

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

AMENDMENT QUESTIONS #4 - Updated

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. Please provide a breakdown of 2024 PET-CT scan volume by clinical indication.

FDG Tumor Imaging by Diagnosis	2024 Selected Locations
Abdominal	9
Anal	22
Bladder	44
Bone	60
Breast	99
Cardiac sarcoidosis	6
Cervical	22
Colon	10
Colorectal	38
Duodenum	4
Esophageal	79
Eyes	1
Gallbladder	8
Head & Neck	103
Kidney	25
Leukemia	17

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Liver	31
Lung	484
Lymphoma	235
Mass	2
Melanoma	73
Merkel Cell	1
Myeloma	100
Ovarian	20
Pancreas	15
Penis	2
Sarcoid	0
Sarcoma	1
Skin	15
Soft Tissue	1
SPN	349
Stomach	18
Testis	4
Thymus	0
Thyroid	3
Uterine	39
Vaginal	13
(Other)	92
Subtotal FDG	2045

Prostate (PSMA)	509
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Neuroendocrine Tumor (Dotatate)	31
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Brain (Amyloid and Metabolic)	173
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2024 PETCT total	2,758
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2. How does the Holder distinguish need versus demand when it comes to increasing PET-CT volume at SSH?

In the Determination of Need (DON) context, the terms “need” and “demand” are closely related. Need reflects the services and/or facilities reasonably deemed required to offer clinically appropriate medical treatment and diagnosis, over a defined period of time, for a subject patient panel based on, among other things, the current and anticipated prevalence of disease. Demand reflects the ability to meet the demonstrated evolving needs of the same patient panel with current and anticipated medical technology and facilities. Need and demand, as they relate to this Project, are also partly a reflection of clinicians’ judgment as to what technology is the appropriate means to most effectively and efficiently help identify their patients’ diagnoses, staging, and treatment planning options. And, finally, need and demand are partly a reflection of (and are affected by) changes in techniques and procedures, as well as new findings relating to how certain technologies (e.g., PET/CT) can be utilized to improve diagnoses, treatment plans, and/or outcomes.

Based on the Holder’s analyses and projections, which include consideration of historical data, changes in techniques, procedures, and uses of PET/CT, and demographic changes and forecasts (all of which are cited in our application and responses to questions from DPH), the Holder believes it has demonstrated that current access for PET/CT services at the South Shore site is falling behind the need and demand for those services. As further evidence of this fact, the Holder’s appointment templates are at capacity weekly and the pending order queue is elevated beyond three to four service days. A queue of four service days translates into exams being scheduled out 14 calendar days, given that this service operates on a limited service schedule. This is significant because, without timely access to PET/CT imaging, critical disease diagnosis may be delayed, allowing a disease to unnecessarily progress; crucial information about a patient’s response to treatment can lead to a missed opportunity to salvage a therapy or introduce an alternative intervention; and patients can suffer unnecessary anxiety. Studies show that delays in patient care are associated with worse health outcomes, higher medical costs and lower patient satisfaction.

- a. What factors demonstrate that the increasing PET-CT scan volume at SSH reflects increasing need amongst the Holder’s patient population for PET-CT and not new demand due to available capacity?

Utilization of PET/CT is influenced by factors such as patient panel demographics (the implications of which, for purposes of this Project, are outlined in the application and responses to prior responses), a progressive Cancer Program with year over year increases in diagnosed cancer cases (which are reflected in South Shore Hospital tumor registry data), and the diversification of PET/CT procedures that address specific cancer

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and other disease types, such as the introduction of PSMA for prostate Imaging, improving sensitivity of metastatic tumor detection, amyloid PET for patient selection for recently FDA approved Alzheimer's Disease treatment, and general outcome improvements for populations that have equivocal exam results as in SPECT cardiac imaging. As regards the latter example, Cardiac PET/CT perfusion imaging is an improved option for patients with suspected coronary artery disease (CAD), as it offers patients reduced radiation exposure and the ability to quantify myocardial blood flow, and also provides better overall diagnostic accuracy as opposed to lesser sensitive imaging options; and for prostate imaging, PETCT offers improved detection of metastatic prostate cancer compared to CT/bone scans. All of the above demonstrate that the increasing PET/CT volume at SSH reflects increasing need for PET/CT among the Holder's patient population.

- b. What measures are in place to ensure that PET-CT scans are clinically appropriate and to reduce unnecessary utilization of PET-CT scans?

Medicare, MassHealth and commercial carriers all require medical necessity criteria to be met for every PET/CT scan through rigorous prior authorization requirements. Medical necessity must meet the burden of appropriateness, and expectations of improvement, safety, and efficiency. As an example, for Amyloid PET scans of the brain, proof of the following prior exams must be part of the patient medical record when filing a payment claim:

- 1) Clinical evaluation with mental status testing results
- 2) Supporting medical records for cognitive decline
- 3) Rule out Vitamin b12 deficiency by lab testing
- 4) Rule out untreated thyroid disease by lab testing
- 5) Prior MRI to rule out trauma or encephalopathy

This example supports a rigorous appropriate test selection protocol which applies to all PET/CT exams.

