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Seema Verma Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Dear Administrator Verma:

The American College of Allergy, Asthma, and Immunology is pleased to provide feedback on the proposed Asthma/COPD Cost Measure. Our members are all physicians who are board-certified in allergy and immunology and who are specialists in the care of asthma and allergic disease. The comments below are based on feedback we have received from members and our observations on the measure specifications and field test report.

At the outset, we believe CMS should delay implementation of this cost measure for at least a year to allow for further testing and review. During this period, the measure could be informational only and affected physicians could have time to familiarize themselves with it. The COVID-19 pandemic has put enormous pressure on physicians. Those in the areas impacted by the west coast wildfires are especially burdened. Trying to introduce this measure during these stressful times seems ill-advised. The limited feedback we have received from members on the measure and the Field Test Report is that it is overwhelmingly complex and key data points that might make the Report more useful are missing. At least one member reports that they would rather risk a penalty than try to unravel the complexities of this cost measure. Some of these issues could be resolved if there was additional time for refinement and testing. We urge that CMS reconsider its implementation timetable.

We also want to make CMS aware that the ACAAI submitted an <u>Asthma Alternative Payment Model</u> to PTAC which proposes a bundled payment for integrated asthma care involving the specialist and the primary care physician working as a team. It received a favorable recommendation from the PTAC and is now being considered by CMS. If approved, it would provide a model for improving care and addressing gaps in care that would be of significant benefit to Medicare beneficiaries with asthma.



Responses to Questions on Measures Specifications

1. Other types of clinically related services that should be included

Clinically related services that should be included are:

- exhaled fractional nitric oxide (FeNO, CPT code 95012)
- inhalation bronchial challenge (CPT Code 95070) and bronchodilation responsiveness spirometry (CPT Code 94060)
- Laboratory CBC with total Eosinophil count and IgE level

2. Inclusion of thoracic and lung surgeries and allergen treatment

CMS states that these high-cost services are currently assigned to the Asthma/COPD episode and asks whether it is appropriate to consider these costs as clinically related. We do not believe lung or thoracic surgery would ever be clinically related to asthma care and recommend that they not be included in the asthma subgroup.

With respect to costs for allergen treatment or allergen immunotherapy, we do not believe they should be attributed in this cost measure. Allergen immunotherapy (CPT Codes 95165, 95144 and allergy injection codes 05115 and 95117) is predominantly a service provided by allergists/immunologists and can be for asthma, allergic rhinitis, or both. It is rarely furnished by other specialties for treatment of asthma. Assigning allergen immunotherapy costs to an asthma/COPD episode will inevitably result in allergists having higher costs than other specialties that are not trained in this treatment. Unless the measures reporting can be made specialty specific, including these costs would penalize allergists.

3. Inclusion of non-specific symptoms

CMS asks whether certain non-specific symptoms such as malaise, syncope, and chest pain should be included as complications to differentiate good care of asthma or COPD from poor care. These symptoms are not at all common in asthma and we strongly urge that they not be included. Nor are we aware of data showing that asthma increases the risk of heart attacks.

4. Post-Acute Care

Post-acute care is generally not required for asthma and we do not believe PAC costs should be attributed to the asthma subgroup.



5. Clinically related Part D drugs

The list of Part D drugs should include the biologics dupilumab and reslizumab.

6. Attributing the Episode Group to Clinicians

The attribution methodology needs to recognize that many patients are misdiagnosed by non-specialists as having asthma based on patient reported symptoms but, when referred to a specialist, they are determined, based on pulmonary function testing (PFT), and other guidelines, as not having asthma. It is critical that the costs of care for these patients who do not have asthma or COPD not be counted under this measure. This happens frequently with patients who have gastroesophageal reflux disease (GERD) that causes vocal cord dysfunction which mimics asthma. Often these patients are high utilizers of the health care system, at least until they receive an appropriate diagnosis. The triggers for assigning a patient to the asthma/COPD measure must differentiate between patients who truly have asthma and those who may be misdiagnosed. One member reports that their Field Report included patients the physician diagnosed as not having asthma and/or COPD based on their PFT.

We are also concerned that the attribution methodology will assign costs of other physicians or acute care providers to specialists. As specialists, we are often referred patients who have been diagnosed incorrectly with asthma and started on high-cost and inappropriate treatments such as expensive inhalers by other providers in acute care settings without proper evaluation. If these patients are later referred to specialists, the costs of this inappropriate treatment may be attributed to the specialist.

We question the inclusion of "nurse practitioner" in the list of clinical specialties. Nurse practitioner is not a specialty and treating it as one could result in inappropriate assignment of costs especially if the nurse practitioner is working for a specialty group.

