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MEDCAC Q&A with Louis Jacques, ADVI Chief Medical Officer

On May 16, the Centers for Medicare and Medicaid Services (CMS) released a tracking sheet (link) for a National Coverage Analysis (NCA) for Chimeric Antigen Receptor (CAR) T-cell therapies. CMS simultaneously announced an August 22 public meeting of its Medicare Evidence Development &Coverage Advisory Committee (MEDCAC) advisory panel meeting on CAR-T therapies.

Below, ADVI takes a deeper look into what a MEDCAC is, how stakeholders can engage, and what we can expect on August 22.

Q1. What did CMS announce on May 16, 2018?

- CMS posted a tracking sheet on its website, announcing the opening of a national coverage analysis (NCA) on CAR-T therapies, with a related MEDCAC meeting to be held August 22, 2018.

Q2. What is an NCA?

- An NCA is the process by which CMS reviews evidence and solicits public comment for an eventual Medicare national coverage determination (NCD).

Q3. Does every NCA result in an NCD?

- No. From time to time CMS has conducted an NCA and decided not to publish an NCD. CMS has this discretion based on a US Supreme Court case, Heckler v Ringer.

Q4. What is the MEDCAC?

evidence recommendations to CMS.

Q5. Does the MEDCAC make Medicare coverage policy?

- No. The MEDCAC is asked to make recommendations on the availability and persuasiveness of generally published clinical evidence relevant to a particular condition or technology.

Q6. Does every NCA include a MEDCAC?

- No. CMS is more likely to convene a MEDCAC on high profile topics where there is a lot of public interest and some controversy. On occasion CMS may convene the MEDCAC to call attention to important issues for Medicare beneficiaries that might otherwise be overlooked by the public.

Q7. Does every MEDCAC include an NCA?

- No. CMS has convened the MEDCAC on other topics, e.g. Bayesian trial designs, secondary lymphedema, etc.

Q8. Where can I get more information about the MEDCAC?

- CMS generally publishes a webpage for each MEDCAC, which includes registration instructions, MEDCAC questions, a TA (if one was commissioned), and other details. We expect it will be included soon in the MEDCAC index at https://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx#ResultsSection.
- CMS has general MEDCAC information on its website at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html.

Q9. Why would CMS open an NCA on CAR-T?

- CMS received a formal written request from UnitedHealthcare to open an NCA.

Q10. Given the request, why might CMS consider CAR-T therapy to be a good topic for an NCA?

- CMS has previously published an FR Notice that describes the request process, and factors that may lead the agency to open an NCA. That notice is available at https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf.

In that notice they list the following factors. CAR-Ts appear to meet several of these factors.

- Practitioners, patients, or other members of the public have raised significant questions about the health outcomes attributable to the use of the items or services for the Medicare beneficiary population.

Local coverage policies on a particular item or service may vary in language or implementation. While this may be manifested by LCD variations among Medicare Administrative Contractors (MACs), we note that variability is not a de facto sign of inappropriate local policy and may be appropriate.

- The health technology represents a substantial clinical advance and is likely to result in a significant improvement in patient health outcomes or positive impact on the Medicare program.
- When rapid diffusion of an item or service is anticipated the evidence may inadequately address questions regarding impact on the Medicare population, target subgroup populations, practitioner or facility qualifications, etc., or on beneficiary health outcomes.

Q11. How long does an NCA take?

- The NCA process timelines are established by Congress. In general, CMS takes up to 6 months from opening the NCA to publishing a proposed decision. If CMS commissions an external TA or convenes the MEDCAC, an additional 3 months is added. When the proposed decision is published, the agency opens a 30 day public comment period on the proposal, and must publish a final decision no later than 60 days after the close of the public comment period.

Q12. Why is there a comment period when the NCA is opened, separate from the comment on the proposed decision?

- Though not required by law, CMS has historically in most cases also solicited public comment upon opening. This gives the public an opportunity to share its thoughts on the subject.

Q13. How can I submit a public comment?

- Instructions on submitting comments can be found at: http://www.cms.gov/Medicare/Coverage/InfoExchange/publiccomments.html.

Q14. What types of comments are most likely to be persuasive?

- Comments that cite published scientific evidence are more likely to be persuasive. It is generally not helpful to disclose personal health information about yourself or anyone else, especially since all public comments are publicly viewable on the CMS website. CMS staff will redact personal health information.

Q15. If the NCA results in an NCD, when would the NCD become effective?

- NCDs are effective upon publication of the final decision. If the final decision is published on May 17, 2019, then Medicare claims with dates of service on or after that date would be subject to the NCD requirements.

Q16. Does an NCA or an NCD effect local Medicare contractor (MAC) coverage policies, i.e. LCDs?

that a MAC would undertake an LCD workload if they believed that a superseding NCD would be forthcoming. That would be an inefficient use of resources. It appears more likely that MACs would make claim-by-claim determinations in the interim.

Please reach out to us if you or your team have additional questions or concerns.

All my best,

Marc Samuels

CEO, ADVI