

Shields Imaging of Eastern Massachusetts, LLC (SIEM)
DoN # 25020312-AM

AMENDMENT QUESTIONS #2

Responses should be sent to DoN staff at DPH.DON@State.MA.US

While you may submit each answer as available, please

- List question number and question for each answer you provide
- Submit responses as a separate word document, using the above application title and number as a running header and page numbers in the footer
- When providing the answer to the final question, submit all questions and answers in one final document
- Submit responses in WORD or EXCEL; only use PDF's if absolutely necessary. If "cutting and pasting" charts, provide them in a PDF so they can be clearly seen
- **Whenever possible, include a table with the response**
- **For HIPAA compliance Do not include numbers <11.**

1. Responses to DoN Questions #1 (pg.2) state that the Holder evaluated the following items when determining need for 5 additional days of service:

- a. Centers for Disease Control and Prevention (CDC) reported tumor registry data,

[CDC tumor reporting is available for 2023 currently. For reporting year 2023, an estimating tool, combined with proprietary data, suggested that 200 patients likely sought care at other locations based on appointment availability \(potential 2329 to actual 2135\).](#)

<https://www.cancer-rates.com/>

[https://www.cdc.gov/national-program-cancer-
registries/contact/index.html#MA](https://www.cdc.gov/national-program-cancer-registries/contact/index.html#MA)

- b. Advisory Board national and regional PET/CT trending through Medicare data trends,

[Advisory Board data from 2024 projects PET/CT utilization will grow by 9% per year for the next 5 years.](#)

- c. Incidence per population for specialty exams,

[CDC tumor reporting, combined with proprietary data, illustrates the incidence per population for specialty exams. Specialty exams refer to non-FDG cases. For PETCT, the following diseases are considered specialty exams.](#)

[Neuroendocrine:](#)

35 per 100,000

[Cardiac Sarcoidosis:](#)

10.9 per 100,00 in white American

35.5 per 100,000 in African American

[Prostate cancer:](#)

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1 in 54 (men 50-59)

1 in 19 (men 60-69)

1 in 11 (men 70+)

<https://www.cancer-rates.com/>

<https://www.cdc.gov/national-program-cancer-registries/contact/index.html#MA>

- d. Alzheimer's Association data for patients seeking anti-amyloid therapy,

There are 6.9 million people in the US with early onset cognitive decline.

This translates to approximately 134,000 people in Massachusetts (2.06% of US population). This population would be the primary population seeking anti-amyloid treatment. If choosing to pursue anti-amyloid therapy, patients would need a lumbar puncture or the preferred PETCT scan

<https://www.alz.org/alzheimers-dementia/facts-figures>

- e. Hospital Data and incidence per population for cardiac procedures, and

10-15% of nuclear medicine stress tests result in equivocal results with respect to coronary artery disease, due to body habitus, diabetes, and being of female gender.

PET/CT is the preferred imaging tool for this population. South Shore Hospital provides nuclear medicine stress tests to approximately 2500 patients per year. Of those patients, approximately 250 - 375 would be better served by PET/CT due to higher sensitivity, than the nuclear medicine stress test.

- f. Industry trends in new protocol and tracer development.

FDA has approved Novartis radioligand therapy Pluvicto® for earlier use before chemotherapy in PSMA-positive metastatic castration-resistant prostate cancer
<https://www.novartis.com/news/media-releases/fda-approves-novartis-radioligand-therapy-pluvicto-earlier-use-chemotherapy-psma-positive-metastatic-castration-resistant-prostate-cancer>

Recent FDA approval of donanemab (Kisulna) for amyloid plaque removal will use serial PET/CT to evaluate treatment termination. (Leqembi treatment requires one PET/CT scan) <https://radiologybusiness.com/topics/healthcare-management/healthcare-economics/implications-radiology-following-fdas-approval-new-alzheimers-treatment-eli-lilly>

New imaging biomarker for renal cancer expected to have FDA approval in 2025 for PET/CT. Renal carcinoma is a new population for PET/CT. (TLX250-CDx, Zircaix®³ (⁸⁶Zr-girentuximab)
<https://telixpharma.com/our-portfolio/pipeline/>

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Please provide a brief description of the findings that came out of the Holder's evaluation of each of the items listed above and how the findings impacted the determination of need for additional days of PET-CT services.