that rate to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information. Estimated private payor rates and volumes are also not considered applicable information.

Schedule for Data Collection and Reporting
The next data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) is from January 1, 2019, through June 30, 2019. A 6-month review and validation period follows the data collection period and precedes the data reporting period (the period where applicable information must be submitted to CMS).

During the 6-month review and validation period between the end of the data collection period and the beginning of the data reporting period, laboratories and reporting entities should assess whether the applicable laboratory thresholds are met. That is, determine whether each laboratory component of the reporting entity meets the majority of Medicare revenues threshold and low expenditure threshold from final Medicare paid claims received during the data collection period. Applicable laboratories and their reporting entity should also use this time to review and validate applicable information (private payor data) before it is reported to CMS.

The next data reporting period (the period where applicable information for an applicable laboratory is reported to CMS) is from January 1, 2020, through March 31, 2020. CMS will use the next data collection and reporting cycle to determine CLFS payment rates for CY 2021 through CY 2023.

This table illustrates the next data collection and reporting periods for CDLTs.

<table>
<thead>
<tr>
<th>Data Collection Period</th>
<th>Six-Month Review and Validation Period</th>
<th>Data Reporting Period</th>
<th>Used for CLFS Rate Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continues every third subsequent calendar year</td>
<td>Continues every third subsequent calendar year</td>
<td>Continues every third subsequent calendar year</td>
<td>New CLFS rate every third year</td>
</tr>
</tbody>
</table>

While reporting is required every 3 years for CDLTs (that are not ADLTs), reporting entities must report applicable information annually for ADLTs, except for ADLTs in an initial data collection period (in which case a reporting entity will report by the end of the second quarter of the new ADLT initial period). We have issued additional information about ADLTs through separate instructions.

Reporting Entity
The TIN-level entity reports applicable information individually for all its laboratory components that are applicable laboratories. As noted above, an applicable laboratory is a CLIA-certified laboratory and, using its billing NPI or the 14x TOB (in the case of a hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI), meets the majority of Medicare revenues
threshold and low expenditure threshold. Please note that we discuss a condensed data reporting option later in this section.

I. Reporting for an Applicable Laboratory That Bills Medicare Part B Under its Own NPI

This section provides examples of reporting entities reporting applicable information for independent laboratories and physician office laboratories that bill Medicare Part B under their own NPI and hospital outreach laboratories that bill Medicare Part B under their own NPI (separate from the hospital’s NPI). The examples below illustrate reporting entities that must report applicable information individually for all NPI-level components that are applicable laboratories:

Example 1: A TIN-level entity consists of five CLIA-certified laboratories. Each laboratory bills using its own unique NPI and all five CLIA-certified laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of five unique applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that is an applicable laboratory (not collectively for all NPIs that are applicable laboratories under the TIN). The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for five applicable laboratories.

Example 2: A TIN-level entity consists of five CLIA-certified laboratories, each billing for services under its own unique NPI. However, only three of the laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold while the remaining two laboratories do not individually meet the low expenditure threshold. In other words, two of the five CLIA-certified laboratories receive less than $12,500 of revenue under the CLFS during the data collection period. This TIN-level entity consists of three unique applicable laboratories. In this case, the reporting entity will report applicable information associated with each individual NPI that is an applicable laboratory, but will not report information on the two individual NPIs of the laboratories that are not applicable laboratories. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for three applicable laboratories.

Example 3: A TIN-level entity consists of five CLIA-certified laboratories and each laboratory has the same NPI and bills Medicare Part B under the same NPI. Collectively, the five CLIA- certified laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of one applicable laboratory. In this case, the reporting entity reports applicable information for all laboratories associated with the same NPI as a single applicable laboratory. In other words, in this example, CMS considers the five CLIA-certified laboratories as one applicable laboratory for purposes of reporting applicable information because they all have the same NPI and all bill Medicare Part B under the same NPI.

Example 4: A TIN-level entity includes three CLIA-certified hospital outreach laboratories. Each hospital outreach laboratory bills using its own unique NPI (separate from the hospital’s NPI) and all three CLIA-certified hospital outreach laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of three applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that is an applicable laboratory (not collectively for all NPIs that are applicable laboratories under the TIN). The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for three applicable laboratories.

Example 5: A TIN-level entity consists of three CLIA-certified hospital outreach laboratories, each billing for services under its own unique NPI (separate from the
Example 6: A TIN-level entity includes three CLIA-certified hospital outreach laboratories and all three laboratories have the same unique NPI and bill Medicare Part B under the same unique NPI (separate from the hospital’s NPI). Collectively, the three CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of one applicable laboratory. In this example, CMS considers the three CLIA-certified hospital outreach laboratories as one applicable laboratory for purposes of reporting applicable information because they all have the same NPI (separate from the hospital’s NPI) and all bill Medicare Part B under the same NPI.