3. Explain the Holder's rationale for offering cardiac PET perfusion.

- a. How will offering cardiac PET perfusion address existing need among the Holder's patient population?

Cardiac PET perfusion imaging is an improved option in comparison to SPECT for patients with suspected coronary artery disease (CAD) as it offers patients reduced radiation exposure, the ability to quantify myocardial blood flow, and provides better overall diagnostic accuracy. It serves a specific role for patients with BMI over 30, diabetes, and has also been shown to be beneficial with female patients primarily due to its inherent attenuation correction, fewer shadow artifacts and higher image resolution.

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The American Society of Nuclear Cardiology has made the following statement about Cardiac PET Perfusion:

*Preferred: Rest-stress myocardial perfusion PET is a first line preferred test for patients with known or suspected CAD who meet appropriate criteria for a stress imaging test and are unable to complete a diagnostic level exercise stress imaging study. **There are no clinical scenarios where PET should not be considered a preferred test for patients who meet appropriate criteria for a stress imaging test and who require pharmacologic stress***

4. In 2002, Shields Imaging of Massachusetts received approval for a single, mobile PET-CT unit to provide PET-CT services at 3 separate sites: South Shore Hospital, UMass Memorial Medical Center, and Baystate Medical Center. In 2006, the DoN was amended to convert the DoN approval to the three licensed services: Shields Imaging of Eastern Massachusetts, Baystate MRI and Imaging Center, and UMass Memorial Medical Center. Explain the schedule of operation of the mobile PET-CT unit at the three approved sites, including a breakdown of the days of operation and the hours of operation at each of the three locations.

Shields Imaging of Massachusetts, LLC was a consortium that received DoN Approval in 2002 for Project 4-4886 to acquire a mobile PET/CT unit to provide services at three host sites, Baystate Medical Center, South Shore Hospital and UMass Memorial Medical Center. The consortium was comprised of Shields Imaging of Eastern Massachusetts, LLC (for South Shore Hospital); Shields Imaging of Worcester, LLC (for UMass Memorial Medical Center); and Shields Imaging of Springfield, LLC (for Baystate Medical Center). In 2003, a fourth host site at Berkshire Medical Center was added through a DoN amendment. In 2005, the DoN was further amended to add a fifth host site at HealthAlliance Hospital's Burbank Campus. In 2006, a DoN amendment was approved to acknowledge the licensure of the sites as separately licensed clinics and remove Shields Imaging of Massachusetts, LLC as the DoN holder. Accordingly, the three original sites were licensed to the following entities: Baystate MRI and Imaging Center, LLC (BMIC); Shields Imaging of Eastern Massachusetts, LLC (SIEM); and UMass Memorial MRI and Imaging Center, LLC ("UMMIC"). In converting the license to three separate clinics, the clinics each, in effect, acquired the right to operate DoN approved PET/CT service days, which they accomplished by leasing a second PET/CT unit.

In 2011, the DoN was again amended--to add an additional host site of UMMIC at Wing Memorial Hospital and Medical Center; however, this site was not implemented. Then, in 2013, an amendment was approved to add a host site of the BMIC clinic at Berkshire Medical Center. However, in 2017, the Berkshire Medical Center site was converted to a separate DoN approved joint venture known as Shields PET-CT at Berkshire Medical Center, LLC.

Pursuant to the original DoN and amendments, UMMIC has DoN Approval for 7 days of PET/CT services at Shrewsbury which are being phased in over time (currently operates 5 days per week), Baystate has DoN Approval for three days of service, and SIEM has DoN Approval for two service days. Taken together, this represents 12 days of DoN Approved service days, and 10

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days of operationalized PETCT service days. UMMIC and SIEM are serviced exclusively by the mobile PET/CT unit that was acquired via the original DoN, and BMIC and SIEM are serviced by the leased mobile PET/CT unit.

Clinic Schedules:

UMASS Memorial Medical Center:

Monday: 6:30 am to 8:30 pm

Wednesday: 6:30 am to 8:30 pm

Friday: 6:30 am to 8:30 pm

Saturday: 6:30 am to 7:00 pm

Sunday: 6:30 am to 7:00 pm

South Shore Hospital:

Tuesday: 6:30 am to 10:00 pm

Thursday: 6:30 am to 10:00 pm

Baystate MRI and Imaging Center:

Sunday: 7:00 am to 4:00 pm

Monday: 7:00 am to 8:30 pm

Thursday: 7:00 am to 8:30 pm