Press Release

THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DRAFT DECISION COULD LIMIT PATIENT ACCESS TO NEW TECHNOLOGY THAT MAY HELP IN DIAGNOSING DEMENTIA

Piramal Imaging Urges Public Participation During the CMS Public Comment Period on the use of Beta-Amyloid Imaging in Dementia

Berlin/Boston/Mumbai, July 25, 2013 – On Wednesday, July 3, 2013, the Centers for Medicare & Medicaid Services (CMS) released its proposed decision memorandum regarding the use of beta-amyloid imaging in dementia and neurodegenerative disease.[1]

Piramal Imaging is concerned about CMS' proposal, which appears to take an overly cautious approach to expanding Medicare coverage for positron emission tomography (PET) tracers to include beta-amyloid imaging agents. Limiting Medicare coverage only to patients enrolled in CMS-approved clinical trials imposes restrictions that reduce patient access to long-awaited diagnostic tools.

"We are concerned that the CMS draft coverage decision is too restrictive and, if finalized in its current form, will place an undue burden on physicians, patients and caregivers by delaying the definitive diagnosis of certain types of dementia and neurodegenerative disease, including Alzheimer's," said Dr. Ludger Dinkelborg, Director of the Board, Piramal Imaging SA.

In Piramal Imaging's view, the CMS decision needs to be reviewed for the following reasons:

- The draft decision does not reference the Appropriate Use Criteria (AUC) that was developed by the Society for Nuclear Medicine and Molecular Imaging (SNMMI) and the Alzheimer's Association. The taskforce was comprised of a cross-section of experts including radiologists, nuclear medicine specialists and neurologists.[2]
- It lacks clear guidance on clinical trial designs that should be practical and provide CMS with the requested evidence in a reasonable timeframe.
- There is general disagreement with the relevance of autopsy as an appropriate endpoint to demonstrate clinical utility in the intended population.

The use of new beta-amyloid imaging agents should help to reduce uncertainties in the diagnosis of Alzheimer's disease and related dementias, which is of importance for patients and their caregivers. Piramal Imaging is hopeful that CMS will moderate its position when it renders its final decision by finding less restrictive ways to gather the information it seeks regarding health outcomes.

CMS is accepting public comments on its proposed decision from all stakeholder groups and is accepting public comments now through August 2, 2013. Comments can be posted at: http://www.cms.gov/medicare-coverage-database/indexes/nca-open-and-closed-index.aspx.

"We urge anyone concerned with Alzheimer's disease—patients, caregivers, healthcare professionals, patient advocacy groups and the general public—to share opinions on the value of beta-amyloid PET imaging during the initial 30-day public comment period," said Dr. Dinkelborg. "Every letter will have an impact on CMS' final decision in September."

About the value of beta-amyloid PET imaging
Today, Alzheimer's disease is usually diagnosed after a person with a cognitive impairment undergoes an extensive clinical examination which typically includes family and medical history, physical and neurological examinations, laboratory tests, and imaging procedures such as computed tomography (CT) and magnetic resonance imaging (MRI) scans. Still, a definitive diagnosis of Alzheimer's disease can only be made after death where an autopsy can reveal the presence of beta-amyloid plaques and neurofibrillary tangles in the brain. However, post-mortem studies looking for accumulations of beta-amyloid in the brain have shown that 10 to 30 percent of diagnoses based on clinical examinations are incorrect.

Beta-amyloid PET imaging holds the promise to detect beta-amyloid plaques in live patients. Because beta-amyloid progresses in the brain for as long as a decade before classic signs and symptoms Alzheimer's disease become clear to diagnosticians, early detection of the pathophysiology in symptomatic patients is crucial to a more accurate assessment of the patient's condition, which may lead to a targeted and accurate therapeutic approach for those affected.

About Piramal Imaging SA
Piramal Imaging SA, a division of Piramal Enterprises, Ltd., was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG. By developing novel PET tracers for molecular imaging, Piramal Imaging is focusing on a key field of modern medicine. Piramal Imaging strives to be a leader in the Molecular Imaging field by developing innovative products that improve early detection and characterization of chronic and life threatening diseases, leading to better therapeutic outcomes and improved quality of life. Piramal Imaging's beta-amyloid PET tracer, florbetaben F18, is currently being reviewed by the Food and Drug Administration (FDA) and European Medicines Agency (EMA) for use in the visual detection of beta-amyloid in the brains of adults with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive decline. For more information please go to http://imaging.piramalenterprises.com.

About Piramal Enterprises Ltd.
Piramal Enterprises is one of India's largest diversified companies, with a presence in pharmaceutical, financial services and information management sectors. Piramal Enterprises had consolidated revenues of over $650 million in FY2013. In the pharmaceutical space, PEL is one of the leading custom manufacturing players globally, has presence in the global critical care segment with a portfolio of inhalation and injectable anesthetics and its OTC business is ranked no. 7 in India. PEL is also engaged in drug discovery & research and has a strong pipeline of development products. In the financial services space, PEL has a real estate focused PE fund – Indiareit and a NBFC that is focused on lending to the real estate and education sectors. PEL's information management business, Decision Resources Group is a leading provider of information based services to the healthcare industry.

Source: U.S. Centers for Medicare and Medicaid Services. National Coverage Analysis (NCA) Tracking Sheet for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N). CMS website: http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=265&NcaName=Beta+Amyloid+Positron+Emission+Tomography+in+Dementia+and+Neurodegenerative+Disease&bc=ACAAAAAACAAAAA%3d%3d&

[1] Centers for Medicare & Medicaid Services. Proposed decision memo for beta amyloid positron emission tomography in dementia and neurodegenerative disease (CAG-00431N). http://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=265&NcaName=Beta+Amyloid+Positron+Emission+Tomography+in+Dementia+and+Neurodegenerative+Disease&CoverageSelection=National&KeyWord=beta-amyloid&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAACAAAAA%3d%3d&. Published July 3, 2013. Accessed July 3, 2013.

[2] Johnson KA, Minoshima S, Bohnen NI, et al. Appropriate use criteria for amyloid PET: a report of the Amyloid Imaging Task Force, the Society of Nuclear Medicine and Molecular Imaging, and the Alzheimer's Association [published online ahead of print January 28, 2013]. Alzheimer’s Dement. doi:10.1016/j.jalz.2013.01.002.

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