Determination of Need-Required Equipment and Services Guideline

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Massachusetts Department of Public Health

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Overview

In support of the Massachusetts Department of Public Health's (DPH) revision of 105 CMR 100.000, *Determination of Need* ("DoN Regulation"), the Determination of Need Program ("DoN Program") has developed and issued a series of sub-regulatory Guidelines. This document, the *Determination of Need-Required Equipment and Services Guideline* (or "the Guideline") supports the requirement that certain equipment and services receive a Notice of Determination of Need prior to acquisition and operation pursuant to 105 CMR 100.000 and M.G.L. c. 111, §§ 25B-25C.

The Guideline is a part of DPH's efforts to ensure that high-cost equipment and services for which there is evidence of their potential to be over-utilized are reviewed on a case-by-case basis through an application for DoN. DPH's objective is to achieve this goal without unnecessarily restricting equipment and services that are innovative and are used in an appropriate manner on the appropriate Patient Panel so as to add value for Massachusetts consumers (e.g. lead to lower cost of care and improved patient outcomes). While technological advances in health care have helped to control costs by eliminating waste and increasing productivity, it is estimated that half of the increase in health care spending is associated with the overuse and misuse of technology as preventive medicine.[i]

The inclusion of any equipment or service in the Guideline ***does not*** constitute or imply a moratorium or prohibition; rather, inclusion indicates that the equipment or service warrants a case-by-case review by the DoN Program in the context of the Proposed Project.

Inclusion Framework

The DoN Program considers whether equipment and services should be included in the Guideline for reasons of:

- **Quality**: Meaning improved patient health outcomes; or,
- **Access:** Meaning a demonstrable increase in access and reasonable assurances of health equity, including but not limited to a decrease in price; or,
- **Cost:** Meaning a reduction in the Commonwealth's Total Health Care Expenditure.

The DoN Program takes these factors into account by considering whether the use of specific equipment or service may result in increases in health care spending without associated benefits to the public in terms of improved patient health outcomes or improved access to health care.

DPH conducted a review of equipment and services utilizing the inclusion framework. Based upon that review, the following equipment and services are deemed "DoN-Required Equipment" and "DoN-Required Services," and therefore require a Notice of Determination of Need:

DoN-Required Equipment	DoN-Required Service
Computerized Tomographer (CT) Magnetic Resonance Imager (MRI) Positron Emission Tomographer (PET)* *Includes PET/CT and PET/MRI	Air Ambulance Megavoltage Radiation Therapy (MRT)

Note: *For additional details, please see equipment- or service-specific rationale for inclusion.*

Process for the Inclusion or Removal of DoN-Required Equipment or DoN-Required Services

Pursuant to 105 CMR 100.000, the DoN-Required Equipment and Services included within the Guideline will be reviewed and evaluated by DPH on, at a minimum, an annual basis. In reviewing which equipment and services are included within the Guideline, DPH will utilize the Inclusion Framework above, and will be guided by industry-accepted frameworks for evaluation.

DPH will use publicly available resources, including but not limited to, documentation produced by the Food and Drug Administration (FDA) or other published literature to support the identification and review of equipment or services within the health care market.

At any time, individuals may submit a written request to the DoN Program detailing a rationale and supporting evidence that an equipment or service should be considered for inclusion or exclusion from the Guideline based on the Inclusion Framework by sending mail or e-mail to:

Determination of Need Program
Massachusetts Department of Public Health
250 Washington Street
Boston, MA 02108
Telephone: (617) 753-7340
E-Mail: dph.don@state.ma.us

Additionally, the Commissioner of Public Health will convene an Advisory Committee to support the DoN Program's identification and review of equipment and services. At a minimum, the Advisory Committee shall include representatives or their designees from the following affiliations: the Director of the DoN Program, who shall serve as chair; Center for Health Information and Analysis (CHIA); Health Policy Commission (HPC); MassHealth; Office of the Attorney General, Health Care Division (AGO); Atrius Health; Blue Cross Blue Shield of Massachusetts (BCBSMA); the Conference of Boston Teaching Hospitals (COBTH); Massachusetts Association of Ambulatory Surgery Centers (MAASC); Massachusetts Association of Health Plans (MAHP); Massachusetts Council of Community Hospitals, Inc. (MCCH); Massachusetts Health and Hospital Association, Inc. (MHA); Massachusetts Medical Society (MMS); MassMEDIC; Steward Health Care; and, two members from the public specializing in health care finance, health care economics, or health care policy.

