

PRT Questions from first review of: *The COPD and Asthma Monitoring Project (CAMP)*, submitted by Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group Inc. of Sacramento, California

Questions for Submitter

Questions about the provider network:

1. Please clarify the relationship of primary care providers to CAMP. How do primary care providers share in the financial risks and incentives? How does CAMP share risk with the regional provider and is this the same as the PCP? Do you plan on (and if so how exactly do you plan on) sharing compensation (e.g., part of the \$175 PBPM telemonitoring management fee) or two-sided risk payments with the “regional” providers?

We attempted to model something that involved PCPs and did not arrive at an option that was viable before submission. At this time, we do not intend to share the financial risk with PCPs. Without sufficient numbers of patients to normalize a cost distribution, this program is considered too high a risk for individual PCPs to participate in. We propose both a shared compensation arrangement and a risk sharing agreement to allow regional provider to manage patients in their respected regions and qualify regional providers with an AAPM designation as in this setting a large enough cohort of patients can be managed that will provide a more stable and predictable cost distribution curve.

2. By “regional providers,” do you mean the regular PCPs and specialists managing the patient before CAMP got involved? Is there any hospital involvement in the “regional provider” network or compensation plan?

The definition of regional providers will be specialists, Board eligible or certified in Pulmonary Medicine. Depending on the regional provider’s employment relationship with a hospital or healthcare system it is possible that hospitals will have a financial relationship with CAMP as a result of the regional provider’s employment agreement.

3. Why is the Stark Safe Harbor exemption needed? What “kickbacks” are you concerned will be triggered or necessitated in CAMP’s relationships to whom?

In our interpretation of the law, regional providers will be entering a financial relationship with an outside entity (CAMP) and will be in a position of referring patient’s they already have a relationship with. These regional providers may be seen as “self-referring” their patients to CAMP for financial gain. By this logic, fees earned through their financial relationship with CAMP may be viewed as a “kickback” even though the regional providers will be at risk for any losses incurred for the population of patient they provide care for. This perception of how the law may be interpreted will act as a barrier in recruiting regional providers for CAMP. If our interpretation of the law is incorrect than an exemption from Stark will not be needed. We would, however request a review by the AG’s office for confirmation as well as a written statement to that effect.

Questions about targeted patients:

4. Is there any distinction to be made in the model and its application regarding the severity of symptoms of asthma and COPD or does the model aim to address anyone with multiple chronic diseases who have any degree of these two illnesses? (There is a great deal of difference between chronic intermittent asthma and chronic persistent asthma with respect to treatment and outcomes for example; or between someone with a spirometry FEV1/FVC ratio of 70% versus 30% for example.)

As we could find no good data regarding the cost and distribution of Medicare Beneficiaries based upon the severity of lung disease or the actual definition, based upon CPT codes, we abandoned this methodology in establishing a benchmark for a risk sharing agreement. As there is excellent data regarding the cost of care based upon the number of chronic conditions a Medicare Beneficiary has we anticipate that the severity of lung disease will have a positive correlation with an increasing number of chronic conditions. We intend to monitor and study this relationship.

5. The proposed Physician- Focused Payment Model (PFPM) discusses the service as being offered to all Medicare beneficiaries with asthma and COPD irrespective of health care affiliation. Do you have any experience with non-Medicare populations with this model?

We do not have any experience with CAMP as we have not been able to establish a payment model for the service in a non-Medicare population with our local providers.

6. Couldn't a very similar system be used for CHF? Would you be willing to engage in your proposed model if it was broadened to include other patients such as those with CHF?

We have considered whether we would also use our model to manage other chronic disease states other than COPD. Although it is likely that we will be in a position to manage other chronic disease states in our population of COPD patients, we have concerns about the cost and increased complexity of doing so during the pilot phase of the proposal. As we gain experience with the model, we will determine whether we have the capability of such an expansion. We will specifically not expand the program to include CHF at this time as we believe a risk sharing agreement to constitute too high a risk using the CAMP model with CHF as the anchoring chronic condition. Our major concern is the dramatic increase in the use of continuous infusion outpatient inotropes and Left Ventricular Assist devices for the destination management of end stage CHF. With the popularity of these treatment strategies increasing in our region we have concerns that our local cost will far exceed national costs.

Questions about care delivery:

7. How developed are the clinical algorithms proposed for use in the model? What are they based on?

Clinical algorithms have not yet been developed for but will be based upon a combination of the breathlessness, cough and sputum score in combination with peak flow changes and change in frequency of rescue inhaler use.

8. Given the offering of services irrespective of health care affiliation, how will information recorded in the electronic health record be transmitted to regional PCPs that are on other EHRs?

For PCP with or without EHRs that do not directly communicate with the EHR used by CAMP, information created by CAMP providers is documented into the CAMP EHR and immediately faxed to providers upon completion of documentation. Quarterly and monthly reports will also be faxed to PCPs.

9. The proposal would use a centralized system for supporting patients and clinicians. Is such a system replicable in other geographies? Please explain what you think a national network of such centers might look like.

