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Letter from the Editor

This issue includes an overview article on the MACRA or the Medicare Access and CHIP Reauthorization regulation. CMS recently posted two major proposed rules for calendar year 2017, including the Medicare Inpatient Prospective Payment System rule, which covers hospital inpatient payments, and—MACRA, which covers CMS’s proposed rule to respond to Congressional direction to move the Medicare program from a fee for services payment model to a “value-based” purchasing model. The bottom line on MACRA is, nearly all Medicare participating physicians will find future Medicare payments tied to how physicians do on an index of performance measures. The index includes a mix of cost, quality, electronic data use and clinical practice improvement activities. A third important rule, the Medicare Physician Fee Schedule, which covers Medicare Part B payments to physicians and other Part B providers, is expected shortly for 2017. A new class of drugs – monoclonal antibodies for the treatment of asthma – are proliferating the market. These new drugs will require practices to consider the buy-and-bill model for these physician administered drugs. This issue includes an article on the buy-and-bill reimbursement model and how it will likely apply to these new asthma medications.

EBUS billing to avoid problems with NCCI edits is also covered in this issue. As always, you can find answers to your pulmonary, critical care and sleep coding and billing questions.

I hope this issue provides useful information for you and your practice. I will welcome your input on topics to cover in future issues.

Sincerely,

Alan L. Plummer, MD
Editor



MEDICARE ACCESS AND CHIP REAUTHORIZATION ACT OF 2015 (MACRA)

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was signed into law on April 16, 2015. This act repealed the sustainable growth rate (SGR) formula that had been used to calculate Medicare payments to physicians. While this was a much anticipated change, there were other impacts on Medicare payments to physicians. MACRA also created a framework for a reimbursement system that is based on providing higher value and quality care, rather than a volume-based model. Beginning in 2019, providers will participate in either the Merit-based Incentive Payment System (MIPS) or the Advanced Alternative Payment Models (APMs), with the option to change their selection annually. Physicians participating in the MIPS track will have payments increased or decreased based on relative performance, while those choosing the APM track will receive incentive payments based on participation.

The current implementation timeline for MACRA defines a 0.5 percent physician fee schedule update each year from 2016 through 2019. The reimbursement level in 2019 will be the starting point for incentives for either program. Most physicians will participate in Medicare reimbursement through the MIPS track until more qualified, eligible APMs become available. From 2020 through 2025, the Medicare physician fee schedule updates will remain at 2019 levels with no changes. Beginning in 2026, additional increases in the physician fee schedule will occur. However, they will be greater for those participating in APMs (.75 percent) compared to those in MIPS (.25 percent).

A “Notice of Proposed Rule Making” for MACRA was published April 27, 2016 and some of those details are included in this discussion. There are several changes in this proposed rule, particularly in the components and their weights of the MIPS compared to previous reports about MACRA. The Department of Health and Human Services (HHS) will accept feedback on the proposed rule until June 26, 2016 on the Center for Medicare and Medicaid Services (CMS) website (<https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/eRulemaking/index.html?redirect=/eRulemaking%20>).

Merit-based Incentive Payment System (MIPS)

The Merit-based Incentive Payment System (MIPS), a modified fee-for-service model, consolidates three existing quality reporting programs: the Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VBPM), and Meaningful Use (MU), as well as adding a new program, called Clinical Practice Improvement Activities (CPIA). The final reporting period for the PQRS, VBPM, and MU

programs will be 2016. As of 2019, they will cease to exist as stand-alone programs. However, these programs along with the CPIA, will begin to collect data in 2017 for use in a composite score. Data from four categories will yield a single number ranging from 0-100, called the MIPS Composite Performance Score. This score will be used to determine physician payment. The composite performance score is established from the following weighted categories:

- Cost (10 percent)
- Quality (50 percent)
- Advancing Care Information (25 percent)
- Clinical Practice Improvement Activities (15 percent)

The **Cost** component of MIPS will be 10 percent of the total score in year 1 and replaces the cost component of the Value Modifier Program (Resource Use). The score would be based on Medicare claims, with no new reporting requirements for clinicians. This category will use more than 40 episode-specific measures to account for differences among specialties¹.

The **Quality** component of MIPS will be 50 percent of the total score in year 1 and replaces the Physician Quality Reporting System and the quality component of the Value Modifier Program. Clinicians would choose to report six measures instead of the nine measures currently required under PQRS. This category gives clinicians reporting options to choose from that accommodate differences in specialty and practices¹.

The **Advancing Care Information** component of MIPS will be 25 percent of the total score in year 1 and replaces the Medicare EHR Incentive Program (Meaningful Use). Clinicians would choose to report customizable measures that reflect how they use electronic health record (EHR) technology in their day-to-day practice, with a particular emphasis on interoperability and information exchange. Unlike the existing Meaningful Use program, this category would not require all-or-nothing EHR measurement or quarterly reporting¹.