7. Risk Adjustment

Accurate risk adjustment is especially important for episode measures for chronic conditions such as asthma/COPD. The costs of caring for a patient with asthma are directly related to disease severity and, although less than 10 percent of people with asthma have severe disease they account for over 50 percent of costs. (See Dougherty RH, Fahy JV. *Clin. Exper. Allergy*, 2009;39(2):193-202.) As asthma specialists, we generally care for the most complicated and therefore mostly costly patients. Further, asthma is a disease that is particularly impacted by social determinants of health (SDOH) such as economic disparities and workplace and home exposure to environmental



triggers. It is therefore critical that the risk adjustment methodology include these factors. We are concerned that CMS's risk adjustment model does not adequately account for those SDOH that are likely to impact severity of asthma and associated costs and that it could encourage patient "cherry picking" and result in reduced access for the most vulnerable patient populations. We urge CMS to properly account for SDOH in developing risk models for asthma and other chronic conditions.

Impact of COVID-19 pandemic and West Coast Wildfires on Asthma/COPD Measures

The catastrophic wildfires throughout the west coast states and the resulting hazardous air quality will inevitably result in asthma exacerbations and increased ED visits and hospital admissions as well as more physician visits and prescriptions. It is critical that the risk adjustment methodology account for these factors contributing to higher costs of care in certain geographic areas and that it not penalize physicians caring for individuals in these parts of the country.

As a result of the COVID-19 pandemic, use of pulmonary function tests (PFTs), one of the mainstays of asthma management, may be viewed as a high-risk procedure with the potential to aerosolize and spread COVID-19. This has and will continue to result in a decrease in PFTs during the COVID-19 pandemic, making it more difficult to properly manage asthma in the office setting.

We ask that CMS consider the impact of these public health emergencies in its implementation timetable and that it consider whether certain hardship exceptions may be necessary.

Including Part D Drugs in the Measure Cost Calculations

We have concerns about the impact of including Part D drug costs in the general episode cost calculations. Physicians have no control over the cost of medications which are set by drug manufactures, pharmacy benefit managers, and payers. Moreover, physicians will generally have no information about a Part D plan's coverage policies and fee schedules. We support meaningful measures of pharmacological management, but we question whether the Part D pricing methodology used in the asthma/COPD episode cost measure is sufficiently developed to allow for such meaningful comparisons. For these reasons, we recommend that CMS begin by providing Part D cost data on an informational basis. This would allow for further testing and refinement of the methodology and would give physicians a chance to become familiar with how Part D costs contribute to their score on this measure.



Comments on Field Testing Measure Report

CMS states that cost measures are intended "to help inform clinicians on the cost associated with their decision-making and to incentivize cost-effective, high-quality care." Further, a cost measure "offers opportunity for improvement if clinicians can exercise influence on the intensity or frequency of a significant share of costs during the episode." (Asthma/Chronic Obstructive Pulmonary Disease. Measure Testing Form. Summer 2020 Field Testing.) With respect to asthma, CMS indicates that there are several gaps in care including appropriate use of pharmacological therapy, patient education on proper inhaler techniques, promotion of physical activity and exercise, and promotion of smoking cessation. Given these gaps in care, one would expect that the Measure Test Report would help physicians identify in which of these areas they may fall short. However, we find that it is very difficult to glean this information from the Field Test Report and that it gives allergists little help in identifying areas for improvement.

1. Relationship of Cost to Quality of Care

As a threshold matter, the measure fails to establish a connection between cost and quality. High costs can be an indicator of high-quality care; they can also suggest poor quality. Many of these costs are not within the control of the physician. Including all costs (both good and bad) in a single cost score as presented in Table 1 is not informative because there is no way to differentiate good costs (e.g., costs spent on smoking cessation, appropriate pharmacologic management) or bad and preventable costs such as emergency department (ED) visits or hospital admissions.

Table 5 of the Report on Cost and Use by Medicare Setting and Service Category provides more detail, but the data is confusing. For example, one member Report we reviewed showed, in Table 1, a high cost measure score – indicating that this provider was in the top quartile for costs. Yet Table 5 indicated the provider was well below the national average for the share of episodes with high cost categories (e.g., hospital inpatient, ED, post-acute). This would seem to suggest the provider was doing a good job of keeping patients out of the ED and the hospital. It is unclear how to reconcile the data in Table 5 with those of Table 1 indicating significantly higher costs. It would be helpful if the Report could provide more information on how to interpret this information.