Once established and proven, we believe that a national network implementing CAMP will work well. After the technology component of CAMP is established with proven results a national network will probably be segregated into regions initially centered around population centers where a large enough cohort of patients can be supported. For rural areas, we anticipate these areas will be covered as an extension of population based hubs or alternatively as a geographic hub linked to a rural health network. Other alternatives may include a large healthcare multi-hospital based system, taking into account the need for individual state wide licensure and credentialing.

10. Telemonitoring works on a small sick subset of COPD patients. It would be helpful to better understand how big that subset is using a claims based method to define the denominator. Can you provide these data or suggest diagnosis codes that PTAC/CMS might use to estimate the size of key group(s)?

Unfortunately, we could not find any good cost data based upon diagnostic codes to create a reasonable risk sharing benchmark based upon CPT codes. If CMS has such data, with subsets of data that define the Part A and Part B components of the cost data, we would be willing to look at a diagnosis based payment proposal. As CMS has already provided incidence and cost data on beneficiaries with COPD and Asthma with multiple chronic conditions we will accept the risk that the severity of COPD will correlate to individuals with increasing numbers of chronic conditions.

11. Adherence to daily prompts in an app in an RCT setting is likely to be quite different from adherence in a less motivated group. Do you have any estimates of the impact of adherence on the effectiveness of the intervention?

Adherence will be closely monitored in our model. With the ability to flag patients who do not report in on a regular basis we have built in text and phone interventions to explore why a patient is not reporting his or her data. In our originating contract with each patient we will emphasize the goals of the program to empower the patient to take greater responsibility of his health and give him the needed coaching and guidance to make that patient successful. Incentives, such as discounted pricing on expensive medications and no co-payment responsibility will enhance continuous patient interaction and adherence.

12. The proposal only cites non-American study sources. Is there any information available with respect to cultural differences in adherence that should be understood?

We are unaware of any specific cultural differences that require understanding. There have been other telehealth studies centered around hypertension and diabetes management in the United States that have proven successful. One of our projected partners in this project, Twine Healthcare, provided the technology interface for these studies. More information on Twine Healthcare can be viewed on their web site <https://www.twinehealth.com>.

Questions about reimbursement and costs

13. Could you please explain the actual information and funds flow for payments starting with the definition of the enrolled and how enrollment is communicated to CMS, when payments start, how (under what circumstances) are patients disenrolled; and are all costs included in the risk?

We envision the establishment of 4 unique service codes to define our payment proposal.

The first code, xxxx01 will be submitted to CMS upon obtaining a signed agreement from the Medicare beneficiary to participate in the program. The date of this charge will define the start date for each individual patient.

The second code, xxxx02 will be submitted on the 1st business day of each subsequent month as long as the patient is enrolled in the program

The third code, xxxx03 will be submitted upon notification of the patient's voluntary withdrawal from the program, is lost to follow up or upon notification that the patient has expired.

Payment between submission of the 1st code and the initial submission of the 2nd code will be prorated to the first day of the month. Upon the patient's expiration or withdrawal from the program a prorated payment will be refunded to CMS.

A 4th code, xxxx04 will be submitted for the cost of the peak flow device.

The cost for replacement mouth pieces will be included in the monthly fee as will the cost for any replacement peak flow devices. This proposal included only Medicare Part A and Part B costs. Part D costs were not included as we have no trending incidence or cost data to determine the impact of adding Part D costs to the proposal.

14. Please indicate if the following explains the risk sharing component of the payment model and if not, please correct our understanding of your proposal:

- a. with no change in utilization, you expect the PBPM payment of \$175 and the Medicare-financed costs of the Peak Flow Meters to be distributed to enrolled patients to increase Medicare spending by about 6% of baseline target spending;

This statement is correct.

- b. If the CAMP intervention saves Medicare Parts A, B, and D less than 6% off the risk adjusted baseline, then CAMP (however it distributes savings to its partners, if at all) gets no share of the savings.

This statement is not correct. We did not include Part D costs into this proposal as there was no published data that would allow us to evaluate risks associated with the incidence, total cost and changes in Part D costs over time. As a result, we submitted this proposal under the assumption that the risk sharing agreement would involve Part A and Part B costs only.

- c. If the CAMP intervention saves 6% or more, up to 26%, CAMP (and its partners) would get HALF of the savings above 6%. For example, if CAMP saved 7%, then CAMP would get ½ of 1% as a shared savings amount.

This statement is correct.

- d. If the CAMP intervention costs Medicare Parts A, B, and D, money, over and above the “baseline target,” independent of the PBPM payment of \$175 and the cost of the Peak Flow Meters, then CAMP would pay Medicare ½ of the extra cost, up to 10% of baseline, or up to ½ of the spending increase of up to 20%.

We intent to pay Medicare up to ½ of the spending increase of up to 20%.

- e. in computing the baseline risk adjusted target amount, you mentioned using a combination of dual (Medicare plus Medicaid) enrollees’ + non-dual (Medicare only) enrollees’ expenses, arrayed by the number of chronic conditions, 1 to 10, as the risk adjusted target spending amount per enrollee, to aggregate into the breakeven point of the shared savings calculation, once the number of chronic conditions of CAMP’s actual enrollees were known. You would then use the entire universe of Medicare enrollees to compute the per chronic condition number risk adjusted spending amount. Did you intend for these targets per chronic condition spending amounts to be calculated conditional on having COPD or Asthma diagnosis, or did you intend for your baseline to be computed on the entire universe of Medicare enrollees?

