



Avalere
Health
Outlook

2012

Medicare's 2012 NCD List: Will CMS Focus
on Oncology and Molecular Diagnostics?

CMS Has Acted on 7 of the 20 Topics on the 2008 Potential NCD List

In an effort by CMS to increase transparency around the national coverage determination (NCD) initiation process, CMS posted 20 potential Medicare NCD topics for public comment on July 30, 2008. Of the 20 topics on the list, CMS has acted on 7 by either issuing a NCD or formally evaluating the evidence through a technology assessment (TA) and/or a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC).

Potential NCD Topic	Outcome	Date
Ablation for atrial fibrillation	MEDCAC	2009
Biological therapies for chronic wounds	AHRQ TA	2009
Bone morphogenetic protein	AHRQ TA, MEDCAC	2010
Erythropoiesis stimulating agents	MEDCAC, NCD	2010, 2011
Minimally invasive methods for bariatric surgery	NCD	2011
Pharmacogenomic testing	AHRQ TA, MEDCAC, NCD on PGx for warfarin	2009, 2010
Proton beam therapy for prostate cancer	AHRQ TA, MEDCAC	2009, 2010
Artificial cervical disc	No action taken	
Bisphosphonates		
Gene expression profiling tests		
Hip resurfacing		
Levocarnitine		
Lumbar fusion for degenerative disc disease		
Off-label use of drug eluting stents		
Parenteral iron supplementation		
Peripheral arterial stenting and vascular intervention		
Thrombopoiesis stimulating agents		
Treatment of wet age-related macular degeneration		
Vertebroplasty/ kyphoplasty		
CMS' potential NCD selection process		

Likely Topics on Medicare’s 2012 NCD Radar

In light of Medicare’s plans to update its 2008 Potential NCD List, Avalere conducted an analysis to identify the potential items and services likely to be on Medicare’s radar for an NCD in 2012. Although CMS intended to issue quarterly updates to the list after it was first introduced, no updates have been made since 2008. However, on September 28, 2011, CMS requested that stakeholders weigh in on how to revise the list.¹ CMS plans to post a revised list after its review of public comments, which were due on November 27, 2011.

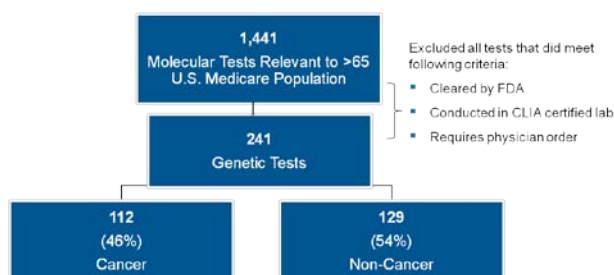
Focus on Personalized Medicine for Cancer

Though the 2008 Potential NCD list did not place a heavy emphasis on oncology, recent changes to the oncology healthcare landscape may likely influence CMS’ decision making in the near future. Of the 20 topics proposed in 2008, only one focused on oncology: proton beam therapy for prostate cancer. Though CMS has commissioned an AHRQ TA and MEDCAC on this topic, CMS has yet to initiate an NCA.

Since 2008, the rate of change in the oncology healthcare landscape has been drastic. As articulated in a recent report by the ECRI Institute, there has been an influx of many new and high-cost oncology therapies with per-patient price tags of \$100,000 and up.² Moreover, there are an estimated 400 cancer chemotherapy agents in development.³ The majority of these new-to-market and pipeline agents are add-ons to existing therapy regimens for cancer, not replacements to existing interventions.⁴

The rise of personalized medicine has and continues to have a profound impact on the oncology space. Researchers are using genetic information to match oncology treatments to the biological drivers of tumors in patients to more effectively treat the individual patient. As a result, molecular tests are emerging at a rapid rate in oncology (Figure 1).^{5,6} 46-percent of the 241

Figure 1 / Universe of Molecular Tests of Potential Interest to U.S. Medicare Population



¹ CMS. “Potential NCD Topics.” September 28, 2011.

² ECRI Institute. “ECRI Institute’s Top 10 C-Suite Watch List: Hospital Technology Issues for 2012.” January 3, 2012.

³ Campbell, Maude L., Michele B. Kaufman, and Jeffrey Bendix. “Drug Topics: Oral Oncology Drugs.” *Modern Medicine Network*. February 1, 2009.

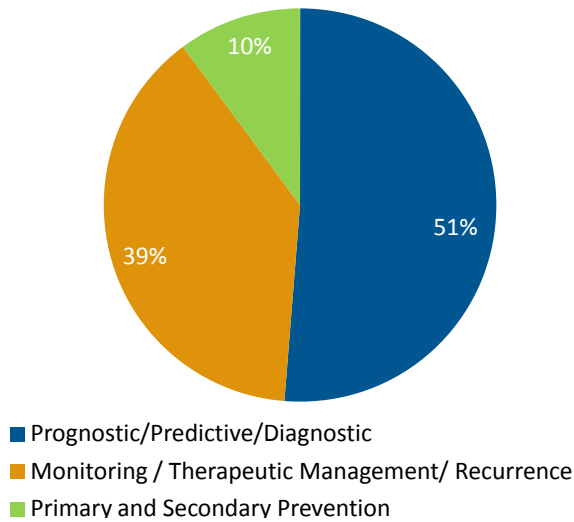
⁴ ECRI Ibid.