The Advisory Committee shall meet at the request of the chair and shall support and advise the DoN Program in conducting its regular review and evaluation of the Guideline, as well as any written requests submitted to the DoN Program.

Rationale for DPH Inclusion of Equipment of Services

Computerized Tomography (CT)

Following a literature review and analysis, the DoN Program has identified CT as equipment that warrants a case-by-case review based on DoN application-specific information due to its potential for clinically unnecessary utilization that in aggregate, can result in a significant increase in health care spending without an associated benefit to the public in terms of better health outcomes, or access to needed care. As such, the DoN Program has designated CT as a DON-Required Equipment.

Computerized Tomography (CT) combines a series of X-ray images to create cross-sectional images of bones, blood vessels, and soft tissues. These images provide more detailed information than traditional X-rays.[ii] Although CT and other imaging technologies are essential diagnostic tools for many conditions and patient populations, the federal Food and Drug Administration (FDA) reports that 30-50% of these tests are medically unnecessary, meaning they are costly without increasing patient outcomes.[iii,iv] In addition, unnecessary utilization increases lifetime cumulative cancer risk due to unnecessary radiation exposure.[7,8,v]

The use of diagnostic imaging, including CT, has increased dramatically since the development of this technology in the 1970s.[vi] As of 2015, approximately 80 million CT scans were performed each year in the United States compared to 3 million annual scans in 1980.[vii] The market for CT and other forms of nuclear imaging equipment are projected to show the highest growth amongst all health care market segments due to their ability to diagnose large numbers of diseases in expedited time.[viii] Research indicates that compared to other developed nations, the United States had the third highest volume of CT scanners (43.5 per million population) but performed the most CT scans (240 scans per 1,000 population).[ix] Data also indicates that the average commercial diagnostic imaging fee of $896 for an abdominal CT scan is far higher than what is charged in almost every other high-income country.[x] This combination of high volume and high cost demonstrates that the use of CT has the potential to increase total health care expenditure.

See *Appendix A* for example of uses of CT that have been identified by The Choosing Wisely Campaign to not lead to better patient outcomes or more cost-efficient care.

Magnetic Resonance Imager (MRI)

Following a literature review and analysis, the DoN Program has identified MRI as equipment that warrants a case-by-case review based on DoN application-specific information due to its potential for clinically unnecessary utilization that in aggregate, can result in a significant increase in health care spending without an associated benefit to the public in terms of better health outcomes, or access to needed care. As such, the DoN Program has designated MRI as a DoN-Required Equipment.

The use of diagnostic imaging, including MRI, has increased dramatically; from 1997 to 2006, MRI imaging increased an average of 26% per year, from 22 to 72 examinations per thousand patients annually.[xi] Factors contributing to this increase may include the widespread accessibility of technology, increased physician- and patient-generated demand, favorable reimbursement, and advances in the technology that make the criteria for ordering an MRI less strict.[15] Furthermore, increased use of MRI often causes a need for additional imaging due to false-positive findings, therefore creating additional costs.[15,xii]

The market for MRI equipment is projected to reach $7.5 billion in the United States by 2020, driven by an aging population, growing patient pools, and an increased preference for diagnostics that do not utilize ionizing radiation.[xiii] Demonstrating the potential risk to increasing total health care expenditure, data indicates that in the United States, the commercial average diagnostic imaging fee of $1,119 for an MRI is far higher than what is charged in nearly every other developed country.[xiv] Within radiology, the greatest profit margin is for MRI.[15] All of these factors support including MRI as a DoN-Required Equipment.

See *Appendix B* for example uses of MRI that have been identified by The Choosing Wisely Campaign to not lead to better patient outcomes or more cost-efficient care.

Positron Emission Tomography (PET)[1]

Following a literature review and analysis, the DoN Program has identified PET as equipment that warrants a case-by-case review based on DoN application-specific information due to its potential for clinically unnecessary utilization that in aggregate, can result in a significant increase in health care spending without an associated benefit to the public in terms of better health outcomes, or access to needed care. As such, the DoN Program has designated PET as a DoN-Required Equipment.

