December 28, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5522-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1676-P; Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

Dear Administrator Verma,

On behalf of the 13,500 U.S.-based members of the American Academy of Dermatology Association (AADA), we are writing to provide comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program. The AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology; and supporting and enhancing patient care to reduce the burden of disease. We appreciate the opportunity to provide comments on the final rule and urge CMS to take these recommendations and concerns into consideration when formulating future policy.

Valuation of Specific Codes

Technical Corrections to Direct PE Input Database
CMS finalized the proposal to refine direct PE inputs to address discrepancies found in Table 6¹ of the final rule, in an effort to update the direct PE database. We are disappointed with some of the decisions because the refinements in the final rule are not accurate. Please see our comments below for the specific issues.

³ 82 Fed Reg 52994.
CMS switched the microtome blade (SF0004) to surgical super-sharp blade (SF044) for Mohs surgical code 17313. **We ask CMS to reconsider maintaining the use of microtome blade for all Mohs surgery codes.** Dermatologists use microtome blade (SF004) to perform the frozen section histology that is an inherent part of the Mohs procedure. The super-sharp blade is not for cutting histology tissue and is therefore inappropriate in this situation.

CMS removed the sterile gauze (SG056) from Mohs codes 17313 and 17314. The sterile gauze is used intraoperatively to remove blood from the surgical field. For the Mohs procedure, the three ten packs of gauze for 17313 and two ten packs of gauze for 17314 currently in the practice expense are the intraoperative gauze in the surgical portion of the procedure. The additional single piece of gauze in these codes is used in the laboratory portion of the Mohs procedure in preparing the tissue for processing. Both gauze inputs are necessary and always employed. As specified, there is no gauze provided in the supplies to soak up blood during the removal of the skin cancer. **We ask CMS to maintain the current inputs for gauze in all Mohs surgery codes.**

CMS reduced the volume of OCT tissue-Tek (SL097) in Mohs codes 17312 and 17314 from 8 to 6. All 8 OCT tissue-Tek are needed to perform this procedure. **We recommend CMS maintain the current volume of (SL097) of 8 in 17312 and 17314.**

CMS reduced the number of 2-inch units of Microfoam tape (SL088) from 10 to 8 in Mohs code 17313. It is not clear to us why CMS is proposing the change. Ten (10) inches of Microfoam tape is needed in this procedure. **CMS should maintain the current value of 10 for (SL088) in 17313.**

**Methodology for Proposing Work RVUs**

In the proposed rule, CMS stated that there is an overlap in time and work between the E/M code that is reported on the same day as the service that is being rendered. CMS removes two minutes pre- and post-times from codes that are typically reported with E/M services on the same day to account for the overlap. CMS also removes work Relative Value Unit (RVU) of 0.09 (4 minutes multiplied by 0.0224 Intra Work Per Unit Time (IWPUT)). These adjustments have been made on many of the recently RUC reviewed services already. In doing this, CMS is making refinements to additional RVU Update Committee (RUC) recommended values where the RUC discerned adjustments were not necessary.²

CMS adjusts work RVUs to account for significant changes in times to reconcile the recommended work RVUs with the recommended time values. CMS makes the adjustments using many methodologies, including survey data, building block, cross walking to key reference code(s), and comparison of old times and new times. The RUC has objected to such adjustments.

² 82 Fed Reg 53032.
The AADA recommends CMS accept RUC recommended times and RVUs. The RUC thoroughly vets the times and the values of the procedures it reviews. CMS should depend on the RUC recommended values instead of trying to create arbitrary, new methodology that lacks reliability.

The AADA urges CMS to educate Medicare Advantage Organizations (MAOs) about the reductions that have already been made to account for the overlapping work. Some private payers are reducing payments for procedures typically reported with an E/M, not realizing that the values have already been reduced by the RUC and CMS. CMS needs to make this policy clear to payers in order to assure that the reimbursement of services is not inappropriately reduced twice. AADA also recommends CMS have a mechanism that restores the value of a procedure if concurrent Evaluation and Management (E/M) billing declines. When E/M billing along with a procedure declines to less than 50% of the time for two consecutive years, the procedural value should be automatically restored.

Acne Surgery (10040)
The AADA commends CMS for finalizing RUC recommended work and PE values for the Acne surgery code 10040. We would like to point out that the one post-operative visit is medically necessary for this procedure. The typical patient is a teenager who will often need to return due to the management of medication, including changing topical treatment and/or adjusting retinoid dosage. Patients also may have new lesions that need to be treated within the global period. Furthermore, even though the survey respondents indicated a 99213 office visit was typical, the RUC reduced the visit to a 99212 to better align with clinical appropriateness during the review process.

We also urge CMS not to decrease the clinical labor time for assisting the physician. The clinical staff is present for the entire procedure, assisting the physician by stabilizing the patient's head, holding pressure to bleeding areas, and passing instruments. The assistant is gloved the whole time with no opportunity for overlapping responsibilities or multitasking.