⁵ Figures 1 to 3 are based on an analysis of data from the following reports:

- AHRQ. Quality, Regulation, and Clinical Utility of Laboratory-Developed Tests. May 19, 2010.
- AHRQ. Update on Horizon Scans of Genetic Tests Currently Available for Clinical Use in Cancers. April 15, 2011.
- AHRQ. Update on Genetic Tests for Non-Cancer Diseases/ Conditions: A Horizon Scan. March 18, 2010.
- AHRQ. Genetic Tests for Non-Cancer Diseases/ Conditions: A Horizon Scan. August 28, 2007.

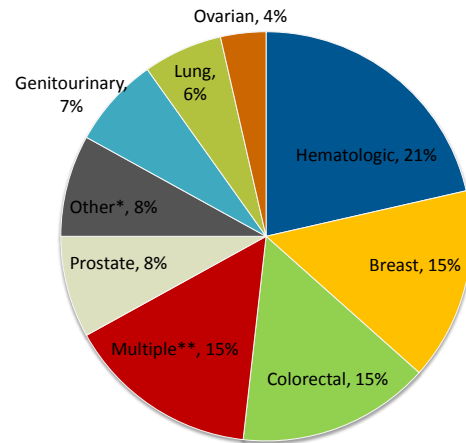
genetic tests currently available for clinical use are for cancer. The profile of these tests by cancer type can be seen in Figure 2. Over time, the number of cancer tests has grown more rapidly than non-cancer tests, especially those for lung, prostate, and breast cancers. Moreover, in the therapeutic area of cancer, the majority of tests are used for predictive/diagnostic purposes and therapeutic management (Figure 3).⁷

Figure 2 / Breakdown of Genetic Tests for Clinical Use in Cancers by Cancer Type



N=197*
*A genetic test may have more than one clinical purpose

Figure 3 / Clinical Purposes of Genetic Tests Used in Cancers by Cancer Type



N=112
*Includes brain, liver, and upper GI
**Includes breast, colorectal, lung, ovarian, prostate

To date, there are no NCDs on molecular tests for oncology; however, there are several Medicare local coverage determinations (LCDs) on molecular diagnostics with the following tendencies:⁸

- All LCDs pertain to cancer diagnostics
- Many reflect denials
- Denials cite lack of evidence, ranging from nonexistence of clinical trials to insufficient demonstration of clinical utility, but discussion of evidence was not as complete as that for NCDs

Given the entrance of advanced oncology therapies and the growing interest in molecular tests for oncology among local Medicare contractors, Avalere conducted an analysis to

⁶ Hughes, Kathleen, Jenny Gaffney, and Reginald Williams. "The Role of Molecular Tests in Shaping Comparative Effectiveness Research (CER)." *International Society for Pharmacoeconomics and Outcomes Research*. Presented November 7, 2011.

⁷ AHRQ has used all of the categories mentioned here variously in its reporting from 2006 to the present. While recognizing the differences in the categories, we have amalgamated them to allow for longitudinal tracking

⁸ Tendencies were observed from an internal analysis of nine Medicare LCDs and articles on molecular diagnostics, performed October 2011.

determine the likelihood of whether oncology and personalized medicine for cancer care are likely to be on Medicare's radar in the near future.

Analysis Overview

To inform the analysis, Avalere reviewed the following sources whose reviews and/or topic lists are typically correlated with past NCDs and therefore may be inputs to Medicare's NCD horizon scanning:

- Topics on Medicare's 2008 Potential NCD List that have not been acted upon
- Topics identified by key stakeholders (e.g. AHIP) as ones that should be on Medicare's updated Potential NCD list during the comment opportunity
- Washington State Health Technology Assessment (HTA) list of proposed topics for review in 2012
- AHRQ's In Progress TAs and Comparative Effectiveness Reviews
- U.S. Preventive Services Task Force (USPSTF) Topics in the Pipeline for Review
- BCBS Technology Evaluation Center's In Progress Reviews
- Topics that have recently been the subject of an OIG report or are listed on the 2012 OIG Work Plan
- Recent Medicare LCD activity restricting coverage

Avalere compiled a list of the items and services identified by each source, generating a list of over 80 potential topics. Of these 80 topics, about a quarter of them were oncology related. Of the oncology-related items and services, nearly half of them were related to genomics. The topics that appeared most frequently across all sources were the following:

- Screenings for prostate and lung cancer
- Treatments for localized prostate cancer
- Therapies in the management of non-small-cell lung cancer
- Pharmacogenomic testing for breast and colon cancers

This evaluation represents Avalere's analysis of items and services on which Medicare may consider and is based on only a subset of factors that may be considered by CMS in its decision to initiate an NCD. CMS has the discretion to open an NCD on any Medicare Part A or B item or service at any time and the public has the ability to request an NCD on any Medicare Part A or B item or service. However, this analysis demonstrates that the incoming wave of innovation in oncology may receive increased scrutiny by CMS.