Although PET scans have enhanced clinical care in oncology, neuroimaging, and the diagnosis and treatment of infectious and chronic diseases, in recent years, its application has expanded beyond conditions and procedures with demonstrated value.[xv] As PET applications continue to expand, it is often used in combination with other imaging and diagnostic technologies such as CT and MRI.[xvi] There is evidence to suggest that PET and PET/CT scans may expose individuals to high levels of ionizing radiation that can accumulate to have dangerous effects over the course of a lifetime.[19]

PET scanners require a large initial capital investment and long-term operating expenditures.[xvii] Despite the high cost of implementation and ongoing operations, PET scanners are readily available in Massachusetts. In 2014, estimates indicated that just over half of Massachusetts hospitals had access to PET technology.[xviii] The cost for a PET scan varies widely, from approximately $4,000 for a whole-body scan, to $6,800 for a scan of the heart.[xix] These figures vary by geography, facility, and nature of the test and do not include the cost of subsequent tests and procedures that may be performed due to false positive results.[23] Due to high variation in the reimbursement rates, as well as the relatively high capital costs of PET, many states continue to regulate PET, PET/CT, and PET/MRI through their DoN programs.

See *Appendix C* for example uses of PET that have been identified by The Choosing Wisely Campaign to not lead to better patient outcomes or more cost-efficient care.

[1] Includes PET/MRI and PET/CT

Air Ambulance

Following a literature review and analysis, the DoN Program has identified air ambulance as a service that warrants a case-by-case review based on DoN application-specific information to ensure that air ambulance services are added to areas only when there is absence, reduced availability, or an insufficient level of care that cannot be corrected by modifying or improving existing resources.[xx] While some patients with obvious anatomic injuries are logical air transport candidates based on likelihood of survival, other patients may have injuries that are not time-sensitive.[xxi] Research suggests that nearly one-third of patients transported by helicopter had injuries that could have been transported appropriately via ground transport.[xxii] For these reasons, the DoN Program has designated air ambulance as a DoN-Required Service and as such, will review each application for air ambulance on a case-by-case basis.

Best practices suggest that air ambulance services should not operate independently of health care environments; rather, they should be fully integrated within local, regional, and state emergency care systems to bolster sustainability.[xxiii] Air ambulances are critical care aircraft specially equipped as flying intensive care units.[xxiv] There are two types of air ambulance aircraft used for medical transport: helicopters, typically used for short-haul trauma-related flights and usually managed by hospitals or city, state, or county Emergency Management Systems (EMS), and fixed wing airplanes, typically used for non-emergency transport.[xxv] For the purpose of the DoN Regulation, the Guideline will refer to both types of aircraft. Air ambulance aircraft is equipped for patients that require extensive or urgent medical assistance and is regarded as a method of medical transport for distances of usually 100 miles or more.[29] The aircraft is staffed by a specially trained medical flight crew that carries equipment including, but not limited to, respirators, medications, an ECG and monitoring unit, CPR equipment, and stretchers.[29]

DoN review helps to ensure that protections are in place to limit non-clinical drivers of use, such as convenience and economics, which can lead to variability and care decisions that are not patient focused, resulting in unnecessary transports and excessive health expenditures. [24, 27]

Megavoltage Radiation Therapy (MRT)

Following a literature review and analysis, the DoN Program has identified MRT as a service that warrants a case-by-case review based on DoN application-specific information due to its potential for clinically unnecessary utilization that in aggregate, can result in a significant increase in health care spending without an associated benefit to the public in terms of better health outcomes, or access to needed care. As such, the DoN Program has designated MRT as a DoN-Required Service.

MRT is a clinical treatment involving the delivery of ionizing radiation through an MRT unit.[xxvi] An MRT unit is a linear accelerator, cobalt unit, particle accelerator, or other piece of equipment operating at an energy level equal to or greater than 1.0 million electron volts to emit x-rays, gamma rays, or a beam of charged particles (e.g. electron beam, proton beam, neutron beam, heavy-ion beam).[xxvii] For the purposes of the Guideline, MRT does not include brachytherapy or systemic radiation therapy.