The **Clinical Practice Improvement Activities** component of MIPS will be 15 percent of the total score in year 1. Clinicians would be rewarded for clinical practice improvement activities, such as activities focused on care coordination, beneficiary engagement, and patient safety. Clinicians may select activities that match their practices’ goals from a list of more than 90 options. Additionally, clinicians would receive credit in this category for participating in the Advanced Alternative Payment Models and in Patient-Centered Medical Homes¹.

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For those in the MIPS program, payment adjustments to the fee schedule will be exclusively based on performance. Clinicians will have the option to be assessed as a group or an individual. Since MIPS measures overall care delivery, clinicians do not need to limit their MIPS reporting to the care just provided to Medicare beneficiaries.

Beginning in 2019, providers in MIPS will be eligible for positive or negative Medicare payment adjustments that gradually increase to 9 percent in 2022, where they are targeted to remain.

- 2019 – 4 percent
- 2020 – 5 percent
- 2021 – 7 percent
- 2022 – 9 percent

The threshold for these payment adjustments will be the mean or median composite score for all MIPS-eligible professionals during the previous performance period. Payment adjustments will follow a threshold where half of eligible physicians will be above the performance threshold and half below. CMS will calculate and apply a scaling factor to ensure budget neutrality. Payment adjustments will be based on the following:

- Physicians who score at the threshold will receive no payment adjustment.
- Physicians whose composite score is above the mean will receive a positive payment adjustment on each Medicare Part B claim for the following year.
- Physicians whose composite score is below the mean will receive a negative payment adjustment on each Medicare Part B claim for the following year.

For 2019 through 2024, an additional positive payment adjustment of up to 10 percent will be available to “exceptional” performers. Exceptional performers will be physicians in the top 25 percent of the composite score. \$500 million has been allowed for this performance bonus that is not subject to budget neutrality. Beginning in 2026, all physicians participating in MIPS will be eligible for a 0.25 percent increase in their physician fee schedule payments each year. CMS will calculate and apply a scaling factor to ensure budget neutrality.

There are exemptions from participation in MIPS for some providers including: providers in their first year of billing Medicare, providers whose volume of Medicare payments and patients fall below a threshold (less than or equal to \$10,000 in Medicare charges and less than or equal to 100 Medicare patients), and providers who are significantly participating in an Advanced Alternative Payment Model. Additionally, it is

anticipated that providers practicing in rural health clinics or Federally Qualified Health Clinics (FQHCs) may also be exempt from MIPS.

Advanced Alternative Payment Model (APM)

Physicians who choose to adopt new payment and delivery models approved by the Centers for Medicare and Medicaid Services (CMS) may be eligible for the Advanced Alternative Payment Models (APM) track. Physicians who choose to be paid under eligible APMs are exempt from participating in MIPS. The APM track is continuing to evolve. APMs largely involve accepting risk based on the quality and effectiveness of care provided. However, Patient-Centered Medical Homes (PCMHs) can qualify as an APM without taking on financial risk. Over time, additional APM options will become available. Under the law, MACRA defines the following as a qualifying APM:

- Center for Medicare & Medicaid Innovation (CMMI), Innovation Center Models
- A Medicare Shared Savings Program (MSSP)
- Medicare Health Care Quality Demonstration Program or Medicare Acute Care Episode Demonstration Program
- Another demonstration program required by federal law.

However not all APMs are “eligible APMs.” Eligible APMs must meet the following criteria:

- Base payment on quality measures comparable to those in MIPS
- Require the use of certified EHR technology
- Either (1) bear more than nominal financial risk for monetary losses OR (2) identify as a Patient Centered Medical Home (PCMH) as expanded under the CMS Innovation Center authority.

The proposed rule includes a list of models that would qualify Advanced APMs, including:

- Comprehensive ESRD Care Model (Large Dialysis Organization arrangement)
- Comprehensive Primary Care Plus (CPC+)
- Medicare Shared Savings Program—Track 2
- Medicare Shared Savings Program—Track 3
- Next Generation ACO Model
- Oncology Care Model Two-Sided Risk Arrangement (available in 2018)

All clinicians must report through MIPS in the first year of the program to determine whether they meet requirements for the APM track. For a physician to receive incentive payments for

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participation, a designated percentage of Medicare payments or patients through a qualified, eligible APM is required. The designated percentage of payments/patients to qualify for incentive payments increases each year. In 2019, 25 percent of payments and 20 percent of patients for an individual physician must be through an Advanced APM. Those percentages increase to 75 percent for payments and 50 percent for patients by 2024. In 2019 and 2020, the participation requirements for Advanced APMs are for Medicare payments or patients only. However starting in 2021, the participation requirements may include non-Medicare payers and patients. CMS estimates that up to 90,000 clinicians will participate in Advanced APMs in the first payment year.