Thank you for asking for clarification. We intend for the targets per chronic condition spending amounts to be calculated conditions on having COPD or Asthma diagnosis in both the population of patients managed by CAMP as well as the national comparison group, and not have CAMP compared to the entire universe of Medicare enrollees.

- 15. The decrease in overall cost of care of Medicare patients enrolled is impressive, but doesn’t it depend upon the criteria for enrollment with respect to disease severity?

To the extent that the number of chronic diseases correlate with disease severity of COPD and our ability to limit ED visits and hospital admissions we will be successful in reducing the cost of care to Medicare, where the proportionate cost of Part A spending increases as the number of chronic conditions increase. Without the availability of cost data defined by disease severity we are unable to answer this question.

16. Is the two-tailed risk-sharing model tied to meeting their 10%, 20%, and 30% goals or simply on a more standard cost of care reduction?

This question was addressed in question 14.

17. The financial incentives are for “compliant” patients enrolled in the program. How is patient compliance determined? What criteria will be used to determine compliance? Are there any barriers to compliance that are discriminatory and should be taken into account?

We will be monitoring adherence to patient reporting of their peak flows and surveys as the primary means of measuring compliance. Alerts designed to monitor for non-adherence to requested tasks will be built into the technology. Non-adherence will trigger additional conversation and coaching between CAMP and patients with the intent to further enable patient to be more self-aware of their underlying disease and thus be more compliant as an end result.

18. How did you determine the fee for the Bluetooth Peak Flow Meter?

We based initial pricing of the Bluetooth Peak Flow Meter on European Pricing for the device we anticipate using.

19. What is the relationship between the proposed PMPM and the cost of providing the management services?

There is no current relationship established as we have yet to determine the cost of providing the management services. The PMPM was determined using the Oncology AAPM model as a benchmark for establishing a starting point.

20. What kind of “outside investment” help is involved in the project’s funding? Is it the device company or the pharma company that is already selected as a partner? Do you have a letter of commitment from them?

Until we obtain confirmation of our proposal’s acceptance we have not initiated any agreements or commitments with any outside investment.

21. Page 16 of the proposal states that the model won’t be able to address the 28-day readmission rate because “CAMP is not budgeted to specifically reduce the 28-day readmission rate at the point of patient enrollment.” What does this mean?

The current hospital readmission rate for Medicare beneficiaries with acute exacerbation of COPD is approximately 18-24%. By initiating a chronic disease management program with enrollment of patients who have been hospitalized with a high risk of near term readmission with increased Part B costs as well as increased Part A costs, we are accepting an enrollment cost risk that is much higher than by only enrolling patients after that have been stabilized to their baseline disease state. With new patient’s being enrolled into the program on a continued basis, the overall cost savings to Medicare will not be accurately reflected if we are starting the program in a population of patients who require acute

post discharge management by their local providers. In this setting, CAMP is not designed to replace the primary care provider in the role of acute post discharge management.

22. Since the proposal is requesting exemptions from Medicare co-pays, should there be an arm of the study where this is not a factor to determine its true value?

We believe that any Medicare co-pay will act as a disincentive to a Medicare beneficiary asked to enroll into CAMP. As we are attempting to decrease the cost of care of a very expensive group of patients, we believe that the beneficiary should not bear any additional cost in reaching this goal.

23. The proposal states that the Medicare Part D “donut hole” leads to a reduction in controller medications as patients cut back on meds to control cost. Is this anecdotal or is there data from Medicare showing an increase in readmissions with “donut hole”? Please provide any data to support this statement.

The example cited is antidotal. We know of no actual data to support this statement.

24. If this pilot group was successful, would access to the specific software be required or could there be different telemonitoring and management software used?

There is no proprietary software that is required for CAMP.

25. Isn't there a mismatch between the intervention, focused on a relatively sick subset of COPD patients, and the use of the multi-comorbid illness scheme? Doesn't that group include people without COPD? In a relatively small group (e.g., less than 15,000 people), it seems likely that the expected individual costs and the actual costs could vary considerably, introducing considerable error into the overall benchmark. Please comment on this.

This statement is correct. As stated earlier we could not find cost data in the Medicare population that specifically addressed cost based on the severity of COPD. We have accepted the concept that we are willing to take risk using the number of chronic conditions as a relative proxy for disease severity. Also by targeting patients with recent admissions to a Hospital with a COPD exacerbation, or COPD with pneumonia, we will capture the high-risk population as their hospital admission will pre-define them as likely having moderate to severe COPD. We would like as large a sample size as we can handle and if we could successfully prove a benefit with a sample size of around 2000 we could then scale up to numbers exceeding 15,000 in the next stage of the pilot. As stated earlier, we clarified our desire to use the group of patients with chronic diseases, including COPD, as the benchmark to compare our population.