Note: For a hospital outreach laboratory that bills Medicare Part B under its own unique billing NPI (separate from the hospital’s NPI), the reporting entity reports applicable information by the hospital outreach laboratory’s own unique billing NPI.

II. Reporting for Hospital Outreach Laboratories That Bill Medicare Part B Under the Hospital’s NPI

This section provides examples of reporting entities reporting applicable information for hospital outreach laboratories that bill Medicare Part B under the hospital’s NPI. The examples below illustrate reporting entities that must report applicable information for hospital outreach laboratories that bill Medicare Part B under the hospital’s NPI that are applicable laboratories:

Example 1: A TIN-level entity includes a CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients and bills Medicare Part B using the hospital’s NPI. Based on its Medicare revenues attributed to the Form CMS-1450 14x TOB, the hospital outreach laboratory meets the majority of Medicare revenues threshold and low expenditure threshold and therefore is an applicable laboratory. In this example, the reporting entity reports applicable information for its hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI.

Example 2: A TIN-level entity consists of three CLIA-certified hospital outreach laboratories and each laboratory bills Medicare Part B under the hospital’s NPI. Collectively, the three CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of one applicable laboratory. In this example, the reporting entity collectively reports applicable information for its three hospital outreach laboratories that bill Medicare Part B under the hospital’s NPI.

Example 3: A TIN-level entity includes three CLIA-certified hospital outreach laboratories. Two (out of the three) hospital outreach laboratories bill for laboratory services performed for non-hospital patients using the hospital’s NPI. Collectively, the two CLIA-certified hospital outreach laboratories that bill using the hospital’s NPI meet the majority of Medicare revenues threshold and low expenditure threshold. However, one (out of the three) bills Medicare Part B for laboratory services performed for non-
hospital patients using its own unique NPI (separate from the hospital’s NPI) and meets the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of two applicable laboratories.

In this example, the reporting entity reports applicable information for the hospital outreach laboratories that bill Medicare Part B for non-hospital patients under the hospital’s NPI separately from the hospital outreach laboratory that bills Medicare Part B under its own unique NPI.

**Note:** The reporting entity must report applicable information for hospital outreach laboratories that are applicable laboratories based on the NPI used for billing Medicare Part B. That is, for hospital outreach laboratories that bill Medicare Part B under the hospital’s NPI, (and therefore determines applicable laboratory status based on its Medicare revenues attributed to the 14x TOB) the reporting entity reports applicable information by the hospital’s NPI.

**Only Applicable Information Attributed to non-Hospital Patients is Reported**

As discussed previously in this publication, a CLIA certified hospital outreach laboratory that bills Medicare Part B using the hospital’s NPI must determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold based on its Medicare revenues attributed to the Form CMS-1450 14x TOB. If a CLIA-certified hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI meets the requirements of an applicable laboratory, only the hospital outreach laboratory component of the hospital laboratory (that is, laboratory tests furnished to non-hospital patients) is considered an applicable laboratory.

Therefore, report only applicable information attributed to the laboratory’s non-hospital patients to CMS.

The reporting entity for the hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI, and therefore determines applicable laboratory status based on Medicare revenues attributed to the 14x TOB, may not report applicable information for other parts of a hospital’s laboratory business such as testing performed for hospital outpatients or hospital inpatients.

In circumstances in which a private payor does not require a hospital outreach laboratory to use the Form CMS-1450 14x TOB, the hospital must distinguish between private payor fee for service payments (and the associated volume) made for laboratory tests furnished to non-patients (the applicable laboratory) from private payor fee for service payments (and associated test volume) for laboratory tests furnished to hospital patients.

Even if a private payor’s rate is the same for a given laboratory test code in each setting, that is, the outreach laboratory setting for non-patients, outpatient hospital setting for hospital outpatients and the inpatient hospital setting for hospital inpatients, only the volume of services for hospital outreach laboratory services (non-hospital patient laboratory testing) is permitted to be reported to CMS.

It is the hospital’s responsibility to identify, collect and report the separately payable private payor rates (and the volume of tests paid at those rates) that are associated with only the outreach laboratory portion of the hospital’s laboratory business.