MRT units are costly to build. At the Loma Linda University Medical Center in California, which opened the nation's first hospital-based proton therapy center in 1990, the cost of building a center to deliver proton beam therapy (a specific type of MRT) was approximately $250 million, 40 times that of a center that delivers conventional radiation therapy or intensity-modulated radiation therapy ("IMRT").[xxviii] Many insurers, including Aetna, Cigna Corp, and Blue Shield of California, are no longer covering proton beam therapy for prostate cancer.[31] According to a 2012 Journal of the National Cancer Institute study, median Medicare reimbursement for proton beam therapy for prostate cancer is $32,428, compared with $18,575 for IMRT.[32]

Research has suggested that while proton beam therapy is beneficial for tumors surrounded by sensitive organs and structures where the potential for radiation damage is high, such as the brain, eyes, and spinal cord, there is little data to demonstrate that the therapy is superior in treating prostate cancer or mitigating unwanted side effects; there is limited evidence to demonstrate its comparative benefit to other forms of treatment.[30]

As MRT and its uses continue to evolve, and health care costs continue to rise in the United States, it is increasingly important that costly services are associated with a reasonably proportional benefit to the public in terms of better health outcomes, or access to needed care.

Appendices

Appendix A: Computerized Tomography (CT)

Use	Description	Rationale
Cancer Staging and Surveillance Testing	Scan of the pelvis for asymptomatic men with low-risk clinically localized prostate cancer (American Urological Association)	Unlikely to provide actionable information.[4]
	Routinely ordering [PET/CT] imaging studies for staging purposes on patients newly diagnosed with localized primary cutaneous melanoma unless there is suspicion for metastatic disease based on history and physical exam (Society of Surgical Oncology)	Does not significantly improve staging while increasing risk of false positives leading to unnecessary and potentially harmful treatment.[4]
	Surveillance testing (biomarkers) or imaging (CT, PET, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent (American Society of Clinical Oncology)	No benefit with risk of false positives.[4]
	CT, PET, and radionuclide bone scans in the staging of early breast cancer or early prostate cancer at low risk for metastasis (American Society of Clinical Oncology)	Lack of evidence suggesting this screening improves detection of metastatic disease or survival.[4]
Cancer Staging and Surveillance Testing	Baseline or surveillance scans in patients with asymptomatic, early-stage chronic lymphocytic leukemia (CLL). (American College of Hematology)	Does not improve survival and is not necessary to stage or prognosticate patients.[4]

Use	Description	Rationale
	Surveillance CT scans in asymptomatic patients following curative-intent treatment for aggressive lymphoma. (American Society of Hematology)	Evidence suggests small but cumulative risk of radiation-induced malignancy. Test is costly and has not been demonstrated to improve survival.[4]
	CT/PET as a diagnostic or surveillance tool for recurrent or persistent cervical cancer.	Evidence suggests the use of CT/PET is not cost effective.[xxix]
Cancer Screening	Use of whole-body scans [including CT] for early tumor detection in asymptomatic patients (American College of Preventive Medicine)	No evidence of improved survival; Risk of false positives with associated screening and treatment.[4]
	Use of CT/PET for cancer screening in healthy individuals (Society of Nuclear Medicine and Molecular Imaging)	Low likelihood of finding cancer and risk of false positives.[4]
Emergency Medicine	Use of CT of the abdomen/pelvis in young otherwise healthy ED patients (age <50) with known histories of kidney stones or ureterolithiasis, presenting with symptoms consistent with uncomplicated renal colic.	Lack of evidence that results of CT scans change treatment decisions.
	CT scan of the head in ED patients with minor head injuries who are at low-risk based on validated decision rules.	CT should only be performed on patients at-risk for significant injuries; CT scans expose patients to ionizing radiation that increases lifetime risk of cancer.

Use	Description	Rationale
Diagnostics	Diagnostic CT on adult patients.	Levels of radiation from commonly performed diagnostic CT examinations are higher and more variable than generally quoted.[xxx] Follow-up for false-positive findings adds substantial financial burden to health care system.[xxxi]

Appendix B: Magnetic Resonance Imager (MRI)

