American Pharmacists Association
For Every Pharmacist. For All of Pharmacy.

American Pharmacists Association
House of Delegates – March 22-25, 2024

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Jessica Comstock
(Name)

January 22
(Date)

APhA-APPM Delegation on behalf of the Nuclear Pharmacy SIG
(Organization)

Subject: Access to Radiopharmaceuticals

Motion: To adopt the following policy statement as written

1. APhA advocates for policy and legislation that increase patient access to radiopharmaceuticals.

Background:
Radiopharmaceuticals have been in use for decades. The first FDA approved radioactive product was Iodine-131 in 1951. Since then, the utilization of nuclear medicine has increased, with over 20 million diagnostic studies performed in the United States each year. These radioactive drug products allow patients to undergo a non-invasive diagnostic procedure using small amounts of radioactivity to image internal organs and structures. While other imaging studies show physical structure, nuclear medicine can provide information about physiological processes to show how the body is functioning, detail on organ function, and cancer diagnosis and staging. Because imaging with nuclear medicine allows abnormalities to be identified at an early stage, healthcare teams can create treatment plans and start well before other diagnostic tests could have identified the problem.

Sample of Disease States Nuclear Medicine Can Diagnose or Treat

Alzheimer's Disease	Heart Disease	Neuroendocrine Tumors
Brain Disorders	Kidney Disorders	Parkinson's Disease
Breast Cancer	Lung Disorders	Prostate Cancer
Epilepsy	Lymphoma	Thyroid Disorder
GI Disorders	Melanoma	

Currently Centers for Medicare and Medicaid services classify diagnostic radiopharmaceuticals as a "supply" as part of a packaged payment system for the nuclear medicine procedure even though the radiopharmaceuticals are regulated by the FDA and undergo the same stringent standards as other approved drug products. With the new precision medicine products that have come to market over the last 10 years, this pricing model is restricting access to these life altering products. CMS averages the pricing of all the diagnostics products which has resulted in overpaying for low-cost radiopharmaceuticals and has reduced reimbursement for the higher cost products. These reduced reimbursement rates have resulted in many providers choosing not to offer these services. This model decreases patient access and potentially impacts quality of care.

While this limitation impacts all patients, the decrease in availability disproportionately affects people of color and those of lower socioeconomic classes. Breast and prostate cancer, neuroendocrine cancer, and Alzheimer's disease affect all population groups, but examples of their impact on these groups are outlined below:

- Breast Cancer
    - Black women face a higher likelihood of developing breast cancer before age 45 compared to white women and are more likely to die from breast cancer at every age.[1]
- Alzheimer's Disease
    - 18.6% of Blacks and 14% of Hispanic Americans aged 65 and older have Alzheimer's dementia compared with 10% of whites.[2]
    - Black patients with dementia also have approximately twice the risk of underdiagnosis compared with white patients.[3]

- Prostate Cancer
    - Black men are 1.8 times more likely to be diagnosed with and 2.2 times more likely to die from prostate cancer than white men. Black men are also slightly more likely than white men to be diagnosed with advanced disease.[4]
- Neuroendocrine Tumors
    - Black patients are more likely to be diagnosed with later stages of neuroendocrine tumors and have worse overall survival rates compared to non-Black patients.[5]

Increasing access to patient care has been a priority of APhA through education, training, and advocacy. However, APhA has not been able to advocate for current or past legislation to increase access to radiopharmaceuticals. Currently the Facilitating Innovative Nuclear Diagnostics (FIND) Act centering on changing the payment structure for diagnostic radiopharmaceuticals is under Congressional review. The number of new diagnostic radiopharmaceuticals is expected to match the growing radiopharmaceutical therapy market with several new oncologic treatments anticipated in the next 3-5 years. The need for adequate reimbursement will continue to be a high priority to ensure continuity of patient care.

Adoption of this policy will allow APhA to advocate and act of the behalf of patients now and into the future as nuclear medicine continues to grow.

[1]Yedjou, C.G., Sims, J.N., Miele, L., Noubissi, F., Lowe, L., Fonseca, D.D., Alo, R.A., Payton, M., & Tchounwou, P.B. (2019). Health and racial disparity in breast cancer. Andances in experimental medicine and biology. Retrieved January 14, 2022, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6941147/

[2]Rajan KB, Weuve J, Barnes LL, McAninch EA, Wilson RS, Evans DA. Population estimate of people with clinical AD and mild cognitive impairment in the United States (2020-2060). Alzheimers Dement 2021;17.

[3]Gianattasio, K.Z., Prather, C., Glymour, M.M., Ciarleglio, A. and Power, M.C. (2019), Racial disparities and temporal trends in dementia misdiagnosis risk in the United States. Alzeimer's Dementia: Translational Research and Clinical Interventions, 5: 891-898.

[4]African Americans and Prostate Cancer. (2021, June 23). ZERO – The End of Prostate Cancer. https://zerocancer.org/learn/about-prostate-cancer/risks/african-americans-prostate-cancer/

[5]Zhou, H., Zhang, Y., Wei, X., Yang, K., Tan, W., Qiu, Z., Li, S., Chen, Q., Song, Y., &Gao, S. (2017, November). Racial disparities in pancreatic neuroendocrine tumors survival: A seer study. Cancer medicine.

Current APhA Policy & Bylaws:

2023 – Access to Essential Medications

APhA Advocates regulation, policies and legislation that recognize access to quality and affordable essential medications as a fundamental human right.

(JAPhA. 63(4):1266; July/August 2023)

****Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item content.**

New Business Items are due to the Speaker of the House by **January 22, 2024** (60 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.