**Example 1:** A private payor does not require the Form CMS-1450 14x TOB for hospital outreach laboratory services. The private payor’s final paid claim amount during the data collection period for the HCPCS code of a test is $20 for both hospital outpatients and non-hospital patients. The volume of services paid at $20 for tests furnished to hospital outpatients is 200 and the volume of services paid at $20 for tests furnished to non-hospital patients is 250. In this example, the reporting entity reports the HCPCS code for the test, payment rate $20, volume 250. Do not report the volume associated with tests furnished to hospital patients (200).
Example 2: A private payor does not require the Form CMS-1450 14x TOB for hospital outreach laboratory services. The private payor pays one rate for tests furnished to hospital patients and pays a different rate for testing furnished for non-hospital patients. The private payor’s final claim amount during the data collection period for the HCPCS code of a test is $20 for hospital outpatients and $18 for non-hospital patients. The volume of services paid at $20 for tests furnished to hospital outpatients is 200 and the volume of services paid at $18 for tests furnished to non-hospital patients is 250. In this example, the reporting entity reports the HCPCS code for the test, payment rate $18 with a volume of 250. Do not report the payment rate for hospital patients of $20 and volume paid at that rate (200).

III. Additional Reporting Instructions That Apply to All Applicable Laboratories

This section provides additional reporting instructions for reporting entities reporting applicable information for its component applicable laboratory(s).

Reporting Entity Must Ensure Accurate Collection and Reporting of Applicable Information

The TIN-level entity along with its applicable laboratory(s) should establish their own approach for ensuring that the TIN-level entity can report applicable information to CMS. To that end, applicable laboratories and their reporting entity should determine the best approach to collect applicable information from final paid claims data and for submitting applicable information to CMS during the data reporting period.

Voluntary Reporting is Not Permitted

The reporting entity reports only applicable information for laboratory components that are applicable laboratories (that is, laboratories that meet the definition of an applicable laboratory). Reporting entities do not report applicable information for laboratories that do not meet the definition of an applicable laboratory.

Example 1: A TIN-level entity consists of four NPI-level entities. Three of the NPI-level entities meet the definition of an applicable laboratory, and one NPI-level entity does not meet the definition of an applicable laboratory. In this example, the reporting entity reports applicable information to CMS for only the three NPI-level entities that are applicable laboratories.

Example 2: A TIN-level entity includes one hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI. Based on revenues attributed to the Form CMS-1450 14x TOB, the hospital outreach laboratory meets the majority of Medicare revenues threshold but does not meet the low expenditure threshold. In other words, the hospital outreach laboratory does not receive at least $12,500 in revenues from the Medicare CLFS during the data collection period. Therefore, the hospital outreach laboratory does not meet the definition of an applicable laboratory. In this example, the reporting entity does not report applicable information to CMS for its hospital outreach laboratory.

Reporting Applicable Information is Not Discretionary

Reporting entities must report all applicable information for its laboratory components that are applicable laboratories. Reporting entities do not have the discretion to selectively omit reporting certain applicable information.

Example: An applicable laboratory has various final paid claims for laboratory tests from the data collection period that are only in “hard copy” paper format. The reporting entity along with its applicable laboratory perceives that reporting applicable information derived from the paper claims has minimal impact on the final payment rate calculated for the tests. In this case, the reporting entity cannot selectively omit reporting applicable information due to the perception that reporting such applicable information may not influence the final weighted median private payor rates for a given test. In this example,
the reporting entity must report the applicable information obtained from the “paper-based” claims to CMS during the data reporting period.

IV. Condensed Data Reporting Option

For the next data reporting period, that is January 1, 2020, through March 31, 2020, reporting entities may condense certain applicable information at the TIN-level, instead of reporting individually for each component that is an applicable laboratory. You may use the condensed data reporting option when more than one applicable laboratory under the TIN is paid at the same private payor rate for a specific HCPCS code.

For example, if three of the reporting entity’s corresponding applicable laboratories are paid the same private payor rate for a specific HCPCS code, the reporting entity may report one record of data showing the HCPCS code, the payment rate, and the associated volume, across all three applicable laboratories, rather than reporting three separate records (that is, one for each component applicable laboratory). In other words, the reporting entity may combine the volume paid at the same private payor rate for the same HCPCS code for its component applicable laboratories.

Under the condensed data reporting option, the reporting entity must select one NPI as the reporting NPI. That is, the reporting entity will designate one applicable laboratory’s NPI as the reporting NPI for each instance of condensed reporting. The reporting entity can select any NPI under the TIN that meets the definition of an applicable laboratory and designate that NPI as the reporting NPI for reporting the condensed applicable information.

