CMS NCD for coverage of autologous PRP under CED
AHRQ Systemic Reviews,
CMS Technology Assessments and
Medicare Evidence Development & Coverage Advisory Committee

AHRQ Systemic Reviews
On March 23, the Agency for Healthcare Research and Quality (AHRQ) commissioned its Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Platelet-rich Plasma for Wound Care in the Medicare Population.

The public can submit suggested topics for such reviews or Federal agencies may contract with the EPC Program to conduct evidence reviews through an Interagency Agreements (IAA). These reviews provide Federal agencies with the evidence needed to inform a variety of policy and program decisions. A Simon&Co review of topics submitted by the public does not include the aforementioned PRP for Wound Care evidence review. It is, therefore, reasonably likely that a Federal agency such as the Centers for Medicare and Medicaid Services (CMS) requested this review as part of their coverage process.

Given the timeline for IAAs with the EPC Program, it is possible that CMS requested this review after Reapplix submitted its data from the clinical trials and met with CMS to discuss coding and payment for the protocol to continue the clinical trial under Medicare CED coverage. AHRQ tells Federal agencies to estimate about 5 months from agreement on the scope of work to the start of the project. Five months previous would have been late-October 2019, a month after Reapplix met with CMS staff from the Hospital and Ambulatory Policy Group.

EPC Timeline
- The EPC Program is accepting information until April 22, 2020.
- The EPC Program does not provide a timeline for the systemic review nor for the release of a draft of the review. However, a four to six-month time frame seems plausible: August-October 2020.
- The EPC Program would then open the draft of the review for public comment for four weeks: September-November 2020.

CMS External Technology Assessments
When considering a National Coverage Decision (NCD) to determine whether an item or service is reasonable and necessary, CMS conducts an external Technology Assessment (TA). CMS notes that:

> "While a TA can evaluate many aspects of a technology, interpretation and critical appraisal of the evidence on patients' health outcomes constitutes its key component. Accordingly, the performance of a systematic review [emphasis added] of the evidence from the medical literature is at the core of every TA, whether undertaken internally or commissioned externally by CMS."

CMS primarily issues TAs as part of the NCD process or in advance of Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meetings. CMS currently contracts with the Agency for Healthcare Research and Quality (AHRQ) for TA reports via an interagency agreement for the NCD process. A formal reconsideration of the NCD for coverage of autologous Platelet-rich Plasma (PRP) under coverage with Evidence Development (CED) has not been released. However, CMS may have contracted with AHRQ's EPC Program to conduct this systemic review to bolster the available scientific information to move the NCD process forward due to Reapplix's completion of its CED clinical trials.

Medicare Evidence Development & Coverage Advisory Committee
Alternatively, CMS may be bringing the PRP NCD consideration before the MEDCAC which provides independent guidance and expert advice to CMS on specific clinical topics. The committee is comprised of 100 experts. CMS will ask at least 15 with knowledge specific to the topic in question to serve on the panel for each MEDCAC meeting. Additionally, CMS can recruit non-MEDCAC members who have relevant expertise to provide additional input to panel members and invite experts to make formal presentations to the MEDCAC.

The current MEDCAC roster is attached to this memo. Simon&Co review of the current MEDCAC members did not find anyone specializing in wound care, endocrinology nor podiatry. The one hematologist on the committee is an oncologist. (As of June 2020, 25 MEDCAC membership terms expire. CMS posted a Request for Nominations for Members on October 21, 2019 but has not released information on new members.)

CMS may refer a topic to the MEDCAC under a number of circumstances including that existing published studies have small sample size or opinions of clinical and scientific experts about the medical benefit of the item would affect whether the item or service is "reasonable and necessary" for Medicare. (A full list of these circumstances is in Appendix A.)

Meetings: Once a coverage issue is referred to the MEDCAC, CMS schedules a public meeting to discuss the coverage issue under consideration. CMS develops a structured series of voting questions that form the basis for the MEDCAC's deliberations. At the end of a meeting, each MEDCAC members score the questions. The final score is average of each member's votes.

MEDCAC does not have any meetings currently scheduled. Meetings are announced in the "Federal Register" which Simon&Co monitors on a daily basis.

Appendix A

CMS may refer a topic to the MEDCAC under any of the following circumstances:

- There is significant controversy among experts. The opinions of clinical and scientific experts about the medical benefit of the item or service, the level of competence of providers, the requirements of facilities, or some other significant consideration that would affect whether the item or service is "reasonable and necessary" under the Social Security Act;
- The existing published studies contain potentially significant methodological flaws such as flawed design, inappropriate data analysis or small sample size and do not meet our reasonable and necessary standards;
- The available research has not addressed policy relevant questions;
- The available research has not addressed diseases and conditions or the special needs of the elderly in the Medicare population;
- The existing published studies show conflicting results;
- CMS would like additional expert review of the methods used in external technology assessments (TAs), particularly when there were questions about a TA, complex clinical issues, or specialized methods such as decision modeling.
- CMS would like greater public input by receiving and considering comments on the effectiveness of an item or service that could be subject to varying interpretations. Obtaining the perspective of affected patients and caregivers (e.g., the degree of perceived benefit, subjective assessment of risk, or burden of side effects) through public comments and voting representatives on the panel may be relevant;
- Use of the technology is the subject of controversy among the general public;
- When presentation, public discussion, and clarification of the appropriate scope for the technical review, a preferred methodological approach, or a clinical management issue would benefit future NCDs;
- Dissemination of a technology may a major impact on the Medicare program, the Medicare population, or the clinical care for specific beneficiary groups;
- CMS determines that the NCD process would be better informed by deliberation that incorporates the viewpoint of patient advocates as well as a broad societal perspective of factors not directly related to the scientific review of the evidence but nevertheless relevant to the decision.