Similarly, with respect to Part D costs, it is unclear whether a higher than average cost should be considered an indicator of higher quality care. Similarly, would a substantially higher than average cost in the "Chemotherapy and Other Part B Covered Drugs" category mean that this provider is effectively using higher cost biologics (e.g., Xolair, Nucala) and that his/her peers are falling short in this area? Or would it indicate inappropriate use because the costs are higher than "expected." This is another area where allergists may be penalized because they are trained to administer the high-cost biologics that other physicians may not be trained or inclined to use.



Again, without providing a link between cost and outcomes, it is difficult to use this Report as a basis for improvement.

2. Reporting by Specialty

The national averages and expected costs presented in the Report are derived from all physicians whose claims meet the episode triggers including both specialists such as allergists as well as non-specialists. As indicated above, specialists in asthma typically have a more resource intensive approach to managing the disease including use of allergen immunotherapy, biologics, and more extensive pharmacologic management. These are all potential drivers of increased Part B and Part D costs. Using cost data from all physicians, including non-specialists who do not provide these intensive disease management treatments, to calculate an "expected" cost that inevitably results in higher cost profiles for specialists in these areas. One would hope that this more intensive specialty care corresponds to fewer hospital admissions and ED visits. However, it is impossible to determine this from the Report.

To the extent that these cost measures will impact MIPS scoring and reimbursement, those providing specialty care should be compared with other specialists (in this case allergy/immunology and pulmonology) rather than the entire universe of physicians treating asthma. If not, they may be disadvantaged for providing higher quality but more expensive care.

It would be helpful if the CMS could provide the percentage of claims, by specialty, that accounted for the universe of claims used in calculating the "expected" costs, to allow a better understanding of those contributing to the "expected" number.

3. Including data by clinical subgroup

Table 4 provides a breakout of the number of episodes for each of the subgroups (asthma, COPD, and asthma/COPD). It would be very helpful if the information in Table 5 could be broken out by subgroup as well. COPD and asthma have different cost profiles and it is difficult to determine the extent to which the higher costs and different cost profile for COPD are contributing to the overall costs in Table 5.

4. Tables 5 and 6

Tables 5 and 6 provide cost per episode data and the provider's percentage of episodes with a particular service, compared to national averages. The "share of episodes" data reflected in those tables would seem particularly relevant to a provider in assessing how they compare with other physicians. For example, if a provider has a high percentage of episodes involve ED visits or inpatient hospitalization, this would be something that should be flagged in the Measures Report.



Instead, the Report flags cases in which the costs per episode are higher than expected – something that is arguably of little value, especially for ED and inpatient costs which are not within the control of the physician. What may be within their control, however, is the percentage of their patients, compared to the national average, that visit the ED or hospitalized for asthma or COPD. This information could be very informative.

A case in point: In one Report made available to us by a member, the Report, in Table 5, flagged sepsis costs as being more than one standard deviation above the average. However, that physician's share of episodes with sepsis costs was 1.3% compared to a national average of 11% and 9% in the provider's risk bracket. This would seem to indicate that the provider's sepsis cases are far lower than others in that risk bracket and is more relevant than the cost of the very low number of sepsis episodes.

CSV File

We appreciate the inclusion of the detailed CSV file with the Report. However, many allergists reported that the file was complex and difficult to understand. For example:

- Use of legacy Medicare patient IDs: The CSV file identifies patients by their legacy Medicare number and not their current Medicare number. This made it very difficult to trace or confirm data for individual patients since many physician EHR systems do not maintain the legacy numbers in their system. As a result, practices had to manually search for corresponding patient records by matching dates of birth and gender. We strongly urge that in any further field testing, as well as final Reports, that CMS provide current Medicare numbers in the CSV file.
- Outpatient Facility Costs (Column AC): It is unclear what type of asthma/COPD related services would be included in this category. Would it include, for example, visits to Urgent Care centers? Or is it primarily hospital outpatient department services? In which category are these costs included in Table 5 of the Report? More detail on this category would be helpful.
- **Inpatient and ED Costs:** It would be helpful if the CSV file indicated the number of ED visits and the dates and number of days of inpatient admissions.
- Impact of Care Provided by Other Providers: More detail is needed on cases in which patients received care from multiple other physicians outside of the primary physician's group practice. For example, in one case, a member reported that the patient was seen by 35 other physicians outside of the member's group. It is difficult to assess the extent to which costs of this care are appropriately attributed to this episode without more detailed information that would allow the physician to determine if the patient should or could have been better managed.



Thank you for the opportunity to provide feedback on this proposed cost measure. Please reach out to us with any questions or if we can provide additional information.

Sincerely,

J. Allen Meadows, MD, FACAAI

President

American College of Allergy, Asthma & Immunology