Note that each unique private payor rate for each laboratory test code must be reported to CMS during the data reporting period. The condensed data reporting option is only permitted when a specific laboratory test code is paid at the same private payor rate to more than one applicable laboratory under the same TIN. Unique private payor rates paid to only one applicable laboratory under the TIN, and the volume paid at such rate(s), must be reported individually by applicable laboratory.

Reporting entities have the option of condensing the volume paid at the same private payor rate for a specific HCPCS code during a data collection period across its components that are applicable laboratories. However, if the reporting entity prefers to report applicable information individually for each of its component applicable laboratories, they may continue to do so.

To illustrate how reporting entities may report condensed applicable information when three different applicable laboratories under the same TIN are paid the same private payor rate for the same laboratory test code during a data collection period, see the comparative examples below. These examples are meant to show the difference between the individual applicable laboratory data reporting method that is, by each component that is an applicable laboratory, and the condensed data reporting method and are not intended to be representative of every possible scenario.

<p>| TABLE 1a – Example of Individual Applicable Laboratory Reporting for 2020 Data Submission |
|----------------------------------|-----------------|----------------|--------|</p>
<table>
<thead>
<tr>
<th>NPI</th>
<th>HCPCS Code</th>
<th>Payment Rate</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>400</td>
</tr>
<tr>
<td>2</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>300</td>
</tr>
<tr>
<td>3</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>200</td>
</tr>
</tbody>
</table>

In this example of the individual applicable laboratory data reporting method, three applicable laboratories are paid the same private payor rate for “Lab Test Code 1”. Therefore, the reporting entity reports applicable information individually for each of its component applicable laboratories.
This example illustrates how the scenario presented in Table 1a would be reported under the condensed data reporting method. The reporting entity reports applicable information by combining the volume paid at the same private payor rate for the same HCPCS code at the reporting entity level (TIN-Level). The reporting entity designates one (of its three component applicable laboratories) as the reporting NPI.

### Table 1b - Example of Condensed Reporting for 2020 Data Submission (TIN-Level)

<table>
<thead>
<tr>
<th>Reporting NPI</th>
<th>HCPCS Code</th>
<th>Payment Rate</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designated NPI for Condensed Reporting</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>900</td>
</tr>
</tbody>
</table>

### Table 2a - Example of Individual Applicable Laboratory Reporting for 2020 Data Submission

<table>
<thead>
<tr>
<th>NPI</th>
<th>HCPCS Code</th>
<th>Payment Rate</th>
<th>Volume</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>400</td>
</tr>
<tr>
<td>1</td>
<td>Lab Test Code (1)</td>
<td>$17.00</td>
<td>100</td>
</tr>
<tr>
<td>2</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>300</td>
</tr>
<tr>
<td>2</td>
<td>Lab Test Code (1)</td>
<td>$17.00</td>
<td>150</td>
</tr>
<tr>
<td>3</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>200</td>
</tr>
<tr>
<td>3</td>
<td>Lab Test Code (1)</td>
<td>$17.00</td>
<td>75</td>
</tr>
</tbody>
</table>

In this example of the individual applicable laboratory data reporting method, three applicable laboratories are paid a private payor rate of $15 for “Lab Test Code 1” and the same three applicable laboratories are also paid a private payor rate of $17 for “Lab Test Code 1.” In this example, the reporting entity reports each HCPCS code and each unique private payor rate and the volume paid at each unique private payor rate individually for each of its component applicable laboratories.

### Table 2b - Example of Condensed Reporting for 2020 Data Submission (TIN-Level)

<table>
<thead>
<tr>
<th>Reporting NPI</th>
<th>HCPCS Code</th>
<th>Payment Rate</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designated NPI for Condensed Reporting</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>900</td>
</tr>
<tr>
<td>Designated NPI for Condensed Reporting</td>
<td>Lab Test Code (1)</td>
<td>$17.00</td>
<td>325</td>
</tr>
</tbody>
</table>

This example illustrates how the scenario presented in Table 2a would be reported under the condensed data reporting method. The reporting entity reports applicable information by combining the volume paid at the same private payor rate for the same HCPCS code at the reporting entity level (TIN-Level). In other words, the private payor rate of $15 and associated volume is combined and the private payor rate of $17.00 and associated volume is combined.