Use	Description	Rationale
Breast cancer screening	Routine use of breast MRI for breast cancer screening in average risk women. (Society of Surgical Oncology)	Should be reserved for only those at increased risk.[4]
	Routinely ordering breast MRI in new breast cancer patients. (American Society of Breast Surgeons)	Lack of evidence that MRI lessens cancer recurrence, death from cancer, or need for reoperation after lumpectomy surgery.[4]
		Routine use associated with increased need for subsequent breast biopsies, delays in time for treatment, and higher cost of care.[4]
		Increased mastectomy rates and patient anxiety if MRI finds additional cancers or indeterminate findings.[4]
Pre-term infants	Routine screening of term-equivalent or discharge brain MRIs in pre-term infants. (American Academy of Pediatrics)	Does not improve long-term outcomes.[4]
Cancer Screening	Whole-body scans for early tumor detection in asymptomatic patients. (American College of Preventive Medicine)	Does not improve survival or improve likelihood of finding a tumor.[4]
	Whole-body scans for early tumor detection in asymptomatic patients. (American College of Preventive Medicine)	Risk of false positive findings resulting in unnecessary testing and procedures with additional risk.[4]

Use	Description	Rationale
		Small increase in the possibility of developing cancer and accruing additional medical costs as a result of additional procedures.[4]
Emergency Care	Lumbar spine imaging for adults with non-traumatic back pain. (American College of Emergency Physicians)	Does not accurately identify the cause of most low back pain and does not improve time to recovery.[4]
Sports Medicine	MRI for anterior knee pain without mechanical symptoms or effusion, unless the patient has not improved following appropriate functional rehabilitation program. (American Medical Society for Sports Medicine)	No evidence that MRI helps manage syndrome.[4]
	Evaluation of acute concussion, unless there are progressive neurological symptoms, focal neurological findings upon examination or concern for skull fracture. (American Medical Society for Sports Medicine)	Not associated with clinically relevant abnormalities on standard neuroimaging.[4]
	Imaging for acute low back pain without specific indications. (American Society of Anesthesiologists - Pain Medicine)	No evidence to support that this condition requires imaging. Doing so many reveal incidental findings that diverts attention and increases risk of unnecessary surgery.[4]

Appendix C: Positron Emission Tomography (PET)

Use	Description	Rationale
Cancer Staging and Surveillance Testing	Routine PET-CT in the initial staging of localized colon or rectal cancer or as part of routine surveillance for patients who have been curatively treated for colon or rectal cancer (Society of Surgical Oncology)	Increases cost without improved outcomes.[19]
	Routinely ordering [PET/CT] imaging studies for staging purposes on patients newly diagnosed with localized primary cutaneous melanoma unless there is suspicion for metastatic disease based on history and physical exam (Society of Surgical Oncology)	Does not significantly improve staging while increasing risk of false positives leading to unnecessary and potentially harmful treatment.[19]
	Surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent (American Society of Clinical Oncology)	No benefit with risk of false positives.[19]
	PET, CT, and radionuclide bone scans in the staging of early breast cancer or early prostate cancer at low risk for metastasis (American Society of Clinical Oncology)	Lack of evidence suggesting this screening improves detection of metastatic disease or survival.[19]
Cancer Staging and Surveillance Testing	Diagnostic or surveillance tool for recurrent or persistent cervical cancer.	Evidence suggests the use of PET is not cost effective.[33]
	Surveillance imaging of asymptomatic patients with diffuse large B-cell lymphoma (DLBCL) in first remission.	Surveillance imaging of asymptomatic DLBCL patients in remission offers little clinical benefit at substantial economic costs.[xxxii]
	Staging, restaging, and surveillance of response among patients with lung and esophageal cancers.	No association between PET and two-year survival rates.[xxxiii]

Use	Description	Rationale
Cancer Screening	Use of whole-body scans[including PET] for early tumor detection in asymptomatic patients (American College of Preventive Medicine)	No evidence that PET improves survival; Risk of false positives with associated screening and treatment.[4]
	Use of PET/CT for cancer screening in healthy individuals (Society of Nuclear Medicine and Molecular Imaging)	Low likelihood of finding cancer and high risk of false positives.[4]
Dementia	Use of PET imaging in the evaluation of patients with dementia unless the patient has been assessed by a specialist in this field (Society of Nuclear Medicine and Molecular Imaging)	Potential benefit of PET is unlikely to justify the cost or radiation risk.[4]
	Use of PET in the diagnosis of Alzheimer's disease in patients with mild or moderate dementia.	Addition of PET to standard diagnostic regimen yields limited, if any, benefits at very high costs.[xxxiv]

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