Participants in Advanced APMs will:

- Be paid according to the rules established as part of their APM (e.g., care coordination or infrastructure payments, shared savings, bundled payments, etc.).
- Not be subject to MIPS.
- Receive a 5 percent lump sum bonus payment on their fee-for-service reimbursements for years 2019-2024.
- Receive a higher fee schedule update for years 2026 and beyond (0.75 percent).

Moving Forward

Medicare continues to work out many of the details associated with MACRA. Moving forward, this is the time to start evaluating which model of payment will work best for you. For those of you participating in an APM, determining whether it is an eligible APM is key. If you are in an APM, whether or not it's eligible, you are expected to fare much better under either new Medicare payment pathways. If not already doing so, participating in the current PQRS and/or Meaningful Use programs and reviewing the Quality and Resource Use Report (QRUR) reports that you receive as part of the Value-Based Payment Modifier is another important starting point. These are the programs that will serve as the building blocks of the new MIPS.

¹ Center for Medicare and Medicare Services. (2016, April 27). Notice of Proposed Rule Making: Medicare Access and CHIP Reauthorization Act of 2015. Retrieved from <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/NPRM-QPP-Fact-Sheet.pdf>

PHYSICIAN ADMINISTERED ASTHMA DRUGS AND BUY AND BILL REIMBURSEMENT MODEL

So How Do I Implement Monoclonal Antibody Therapy in My Practice: The Financial Consequences?

Reynold A. Panettieri, Jr., MD and Bradley E. Chipps, MD

Contemporary approaches to managing lung disease incorporate biologics as key agents in improving lung health. Using severe persistent asthma as an example, the availability of omalizumab has markedly impacted clinical outcomes. Despite 13 years' experience with omalizumab and compared to allergists, the use of biological agents by pulmonologists remains challenging. Several reasons may contribute to this disparity: apart from intrinsic differences in patients seeking allergy or pulmonary expertise, the pulmonologist practice sites rarely deliver parenteral therapy and familiarity with billing practices may be an obstacle. With the dramatic increase in new biologic agents such as mepolizumab and reslizumab to manage severe persistent asthma (in the near future another five agents will likely be approved), pulmonologists need to incorporate biologic agents in their therapeutic algorithms. In contrast, oncologists, nephrologists and others have far greater experience in prescribing biologics (1-4). To address the financial challenges

that face practices implementing biological therapy, this brief review describes current obstacles and approaches.

The delivery of biologics to outpatients has generated controversy over the optimal approaches that are cost effective and offer the greatest accessibility (1,2). Three approaches that were initially developed to meet the needs of oncology include: buy-and-bill, white-bagging, and specialty pharmacy. Typically, physician-administered drugs and biologics are purchased by the practice, and the products are billed to the payers under a medical benefit through buy-and-bill. Practices are usually reimbursed at the manufacturer's average selling price plus a percentage. White-bagging occurs when specialty pharmacy distributors dispense the medication to the patient but ships it to the provider for administration. The specialty pharmacy distributor obtains reimbursement from the payer for the drug. The physician neither buys nor bills for the drug but is paid a drug administration fee. Alternatively, specialty pharmacies dispense biologics and offer clinical services including patient education and therapy/adherence approaches for biologics. Specialty pharmacies dispense

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these medications and receive reimbursement from payers, but these specialty pharmacies are not specialty pharmacy distributors. There are advantages and disadvantages to the three models. Importantly, the administration of a biologic by the practitioner provides direct evidence of adherence and continuity of care that differs from administration in a specialty pharmacy (1). In the pulmonary field, most providers are unfamiliar with the three approaches.

Given the cost of biological agents, payers require pre-authorization for most, if not all, patients. Payers vary on their approaches to approval of biologics. Qualifying criteria are established and most pharmaceutical manufacturers provide assistance in navigating the pre-authorization process. **Medicare patients who are prescribed a biologic do not require pre-authorization.** Authorization, however, may be required from a secondary insurance, and that benefit must be clearly defined before the practitioner orders the drug from the specialty pharmacy distributor. Typically for pulmonary-focused biologics, once payer approval is secured there are two models to access the medication. Traditionally, the patient is billed a co-pay and the drug is shipped to the provider for administration (white-bagging) or administered at a specialty pharmacy or infusion center. Accordingly, the practice incurs little financial risk other than the practice time for reconstitution, drug administration and for the requisite patient observation time to assess adverse effects (typically 30-60min).