Photochemotherapy (96910)
We appreciate CMS finalizing the appropriate clinical labor time for “provide preservice education/obtain consent” of 3 minutes and equipment time of 67 minutes for phototherapy UVB measuring device. CMS also updated the price of the UV protective goggles from the initially proposed price of $4.10 to $7.95 in the final rule. ³

³ 82 Fed Reg 52997.
However, we remain concerned with the removal of the clinical labor time for completing diagnostic forms / medical record. Compiling clinical patient information needed for the treatment should not be considered as indirect expense. The subjective, objective, assessment, and plan (SOAP) notes need to be completed by the medical staff for each patient. The SOAP notes include clinical information such as history, location of the lesion(s), severity, treatment plan, treatment dosage, modifying factors, and other clinical assessment information. The AADA disagrees with the removal the clinical labor time for completing the diagnostic forms / medical record.

Photodynamic Therapy (96567,96X73, 96X74)
We commend CMS for finalizing the RUC recommended PE clinical labor times and work values for codes 96573 and 96574. We also appreciate CMS updating the price of the PDT goggles and differentiating the right type of goggles used for PDT by finalizing a new supply safety goggles (SD326) with appropriate price.

We appreciate CMS updating the LMX 4% cream price in the final rule. However, we think the updated price of $1.37 is still lower than current market price. We ask CMS to use the prices indicated in the invoices we submitted along with our comment letter to the proposed rule.

We want to re-emphasize that the times for code 96567 should mirror the times in code 96X73, with additional time (10 minutes) for applying the photosensitizing agent, as the two procedures are similarly performed. There was miscommunication during the RUC process regarding the PE inputs for CPT code 96567. We disagree with the reduction of the value of the existing Photodynamic Therapy code 96567. Code 96567 and 96X73 describe the same procedure with the main difference being the physician involvement in same day evaluation of the patient and application of the photosensitizing agent. The proposed valuation does not provide sufficient staff time to provide the service. The staff time for 96567 should be the same as for 96X73 with additional time for the application of the photosensitizing agent and to check dressings & wound/home care instructions/coordinate office visits/prescriptions.

Currently, the following necessary and commonly performed clinical activities are missing from the proposed 96567 value: Greet patient (3 minutes), Obtain vital signs (5 minutes), Provide pre-service education (2 Minutes), Prepare room/obtain consent (2 minutes), Monitor patient following procedure (35 minutes) and Clean room (3 minutes).

We request that CMS issue a technical correction by looking at this issue closely and reassign values for times that are missing but needed to perform the procedure by the staff (RN/LPN).
The post service time reduction is inappropriate and does not account for the multitude of clinical activities performed during photodynamic therapy.

The activities during the post service period heading of “Monitor patient following procedure” (35 minutes) include:

- Prepare room for patient to incubate with previously applied topical product in dark room for the period of time determined by the physician.
- Monitor patient intermittently during incubation period. The patient is in a dark room with occlusive dressing and light blocking shielding over face. The patient must be monitored for safety and comfort and for needs such as help to bathroom.
- Review treatment requirements and discuss any reactions or complaints regarding photosensitizing agent.
- Use pre-illumination topical skin scrub for removal of topical products.
- Position patient for illumination and proper monochromatic eye protection applied.
- The patient receives irradiation of the affected area with the BLU-U Photodynamic Therapy Illuminator for approximately 17 minutes.
- Position cooling fan used to minimize patient pain during procedure
- Patient must be observed during irradiation, and this process must be continuously monitored to provide intervention to any adverse reaction. The nurse has monochromatic goggle eye protection on and has to be in the room the whole time with frequent application of interventions for discomfort. This procedure is continuously painful for the patient, and there is no opportunity for the nurse to multitask.
- Monitor treatment breaks.
- Once illumination is complete, a photoprotective topical product and dressing are applied.
- The patient receives instructions regarding post procedure skin care, continued duration of photosensitivity, functional risks, and potential complications.
- Post-procedural care and prescriptions are explained to the patient and family.
- A follow up visit is scheduled.

We urge CMS to maintain the equipment time for the power table. The patient has to stay on the table during the illumination period, and the room is not available for other patients’ use.

**Superficial Radiation Treatment Planning and Management (HCPCS Code GRRR1)**

CMS did not finalize its proposal to make separate payment for the professional planning and management associated with SRT using HCPCS code GRRR1 (Superficial radiation treatment planning and management related services, including but not limited to, when performed, clinical
treatment planning (for example, 77261, 77262, 77263), therapeutic radiology simulation-aided field setting (for example, 77280, 77285, 77290, 77293), basic radiation dosimetry calculation (for example, 77300), treatment devices (for example, 77332, 77333, 77334), isodose planning (for example, 77306, 77307, 77316, 77317, 77318), radiation treatment management (for example, 77427, 77431, 77432, 77435, 77469, 77470, 77499), and associated evaluation and management per course of treatment). CM intended for this code to describe the range of professional services associated with a course of SRT, including services similar to those not otherwise separately reportable under CPT guidance and the NCCI manual. Though the AADA recommended establishment of multiple G codes in our comments on the proposed rule, we understand CMS’s reluctance to move forward in the face of inconsistent recommendations from specialty societies and some opposition from SRT users. We urge CMS to continue to consider alternatives for appropriate coding and valuation for SRT-related professional services.

