

Analysis of Coverage with Evidence Development Criteria

Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting

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Conflicts: None

Why We Are Here

- SNMMI appreciates CMS' commitment to transparency in decision-making related to coverage with evidence development (CED) national coverage determinations (NCDs)
- We strongly urge the MEDCAC to recommend that CMS allow targeted and real world evidence collection to satisfy CED requirements
- Most importantly, we urge the MEDCAC to recommend that CMS include criteria for terminating any CED requirements at the time a CED NCD is created and that CMS re-evaluate each NCD with CED every five years to determine whether CED is still necessary or whether the NCD should be retired

Procedural Issues with CED

- CED rarely ends
 - Of 27 therapies subject to CED since 2005, 6 have achieved coverage or can be covered at MAC discretion¹
 - CMS has not set guidelines for duration of CED or timelines for reconsideration or retirement
- CED can inappropriately restrict access to new technologies
 - For some therapies, CMS has combined CED for specific indications with broad non-coverage for other indications
 - Use of technology can evolve rapidly in ways that are difficult for physicians or CMS to predict
 - Broad CED NCDs can limit coverage for new uses that were not conceived of at the time evidence was initially considered
 - CED criteria may not be appropriate to other uses and therefore use of CED can stifle innovation
- CMS has established a process to remove NCDs that no longer reflect current medical practice
 - Removal typically allows for coverage of technology at the discretion of Medicare Administrative Contractors (MACs)
 - Unclear whether or how this standard could be applied to CED NCDs

1 Zeitler, EP, Gilstrap, LG, et al. Coverage with Evidence Development: Where are We Now? *American Journal of Managed Care*, August 2022, Volume 28, Issue 8, Apr 17 2022.

Nuclear Medicine CED NCDs

- Nuclear medicine studies account for almost 15% of current CED NCDs

NCD	Effective Date	Date First Trial Approved	No. of Studies
Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease	September 27, 2013	April 2, 2014	4
FDG PET and Other Neuroimaging Devices for Dementia	September 15, 2004	May 24, 2006	1
NaF-18 PET for Bone Metastasis	February 26, 2010	February 26, 2010	1

- CMS has not responded to multiple requests to retire these NCDs and allow coverage at MAC discretion

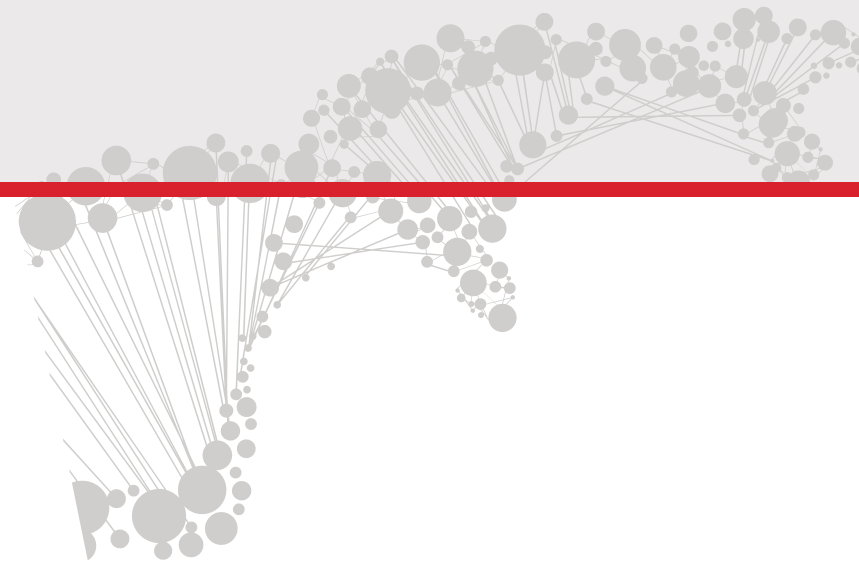
F-18 Sodium Fluoride (NaF) PET

- Originally indicated for diagnostic PET imaging of bone to define areas of altered osteogenic activity
- NCD 220.6.19 limits coverage of NaF-18 PET to identify bone metastasis of cancer to CED trials that answer the following question:
 - Does the addition of NaF-18 PET imaging lead to:
 - A change in patient management to more appropriate palliative care; or
 - A change in patient management to more appropriate curative care; or
 - Improved quality of life; or
 - Improved survival?
 - All other uses and clinical indications for NaF-18 PET are nationally non-covered
- NaF Pet is now the standard of care for a number of non-oncologic indications
 - Recent studies support use in detecting activity related to tears in the outer wall of the aorta and managing patients with acute aortic syndrome¹
- No ongoing studies on NaF PET for oncologic indications and there will be none in the future because NaF PET is now rarely used for oncologic indication
- Result is permanent non-coverage for an important imaging modality

¹ Syed MBJ et al. 18F-Sodium Fluoride Positron Emission Tomography and Computed Tomography in Acute Aortic Syndrome. JACC: Cardiovascular Imaging, available online 16 Mar 2022. <https://doi.org/10.1016/j.jcmg.2022.01.003>

Recommendations

- SNMMI asks that MEDCAC recommend that CMS :
 - Not apply blanket non-coverage for an item that is the subject of an NCD with CED; indications other than those that are the subject of the NCD should be covered at MAC discretion
 - Establish specific criteria as to when CED will end
 - Ensure that any CED NCDs and criteria are designed to allow outstanding coverage questions to be addressed with minimal burden on providers and manufacturers, including prioritizing use of real-world evidence such as data from clinical registries, electronic health records, and administrative claims
 - Review CED NCDs every 5 years and reach out to stakeholders for comment on continuing need for CED
 - Are there ongoing trials and/or will there be future trials developed to address CED questions?
 - Should CED be retired and coverage of the item or service be allowed at MAC discretion?



Thank You