### Table 3a - Example of Individual Applicable Laboratory Reporting for 2020 Data Submission

<table>
<thead>
<tr>
<th>NPI</th>
<th>HCPCS Code</th>
<th>Payment Rate</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>400</td>
</tr>
<tr>
<td>1</td>
<td>Lab Test Code (1)</td>
<td>$17.00</td>
<td>100</td>
</tr>
<tr>
<td>1</td>
<td>Lab Test Code (1)</td>
<td>$18.50</td>
<td>50</td>
</tr>
<tr>
<td>2</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>300</td>
</tr>
<tr>
<td>2</td>
<td>Lab Test Code (1)</td>
<td>$17.00</td>
<td>150</td>
</tr>
<tr>
<td>2</td>
<td>Lab Test Code (1)</td>
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<tr>
<td>3</td>
<td>Lab Test Code (1)</td>
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<td>200</td>
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<tr>
<td>3</td>
<td>Lab Test Code (1)</td>
<td>$17.00</td>
<td>75</td>
</tr>
<tr>
<td>3</td>
<td>Lab Test Code (1)</td>
<td>$20.00</td>
<td>30</td>
</tr>
</tbody>
</table>

In this example of the individual applicable laboratory data reporting method, three applicable laboratories are paid a private payor rate of $15 for “Lab Test Code 1” and the same three applicable laboratories are also paid a private payor rate of $17 for “Lab Test Code 1.” In addition, one of the three applicable laboratories is paid a private payor rate of $18.50 for “Lab Test Code 1.”
rate of $18.50, another applicable laboratory is paid a private payor rate of $19.50, and another applicable laboratory is paid a private payor rate of $20 for “Lab Test Code 1.” The reporting entity reports the HCPCS code and each unique private payor rate and the volume paid at each unique private payor rate individually for each of its component applicable laboratories.

<table>
<thead>
<tr>
<th>Reporting NPI</th>
<th>HCPCS Code</th>
<th>Payment Rate</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designated NPI for Condensed Reporting</td>
<td>Lab Test Code (1)</td>
<td>$15.00</td>
<td>900</td>
</tr>
<tr>
<td>1 Designated NPI for Condensed Reporting</td>
<td>Lab Test Code (1)</td>
<td>$17.00</td>
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</tr>
<tr>
<td>3</td>
<td>Lab Test Code (1)</td>
<td>$20.00</td>
<td>30</td>
</tr>
</tbody>
</table>

This example illustrates how the scenario presented in Table 3a would be reported under the condensed data reporting method. As discussed previously, the reporting entity must report each unique private payor rate for each specific HCPCS code and the associated volume paid at each such rate. Since some private payor rates are paid to only one applicable laboratory under the TIN, a combination of the condensed data reporting method and individual applicable laboratory reporting is used to report applicable information.

The condensed data reporting method may be used when more than one applicable laboratory under the TIN is paid the same private payor rate for a specific laboratory test code. In this example, the volume among the three applicable laboratories for the private payor rate of $15.00 may be combined and the volume among the three applicable laboratories for the private payor rate of $17.00 may be combined.

However, condensed reporting would not be permitted for the unique private payor rates for “Lab Test Code 1” that are paid to only one applicable laboratory under the same TIN. Therefore, the private payor rate of $18.50 paid to “NPI 1”; the private payor rate of $19.50 paid to “NPI 2”; the private payor rate of $20.00 paid to “NPI 3” and the associated volume paid at each of these unique private payor rates must be reported individually for each applicable laboratory.

**Implementation Schedule**

This is the schedule for implementing the next private payor rate-based CLFS update:

- Data collection period for determining CY 2021 CLFS payment rates: January 1, 2019, through June 30, 2019.
- Data reporting period for reporting entities to report private payor rate data to CMS for determining CY 2021 CLFS payment rates: January 1, 2020, through March 31, 2020.
- Annual laboratory public meeting for new tests: June/July 2020. CMS will use crosswalking or gapfilling to set rates for new tests and existing tests for which there is no private payor data collected for the CY 2021 CLFS.
- CMS publishes preliminary CLFS rates for CY 2021: Early September 2020. The public will have approximately 30 days, through early October 2020, to submit comments on the preliminary CY 2021 rates.
- Implementation date for the next private payor rate-based CLFS update: January 1, 2021.

**Additional Information**

For more information about the private payor rate-based payment system including a summary of the private payor rate-based CLFS, the CLFS final rule, related press release and fact sheet,
frequently asked questions on our final policies, a PowerPoint slide presentation of the private payor rate-based CLFS and ADLTs, visit https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.


If you have questions about requirements for the private payor rate-based CLFS, please email them to the CLFS Inquiries mailbox at CLFS_Inquiries@cms.hhs.gov.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

**Document History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>February 27, 2019</td>
<td>Initial article released</td>
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