Other Provisions of the Final Rule

Payment for Biosimilar Biological Products
CMS finalized the proposed policy to separately code and pay for biological biosimilar products under Medicare Part B. The former policy had biosimilar biological products included within the same billing and payment code and went into effect January 1, 2016. Completion of changes is expected in mid-2018. CMS is changing the policy given the majority of comments that supported separate billing codes.

The AADA appreciates CMS’s thoughtful consideration of the comments received regarding its Medicare Part B biosimilar biologic product payment policy. In this rule, CMS is finalizing a change to separately code and pay for biological biosimilar products, effective January 1, 2018. The AADA generally supports increased competition and lowering prices of pharmaceuticals. Given that the ultimate impact of the finalized policy is unclear at this time, we ask that CMS monitor the policy’s impact on the market and access (including as reported by stakeholders), and respond appropriately as needed.

We remain concerned about the impact on patients who are stable on a biologic product but could be switched for non-medical reasons. Competition in the market should facilitate, not restrict, access including decreased costs for patients with moderate to severe disease who are stable on current therapy. Patients must be able to remain on their current treatment without penalty, including in Medicare Advantage and on private insurance plans. Forced switching of therapy poses a significant risk to the patient of flaring of disease, immunogenicity (negative immune response), adverse effects, and secondary nonresponse. Additionally, the treating physician

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4 82 Fed Reg 53082.
should always be informed of the specific product, by brand name and chemical name, dispensed to a patient so they may be able to determine and report if a product correlates with an adverse event.

**Physician Quality Reporting System (PQRS) and Meaningful Use (MU) Reporting**
CMS finalized its proposal to reduce the number of required quality measures from 9 to 6 and the 3 National Quality Standard (NQS) domains to no domain or cross-cutting measurement requirements, to achieve full credit for PQRS reporting.\(^5\) This means that more individuals will avoid the payment reductions associated with underreporting. Similarly, CMS reduced 2016 Meaningful Use CQM requirements to 6 measures with no NQS domain requirement for eligible professionals (EPs) and groups that attested via PQRS portal. **We are pleased that CMS implemented this retroactive requirement reduction, which the AADA requested.**

**Value-Based Payment Modifier (VM) and Physician Feedback Program**
CMS reduced the overall scope and size of VM penalties in 2018 based on 2016 performance. First, for practices who fell short of PQRS criteria, the agency will decrease the automatic VM penalty from 4% to 2% for groups of 10 or more EPs, and from 2% to 1% for group practices of nine or fewer EPs or those consisting of only non-physician EPs. Second, CMS will not penalize any practices who fully satisfied the modified PQRS reporting requirements.

CMS will not move forward with previously-finalized plans to publicly report to the Physician Compare website practice-specific 2016 VM performance and payment adjustment information, including whether a group chose not to report PQRS quality measures. However, the agency will proceed with publicly reporting public files containing non-practice-specific VM data and certain 2016 PQRS quality data.

**The AADA is pleased with the reduced VM penalties and with the decision to not require VM performance and payment adjustment reporting on the Physician Compare website.**

**MACRA Patient Relationship Categories and Codes**
CMS finalized its proposal to use Level II HCPCS modifiers as patient relationship categories. The patient category codes will be used to attribute patients and episodes to one or more clinicians. Starting January 1, 2018, clinicians may start reporting the new patient relation codes listed below on Medicare claims on a voluntary basis, while clinicians gain familiarity.\(^6\)

\(^5\) 82 Fed Reg 53202.
\(^6\) 82 Fed Reg 53233.
<table>
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<th>No.</th>
<th>HCPCS modifier</th>
<th>Patient relationship categories</th>
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<td>Continuous/broad services</td>
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<tr>
<td>2x.</td>
<td>X2</td>
<td>Continuous/focused services</td>
</tr>
<tr>
<td>3x</td>
<td>X3</td>
<td>Episodic/broad services</td>
</tr>
<tr>
<td>4x</td>
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<td>Episodic/focused services</td>
</tr>
<tr>
<td>5x</td>
<td>X5</td>
<td>Only as ordered by another clinician</td>
</tr>
</tbody>
</table>

While the AADA appreciates of the effort to make reporting voluntary, we urge CMS to offer a small payment for reporting these modifiers. This would offset the additional administrative reporting burden and also encourage more widespread use.

**Conclusion**

The AADA appreciates the opportunity to provide comments on the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program final rule. We look forward to additional opportunities to discuss these issues and to provide feedback that may help guide policy development. Please contact Helen Olkaba, Assistant Director of Healthcare Economics, at (202) 842-3555 or holkaba@aad.org if you require clarification on any of the comments in this letter or would like more information.

Sincerely,

Henry W. Lim, MD, FAAD
President, American Academy of Dermatology

CC: Suzanne Olbricht, MD, FAAD
    President-Elect, American Academy of Dermatology