In other instances, the payer may use the buy-and-bill model that requires the practice to purchase the drug and then bill the payer after administration. Financially, the practice incurs an upfront cost that is reimbursable, but this approach may be unfamiliar to pulmonologists and pose challenges. Buy-and-bill orders generally have 90 to 120 days for repayment to the specialty pharmacy, allowing time to collect the amount due from the primary payer. **It is important that a thorough benefit analysis be completed before any transactions are**

undertaken. Plausibly, practices will secure some additional income over the obligated cost of the drug, but this is minimal. The future of novel therapeutic approaches to manage lung disease will include the robust use of biologics. In our field, it will be imperative to become familiar with these approaches which will offer our patients the optimal current and effective approaches to promote lung health.

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EBUS BILLING AND NCCI EDITS

On January 1, 2016 the CPT code for endobronchial ultrasound (EBUS) 31620 was replaced by three new codes that better describe the procedure as it is currently performed. The codes now differentiate the use of EBUS in sampling proximal lesions using a convex probe and more distal lesions using a radial probe. As with all bronchoscopy procedures, the diagnostic code, 31622, is included within these three new codes and the multiple endoscopy rule applies.

CPT code 31652 *with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures* is utilized when one samples two or less proximal structures. CPT code 31653 *with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures* is utilized when one samples 3 or more structures. 31652 and 31653 may NOT be used together.

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Use the code that best describes the work that was performed. These two codes include the work of sampling and therefore one does NOT use the transbronchial needle aspiration codes 31628, 31629 31632 and 31633 with either 31652 or 31653 if only sampling of the mediastinal and hilar structures occurs. If additional bronchoscopic evaluation is performed on structures distal to the hilar structures then use of other bronchoscopic codes is appropriate with codes 31652 and 31653.

CPT code 31654 with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (List separately in addition to code for primary procedure[s]) is an “add-on” (ZZZ) code that is used when peripheral lesions (distal to the hilar structures) identified by radial EBUS are sampled. As such, code 31654 MAY be used with any other bronchoscopy codes.

Unfortunately, when CMS originally published the National Correct Coding Initiative (NCCI) edits for the new codes there were errors present. NCCI edits are used to instruct CMS payers and clinicians when two distinct CPT codes may or may not be used together. The NCCI edits for 31652 and 31653 published on January 1, 2016 had a values of “0” for all

other bronchoscopy codes. This instructed payers to reject any claims for 31652 or 31653 if any other bronchoscopy code was appended. The societies alerted CMS to these problems and the NCCI edits were corrected. It is now appropriate to code for bronchoscopy procedures performed in addition to EBUS with a convex probe sampling proximal lesions. However, the corrections did not take effect until April 1, 2016. It is, therefore, possible that some claims using codes 31652 and 31653 will have been rejected by CMS and other carriers from January 1 until April 1. Therefore, all claims for EBUS procedures using these codes during this time should be reviewed and resubmitted if rejected by payers.

Q&A

Q. I am a physician practice manager and responsible for monitoring my group’s productivity. I understand that Medicare publishes a list of relative values by CPT codes. Does this list also have times associated with the CPT codes?

A. Yes, CMS publishes all CPT and HCPCS active codes with relative values on a quarterly and annual basis. Those values are broken into Physician work, Practice Expense and Professional Liability Insurance (Malpractice). These RVU files can be found at the following URL: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html>. As an example, RVU16C would be the RVU file for 2016 and C means that it is the third update, likely for July 2016. Those downloadable zip files have lots of information. Look for the file that starts with PPRRVU. This is the file that will have the RVUs and the conversion factor. Unfortunately, CMS does not post the RVU and the times in the same files, but they do post them. To locate the times for

each CPT code, go to <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html> the PFS Federal Regulation Notices, where proposed and final rules are posted each year. Select the final rule or the most current rule if there are corrections or updates for the year of interest. If you were obtaining the most current as of March 26, 2016 you would select the following URL, updated March 2016 <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1631-F2.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>. Here you will find again many downloadable files, however for times you would select the file that says, FINAL RULE WORK TIME in the title. That will contain the breakdown and total time by CPT code for your information. If you have questions, you may always contact ATS staff at coding@thoracic.org

Q. I work in a large community based pulmonary critical care group practice. We recently acquired a group of NPPs (Non

Physician Providers) who work exclusively in the ICU and were previous employees of the hospital. They will now be covering nights in the ICU and working with our physicians during the day. Can they bill critical care? What about procedures? Can they do shared/split billing with our physicians?

A. NPPs are able to bill independently for critical care services (and be reimbursed at 85 percent). A physician need not be present physically for this to occur. So, your group can and should bill for critical care services performed by the NPPs and the same documentation rules apply as for any provider. Additionally, cosignature and supervision are not required. The NPPs may perform procedures and bill for them as well, acknowledging hospital credentialing rules. Even if a physician is needed to supervise the procedure, the NPP bills for the procedure. Shared/split billing is recognized by CMS and may be done on specific E&M services. Shared/split billing is however NOT allowed with critical care (99291-99292).